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Viewpoint

Back to the Future: Achieving Health Equity Through Health Informatics and Digital Health

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Abstract

The rapid proliferation of health informatics and digital health innovations has revolutionized clinical and research practices. There is no doubt that these fields will continue to have accelerated growth and a substantial impact on population health. However, there are legitimate concerns about how these promising technological advances can lead to unintended consequences such as perpetuating health and health care disparities for underresourced populations. To mitigate this potential pitfall, it is imperative for the health informatics and digital health scientific communities to understand the challenges faced by disadvantaged groups, including racial and ethnic minorities, which hinder their achievement of ideal health. This paper presents illustrative exemplars as case studies of contextually tailored, sociotechnical mobile health interventions designed with community members to address health inequities using community-engaged research approaches. We strongly encourage researchers and innovators to integrate community engagement into the development of data-driven, modernized solutions for every sector of society to truly achieve health equity for all.

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health informatics; digital health; mobile health; eHealth; community-based participatory research; health equity

Introduction

There has been recent growth in the use of high-tech health devices such as exercise trackers, heart rate monitors, and other devices. There has also been an explosion of new ways of working with health information and health care providers (doctors, nurses, community health workers, etc), including video doctor visits, text message reminders to take medicine or exercise, and other ways for people to get their health information when and how they want and need it. These devices and the way they are used are known as health informatics and digital health. Their use will continue to grow and impact the health of many people. But, there are real concerns about how these technologies may lead to bad effects. For example, technology may cause differences in health for groups of people without many resources. It is important that people and companies who develop these new technologies understand the challenges faced by disadvantaged groups. These challenges prevent community members from being as healthy as possible. This paper gives examples of health programs using technology created *with* community members to help them improve their health. These programs are based on where people live, work,

play, and pray. We believe that researchers and developers should work together with communities to build modern tools to make everyone healthier.

Digital Disadvantage for the Disadvantaged

"The world of Pokémon GO is all around you…!" This was the seemingly all-embracing community experience promised by the highly popular augmented reality game, Pokémon GO (Niantic, Inc), one of the most frequently used mobile apps worldwide [1,2]. The app-based game was centered on the premise of incentivizing users for acquiring virtual goods at a variety of physical locations termed PokéStops or Gyms. There was also excitement among medical and public health communities for the potential use of this innovative and engaging tool to promote regular physical activity. However, racial and ethnic minority groups in low-income, urban areas across the United States soon took notice of the lack of PokéStops within their neighborhoods. This issue was heavily played out on social media under the hashtag #mypokehood [3,4] and inspired researchers to probe the issue further. It was indeed found that neighborhoods consisting of predominantly African American and Hispanic residents in major cities such as Chicago, Detroit, and New York had significantly fewer PokéStops than white and Asian neighborhoods [5,6]. Digital redlining, or limiting a particular community from essential services based on race and ethnicity, was deemed the culprit. The Pokémon GO app developers relied on maps from one of their prior apps that were crowdsourced from a majority white male demographic in commercial areas. This unearthed structural-digital inequity demonstrates how technologies, although not necessarily deliberate, can place certain groups at a *home-court* disadvantage. Community engagement in the development and tailoring of this technology could have thwarted this unfortunate faux pas.

Another unsettling discovery of inequities related to digital innovation is recent reports that smartwatches and other physical activity trackers demonstrate less reliability in accurately monitoring heart rates in people of color, particularly those with darker skin tones [7]. Although there has been scant media attention surrounding this issue, it is well documented in the scientific literature that the inherent optical sensors or *green lights* of these devices are readily absorbed by melanin (skin pigment), presenting a problematic challenge to accurate monitoring of heart rate [7-10]. There are other available technologies to potentially overcome this issue, such as balancing with the use of red light sensors (referred to as near infrared spectroscopy) [7,11]; however, nearly all large manufacturers of these devices rely solely on green light sensors through a process called photoplethysmography as they are simpler and less expensive [11]. One study provided evidence that these devices were *within acceptable error range*, but this existing bias is unacceptable considering the surge in clinical research studies integrating these wearable technologies [9]. This not only limits the potential clinical implications of the use of these devices but could also lead to downstream health disparities. Again, purposeful examination of racial and ethnic differences in the utility of these devices could have been achieved through active community engagement within diverse populations.

The Divided Digital Revolution

With each hour of the day, hundreds of novel health informatics strategies, telemedicine devices, wearables, and other digital technologies are released at lightning speeds, which has amplified into a US $80 billion industry with a projected increase to over US $500 billion by 2020 [12,13]. Mobile health (mHealth) is a growing field, revolutionizing health promotion and health care delivery through sophisticated digital technologies (eg, mobile/digital apps, SMS/text messaging, and wearable devices), and it provides an unprecedented opportunity to reach and engage communities [14-17]. Racial and ethnic minorities outnumber their white counterparts in the use of mobile/digital apps and are more likely to use their smartphones to access health information [18,19]. African Americans have similar smartphone ownership to the general population (80% vs 81%, respectively) [20], and they are receptive to participating in mHealth research [21]. However, there is a dearth of socioculturally tailored mHealth interventions that include racially and ethnically diverse patients or community members in their development and implementation beyond usability studies [22]. As a result, these acontextually developed innovations may largely benefit health outcomes in one sector of society while inadvertently creating, sustaining, or increasing health disparities in another. This can further perpetuate health inequities through the creation of a new configuration of the digital divide—a paucity of culturally informed or culturally useful health informatics or digital health interventions.

Interestingly, community members have had keen foresight of this potential dilemma and have advocated for more inclusive development processes of these interventions. Community engagement is an evidence-based and practical means to bring overlooked communities into the fold of our rapidly changing health care landscape abound with proliferating digital health innovations. In this viewpoint, we present 2 case studies of community-based mHealth interventions designed and developed alongside community members to effectively address health disparities. Both interventions were born out of community members' requests for cutting-edge technological interventions to apply within their respective communities and sensible inquiries of "why not us?" to academic researchers. Next, we discuss the origins of health disparities that are essential to understand before engaging with underserved communities. Finally, we present the health informatics and digital health fields with best practices for community engagement in digital innovation.

Innovation Through Community-Engaged Research: Case Studies

At the heart of community-engaged research is an academic-community partnership for coproducing research to enact social justice for disadvantaged communities through improved health and receipt of high-quality care [23]. In this

construct, investigator-driven research is replaced with collaboration, shared decision making, reciprocal relationships, colearning, trust, and transparency [23]. Under the umbrella of community-engaged research is community-based participatory research (CBPR), which incorporates community member input at every phase of the research process, ranging from conception to results dissemination [24,25]. Community members view CBPR as a transformation of traditional research tactics, in which participants may feel *used* and at the mercy of a researcher, to a more active opportunity to work with researchers as equal partners in contouring interventions for the betterment of the health of their communities. There is a gap in the literature of research applying CBPR principles to develop context-sensitive, mHealth innovations that address health inequities [26]. The 2 mHealth interventions described below strategically merged CBPR with health services research for intervention development and implementation (see Table 1).

Table 1. Embedded community-based participatory research principles in case studies.

CBPR[a] principle	FAITH![b]	PeerTECH[c]
Community as a unit of identity	• African American adults affiliated with local African American churches. • Shared sociocultural influences of the African American faith community and marginalization in underresourced areas in small and large metropolitan areas in Minnesota.	• Older adults, aged 60 years and older, with an SMI[d]. • Shared experiences of marginalization and mental health condition with certified peer specialists.
Strengths and resources within the community	• Community partner with a long-standing role as a community activist and community outreach director of a federally qualified health center. • Established social infrastructure of the Black church for recruitment. • Church pastors and church-designated champions, FAITH! Partners leveraged for trust building and *buy-in*.	• Certified peer specialists who provide peer support mental health services and are trusted leaders of community. • Certified peer specialists who facilitate trust building, co-ownership, and an equitable partnership.
Collaborative partnerships in all research phases	• Community members involved in the selection a of mixed methods study design to incorporate community members in intervention development (selected mobile app modality). • FAITH! Partners designated to refine recruitment, implementation, and results dissemination processes. • Academic partner assisted with capacity-building of health ministries within partnering churches.	• Community members involved in weekly research team meetings assisted with the development of the smartphone app content, selection of study site, instruments, hiring, training, and retaining interventionists.
Integrate research results for mutual benefit	• Research directly led to an mHealth[e] intervention aimed at addressing cardiovascular health disparities identified by the academic-community partners within the African American faith community.	• Research directly led to a peer-delivered and technology-supported mHealth intervention aimed at addressing early mortality in people with an SMI; health issue identified by academic and community partners.
Cyclical and iterative process	• Community members were heavily involved in formative process for mHealth intervention design through iterative focus groups and community meetings.	• Community members were actively involved in all research phases from conception and research design to dissemination. • Community members are currently involved in the next iteration of PeerTECH.
Colearning and empowerment, with awareness of social inequalities	• CSC[f] established to guide academic partners in project focus and community centeredness. • Academic-community partners attend a longitudinal CBPR course to ensure ongoing adherence to principles.	• Academic partners learned of the history, philosophy, and practice of certified peer support specialists. • Certified peer support specialists learned experientially about conducting and disseminating scientific research.
Incorporate positive and ecological perspectives	• Research question and study design were born out of community input and preferences to overcome marginalization. • The intervention incorporated relevant psychosocial and sociocultural influences on cardiovascular health (eg, cultural norms of collectivity and spiritual messaging).	• Smartphone app was developed based on community input and incorporates a sociocultural and environmental approach to addressing early mortality in people with an SMI, including relationship building skills, stress management, and how to navigate the health care system.
Disseminates knowledge to all partners	• Presentations were held in both academic and community settings to share research results. • Promoted a culture of health in community dissemination efforts as identified by community partners and CSC (eg, community walk and health fair). • Culturally tailored infographics were developed to highlight results for participants, CSC, and public. • Academic-community partners coauthored manuscripts/grants and copresented at scientific and community meetings.	• Presentations were held in both academic and community settings (international, national and regional conferences) to share research results. • Blogs were written by patient partners and certified peer specialists. • Academic-community partners coauthored peer-reviewed manuscripts/grants and copresented at scientific meetings.

[a]CBPR: community-based participatory research.

[b]FAITH!: Fostering African-American Improvement in Total Health.

[c]PeerTECH: Peer- and Technology-Supported Self-Management Training.

[d]SMI: serious mental illness.

[e]mHealth: mobile health.

[f]CSC: community steering committee.

Fostering African-American Improvement in Total Health

The Fostering African-American Improvement in Total Health (FAITH!) intervention, cultivated from a community desire to improve the cardiovascular health of the African American community, is a translation of a face-to-face, church-based health education program into an mHealth intervention [14,27]. Community members expressed directly to the collaborating research team the dire need for easily accessible and trusted health information and an infrastructure for social support through the use of mobile technology [28]. This was further fueled by their mutual desire with the project leader to confront persistent cardiovascular disease (CVD) disparities in Minnesota, as African Americans have a higher CVD incidence and nearly double the CVD mortality rate than whites [29]. Prior efforts to mitigate these disparities have been hindered by social marginalization and structural racism [30].

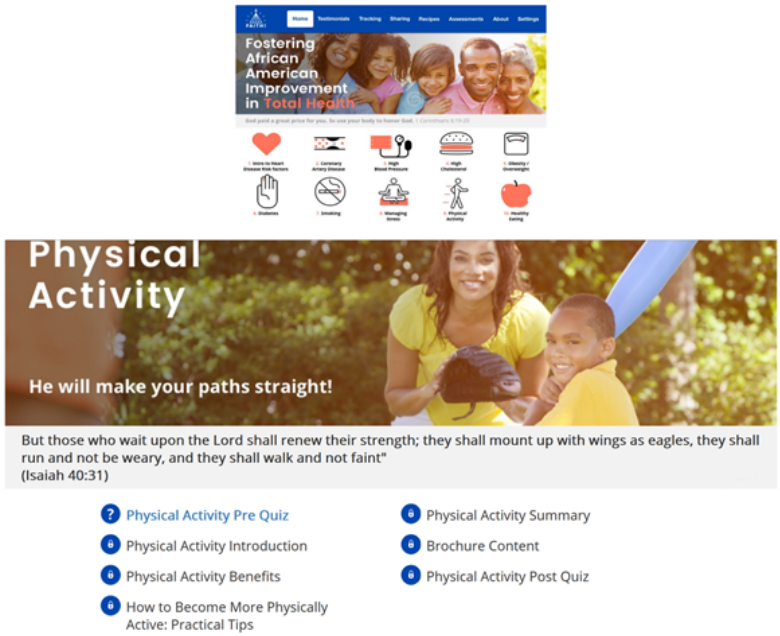
FAITH! Partners, or church-designated champions, were intricately involved in defining the research questions and study design to assess the feasibility of the mHealth intervention and in selecting its actual delivery modality in the form of a mobile app. An iterative, formative design process was employed to jointly create the *FAITH! App* with African American community partners and an interdisciplinary research team including clinicians, technologists, and social and behavioral scientists [31]. FAITH! Partners provided the research team with valuable insights on the psychosocial needs and preferences of the African American faith community, which undoubtedly improved the design of the intervention. For example, incorporation of biblical scriptures and spiritual messaging was a strong recommendation from the community partners during the app prototyping phase. Our inclusion of these inferences was viewed as cultural humility by the research team and resulted in the high ratings of the app's acceptability, usability, and satisfaction by our study participants (see Figure 1) [31].

Figure 1. Community members interacting with a community-based mobile health intervention, the *FAITH!* (Fostering African-American Improvement in Total Health) *App*. Researchers and African American churches partnered to codevelop the *FAITH! App* to promote cardiovascular health within faith communities. Used with permission from the Mayo Foundation for Medical Education and Research.

Further integration of evidence-based behavioral change theoretical frameworks into the app features resulted in a culturally aligned intervention that positively impacted the cardiovascular health of the study participants (blood pressure, diet, and physical activity; all *P* values<.04) [32]. See Figure 2 for images of the app homepage and sample education module.

Unsurprisingly, community involvement and trust building facilitated exceptional recruitment and retention rates of study participants (100% and 98%, respectively) not traditionally involved in the research process [14,32]. Culturally tailored, visual depictions of study results through infographics were developed with community partner feedback and were distributed within the partnering churches, at local community events, and at public health departments. The academic-community partnership has recently secured federal funding to expand the reach of the FAITH! intervention. On the basis of community input, there are also ongoing plans to disseminate the FAITH! App not only to the African American faith community at large but also within community health centers [33]. In addition, the genuine relationships forged between the academic medical institution and the marginalized community in codeveloping the intervention strengthened the diversity and inclusion efforts led by the institution, including revitalizing its branding strategy for patient accessibility [34].

Figure 2. Screenshots of the co-designed *FAITH!* (Fostering African-American Improvement in Total Health) *App* home page and education module. Used with permission of the Mayo Foundation for Medical Education and Research.



Peer- and Technology-Supported Self-Management Training

Another CBPR partnership focused on addressing premature mortality in people with a serious mental illness (SMI; eg, bipolar disorder, major depressive disorder, and schizophrenia), which was identified by the partnering academic-community team as a major health disparity affecting this vulnerable population [35]. This partnership led to the cocreation of a smartphone app–based intervention, *Peer- and Technology-Supported Self-Management Training* (PeerTECH), which is aimed at the *simultaneous* management of mental and chronic health conditions in patients aged 60 years and older (see Figure 3) [23,36].

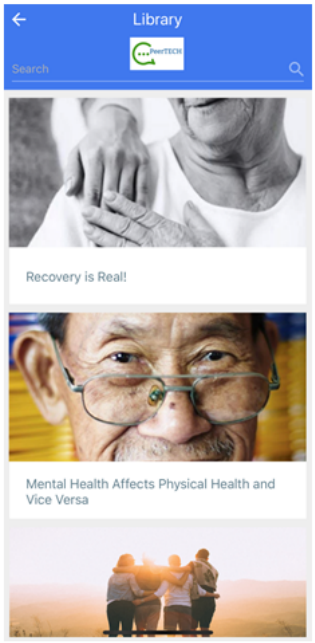
PeerTECH was developed in *equal* partnership between patients, certified peer specialist (CPS) leaders, and scientists from idea conception, defining of research questions, intervention development, and usability testing extending to dissemination. CPS leaders are individuals with a lived experience of a mental health condition who are trained to provide peer support in mental health services. They are deep-rooted advocates for developing programs with community input and the resounding motto of "nothing for us, without us." CPS leaders expressed concern to the research team over the lack of resources available to engage older adults living with SMI and wanted to devise a solution to improve outreach to these individuals who otherwise might not engage in traditional mental health services [37]. Digitally supporting geriatric mental health was identified as an innovative means to overcome geographic barriers by remotely delivering customized services based on patients' preferences and recovery goals while simultaneously addressing comorbidities [38,39]. An iterative app coproduction process with CPS input transformed the app from a highly medicalized self-management approach to one with an emphasis on recovery through a self-management app. For instance, instead of solely targeting psychiatric symptoms from a medical standpoint, PeerTECH utilizes a biopsychosocial approach and targets multiple dimensions of health including, but not limited to, *how to make friends* (social support), *what to do when you are lonely* (loneliness), and *how to stick up for yourself at the doctor's office* (self-advocacy). By including the insights of older adult patients with an SMI, PeerTECH has the potential to promote widescale acceptability among this highly marginalized group and improve population health.

PeerTECH was delivered in person by a CPS, who has the personal experience of an SMI and skills to provide services to a patient with similar health issues. PeerTECH was further augmented with the smartphone app [40]. PeerTECH sought to improve psychiatric and chronic disease management among patients with an SMI through self-monitoring of psychiatric distress, medication adherence, and peer support. PeerTECH was found to be feasible and acceptable among patients and CPS leaders [41]. The use of PeerTECH was associated with statistically significant improvements in psychiatric self-management (P<.001) and improvements in medical self-management, hope, quality of life, and empowerment. This coproduction team has presented to international audiences and has received foundation and federal funding to continue their work.

Both of the case study projects confront health disparities through digital health interventions at multiple levels (individual and meso levels) by tapping into existing social and community networks [42]. Both interventions support marginalized populations through collective mobilization and enhancement of resources, reduction of social isolation through social networking, and sharing of knowledge through technology-mediated solutions to promote positive health behaviors. By *leveling up* to upstream contextual and societal influences on health and health disparities [43], these interventions provide comprehensive yet pragmatic models for

future health informatics and digital health design and implementation. We hope that these exemplars of integration of user-centered design (UCD) and participatory design (PD) processes into technology development can serve as examples for others as we usher in the accelerated advancement of the health informatics and digital health fields.

Figure 3. Screenshot of the educational library in the co-designed PeerTECH (Peer- and Technology-Supported Self-Management Training) app.



Understanding the Origins of Health Disparities and the Social Determinants of Health

Before engaging with communities, researchers, clinicians, and regulatory agencies focused on health informatics and digital health must first understand and critically examine the origins of health disparities among marginalized and underresourced communities. A lack of acknowledgment of these inequities could lead to their further propagation and widen the digital divide by disproportionately providing beneficial technologies to nonmarginalized groups that already have health-related advantages [42,44].

Health disparities are metrics to monitor advancement toward health equity [45]. According to the World Health Organization, *health equity* implies that everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential [46]. Unfortunately, the reality is that many are not afforded this *golden* opportunity to achieve optimal health as a result of complex socioeconomic, political, environmental, and sociological factors [24]. These psychosocial factors or social determinants of health (SDOH) are critical in predicting health outcomes and are tied to the majority of health inequities [47-49]. They are defined as "conditions in which people are born, grow, live, work and age" and are "shaped by the distribution of money, power and resources at global, national and local levels" [47].

The SDOH do not occur at random but cluster at the intersectionality of social identities/position (such as one's race or ethnicity, gender, or educational attainment), which may have a multiplicative, adverse impact on health outcomes [50-55]. Racial and ethnic minority populations are faced with a unique milieu of disenfranchising SDOH, which include inadequate access to quality health care and health care providers, multitiered and systemic racism, food and housing insecurity, and lack of employment opportunities, which further impede their opportunities for ideal health and wellness. Despite progress made toward improving the health of the US population as a whole, racial and ethnic minorities shoulder the heaviest burden of health disparities related to higher prevalence and premature mortality from chronic health conditions [56,57] including CVD [58-60], diabetes [61,62], obesity [63], and SMI [64,65]. There is also evidence linking stress related to racial discrimination to increased risk of these chronic health conditions and negative health outcomes [66-71]. In addition, reduced community-level social capital stemming from oppression/privilege and institutional/structural racism toward African Americans has been correlated with a hindrance of their economic prosperity and increased mortality risk [55,72]. Moreover, racial and ethnic minority groups have been historically faced with negative stereotyping bias [73-76] and unjust criminal sentences [77,78], which unfortunately have been recently promulgated through present-day data discrimination via search engines [79] and machine learning algorithms [80,81]. An intersectional approach considers the complex interaction of all these factors and could synergistically address the strata of the SDOH in tandem with health disparities. This approach is not *one size fits all*, but it proactively aims to design multiaxis interventions and programmatic strategies to meet the unique needs of vulnerable populations.

Addressing the SDOH through innovative digital technologies is a promising channel to overcome health inequities experienced by racial and ethnic minorities and other underresourced populations, including older adults, rural residents, and the economically disadvantaged. This will require innovators to demolish insulated siloes and reach beyond the confines of traditional research and clinical settings to better understand underserved communities. This approach is also known as sociotechnical, or one with a recognition of the interrelatedness of the *social* and *technical* factors of a particular environment to create optimal conditions or tools to maximize productivity and well-being [26,82]. Leaders within the Computing Community Consortium and the Society for Behavioral Medicine from interdisciplinary fields, including computing, health informatics, behavioral medicine, and health disparities, have recently called for an integrative research agenda to improve the health of the socioeconomically disadvantaged through advanced sociotechnical interventions [43,83]. As a consensus, the group agreed that reducing disparities will require a method that engages the affected populations "at all stages of intervention design, implementation and evaluation." This approach moves beyond an instrumental view of the technical and logistical aspects of interventions to that of engendering value in the sociocultural-centric context of the *where and how* of intervention deployment for exceptional patient experience. Ultimately, this will allow for the development of multidimensional health informatics and digital health interventions with a more informed awareness of the social context in which people actually live, learn, work, play, and pray.

The Roles of Health Informatics and Digital Health in Advancing Health Equity

Community Engagement for Digital Intervention Design

We understand that an all-encompassing CBPR co-design approach between researchers and end users in the design of digital interventions (as integrated in the case studies above) may seem overwhelming. CBPR can also lend challenges in academics for a multitude of reasons, including the pressures of scholarly productivity mainly driven by timeline constraints, resources, lack of expertise, and funding. However, there are several other sociotechnical approaches along the spectrum of community engagement that scientists and innovators may adopt for technology design and implementation. These include UCD [84,85] and PD [86,87], which also align with the overarching goal of CBPR to incorporate preferences and perspectives of intended end users into technology design. These approaches also allow for the integration of similar methodologies of CBPR adaptable to varying degrees of community involvement (ie, focus groups and think-aloud sessions). Nonetheless, these design strategies can be applied to develop technology interventions within the social construct lens of diverse communities rather than solely based on developer-driven needs. Interventions designed with community involvement are better equipped to address the inequities that their contexts create—which is especially important for racial and ethnic minority groups.

The UCD approach has a central theme of involvement of end users throughout the technology development process to optimize value and usability (inclusive of safety, efficiency, and effectiveness) for users [88]. Although previously considered costly and time consuming, UCD actually reduces development time considerably by integrating real-time quality improvement and prototype testing with users [89]. This not only improves functionality but also increases the probability that interventions will promote positive health behaviors or outcomes and that intended users will embrace and sustain use of the technology [90]. An example of how UCD can yield technological interventions tightly coupled to specific user needs and challenges to address the SDOH is that of an initiative to alleviate transportation barriers to medical appointments for underserved patients at Hennepin County Medical Center in Minneapolis, Minnesota [91]. On the basis of the bidirectional exchange between researchers with patients and health care providers, an electronic health record (EHR)–linked SMS text message system was developed to provide patients with free, convenient transportation via rideshare services to and from outpatient clinics. This is a win-win situation for patients and health care providers as it improves health care access and helps in mitigating unnecessary emergency department visits and hospitalizations. Similar to UCD, PD harnesses the collaboration of end users with researchers and developers in iterative co-design cycles to increase intervention acceptability and engagement of target audiences [92,93]. PD methodologies have been particularly successful in the development of patient-centered digital interventions to stigmatized populations, including those to deliver language services for individuals with limited English proficiency [94], mental health services to low-income women in urban areas [95], social support for people living with HIV [96], and research participation outlets to underrepresented minority groups [97,98]. Both UCD and PD have the advantages of reducing the lag between research and development to translation, which is vital given the rapid pace of technology turnover. In addition, these approaches offer continuous insight into the dynamic nature of individuals' environment, which can prevent outdated/stagnant interventions with limited value and lead to the discovery of modernized solutions over time.

Community Engagement for Epidemiologic Surveillance and Population Health Informatics

Reliance on data and analytics to identify and surveil epidemics and allocate resources to protect the health of underserved populations was traditionally the foundation and moral fiber of medicine and public health [99]. In fact, the health informatics field itself was spurred by the Centers for Medicare and Medicaid Services *meaningful use* incentive program, which encouraged widespread health system adoption of the EHR to optimize patient care and health outcomes [41,100]. The *timely intelligence* of the rapidly evolving digital age presents an inviting and yet germane doorway to leverage robust data and

technology in ways unimaginable to address health disparities and upstream SDOH [99].

However, it is important to recognize that not all communities have readily available access to high-quality population data or even the capacity for data collection, sharing, or analysis to identify or monitor health inequities among racial and ethnic minority or marginalized populations [101]. For example, local health departments in rural settings are faced with a *double disparity* as they are ill-equipped for data-informed decision making to combat health disparities, which negatively influences relationships with community organizations. Overcoming this *information system challenge* through improved informatics infrastructure could advance community-engaged approaches to utilizing population-level data to understand and act upon health issues faced by underserved communities. Community health informatics, a subdomain of health informatics, aims to generate and maintain relevant data on community health needs assessments from community-level stakeholders [102]. Partnering with community members in gathering and synthesizing *granular and place-based* data (eg, from churches, barbershops, tribal areas, or community meetings) could promote health equity through culturally appropriate solutions to ascertained health disparities.

In addition, population health informatics tools, including EHRs, could be tapped as knowledge hubs (or repositories) by health care ecosystems and public health agencies to disentangle the determinants aggravating health disparities affecting socially disadvantaged groups [99]. Synthesizing data from these hubs could better detect, track, respond to, and predict sources of health disparities such as differential, guideline-concordant preventive screening and care; poor patient-provider communication from stereotyping and bias; and errors in clinical decision making, which all drive poor health outcomes among racial and ethnic minorities and other vulnerable populations. It has been postulated that EHR data streams could potentially facilitate the creation and longitudinal surveillance of standardized quality metrics of health equity for use by health systems to reduce disparities [103,104], lower health care costs, and ultimately improve patient experiences and health outcomes. EHRs also provide an extraordinary platform for enhanced ascertainment and documentation of the SDOH, which could lead to improved care coordination, patient-clinician shared decision making, and resource allocation to underserved patients [48,105]. Pairing EHR monitoring technologies and sophisticated data platforms with interdisciplinary service providers (community health workers, nurses, and social workers) within resource-constrained settings could address the SDOH through population health management [106-108].

There is also a need for more culturally and linguistically sensitive strategies to increase access, uptake, and engagement with patient portal EHRs by racial and ethnic minorities while accommodating varying levels of electronic health and health literacy as well as technology experience and privacy concerns [22,109-112]. A failure to do so could widen the digital divide by disallowing these patients the opportunity to benefit from this form of health care access. Likewise, we must also recognize that machine learning algorithms are oftentimes developed from racially homogenous data flawed with intrinsic biases [81]. We must not let our enthusiasm about the glowing promise of these *superhuman* models blind our view of the potential health inequities that they could propagate among vulnerable populations through inaccurate predictions or withholding of resources [81]. Deepening our understanding of the role of high-quality EHR and fairness in machine learning in addressing health disparities through rigorous research could inform the design of novel technologies (including artificial intelligence) at the individual, health care provider, health systems, and community levels to promote health equity. Embedding the unique perspectives of patients and community members into the development of these technologies and advanced computing power has transformative potential to reach this goal.

Textbox 1 provides further recommendations for best practices in strategic design and implementation of health informatics and digital health interventions in marginalized communities. These recommendations are also provided in the context of the enlightening experiences with the design, implementation, and translation of FAITH! and PeerTECH. These recommendations altogether are indispensable in capacity building for both the research team and the community in tackling and preventing health disparities. Interventions created with these practices in mind will increase the likelihood of their success in informing and shaping further digitally supported interventions, health promotion strategies, digitally supported health systems, health systems informatics tools, and health care policies for the benefit of all populations.

Textbox 1. Best practices in strategic design and implementation of health informatics and digital health interventions in marginalized communities.

1. Increase recruitment and retention of diverse populations throughout the research and development process to allow for assessment of differential responses/outcomes of technologies and to mitigate preferential access to certain population sectors.
2. Leverage established stakeholders and trusted social networks to understand the strengths and resources within underserved communities.
3. Understand the social context of potential end users and populations as this allows for understanding of the social determinants of health and how these are embedded within systems of inequality within underserved communities.
4. Integrate community engagement through user-centered design or participatory design to better understand potential end users' needs and preferences to develop culturally relevant and meaningful interventions.
5. Gain an understanding of community partner technology infrastructure for capacity building to support and strengthen community-based health informatics interventions.
6. Plan the appropriate amount of time and resources to devote to community engagement processes for intervention development and sustainability.

Conclusions

In the current irresolute climate of national health care reform, it is essential for researchers, public health practitioners, informaticians, and technologists working in health informatics and digital health to embrace implementation science and community engagement in our collective quest to eliminate health disparities. With the exponential growth of these fields, we must ensure their *meaningful use* of applications for the betterment of the health of marginalized and underserved communities. Innovation through community engagement presents opportunities to bolster technological advancements to intercept health inequities.

Everyone benefits when community members are fully vested and included in intervention development and implementation. Their valuable perspectives toward addressing population health within the context of their social and physical environments lead to more successful interventions. Investigators must not only *think outside the box* but also examine the box itself and its surroundings to attain real, lasting change to impact health disparities within our communities. This intentional decision to *meet people where they are* in the community, whether culturally or digitally, is a return to the medical profession's core principles of altruism and benevolence and a journey *back to the future* to achieve health equity for all.

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Conflicts of Interest

None declared.

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Abbreviations

CBPR: community-based participatory research
CPS: certified peer specialist
CVD: cardiovascular disease
EHR: electronic health record
FAITH!: Fostering African-American Improvement in Total Health
mHealth: mobile health
NIH: National Institutes of Health
PD: participatory design
PeerTECH: Peer- and Technology-Supported Self-Management Training
SDOH: social determinants of health
SMI: serious mental illness
UCD: user-centered design

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Review

Elements of Social Convoy Theory in Mobile Health for Palliative Care: Scoping Review

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Abstract

Background: Mobile health (mHealth) provides a unique modality for improving access to and awareness of palliative care among patients, families, and caregivers from diverse backgrounds. Some mHealth palliative care apps exist, both commercially available and established by academic researchers. However, the elements of family support and family caregiving tools offered by these early apps is unknown.

Objective: The objective of this scoping review was to use social convoy theory to describe the inclusion and functionality of family, social relationships, and caregivers in palliative care mobile apps.

Methods: Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review guidelines, a systematic search of palliative care mHealth included (1) research-based mobile apps identified from academic searches published between January 1, 2010, and March 31, 2019 and (2) commercially available apps for app stores in April 2019. Two reviewers independently assessed abstracts, app titles, and descriptions against the inclusion and exclusion criteria. Abstracted data covered app name, research team or developer, palliative care element, target audience, and features for family support and caregiving functionality as defined by social convoy theory.

Results: Overall, 10 articles describing 9 individual research-based apps and 22 commercially available apps were identified. Commercially available apps were most commonly designed for both patients and social convoys, whereas the majority of research apps were designed for patient use only.

Conclusions: Results suggest there is an emerging presence of apps for patients and social convoys receiving palliative care; however, there are many needs for developers and researchers to address in the future. Although palliative care mHealth is a growing field, additional research is needed for apps that embrace a team approach to information sharing, target family- and caregiver-specific issues, promote access to palliative care, and are comprehensive of palliative needs.

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KEYWORDS

mHealth; palliative care; caregivers; mobile apps

Introduction

Background

Nearly 1.7 million people will die in the United States each year from a serious chronic illness, including heart disease, cancer, and respiratory disease [1]. These patients experience significant physical and psychological symptom burden and progressive dependence on their family and caregivers [2]. For the months or years leading to death, palliative care provides an interdisciplinary and patient-family centered approach to address the physical, psychological, emotional, and spiritual suffering for patients and families [3]. The primary goal of palliative care is to improve quality of life.

Palliative care is provided by an interdisciplinary team often made up of physicians, nurses, social workers, and chaplains. Specialty services including physical therapy, occupational therapy, and music or art therapy may also be offered. Palliative care strategies target symptom management, medication management, family support and training, advance care planning and goals of care facilitation, caregiver respite, and interventions for emotional and spiritual needs of patients and family [4]. Hospice is a specific type of palliative care provided in the terminal phase of end-of-life care. Hospice provides 24-hours a day palliative care services focused on symptom management, provision of needed medical equipment, psychospiritual and emotional aspects of dying, respite care, family coaching, bereavement, and grief services. In the United States, hospice is specifically associated with the Hospice Medicare Benefit and is provided only to terminally ill patients with a life expectancy of 6 months or less who no longer seek potentially curative treatment such as chemotherapy and dialysis.

Palliative care improves patient and family reported outcomes, including quality of life and satisfaction, reductions in emergency visits and hospitalizations at end-of-life, and increased referral and length of stay with hospice services [5]. However, estimates suggest that only 3.4% of hospital admissions are referred to palliative care. Nearly 1 million patients admitted who could benefit from palliative care do not receive this specialized service [6]. Access barriers to palliative care are commonly attributed to palliative care resource availability, lack of awareness, and provider and patient and family reluctance [7].

Mobile health (mHealth), the use of mobile devices to improve health services and health outcomes, provides modern opportunities for patients and their family to engage in palliative care but is relatively underexplored. mHealth may provide access to palliative care support for patients and families that may not otherwise receive specialty palliative care or hospice services. There are mHealth palliative care apps available commercially, and health-related researchers are currently initiating app design efforts [8,9]. However, the elements of family support and family caregiving tools offered by these early apps is unknown.

On the basis of a national survey of caregivers, an estimated 40% to 65% of family caregivers are interested in using mHealth to support and monitor the health of their loved ones [10,11]; however, mHealth systems are typically designed for individual users, rather than integrating the patient's family, friends, and social support to maximize benefit. This contradicts the behavioral science findings indicating social support is a critical construct in improving health behaviors and health outcomes. Specifically, Social Convoy Theory [12-14] is well established in the social science literature and provides a framework for understanding the complex relationships of individuals within a group of people that give and receive social support over the life cycle. The convoy can include informal supports such as family members, friends, and neighbors and formal supports such as professional caregivers. Previous research substantiates a link between social convoys and convoy relationships with improved health outcomes, reduced mortality in older populations, and quality of life among patients with serious illness [15-17]. The structure, function, and quality of one's social convoy is associated with quality of life, the primary health outcome for palliative care. Therefore, when designing mHealth specially for palliative care, it is important to incorporate a social convoy perspective considering that the family is a key component of care. As people with serious illness increasingly rely on the support of others to help manage their health, there is a critical need to foster approaches for effective integration of the convoy in palliative care–specific mHealth.

Objective

Although palliative care improves health outcomes and quality of life, there are barriers to accessing specialty services. Growing acceptability of mHealth offers promise in leveraging tools with family and the caregiving team to expand access. The objective of this scoping review was to describe the integration of social convoy theory in current palliative care–specific mHealth. Findings from this work will be used to inform strategies for designing mHealth interventions that are not only addressed to individual patients but also integrate their social convoy of families, friends, and caregivers.

Methods

Scoping Review

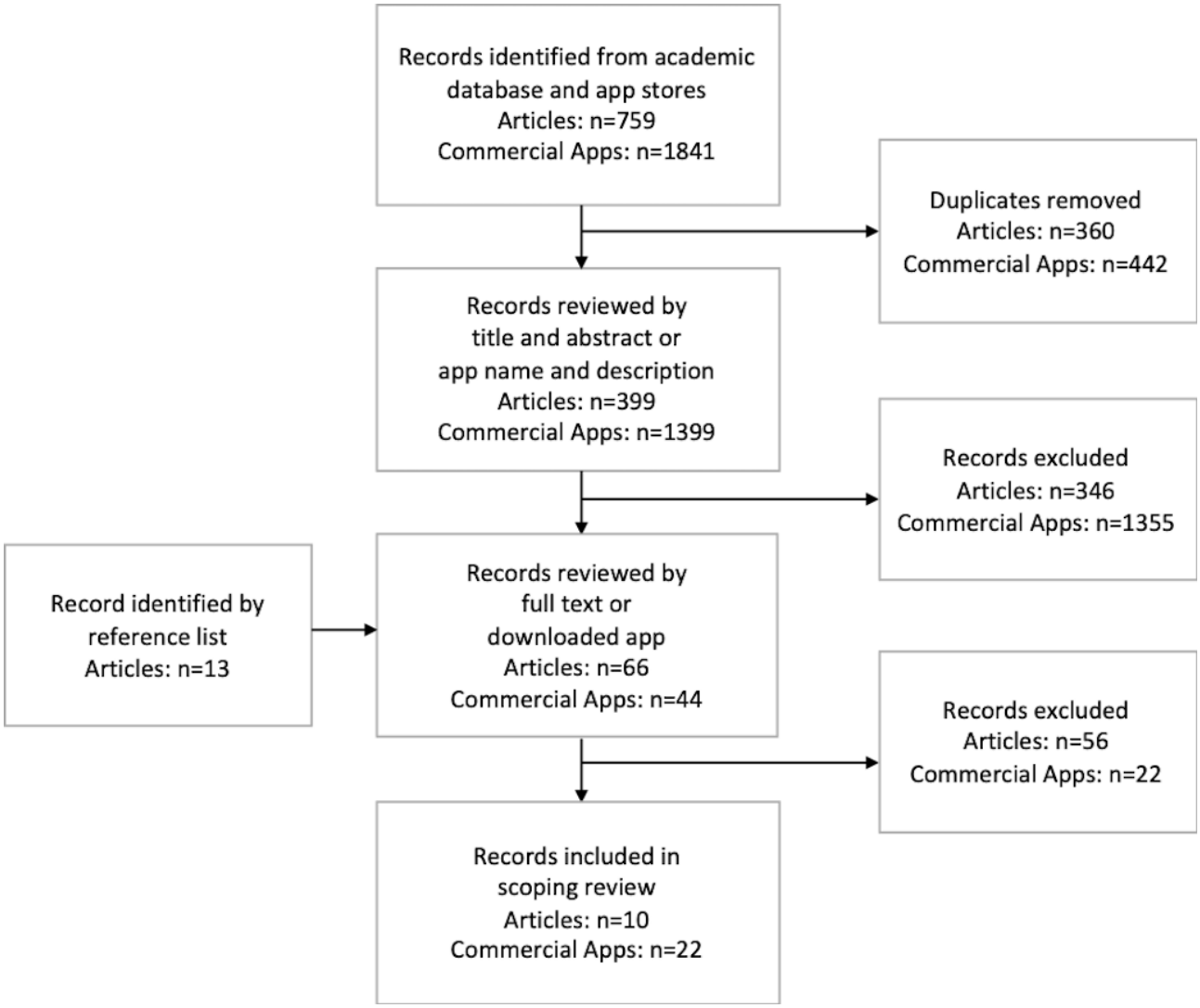
As little is known about palliative care mHealth, a scoping review approach was used to comprehensively review palliative care–specific mobile apps to determine the extent and nature of social convoy features available. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review (PRISMA-ScR) checklist guided the work, informing the search, selection, and evaluation of mobile apps [18]. This review is unique as it applies the PRISMA-ScR method to review both commercially available apps (offered from app stores) and research-based apps (described in the health-related scientific literature) to systematically review all current palliative care–specific apps.

App Search and Screening

To identify research-based apps, the search utilized 3 academic databases including PubMed, PsycINFO, and Web of Science for peer-reviewed palliative care mHealth studies. The search included empirical studies published between January 1, 2010, and March 31, 2019. The search string was restricted to search

terms included in the title and abstract and included: palliative care OR hospice OR end-of-life OR terminal illness OR advance directives OR living will OR symptom OR advanced care planning OR spiritual care OR grief OR bereavement AND mobile OR smartphone OR app OR mHealth. This search string ensured that only mHealth interventions for palliative care specially were identified. Systematic review articles were not included in the final scoping review, rather the specific apps listed in the reviews' results were assessed for inclusion. In addition to research-based apps, an electronic search in April 2019 browsed official app stores for iPhone (Apple Inc [iOS, The App Store]), Google Play (Google, LLC [Android, ChromeOS, Google Play Store]), and Amazon Appstore (Amazon Inc [Android, FireOS, Blackberry, Amazon App Store]) to identify free, commercially available palliative care apps. Identical palliative care terms were used as listed above, which have previously been used to identify mHealth interventions directed toward palliative care [8]. Duplicate articles and apps were removed before screening eligibility. A summary of search and screening process is described in Figure 1.

Figure 1. Flowchart for selection of research-based and commercially available apps.



Mobile apps meeting the following inclusion criteria were included in the review: (1) focused on at least one element of palliative care (quality of life assessment, symptom management, family support including bereavement or grief, spiritual care, psychosocial support, decision support, and patient/family education), (2) targeted adults with serious life-limiting illness and/or their family and caregivers, and (3) offered via a mobile app, that is, articles using websites that can be accessed via a mobile device were not included in this review. The primary reasons apps were excluded from the review are as follows: not available for free, not available in English, not available in the United States, pediatric focus, provider targeted, hospice eligibility and referral only, funeral planning only, and theoretical prototypes. Articles that did not provide detailed description of the mobile app were excluded.

To determine if apps met inclusion criteria, 2 coders (JDP and KE) independently reviewed the academic articles by title and abstract and screened commercial apps by app name and description provided by the app store. The full text of articles was then downloaded and further reviewed for eligibility. Commercially available apps were downloaded, and a user account was established. The coders met regularly to review articles and commercial apps to discuss questions and possible disputes. Both coders agreed on the final apps included in the

review. The search and screening process resulted in 10 articles [19-28] describing 9 individual research-based apps and 22 commercially available apps. Furthermore, none of the included research-based apps were available commercially.

Data Extraction

Once included, information about the apps were abstracted into a Microsoft Excel spreadsheet. Abstracted data covered app name, research team or developer (individual or organization), palliative care element, target audience (patient, convoy, or both), and features for family support and caregiving functionality as defined by Social Convoy Theory. Review of research-based apps was based on the description of app features provided in the article, whereas all tabs and features of commercially available apps were reviewed for the elements listed above. Apps were considered patient-focused if features were designed primarily for patients, such as education or symptom tracking without the ability to share information captured in the app with caregivers; convoy-focused if features were designed primarily for caregivers, such as bereavement tools; and both patient and convoy-focused if app features were designed to share information and facilitate a patient-convoy relationship. Specifically, information was abstracted related to (1) convoy composition—app targets particular convoy relationships such as informal caregivers, formal caregivers, family, neighbors, friend, and/or other convoy members; (2) convoy size—the number of convoy members that can use the app; (3) personal convoy characteristics—app considerations of factors such as age, race, ethnicity, and/or gender of the patient and convoy; (4) contextual convoy characteristics—app considerations of factors such as marriage, social isolation, and/or socioeconomic status of the patient and convoy; and (5) convoy support—app facilitation between patient and convoy.

Results

Summary of Apps

A summary of social convoy elements in palliative care mHealth is provided in Table 1. Overall, 22 commercially available mobile apps (Table 2) and 10 articles describing 9 apps (Table 3) were selected for full review. A total of 11 of 22 apps were available through the Apple app store only, 3 through the Google store only, 7 were available through both Apple and Google stores, 1 through Google and Amazon app stores, and 1 through all 3 app stores. Apps identified in the literature were in various stages of development, which included articles describing at least a minimum viable product. A total of 6 of the 9 apps identified were prototypes undergoing acceptability and/or usability pilot testing, a further 2 apps were under evaluation in randomized controlled trials with no results yet available, and 1 article described results from a randomized controlled trial using an app-based intervention.

Table 1. Commercially available and research app elements (N=31).

Element	Commercial (n=22), n (%)	Research (n=9), n (%)
Primary palliative care component		
Quality of life	1 (5)	0 (0)
Psychosocial support	3 (14)	0 (0)
Decision support	5 (23)	1 (11)
Symptom management	15 (48)	8 (89)
Bereavement or grief	5 (23)	0 (0)
Patient/family education	1 (4.5)	0 (0)
Target user		
Patient	8 (36)	8 (89)
Convoy	5 (23)	1 (11)
Both patient and convoy	9 (41)	0 (0)
Convoy composition and size		
Convoy can be independent app users	4 (18)	1 (11)
Convoy can be independent users but are not connected	3 (14)	0 (0)
Patient shares app-generated content with convoy	10 (45)	0 (0)
Targets patient only	5 (23)	8 (89)
Considers age, race, ethnicity, and gender	6 (27)	1 (11)
Considers marriage, social isolation, and socioeconomic status	2 (9)	0 (0)

Table 2. Summary of commercial apps.

Developer[a]	App name	Element of palliative care	Target users	Description
ADVault Inc	My Directives	Decision support	Patients	Patients can fill out simple medical wishes to auto-populate an advance directive that can be shared with convoy via email, text, or scanner. Allows patient to select a proxy from phone contacts and confirms understanding and willingness of proxy via email.
Ben Delaporte	ChronicPainDiary	Symptom management	Patients	Patients are offered to enter a daily pain score scaled 1-10 daily. A color-coded line graph shows scores over 1 week to 1 month to monitor changes over time.
Boston Scientific, Inc	MyPainScale	Symptom management	Both patients and convoy	Allows patient to track symptoms and share reports with convoy via text.
Center for Advancing Health	AfterShock	Patient/family education	Patient	Provides education for patients after receiving a terminal diagnosis. Ability to share information with convoy members included.
Erin Cole	LifeChest	Psychosocial support	Patient	Stores personal information about the patient (insurance, health, financial, life wishes, etc), including pictures of important documents, which can be shared with convoy members via email.
Final Thoughts LLC	Final Thoughts	Psychosocial support	Both patients and convoy	Offers exchange of legacy projects (multiple media options) at present or scheduled for the future between the patient and convoy. The patient can select who among phone contacts and app users receives legacy information.
Goodgrief Works, LLC	goodgrief	Bereavement or grief	Convoy	Grief social media app connecting people who share similar types of loss. Offers chat wall and personal instant messaging.
Infinite Monkeys LLC	Grief Support Network	Bereavement or grief	Convoy	Offers resources for grief and links to outside sources, connects to radio and YouTube, and provides social network function.
Jeremy Gonzalas	Farewell	Psychosocial support	Both patients and convoy	Provides avenue for exchange of legacy projects to specific convoy groups categorized by family, friends, work, spiritual, and financial. The patient provides passcode to convoy members to access patient-created content.
Nous Foundation	ACPDecisions	Decision support	Patient	Provide ACP tools including definitions for ACP and palliative care, steps for ACP, advance directive forms, and videos about sharing ACP preferences. The app is available in 9 languages.
Prognosis and Therapeutic Harmonization (PATH) Limited	The Fragility App	Quality of life assessment and symptom management	Convoy	Assessment of patient symptoms and function and convoy member stress and access to support completed by convoy member. Ability to send report via SMS to other convoy members or provider phone number.
SCET	Lets Think Ahead-My ACP	Decision support	Both patients and convoy	Allows the patient to enter and share end-of-life medical care decisions with family via email. Also provides assessment of conditions, experience of having a serious illness.
Scott La Counte	iGrief	Bereavement or grief	Convoy	Offers readings and quotes categorized by specific emotions.
Selesti	ButterflyProject	Bereavement or grief	Convoy	Offers resources, mindfulness activities, music, inspirational quotes, and a memory box.
Selesti	SmilesandTears	Bereavement or grief	Convoy (bereaved children)	Features include memory jar, balloon release, virtual gift giving, and diary.
Self Care Catalysts Inc	HealthStoryLines	Symptom management	Both patients and convoy	Facilitates exchange of health information, specifically symptom and mood tracking between the patient and patient-selected convoy members. Also includes appointment and medication features and syncs to sensor technologies.
SILECI Apps	Simple Symptom Tracker	Symptom management	Patients	Allows for unlimited symptoms to be tracked and notation option to describe factors that might influence the symptom. Offers graphs for reviewing symptoms over time.
Smooth Mobile, LLC	Symptom Tracker	Symptom management	Both patients and convoy	Offers symptom tracking and reports, which can be shared with convoy via Excel, Cloud, or printable PDF.

Developer[a]	App name	Element of palliative care	Target users	Description
VJ Periyakoil	AdvanceDirectives Stanford University	Decision support	Patients	Stores patient medical and emergency information, organ donation, and end-of-life medical care decisions, which can be shared with convoy via email. Includes ability to add pictures or video.
Universal Projects and Tools, SL	mPalliative Care App	Symptom management	Both patients and convoy	Patients can track symptoms and share reports with convoy via text.
University of Zurich	Catch My Pain	Symptom management	Both patients and convoy	Patients can track symptoms and share reports with convoy via text.
William Palin	PaperHealth	Decision support	Both patients and convoy	Allows patients to enter and share designated health proxy and end-of-life care preferences with convoy via email or text.

[a]Commercial apps were not directly connected to health care providers or clinical electronic medical record. All apps provided at least one export function for data that could be shared with providers via the patient or caregiver.

Table 3. Summary of research apps.

Study	App name	Element of palliative care	Target user	Description
Agboola et al (2014) [19]; Fishbein et al (2017) [20]	CORA	Symptom management	Patients on oral anticancer medication	Provides daily educational and/or support push notifications, offers symptom reporting and strategies for symptom management, weekly symptom and activity reports, and is customizable to patient needs, abilities, and medications.
Agboola et al (2014) [21]	ePAL	Symptom management	Patients with cancer	Offers on-demand pain assessments, daily educational and/or support push notifications, multimedia resource library including psychosocial support material, prescription refills, and ability to personalize based on self-reported barriers to pain management. Also facilitates patient-provider communication through direct call button and provider access to patient-entered information.
Alnosayan et al (2017) [22]	MyHeart	Symptom management	Patients with heart failure	Symptom tracking and reminders for missing data available through app and sensor technologies. Educational and motivational messages sent daily.
Athilingam et al (2016) [23]	HeartMapp	Symptom management	Patients with heart failure	Offers symptom and vitals tracking through app and sensor technologies, exercises, and heart failure educational resources
Cox et al (2018) [24]	PCplanner	Decision support	Convoy	Family members of patients admitted to the intensive care unit can access palliative care educational resources and complete a needs assessment. Electronic health record triggers allow provider to approve palliative care consultation for patients based on health status and family request through app.
Foster (2018) [25]	HF App	Symptom management	Patients aged >50 years with heart failure	Offers daily symptom and vitals tracking and heart failure educational resources.
Hardinge et al (2015) [26]	Not applicable	Symptom management	Patients aged >50 years with *chronic obstructive pulmonary disease*	Offers symptom and well-being diary, including optional recording of medication use, collected through app and sensor technologies. Personalized plans for self-management and educational material also included.
Moradian et al (2018) [27]	ASyMS	Symptom management	Patients with cancer	Offers functionalities for monitoring and managing chemotherapy-related toxicity with personalized risk prediction modeling and decision support. High-severity symptom reports alert clinicians.
Triantafyllidis et al (2015) [28]	SUPPORT-HF	Symptom management	Patients with heart failure	Offers symptom tracking and reports, educational material, and ability to communicate with clinicians through app.

Elements of Palliative Care and Target User

The majority of apps (15 commercial and 8 research apps) primarily targeted symptom management, followed by decision support (5 commercial and 1 research app) and bereavement or grief (5 commercial apps). Commercially available apps were most commonly designed for patients (8 apps) or both patients and convoy (9 apps), whereas the majority of research apps (8 apps) were designed for patient use only. The research apps primarily targeted a specific condition (8 apps), cancer, heart failure, or Chronic Obstructive Pulmonary Disease, whereas commercial apps focused on a more general population providing functions for multiple symptoms, various psycho-social support, and health decision making resources.

Convoy Composition and Size

Among commercially available apps, features allowing the patient to share app-generated materials, for example, advanced care directives or legacy projects, via email or SMS text message, were the most common (10 apps) in terms of patient-convoy relationship facilitated by the app. Several apps allowed convoy members to be independent users, either connected to the patient and other convoy members (4 commercial apps and 1 research app) or not (3 commercial apps). An additional 5 commercial apps and the majority of research apps (8 apps) did not have a convoy component and targeted the patient only.

Consideration of Personal and Contextual Characteristics

Several apps (5 commercial and 1 research) gave consideration to personal characteristics including age, gender, race, and ethnicity of the patient and/or convoy members. Few apps (2 commercial) considered contextual factors such as marriage, social isolation, or socioeconomic status of patient or convoy members. Furthermore, only 1 app included both personal and contextual characteristics.

Discussion

Principal Findings

mHealth may offer a simple, cost-effective method for keeping individuals connected and involved in care across the course of serious illness. This scoping review described the support for access and use by social convoy members in mHealth apps for palliative care. Overall, this review identified strengths, weaknesses, and areas for future work in mHealth for palliative care.

Results identified 14/22 (64%) commercial apps and 1/9 (11%) research app that included convoy members; however, only 5 in total, all of which were commercial apps, targeted convoy members as primary users. The vast difference in convoy-inclusion results yielded from research-based versus commercial apps suggests that the mHealth market considers caregivers consumers of their product, whereas researchers are focusing on patient-directed care. Although caregivers may be increasingly seen as potential users among developers, a recent review indicates that there are few commercial apps available specifically for caregiving [29] and limited usability evidence for caregiver apps [30]. Even though the inclusion of convoys in multiple apps was promising, convoy members were often passive recipients of information, and few apps targeted convoy-specific issues.

Many of the apps included in this review allowed patients to share information with convoy members regarding symptom management, decision making, and preferences. A strength of this feature is that sharing information may help convoy members understand symptom presentation, burden, and management. This is important in palliative care as families often struggle to identify the presence or severity of key symptoms (eg, pain or psychological distress) [31]. In addition, quick and convenient access to documentation of proxies and patient preferences may help establish consistency in decision making, promote confidence in time-limited decisions, and decrease decisional conflict. However, more research is needed to test the effect of sharing health information with social convoys on positive palliative care outcomes, including quality of life, symptom management, and goal concordant care.

Commercial apps offered tools and resources for a general audience, whereas research apps targeted specific illnesses. Often people with palliative care needs have more than one condition, and disease specific apps may be too limited. However, some mobile interventions may require specificity to address disease specific symptoms and improve health decision making. For example, illness trajectories differ by condition. Therefore, preparing advance directives or goals of care in the setting of heart failure can be different than treatment options for cancer. This specificity may not be available in more generalized palliative care apps.

A limitation of the symptom management and decision-making apps included in this review is that, typically, convoy members were passive recipients of information (ie, a 1-way flow of information from patient to convoy). Although patients' ability to manage the dissemination of information may promote choice and control, there are also limitations to this structure. For example, cognitive impairment, pain, and/or fatigue may hinder motivation or ability to share information with convoy members, which may result in misinformation or conflict. In addition, ideally, palliative care follows a team-based approach with information continually flowing to and from patients, providers, and convoys rather than a single party disseminating information to others. Additional work needs to be done to investigate mHealth methods that support a patient-centered model of care and empower active involvement from convoy members.

The individual, social, or care-related outcomes of a hub (patient) and spoke (convoy members) model of flow of information, consistent with many of the apps included in this review, are unknown. As mentioned, this model may increase choice and control but might also relate with perceived sense of burden for patients. For example, sharing daily pain levels may increase the patient's perceived burden on others and/or convoy members' sense of helplessness. Future research is needed to explore relationships between mHealth use, convoy contact, perceived burden, and other salient outcomes (eg, relationship quality, satisfaction with care, or quality of life).

Coping with bereavement and grief was the most common palliative care component of apps targeting convoy members as primary users. Although grief occurs across the course of serious illness [32], the majority of apps were tailored to coping with bereavement after the death of the patient. These apps included common coping strategies such as connecting with social support, resource sharing and education, affirmations, and tracking behaviors or rituals. Accepted models of bereavement and grief suggest that individuals cope with stressors related to loss (ie, negative emotions) and restoration (ie, negotiating new roles) [33]. However, most of the apps included in this review focused on coping with loss-related stressors only, omitting any focus on restoration. Therefore, current mHealth apps for palliative care may not offer comprehensive coping tools for bereavement and grief and may be most useful early in the bereavement process (ie, soon after the death of a loved one). Future work needs to investigate how convoy members use mHealth apps for bereavement and grief and the impact of such app use on the coping process.

Few mHealth apps included in this review targeted convoy-specific issues other than bereavement and grief. Additional convoy-specific issues in palliative care not addressed by apps in this review include: care roles (eg, defining and providing education on roles among convoy members), skills and coping (eg, time management, stress reduction, or anticipatory grief), and communication (eg, planning family meetings, conflict resolution, or assertiveness training). The aforementioned topics, however, are not a comprehensive list of convoy-specific issues in palliative care, and engaging stakeholders may help developers and researchers design improved apps to meet the specific needs of this population.

A minority of apps included in this review considered convoy characteristics in development. Personal factors such as age, socioeconomic status, marriage, and social support likely influence preferences, needs, and usability for mHealth apps and, thus, should be considered in future works. Distance and relationship quality are also important convoy characteristics that were not considered in any app included in this review. mHealth may be particularly useful for facilitating involvement and meeting the needs of long-distance convoy members; however, this population is rarely given unique consideration in the development of interventions. Attention to relationship quality and conflict among patients, convoy members, and providers may be another important area to consider in future mHealth interventions. For example, apps may choose to offer settings and features to control the flow of information based on the quality of relationship, or offer strategies to address interpersonal conflict. Taken together, developers and researchers should appreciate the heterogeneity of convoy members and populations with unique needs, as this may impact needs, usage, and outcomes.

This review identified multiple areas for future app development and research in mHealth for palliative care. First, there is a need to consider team-based apps that promote active roles and flow of information among patients, convoy members, and providers. Second, few apps considered convoy-specific needs or characteristics, which may limit the reach and benefit of mHealth in palliative care. Next, many apps targeted individuals already connected to palliative services but did not address the potential of mHealth to help promote access to palliative care. Additional apps are needed to provide education and resources for connecting individuals with serious illness and their convoys with palliative care services. Finally, the apps included in this review isolated specific components of palliative care, possibly increasing user burden and/or decreasing usage by requiring various apps to meet palliative care needs. Additional work is needed to develop holistic mHealth apps consistent with the comprehensive palliative model of care (ie, biopsychosocial-spiritual).

Only 1 research app identified in this review included convoy members in any way, and that app did not target convoy members as primary users. The omission of convoys in research limits empirical knowledge on the reach and impact of mHealth in palliative care and raises questions regarding possible research challenges with this population. Previous scholars suggest there are unique challenges related to research with patients with serious illness and their care networks [34], but it is possible that app-based data collection may actually alleviate some of these issues (eg, fewer recruitment challenges). Therefore, it is unknown whether the scientific mission of mHealth apps in palliative care has narrowly focused on patients or if there are methodological limitations that create barriers for including this population in research. Additional work is needed to address best practices for mHealth research in palliative care, particularly related to the inclusion of social convoys.

Strengths and Limitations

To the knowledge of the authors, this scoping review is the first to address the inclusion and function of social convoys in commercial and research mHealth apps for palliative care. As a result, our findings and interpretations may be instrumental for guiding future work in mHealth for palliative care, an emerging area of industry and science. However, there are some limitations to highlight. First, this review only included free commercially available apps from 3 major app stores, which may have biased findings. Furthermore, as apps identified in the research were unavailable commercially, review of research-based apps relied solely on the description of the app in the publication. Second, the scope of review did not consider mHealth solutions other than mobile apps. There are many palliative care digital health initiatives, including telemedicine, websites, and text message programs, currently underway to expand access to palliative care. However, mobile apps have the ability to offer palliative care tools and functions with and without access to the internet. Third, this review considered both commercial apps and apps developed in research settings and reported on features and functions available in the resulting products but did not assess the presence or strength of the evidence base with regard to the impact of any of the apps on their intended outcomes. In the absence of an evidence base, it is difficult to compare apps, and are therefore limited to describing the functions of palliative care apps rather than assessing quality.

Conclusions

This scoping review highlighted important information on the inclusion and functionality of social convoy members in

mHealth apps for palliative care. Results suggest there is an emerging presence of apps for patients and convoy members receiving palliative care; however, there are many needs for developers and researchers to address in the future. Specifically, additional work is needed for apps that embrace a team approach to information sharing, target convoy-specific issues, promote access to palliative care, and are comprehensive of palliative needs. Furthermore, the inclusion of convoys in mHealth research is severely lacking and requires attention in the literature. Limitations and recommendations presented in this review may help guide future development of mHealth apps and scientific studies designed to support the needs of patients and convoy members in palliative care.

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Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Review

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Original Paper

The Mobile-Based 6-Minute Walk Test: Usability Study and Algorithm Development and Validation

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Abstract

Background: The 6-min walk test (6MWT) is a convenient method for assessing functional capacity in patients with cardiopulmonary conditions. It is usually performed in the context of a hospital clinic and thus requires the involvement of hospital staff and facilities, with their associated costs.

Objective: This study aimed to develop a mobile phone–based system that allows patients to perform the 6MWT in the community.

Methods: We developed 2 algorithms to compute the distance walked during a 6MWT using sensors embedded in a mobile phone. One algorithm makes use of the global positioning system to track the location of the phone when outdoors and hence computes the distance travelled. The other algorithm is meant to be used indoors and exploits the inertial sensors built into the phone to detect U-turns when patients walk back and forth along a corridor of fixed length. We included these algorithms in a mobile phone app, integrated with wireless pulse oximeters and a back-end server. We performed Bland-Altman analysis of the difference between the distances estimated by the phone and by a reference trundle wheel on 49 indoor tests and 30 outdoor tests, with 11 different mobile phones (both Apple iOS and Google Android operating systems). We also assessed usability aspects related to the app in a discussion group with patients and clinicians using a technology acceptance model to guide discussion.

Results: The mean difference between the mobile phone-estimated distances and the reference values was −2.013 m (SD 7.84 m) for the indoor algorithm and −0.80 m (SD 18.56 m) for the outdoor algorithm. The absolute maximum difference was, in both cases, below the clinically significant threshold. A total of 2 pulmonary hypertension patients, 1 cardiologist, 2 physiologists, and 1 nurse took part in the discussion group, where issues arising from the use of the 6MWT in hospital were identified. The app was demonstrated to be usable, and the 2 patients were keen to use it in the long term.

Conclusions: The system described in this paper allows patients to perform the 6MWT at a place of their convenience. In addition, the use of pulse oximetry allows more information to be generated about the patient's health status and, possibly, be more relevant to the real-life impact of their condition. Preliminary assessment has shown that the developed 6MWT app is highly accurate and well accepted by its users. Further tests are needed to assess its clinical value.

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KEYWORDS

cardiology; exercise test; pulmonary hypertension; mobile apps; digital signal processing; global positioning system

Introduction

Background

The 6-min walk test (6MWT) is a common clinical instrument for assessing patients' functional capacity. It consists of instructing patients to walk as far as they can during 6 min, usually in a corridor [1], under the observation of a doctor or a physiologist. The primary measurement of the test is the total distance walked, computed as the total number of lengths or laps walked plus the excess distance measured with a trundle wheel, a measuring tape, or with marks along the corridor. Secondary measures can include fatigue and dyspnea, measured with a modified Borg or analogue scale and peripheral arterial oxygen saturation via pulse oximetry. The 6MWT is self-paced, and patients are unlikely to push themselves beyond their endurance or through musculoskeletal pain. The test is easy to administer, well tolerated, and reflects activities of daily living better than other walk tests [2].

The walked distance reflects exercise capacity determined by maximal cardiopulmonary exercise testing in patients with cardiopulmonary conditions and has a strong association with mortality in primary pulmonary hypertension [3], heart failure [4], and chronic obstructive pulmonary disease (COPD) [5]. The test is also used for assessing the effect of therapies such as pulmonary rehabilitation, oxygen therapy, long - term use of inhaled corticosteroids, and lung volume reduction surgery [6]. In the interpretation of the results, a change in walking distance of more than 50 m is usually considered clinically significant in most disease states [6].

Although the test is easy to perform, it involves costs and some practical limitations. To start with, it requires a dedicated corridor in the hospital, of length between 30 m and 50 m and no shorter than 15 m [7]. It also requires a physiologist to observe the test and to note down the measurements. Patients need to get to the hospital clinic where the test is performed, sometimes from a long distance, with associated costs of transport and the accompanying stress for the patient. Owing to these limitations, the 6MWT cannot be performed very often. For example, pulmonary hypertension patients are invited to perform a test every 3 to 6 months only [8].

With the advent of affordable digital devices and mobile phones, it becomes possible to perform the test in (or near) the patient's home, using sensors such as accelerometers or the global positioning system (GPS) to estimate the distance walked.

Objectives

In this paper, we present a mobile phone app which enables patients to perform the 6MWT on their own, at their convenience or in the hospital setting, while augmenting the information collected during the test using off-the-shelf portable pulse oximeters.

Related Work

The walked distance can be obtained using satellite positioning systems when outdoors and with inertial sensors when indoor.

Positioning systems like GPS are already widely used for estimating distance in the automotive sector. Modern GPS receivers provide a signal which is the result of heavy processing and is usually improved and smoothed with well-known techniques [9]. When used with human beings, these systems are known to introduce some error because of the inherent noise that exists in the GPS system and the lower distances travelled [10-12]. Nonetheless, the error is such that it has been considered negligible in previous work when GPS has been applied to estimate distance walked in the 6MWT [13]. As most algorithms used by GPS devices are proprietary, there is a lack of the literature describing how to derive the distance from the raw positions, except for the obvious computation of the distance between the first and the last received positions [12].

With regard to the indoor scenario, there is rich literature related to gait analysis with accelerometers [14-17]. From gait analysis, it is possible to compute the number of steps, which, once multiplied by the length of the step, would provide the distance walked.

In a study by Schimpl et al [18], 12 different algorithms for extracting human speed (and thus distance walked) from accelerometer data were explored. Some proposed algorithms make use of the step length as an input, whereas others rely purely on the accelerometry. From a validation against data recordings obtained from 17 subjects walking at different speeds, the authors found that the best performing algorithm was a support vector regression algorithm that was previously trained on an independent dataset recorded from 15 subjects who participated in 3 outdoor data collection activities. A similar approach was also followed in a study by Cheng et al [19] but using a mobile phone instead of a dedicated sensor. Data were processed in both the time and frequency domains, and 8 gait parameters were extracted as the inputs to a support vector regression model to estimate gait speed. The approach was validated with 6 COPD patients and 6 healthy subjects performing a 6MWT. These machine learning approaches, although accurate, rely heavily on the training data, and may be biased toward the walking style adopted during the data acquisition or the actual devices used.

Gait analysis–based approaches have also been used for the 6MWT. For example, in a study by Schulte et al [20], a telemonitoring system for 6MWT based on body-worn accelerometers was proposed. A simple step-detection algorithm was employed and combined with patient height data to estimate the distance walked. A more sophisticated approach was taken by Capela et al [21,22]; they used a mobile phone app to count steps and identify when the user turns while walking back and forth along a corridor. As the distance walked between U-turns is fixed, it is possible to estimate the step length and, thus, the residual distance walked after the last U-turn by multiplying the number of steps by the stride length. The algorithm uses the azimuth signal provided by Blackberry phones, which is, in turn, estimated from the gyroscope and the magnetometer sensors. Some corrections are introduced to this signal to smooth sudden variations, for example, detecting a turn if the signal changes by more than 100° in 3 seconds. The approach was validated with 15 volunteers and led to less than 1 m average error.

In addition to research papers, it is also worth mentioning the Apple Research Kit, an open-source software framework that allows developers to build mobile health (mHealth) apps with a set of already implemented use-cases. One of these use-cases is the *timed walk*, which can be used to implement the 6MWT. The timed walk activity estimation has already been used in a few studies [23,24], even though the accuracy of the algorithm used to estimate the distance, based on the Core Motion framework, is not publicly disclosed. In a recent study [25], after having used Core Motion for 6MWT with peripheral artery disease (PAD) patients, authors concluded that "the iPhone's built-in distance algorithm is unable to accurately measure distance, suggesting that custom algorithms are necessary for using iPhones as a platform for monitoring distance walked in PAD patients."

Methods

System Design

Our system was co-designed by a team of engineers, cardiologists, physiologists, and patients in a set of *discussion groups* [26], which were part of our Patient and Public Involvement in research strategy [27]. The team focused mainly on patients with pulmonary hypertension, especially because they are treated with pulmonary vasodilator therapies, which are expensive, and uptitration of these depends partly on the results of the 6MWT [28]. There are many types of pulmonary hypertension including idiopathic, chronic thromboembolic, secondary to congenital heart disease, secondary to respiratory, or cardiac disease [29], and therefore, the demographics of the patients can be diverse, for example, patients with congenital heart disease have different characteristics compared with patients with interstitial lung disease. The research team decided to recruit adults, without learning difficulties, who were familiar with mobile phones. Patients had to be able to walk independently and were not using oxygen therapy.

It was also decided to make use of patients' own phones, instead of providing them with dedicated ones. This was because we hypothesized that users would prefer using the devices with which they are familiar; however, this meant that both Android and iPhones had to be supported. This decision also allowed us to collect information about free-living physical activity, as gathered by the phone's sensors or any wearable connected to it.

Given that these patients can desaturate significantly during exertion, it was decided to acquire pulse oximetry data during the 6MWT with a wireless sensor attached to the patient's finger. To complement the observations made by the physiologist with these data, the mobile phone also had to be used during the test at the hospital. In addition, the clinician responsible for the patient's care, in this case the cardiologist, had to be given an interface to review all the patient's data collected by the system.

To summarize these requirements, the following use-cases were identified:

1. A patient performs the 6MWT in the hospital, while being monitored by a mobile phone app.
2. A physiologist supervising the 6MWT enters the observed outcomes on a tablet computer.
3. A patient performs the 6MWT outdoors, in a place of their choice.
4. A patient sends their physical activity data, as measured by passive monitors and activity trackers over the duration of a week.
5. A clinician reviews patient's data on a website.

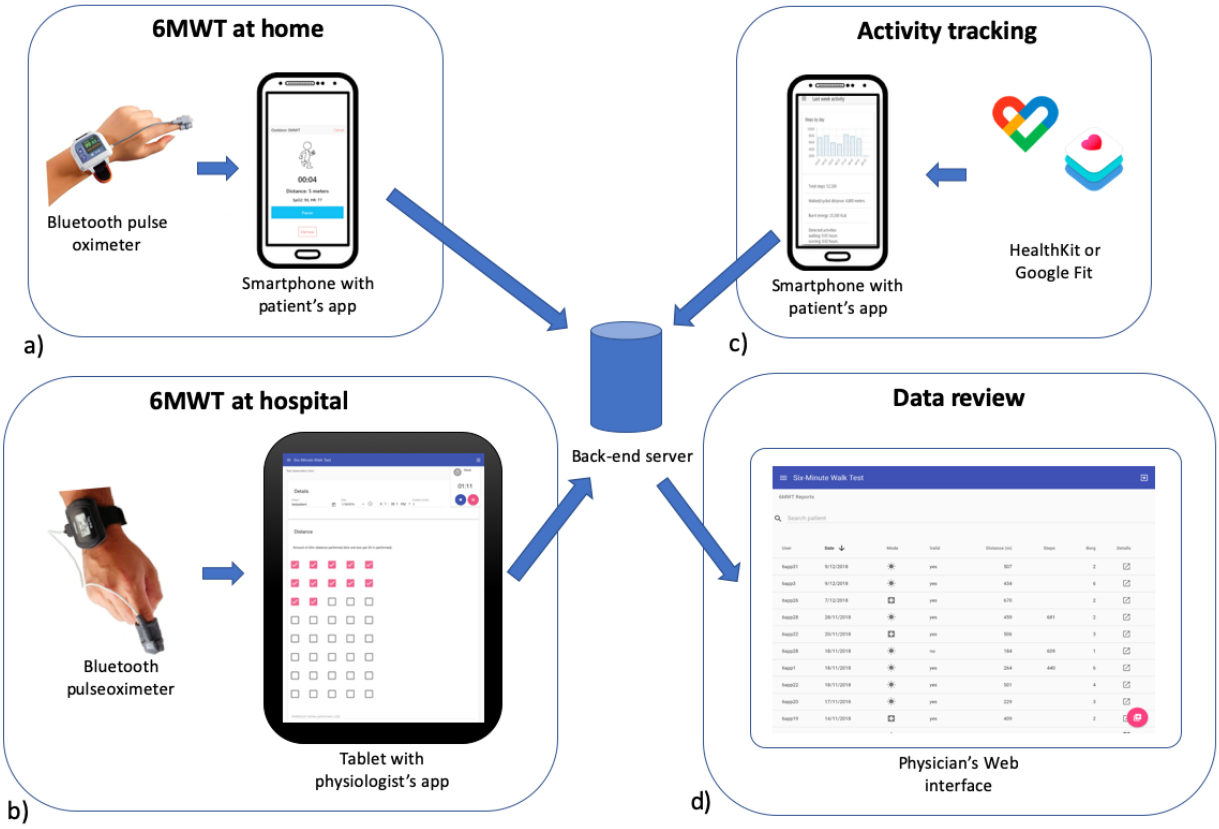
To support the abovementioned use-cases, we designed the client-server architecture shown in Figure 1.

The server includes a database and a website to collect patient data to be subsequently reviewed by clinicians. Physiologists can use a tablet computer with an app that allows them to review patients' information and report the results of the 6MWT. The app also allows connection to a wireless pulse oximeter to retrieve peripheral arterial oxygen saturation (SpO_2) and heart rate values, while the patient is performing the test.

Patients are provided with a mobile phone app, downloaded onto their phones, which allows both indoor and outdoor 6MWT. The indoor test is performed on a walkway of a known length, for example, in a hospital clinic. The outdoor test can be performed in any place where there is a GPS signal of sufficient strength. At the end of each test, the data are sent to the server to be reviewed by clinicians. Patients can also send data about passive activity monitoring using HealthKit for iOS and Google Fit for Android. These can compute steps and activity through either mobile phone sensors or other connected apps.

Patient data are protected by means of well-established techniques, that is, users are authenticated with a username and password, and data are transmitted over an http encrypted channel.

Figure 1. Architecture of the 6-min walk test (6MWT) system. It includes 4 scenarios: (a) 6MWT at home, where patients perform a 6MWT in their home setting using their mobile phone with the app and a wireless pulse oximeter; (b) 6MWT in the hospital, where patients perform the test while being observed by a physician and with pulse oximetry data being collected through a tablet app; (c) activity tracking data retrieved by Google Fit or HealthKit transmitted for subsequent analysis; (d) data review performed by a physician through a Web interface.



Distance Estimation

To compute the distance walked, we developed and tested 2 algorithms: one for the indoor scenario and one for the outdoor scenario.

The accuracy of the algorithms was estimated by performing a set of indoor and outdoor 6MWTs, with the app running on a mobile phone held in one hand and a trundle wheel held in the other hand. Different types of walking styles (from slow to fast), path curviness (from straight to U-turns), and hand shakiness (from still to slightly shaky) were simulated.

Most tests were executed by researchers in lab settings; however, to fine tune the indoor algorithm in real-life conditions, we also asked some patients to hold the mobile phone while performing the 6MWT during a regular clinic visit. Only the distance and an approximate age range were collected.

Accuracy was calculated using the mean, median, and standard deviation of the difference between the reference values and the outputs from our algorithm; the mean, standard deviation, minimum and maximum of the absolute difference; and the Pearson correlation between estimated values and the reference values. In addition, Bland-Altman plots were also generated.

Details about the algorithms are provided as follows.

Indoor Distance Estimation Algorithm

We tried to implement the algorithm described by Capela et al [22], but, possibly as we employed a different operating system, or possibly because of the lack of details in the paper, our implementation was not capable of detecting any U-turn. We therefore decided to develop a new approach.

The underlying concept is to detect changes of 180° in the mobile phone azimuth signal (an example of such a signal is shown is Figure 2). To this end, we made use of the *virtual compass* provided by the Android and iOS programming interfaces, which computes the azimuth by combining the signals provided by the accelerometer and the magnetometer. The result of this estimation may lead to some distortions and inaccuracies but, given that we are only interested in large *changes* in the azimuth signal, these are mostly negligible. One exception is the fact that the maximum amplitude of the signal, on which the algorithm relies, may be less than 360°. To account for this, the algorithm requires a simple calibration phase, in which users are asked to execute a 360° turn with the mobile phone in one hand, so that the minimum and maximum azimuths are captured.

After calibration, samples of the compass signal are acquired every 500 ms. If the current sample is more than *min_turn_time* milliseconds away from either the start of the test or the latest detected U-turn, the sample is compared against past samples collected in a buffer. If the minimum difference between the angles of any of those samples is less than a predetermined threshold, then a U-turn is detected.

The parameters to be optimized in this algorithm are *min_turn_time*, the length of the buffer, and the threshold, which is set to be 35% of the difference between the maximum and

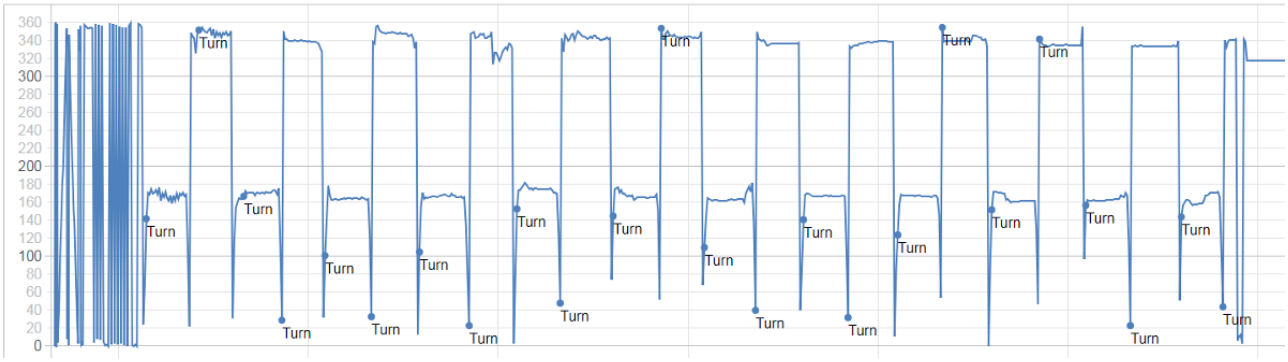
the minimum values observed during the calibration. As for the *min_turn_time*, it is given an initial value of 10 seconds, and then adapted to the actual walking speed of the patient; each time a U-turn is detected, *min_turn_time* is updated to be the minimum observed time needed to complete a lap, minus 20%. If *min_turn_time* is such that the speed of the patient would be more than 2 m/s, it is capped. The length of the buffer is initialized to contain 4 seconds' worth of samples. This number of seconds is then updated, every time a U-turn is detected, to half of *min_turn_time*, but capped at 5 seconds.

Once U-turns are detected, the walked distance is computed by multiplying the number of U-turns by the length of the lap. Any residual time between the last U-turn and the end of the test is accounted for by multiplying it by the median of the detected times between U-turns.

If a step counter is available, it is used to improve the residual distance estimation. Specifically, instead of using the median *between U-turns* completion time, the average step length (ie, the total distance divided by the total number of steps up to the last U-turn) is multiplied by the residual number of steps since the last U-turn.

The source code of the algorithm is provided in the Multimedia Appendix 1.

Figure 2. Example of mobile phone azimuth signal. The first seconds show the calibration phase, after which U-turns are detected when the difference between near angles becomes greater than the set threshold within a short time window.



Outdoor Distance Estimation Algorithm

The outdoor algorithm works by using the localization information provided by the GPS system embedded in the phone (an example is shown in Figure 3). The principle is based on down-sampling the positioning signal, calculating the *as the crow flies* distance between each sample and summing up the distances thus obtained. Down-sampling is used as a strategy to reduce the noise contained in the signal, but instead of simply taking a sample every x seconds, we adopted a more sophisticated approach.

As the mobile phone GPS system needs some time to be fully connected, we let the user wait until a *good* signal is available. Both Android and iOS operating systems provide an error estimation for each positioning sample, based on the number of visible satellites. We experimentally observed in lab tests that an error lower than 15 m indicates that the GPS system has found enough satellites to localize the phone and, likely, the error would decrease further. If the error does not decrease below 15 m within 2 min after the start, the test is flagged as possibly affected by low accuracy.

After this simple signal quality step, positioning samples start to be collected. Every *selection_period* seconds, the algorithm selects the sample with the lowest estimated error within those available within the last 25% of *selection_period*. Once a sample has been selected, the distance between the previous selected sample and the newly selected one is computed and added to the total.

The *selection_period* parameter needs to be optimized. A faster sampling period will allow more samples to be used and therefore more noise to be accounted for in the distance estimation. A longer period is problematic if the path walked by the user is not straight (in a perfectly straight path, in fact, just the first and the last sample would suffice). To optimize this parameter, we computed the mean and maximum distance estimation error using the tracks acquired during our tests and varying *selection_period* from 0 second to 20 seconds with 1-seconds steps. The value that minimizes both mean and maximum error is 5 seconds, as shown in Figure 4.

If step counting is available, we use it to exclude samples for which the number of steps does not increase. For example, a perfectly still mobile phone will produce positioning samples with jitter around them because of noise, and the algorithm will sum up the distances between them. By using the step counter, it is possible to identify when the user is still, thus not accumulating those erroneous distances.

The source code of the algorithm is provided in the Multimedia Appendix 2.

Figure 3. Example of a positioning trace (in red) retrieved from the mobile phone. The walking man figure indicates the starting point of the test; the flag indicates its end. Comparing the trace with the underlying picture shows that the position is sometimes affected by an error, for example, near tall buildings which reflect the signal or because of trees obscuring the global positioning system satellite's signal.

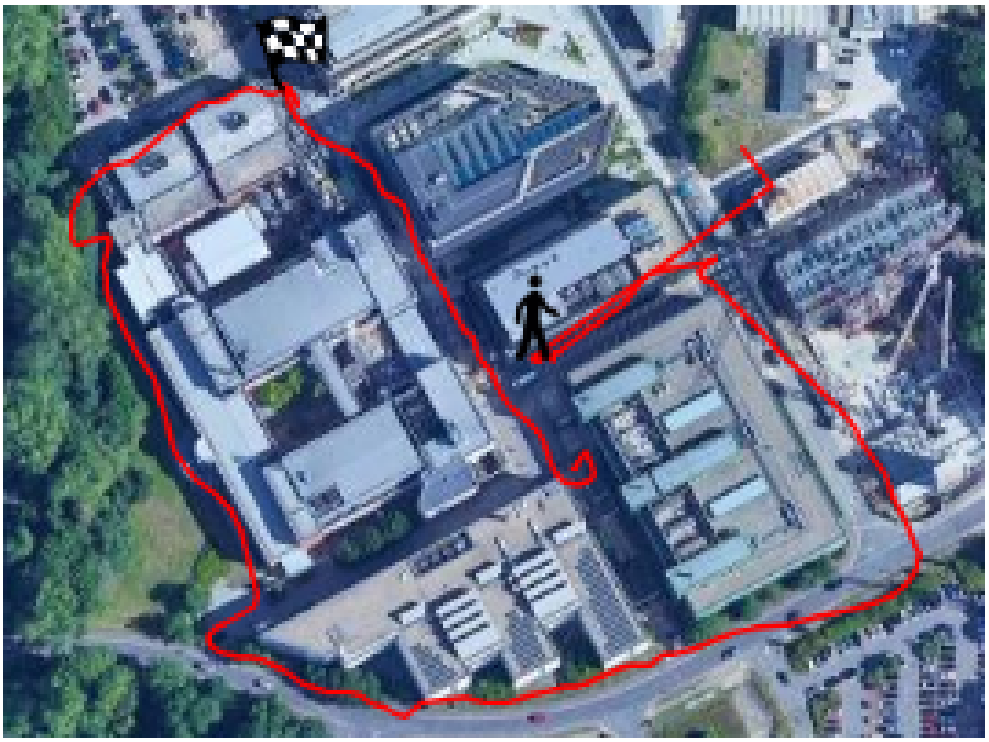
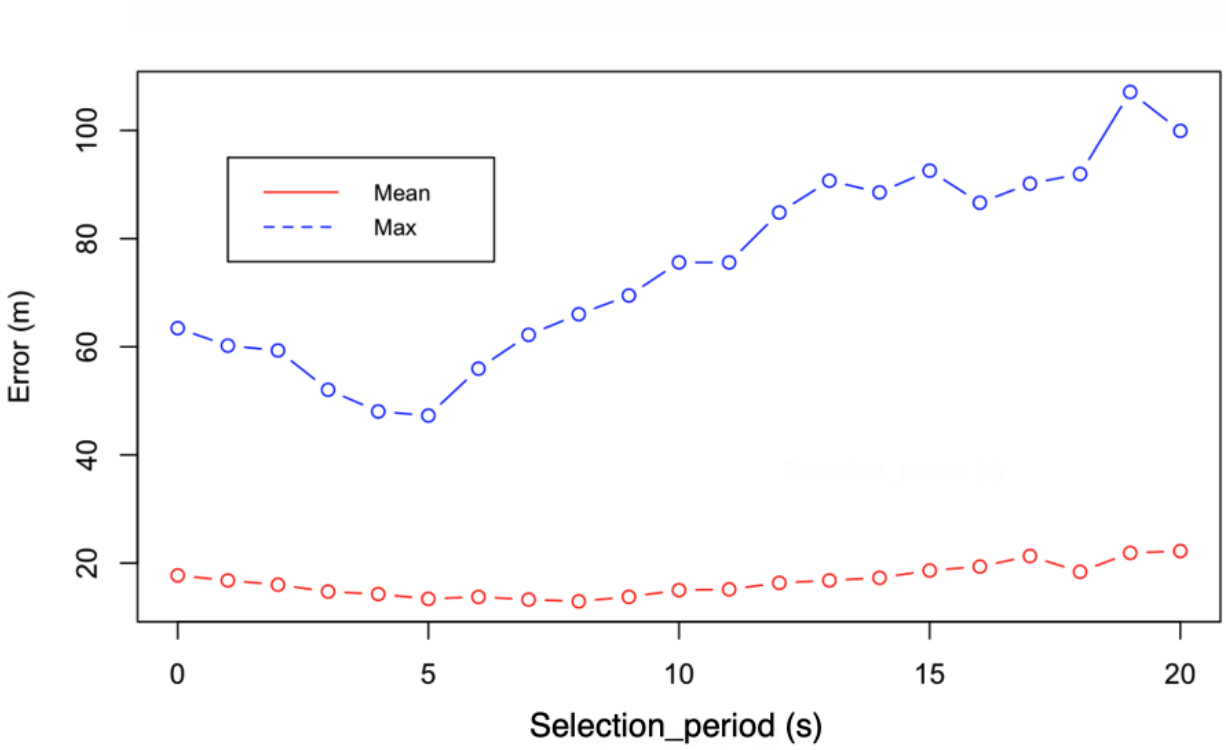


Figure 4. Maximum and mean error of the distance estimation versus the sampling period of the localization signal selection_period computed on all available tests. The 5 seconds value minimizes both mean and maximum error.



User Aspects

To understand user aspects such as the usability and technology acceptance of our system, we organized a discussion group to collaboratively analyze one of the first prototypes that had been developed. Different types of stakeholders were invited to the group including patients, physiologists, physicians, and engineers. Participants were informed that the outcomes of the discussion could be used for scientific publications, and patients were required to sign an informed consent form.

To structure the content of the discussion group, we used the mHealth technology acceptance model form [30], which integrates common technology acceptance and health behavior theories. The model includes 8 constructs: response efficacy, perceived ease of use, subjective norm, response cost, self-efficacy, perceived vulnerability, perceived severity, and intention to adopt. Of these, we selected perceived ease of use, response cost, self-efficacy, response efficacy, perceived vulnerability, and intention to adopt as the most appropriate to our project and stage of development.

The discussion group was led by one researcher, who explained the system and its capabilities and asked the attendees questions. The content was split into 5 parts. In the first part, 2 questions were asked to understand what the current limitations and needs were in relation to a conventional 6MWT:

- Q1. What are the most annoying things about the 6MWT as it is done now?
- Q2. How does the test compare with your normal level of fitness; do the test's results adequately reflect the way you feel?

After a discussion of the answers to these 2 questions, a general presentation of the system was given (part 2), after which, other questions were asked about the overall concept (part 3):

- Q3. What do you think are the advantages of the system you have just seen?
- Q4. What are the disadvantages?

The fourth part of the discussion consisted in letting patients download the app on their phone and use it in a test run, while the research team recorded difficulties, technical issues, and general comments.

Finally, in part 5, a further set of questions were asked about usability and acceptance:

- Q5. Do you find the system easy to use?
- Q6. Would you suggest any changes to it?
- Q7. Do you see yourself performing the test at home?
- Q8. Would you need someone to help you?
- Q9. Would you use the indoor or the outdoor test?
- Q10. How often do you think you will be doing it?
- Q11. Do you see yourself using the app in the long term (2 years or more)?

These questions were mapped to the constructs under analysis as follows: perceived ease of use: Q5, self-efficacy: Q7 and Q8, response cost: Q4, response efficacy: Q3, perceived vulnerability: Q1 and Q2, intention to adopt: Q9, Q10, and Q11.

The discussion was audio-recorded for later analysis.

Results

System Design

We developed 2 apps, 1 for the patient and 1 for the physiologist, as well as a server for the back-end system.

Having decided to use the patients' own mobile phones, we needed to support both Android and iOS operating systems. We therefore implemented the patients' app using the Apache Cordova framework. In addition to Cordova, the app makes use of the Ionic framework (first version), which uses Angular as the front-end JavaScript framework.

To retrieve the data about passive monitoring, we connected the app to Google Fit on Android and HealthKit on iOS. Both systems provide an *aggregator* for wearables and fitness apps and are able to compute steps and basic activity recognition (still, walking, running, and on a vehicle) relying on the mobile phone's sensors.

For ambulatory pulse oximetry, we chose the Nonin WristOx (only compatible with Android) and Creative Medical PC68B (compatible with both Android and iOS) because they are wrist-worn, with a finger probe, and because of their Bluetooth wireless connectivity.

The outdoor 6MWT use-case is shown in Figure 5: the patient triggers a new test on the mobile phone's home screen; the app shows suggestions on how to perform the test in the best conditions, then waits for the pulse oximeter to be connected, and records a baseline measurement of heart rate and oxygen saturation at rest. The patient is then invited to walk for 6 min, during which the walked distance estimation and a timer are shown. The patient is allowed to pause or cancel the test at any point. At the end of the 6-min period, the patient is again invited to rest, while recovery heart rate and oxygen saturation are measured. Finally, the patient answers the Borg scale question and can add some general comments. During the test, the app also retrieves the local weather information from a Web-based service. This is used to explore the relationship between compliance or exertion levels and weather.

The server system consists of a nonrelational database (ArangoDB), a REST API developed with Nodejs, and a front-end website developed with Angular. The Web interface (Figure 6) allows physiologists and doctors to manage users, enter the results of a hospital 6MWT, review the data produced both by the app and hospital tests, and analyze trends for each patient. The physiologists' app is a Cordova app that uses the same front-end code as used for the server with some modifications to allow the data to be retrieved from wireless pulse oximeters.

Figure 5. Screenshots of the patients' app. (a) Home page, (b) instructions about how to perform the test, (c) connection to the pulse oximeter and baseline measurements at rest, (d) estimation of the distance during walk, (e) total distance estimation and recovery at rest, (f) Borg scale questionnaire.

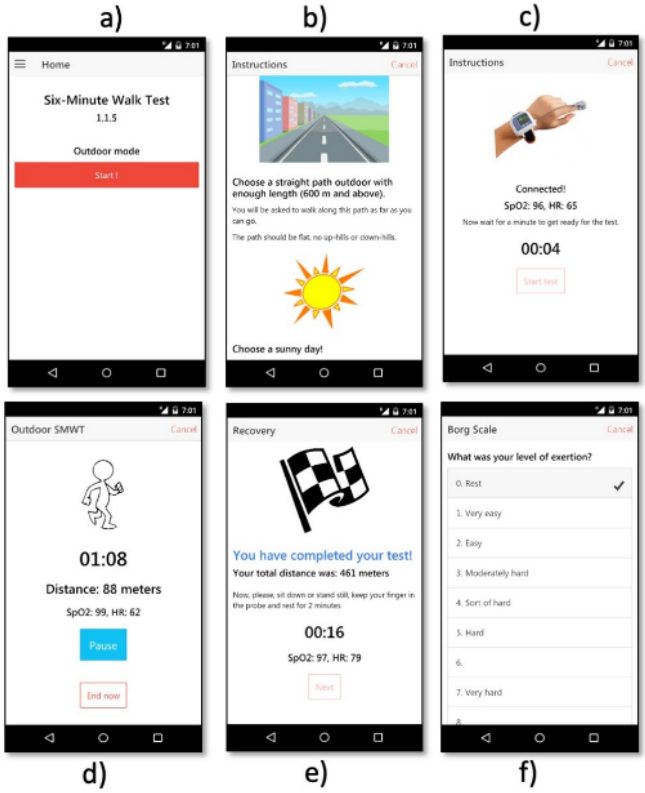
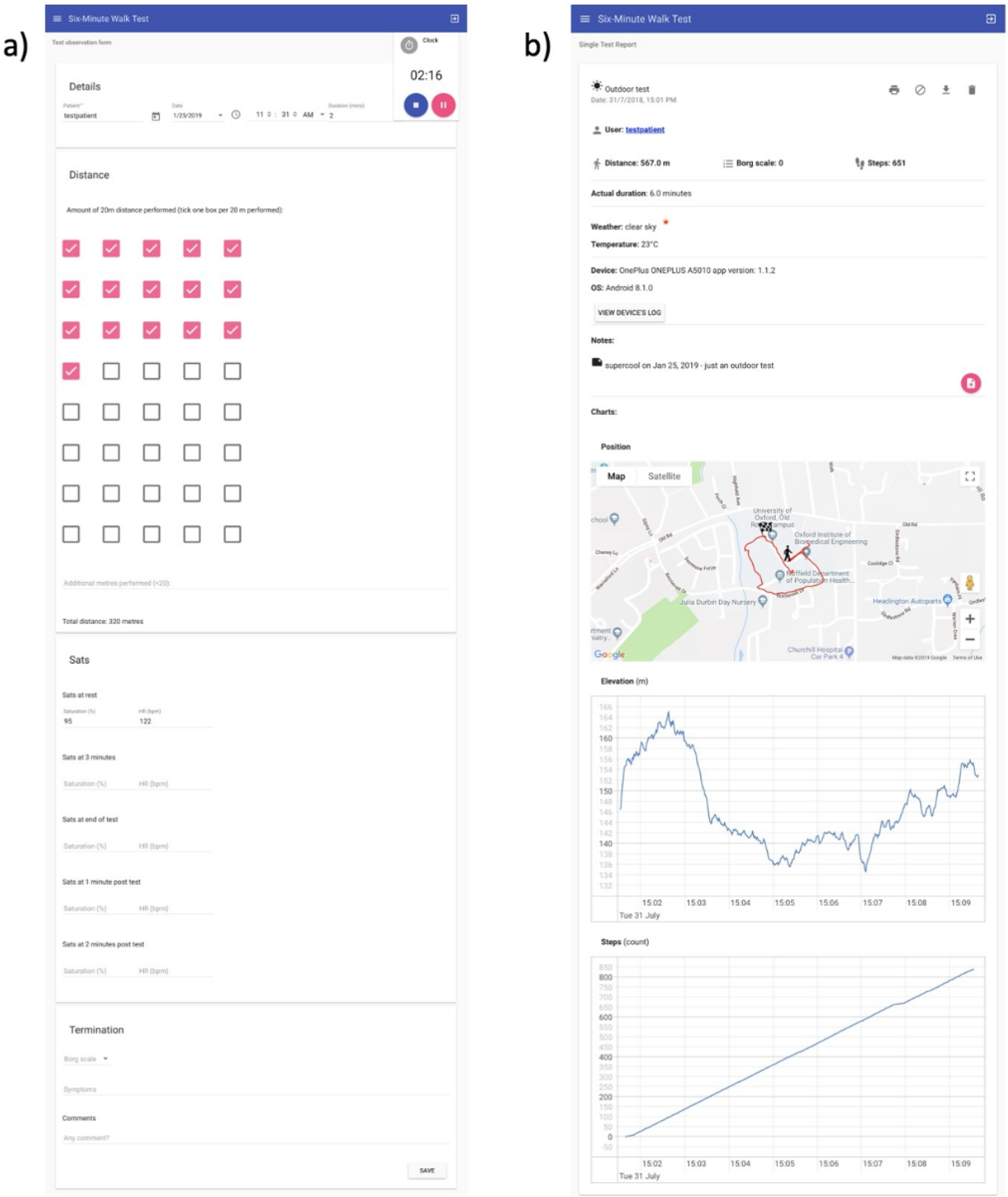


Figure 6. Screenshots of the server Web interface. (a) The form physiologists fill in when observing a 6-min walk test (6MWT), (b) an example of an outdoor 6MWT results (heart rate and oxygen saturation charts are omitted).



Distance Estimation

A total of 79 indoor and outdoor tests were performed. Lab tests were undertaken by researchers, all males, aged 30, 33, and 37. The distance estimated in regular 6MWT clinics was collected 18 times from both male and female volunteers and with an age span of 15 to 85 years.

The accuracy of the algorithm is reported separately for the indoor and outdoor scenarios.

Accuracy of the Indoor Algorithm

The accuracy of the indoor algorithm was estimated using results from 49 tests. The characteristics of the tests are shown in Table 1.

The difference between the algorithm's estimates and the measurements taken from the trundle wheel are summarized in Table 2, with the Bland-Altman plot shown in Figure 7.

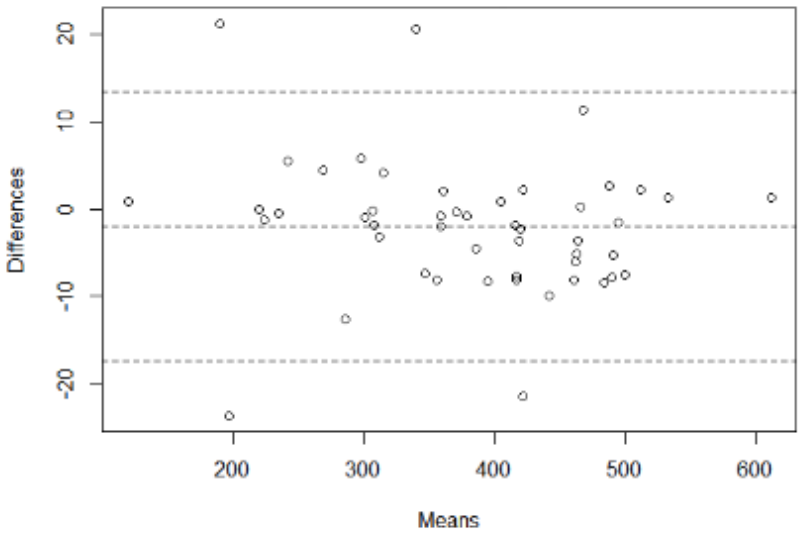
Table 1. Summary characteristics of the indoor tests.

Characteristics	Value
Number of tests	49
Number of different phones tested	11
Walked distance measured by trundle wheel (m), mean (SD)	381.79 (103.90)
Steps, as estimated by the phone's pedometer, mean (SD)	574.10 (146.30)

Table 2. Accuracy metrics for the indoor algorithm. By difference, we mean the difference between the estimated distance as computed by the app and the reference distance, as measured by the trundle wheel.

Accuracy metric	Value
Mean difference (m)	−2.01
Median difference (m)	−1.51
Standard deviation of the difference (m)	7.84
Correlation	0.99
Mean absolute difference (m)	5.55
Standard deviation of the absolute difference (m)	5.84
Minimum absolute difference (m)	0
Maximum absolute difference (m)	23.68

Figure 7. Bland-Altman plot of the difference between the estimated distance walked and the absolute distance. The Shapiro-Wilk test confirms the normality of the data (0.91).



Accuracy of the Outdoor Algorithm

The characteristics of the outdoor tests are shown in Table 3.

The accuracy metrics are listed in Table 4, with the Bland-Altman plot shown in Figure 8.

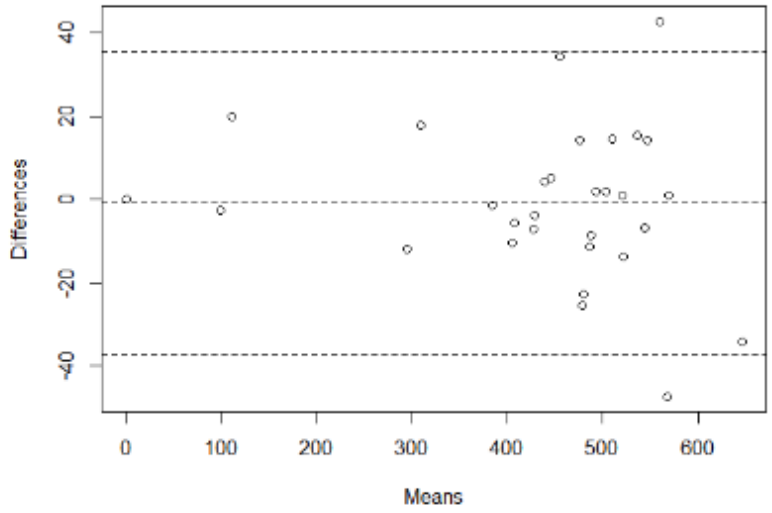
Table 3. Characteristics of the outdoor tests.

Characteristic	Value
Number of tests	30
Number of different phones tested	8
Walked distance measured by trundle wheel (m), mean (SD)	437.99 (147.82)
Steps, as estimated by the phone's pedometer, mean (SD)	696.5 (78.31)

Table 4. Accuracy metrics of the outdoor algorithm. By difference, we mean the difference between the estimated distance as computed by the app and the reference distance, as measured by the trundle wheel.

Accuracy metric	Value
Mean difference (m)	−0.80
Median difference (m)	−0.63
Standard deviation of the difference (m)	18.56
Correlation	0.99
Mean absolute difference (m)	13.39
Standard deviation of the absolute difference (m)	12.65
Minimum absolute difference (m)	0
Maximum absolute difference (m)	47.27

Figure 8. Bland-Altman plot of the difference between the estimated distance walked and the ground truth. The Shapiro-Wilk test confirms the normality of the data (0.97).



User Aspects

The discussion group mentioned in the Methods section was held shortly after the first version of the app was ready. The attendees were 2 engineers, 1 cardiologist, 1 nurse, 2 physiologists, and 2 patients with pulmonary hypertension. One engineer led the discussion, while the other took notes.

From the initial discussion, the main issues with the way that the 6MWT is currently performed in hospital were identified as follows:

1. The corridor being used in the hospital was not ideal, as it was usually busy with other people and patients being moved on trolleys, both of which may affect the walking pace.
2. Patients' performance might depend on their health status on that particular day and may not reflect their average status.
3. The test is only performed rarely (once or twice a year), and episodes of health deterioration may be missed.
4. Younger patients might underperform as opposed to the older ones who may try harder in the hospital test, which might not reflect real-life conditions.
5. White coat syndrome may cause anxiety in some patients and affect their performance.
6. Overall, patients are stressed and rushed in hospital.

After the app and monitoring system were presented, the following advantages were identified:

1. The system allows the patient to perform the test in a more comfortable environment and more often than the hospital tests.
2. Patients can see for themselves how they are progressing.
3. The system can alert in the case of very low oxygen saturations.

In terms of disadvantages:

1. When the test is performed outdoors, the weather can affect the patient's performance.
2. Changes in altitude, as a result of walking up an incline, can affect the results of the test.

During the dry-run test of the system with 2 patients, the following observations were made:

1. The pulse oximeter generates a sound when a low oxygen saturation value is measured, but this can be disabled.

2. A patient had problems understanding how to wear the pulse oximeter.
3. Patients were able to install the app correctly and could understand its structure easily.
4. One patient tried to send their activity tracking data but did not have Google Fit installed.
5. Patients struggled to log in, because complex passwords with capital and lower case letters were originally assigned to them.
6. During a test, the pulse oximeter produced artefactual values.
7. A physiologist asked to be able to discard the results of a test if the data recorded did not appear to be accurate enough to them.

With respect to the usability of the app, the patients' comments were as follows:

1. The app is usable and easy to understand.
2. It would be better to show how many seconds are left until the end of the test, rather than how many seconds have elapsed since the start.
3. One patient asked for a sound to be generated at the end of the test to allow them not to have to look at the mobile phone screen all the time.

Regarding the willingness to use the app, the following points were noted:

1. Both patients said that they would use the app regularly and would not need any help to do so.
2. One patient would prefer performing the test indoors during winter because the cold weather affects their breathing, whereas the other patient only wanted to use the outdoor version.
3. As indoor tests require a long passageway, it was suggested that shopping malls could be used for these tests.
4. One patient would like to place the mobile phone on an armband or in a pocket during the test.
5. Patients identified scenarios for which they could perform the test while doing some other activity, for example, taking children to and from school.
6. Both patients agreed to use the app in the long term.

Discussion

Distance Estimation

The results from our tests show that, in both the indoor and outdoor scenarios, the difference between the distance estimated by the app and the ground truth is always below 54 m, when 50 m is considered to be the clinically significant threshold for detecting changes in disease state [6].

If we compare our accuracy results with those reported in the literature, for the outdoor scenario, an average error of a few meters, up to a maximum of 20 m, was reported by Gray et al [10], which is consistent with our findings, although our maximum difference was higher. For the indoor scenario, in a study by Schulte et al [20], an average absolute error of 4% was reported, as compared with our 0.02%. One difference between the approach adopted by Capela et al [21] and ours is that the authors used inertial sensors worn on the body, not the sensors in a mobile phone. In the studies by Capela et al [21,22], the reported maximum error in distance estimation was 2 m compared with our maximum of 23 m. We should point out, however, that the method described in those papers was only validated with 1 phone and with 15 tests, as compared with our 11 mobile phones and 49 tests.

As limitations to our approach, we should mention that most of the accuracy tests were performed by researchers in a lab environment. Although we tried to simulate worst-case scenarios, it is possible that the distance estimation algorithm may perform worse *in the wild*. For example, the indoor algorithm is based on the assumption that the azimuth signal is not very noisy, and it requires the user to hold the phone relatively still, which may be not always be the case for some users. The outdoor algorithm is instead based on the assumption that the path walked by the user is straight or gently curved. To mitigate these factors, the app displays clear instructions before each test is initiated. In addition, we are planning to deliver a leaflet with written instructions and to provide a short training session before regular use of the app by the patient.

User Aspects

In terms of user aspects, the results from the discussion group suggest that the way the 6MWT is performed in hospitals has significant limitations (a *perceived vulnerability* [30]) that our system, at least partially, addresses, thus offering *response efficacy* in relation to that vulnerability. But a *response cost*, that is, limitations to the validity of the measurements in the case of bad weather or a slope, was also pointed out.

In terms of *perceived ease of use*, patients were immediately able to use the app by themselves. This may also be justified by the fact that they regularly used a mobile phone and, thus, were also highly *self-efficient*.

Given the positive answers provided for its associated constructs, *intention to adopt* would be expected to be high. Indeed, patients declared to be willing to try the app. The fact that they tried to contextualize its use in their life, for example, while shopping or taking children to school, may indicate a genuine interest in this technology.

Although the indications of the discussion group were generally supportive of the system, there are risks that can affect its actual use; particularly, the fact that it has to be either used outdoors, which is limited by the weather, or indoors but in a long corridor, which is limited by the availability of space. In addition, the integration with the sensor and external apps makes the overall user experience more cumbersome, a fact that may affect some less tech-savvy users.

Conclusions and Future Work

The system described in this paper allows patients to perform the 6MWT at a place of their convenience, thus allowing more information to be generated about their general health status, more frequently, and possibly reflecting their general health status better. The algorithms implemented to estimate the distance walked from either the compass or GPS showed good agreement with the reference trundle wheel measurements, with

errors below the clinically significant threshold. Our preliminary user validation also indicates that the app is usable and has the potential to be well accepted among patients.

The system will need to be tested with more patients to assess its feasibility in a real-world scenario. A clinical trial is currently being run with 30 pulmonary hypertension patients to understand the relationship between tests undertaken using the app and conventional in-hospital tests. Further studies will then be needed to assess the clinical significance of the tests in the community and the relationship between passive activity monitoring, for example, through wearables and in-hospital 6MWT results.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Javascript implementation of the indoor distance estimation algorithm.
[TXT File , 6 KB - mhealth_v8i1e13756_app1.txt]

Multimedia Appendix 2
Javascript implementation of the outdoor distance estimation algorithm.
[TXT File , 7 KB - mhealth_v8i1e13756_app2.txt]

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Abbreviations

6MWT: 6-min walk test
COPD: chronic obstructive pulmonary disease

GPS: global positioning system
mHealth: mobile health
PAD: peripheral artery disease

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Original Paper

Spatiotemporal Analysis of Men Who Have Sex With Men in Mainland China: Social App Capture-Recapture Method

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Abstract

Background: In China, the cases of newly diagnosed HIV/AIDS in men who have sex with men (MSM) have increased more than tenfold since 2006. However, the MSM population size, geographical distribution, and migration patterns are largely unknown.

Objective: Our aim is to estimate the number, spatial distribution, and migration of MSM populations in mainland China using big data from social networking.

Methods: We collected 85 days of data on online users of a social networking MSM app in mainland China. Daily online MSM users and their migration across the country were investigated during a holiday period and a nonholiday period. Using the capture-mark-recapture model, we designed an experiment consisting of two independent samples to estimate the total provincial MSM population.

Results: The estimate of MSM in mainland China was 8,288,536 (95% CI 8,274,931-8,302,141), accounting for 1.732% (95% CI 1.729%-1.734%) of adult men aged 18 to 64 years. The average daily number of MSM social networking online across mainland China was 1,198,682 during the nonholiday period. The five provinces (including municipalities) with the highest average number of daily online MSM numbers were Guangdong (n=141,712), Jiangsu (n=90,710), Zhejiang (n=72,212), Shandong (n=68,065), and Beijing (n=66,057). The proportion of daily online MSM among adult men in different cities varied from 0.04% to 0.96%, with a mean of 0.20% (SD 0.14%). Three migrating centers—Guangdong, Beijing, and the Yangtze River Delta (Shanghai-Zhejiang-Jiangsu)—accounted for 57.23% of MSM migrants in the county.

Conclusions: The percentage of MSM among adult men in mainland China is at the middle level compared with other Asia and Pacific countries. However, the number of MSM is very large, and the distribution is uneven. Both MSM distribution and migration are highly affected by socioeconomic status.

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KEYWORDS

HIV risk; men who have sex with men; MSM distribution; migration

Introduction

Men who have sex with men (MSM) have a substantially disproportionate risk for HIV infection, and the number of HIV cases found among MSM continues to increase in most countries [1-3]. In the United States, MSM accounted for 53% and 67% of new HIV diagnoses in 2006 and 2014, respectively [4,5]. In China, the risk of HIV transmission among MSM is estimated to be 45 times higher than that of heterosexual transmission [6]. The prevalence of HIV in MSM sentinel surveillance continues to increase in China, with rates ranging from 0.9% to 8.0% between 2003 and 2015 [7-9]. In 2006, MSM accounted for

only 2.5% of the newly diagnosed HIV/AIDS cases in China, whereas that number was 25.5% in 2017 [10]. To monitor the prevalence of HIV among MSM, China has built 108 national sentinel sites [11]. The sentinel surveillance collects and reports HIV testing data among MSM and the characteristics of the target population by sampling, although they do not collect data on the total number of MSM. The population size of MSM is an important number for calculating various disease rates among MSM. Without the population-level denominators for MSM, it is difficult to accurately describe the burden disparity of HIV among MSM in different regions.

Purcell et al [5] estimated the proportion of men aged 13 years and older in the United States who engaged in same-sex behavior to be approximately 3.9%. By combing multiple data sources, Grey et al [12] developed refined estimates of the size of the MSM population at the county, city, and state levels. Many studies have estimated the population number by surveying MSM with social networking and mobile phone apps (eg, Grindr [13], Jack'd [14,15], Hornet [16], and Blued [17-19]). Using social app technology and internet-based surveys, MSM numbers in two regions of Vietnam (Ho Chi Minh City and Nghe An province) were estimated. The proportions of MSM among adult men in these regions were 1.35% and 0.17%, respectively [20]. Algarin et al [21] examined the spatial distribution of geosocial networking app usage of MSM in Fayette County, a midsize city in the southern United States, and found that user density was highest in areas with higher populations, lower incomes, and more businesses. In China, based on population sampling, some studies suggest that MSM account for 2% to 4% of adult men [22,23]. The MSM population in several other cities has been estimated in many studies, including Beijing [24], Wuhan [25], Shanghai [26], Chongqing [27], and Shenzhen [28]. Despite the growing significance of MSM in the HIV epidemic and efforts in estimating HIV burden, nationwide figures, including population size, geographical distribution, and migration, are still largely unknown in China. Social media big data in China may help fill this gap.

China has experienced dramatic development in information technology in the past two decades. At the end of 2015, 85.3% of young people had access to the internet, 90% of them via mobile phones [29]. Technological development has significantly changed the ways of socializing and seeking same-sex partners for the MSM population. The internet and mobile social networking apps have largely replaced traditional meeting places, such as bathhouses and bars, and they can be conveniently used to socialize and anonymously seek nearby partners in real time, avoiding MSM stigma and harsh local sociocultural environments [30,31]. In this study, we use big data from social networking to estimate the number, spatial distribution, and migration of MSM populations in mainland China.

Methods

MSM Social Networking Big Data

In mainland China, the mobile phone app Blued is the most popular app dedicated to MSM social networking [32]. The app was developed in 2012 by Blued International Inc, a company founded in 2000 [33]. The app has a market share of more than 90% for MSM communication apps in China [34]. Blued allows users to create personal profiles with pictures and personal information, including age, height, and weight. Like other similar social communication apps, such as Jack'd and Hornet, Blued displays nearby users and their profiles [33]. By simulating moving mobile phone positions along with a regular grid covering the whole country, we collected 85 days of data on online users across China from January 7 to March 28, 2018, and October 22 to November 4, 2018. The data-collecting process contained the following steps. First, we created a 5-kilometer regular grid covering the whole of mainland China. Grids with no people living in them were removed based on the 2015 annual Visible Infrared Imaging Radiometer Suite (VIIRS) nighttime light [35]. Second, to simulate position changing, we installed Blued on an android emulator, NoxPlayer, which can run on a computer [36]. The emulator enables users to set a virtual location. Third, by changing the virtual location of the emulator with coordinates of a grid center and then refreshing Blued, the nearby list on Blued could be updated. We recorded the list and repeated the step. After that, we counted the number of users in each grid and removed duplicated records. To accelerate the operation, an auxiliary computer language program was also developed to automate the process.

In the study, the spatial distributions of MSM social networking users in two periods were compared to find out how users were migrating within the country during the Spring Festival holidays from February 16 to 20, 2018, and during nonholidays (ie, after the Spring Festival travel season from March 12 to 28, 2018). The day of February 21, 2018, was excluded from the holidays because of the large number of people returning to work on the last day of the holidays. For nonholidays, we only used the data after Spring Festival travel because most people have usually returned to work, and the population distribution is more stable. The distribution of MSM during the nonholiday period was considered as the regular MSM population pattern, whereas the distribution of MSM during the holiday period was considered as the origin where the MSM population came from because most Chinese people reunite with their families during the traditional Lunar New Year holidays [37,38].

The Gini coefficient was adopted to measure whether MSM were equally distributed among adult men [39]. It ranges from 0 to 1, with 0 representing perfect equality and 1 representing perfect inequality. Spatial pattern similarity between two geographic distributions was measured by Geodetector q statistic [40].

MSM Population Estimation in China

The obtained MSM data were from only a portion of the total social networking MSM population in China. We designed an experiment based on the capture-mark-recapture method to estimate the overall social networking MSM population. Capture-mark-recapture is an efficient method, originating from biological science, to estimate the size of an animal population [41]. The method requires at least two independent capture samples. For the first sample, a number of animals are captured (sample size m), marked, and released back into the population.

Then, in the second sample (sample size n), recaptured animals can be identified (overlapping sample size k). If the two samples are independent, and each animal has an equal capture possibility, then the case number can be estimated by $(m+1) * (n+1)/(k+1)-1$ for a closed population [41,42]. The capture-mark-recapture method is widely used in a variety of applications, including biology, ecology, and epidemiology [42-44]. We designed an experiment consisting of two independent samples, with each sample covering a period of two weeks, to record online social networking MSM on the Blued app. The first sampling was conducted from March 12 to 28, 2018, and the second sampling was performed from October 22 to November 4, 2018. The time interval between sampling periods was approximately seven months. The total provincial number of social networking MSM was then estimated using the capture-mark-recapture method. However, some MSM do not use social networks. Therefore, we estimated the total provincial MSM population by dividing the provincial social networking MSM population by provincial internet penetration, reported in the China Internet Development Report in 2017 [45].

Ethical Statement

The study only collected public data. No private information was collected, stored, analyzed, or published; thus, no ethical approval and patient consent were required.

Results

Provincial Spatiotemporal Heterogeneity of MSM Using the Social Networking App

Data on 3,429,705 social networking MSM in China were collected during the study period from January 7 to March 28, 2018. Among these MSM, 2,010,096 and 2,449,493 were online during the Spring Festival holidays (February 16-20) and nonholidays (after the Spring Festival travel season from March 12-28), respectively. During nonholidays, the average number of daily online MSM was 1,198,682 across mainland China. The 10 provinces (including municipalities) with the highest average number of daily online MSM numbers were Guangdong (n=141,712), Jiangsu (n=90,710), Zhejiang (n=72,212), Shandong (n=68,065), Beijing (n=66,057), Sichuan (n=64,258), Henan (n=54,642), Shanghai (n=51,908), Hebei (n=48,926), and Liaoning (n=45,773). These provinces accounted for 58.75% of the number of daily online MSM in mainland China (Figure 1). The number of social networking MSM in Guangdong, which accounted for 11.82% of daily online MSM across all mainland China during the nonholiday period, was higher than that in other provinces. Qinghai and Tibet provinces had fewer than 5000 daily online MSM. Ningxia and Hainan provinces had fewer than 10,000 daily online MSM. By dividing the number of daily online MSM by the number of adult men aged between 18 and 64 years (from the 2010 national population census), Beijing and Shanghai were found to be the two municipalities with the highest proportions of daily online MSM (0.82% and 0.56%, respectively), followed by Guangdong (0.37%), Tianjin (0.36%), Zhejiang (0.35%), Chongqing (0.33%), Jiangsu (0.32%), Hainan (0.32%), and Ningxia (0.32%) (Figure 1).

The average numbers of daily social networking MSM were similar during nonholidays and the Spring Festival holidays (1,198,682 and 1,250,676, respectively). However, the spatial pattern during the Spring Festival differed slightly from that during the nonholiday period (Figure 2). The similarity of the two spatial patterns was 0.85 ($P<.001$), as measured by the Geodetector q statistic [40]. The 10 provinces or municipalities with the highest average number of daily online MSM during the holidays were Guangdong (n=102,035), Jiangsu (n=81,816), Shandong (n=77,416), Henan (n=75,366), Sichuan (n=74,161), Hebei (n=60,675), Zhejiang (n=58,442), Hunan (n=56,709), Anhui (n=54,751), and Liaoning (n=51,850) as seen in Figure 1. In terms of the proportion of daily online MSM, Beijing was the highest (0.44%), followed by Hainan (0.39%), Chongqing (0.35%), Shanghai (0.33%), Liaoning (0.31%), and Ningxia (0.31%), as seen in Figure 1.

The Pearson correlation coefficient between the number of provincial social networking MSM and provincial gross domestic product in 2018 was .92, which is higher than the Pearson correlation coefficient between the number of provincial social networking MSM and the number of provincial adult men ($r=.81$). The Gini coefficients of provincial daily active MSM on nonholidays (March 12-28) and the Spring Festival holidays (February 16-20) were 0.39 and 0.34, respectively, indicating that the distribution of daily online MSM during holidays was more evenly distributed than during nonholidays because of online MSM living in cities going home. The difference in daily online MSM during nonholidays and the Spring Festival holidays was positive in eight provinces and negative in 23 provinces. The four provinces with positive surplus values greater than 10,000 were (in descending order) Guangdong, Beijing, Shanghai, and Zhejiang. Seven provinces had a negative surplus of less than −10,000: Henan, Anhui, Hunan, Hebei, Jiangxi, Guangxi, and Heilongjiang (in ascending order).

Figure 1. Provincial daily number and proportion of social networking men who have sex with men (MSM) from the Blued app. Numbers after the bars in (a) denote the percent of daily online MSM among the whole country; numbers after the bars in (b) denote the proportion of daily online MSM among local adult men aged 18 to 64 years; the two numbers after each bar are for nonholiday and holiday respectively.

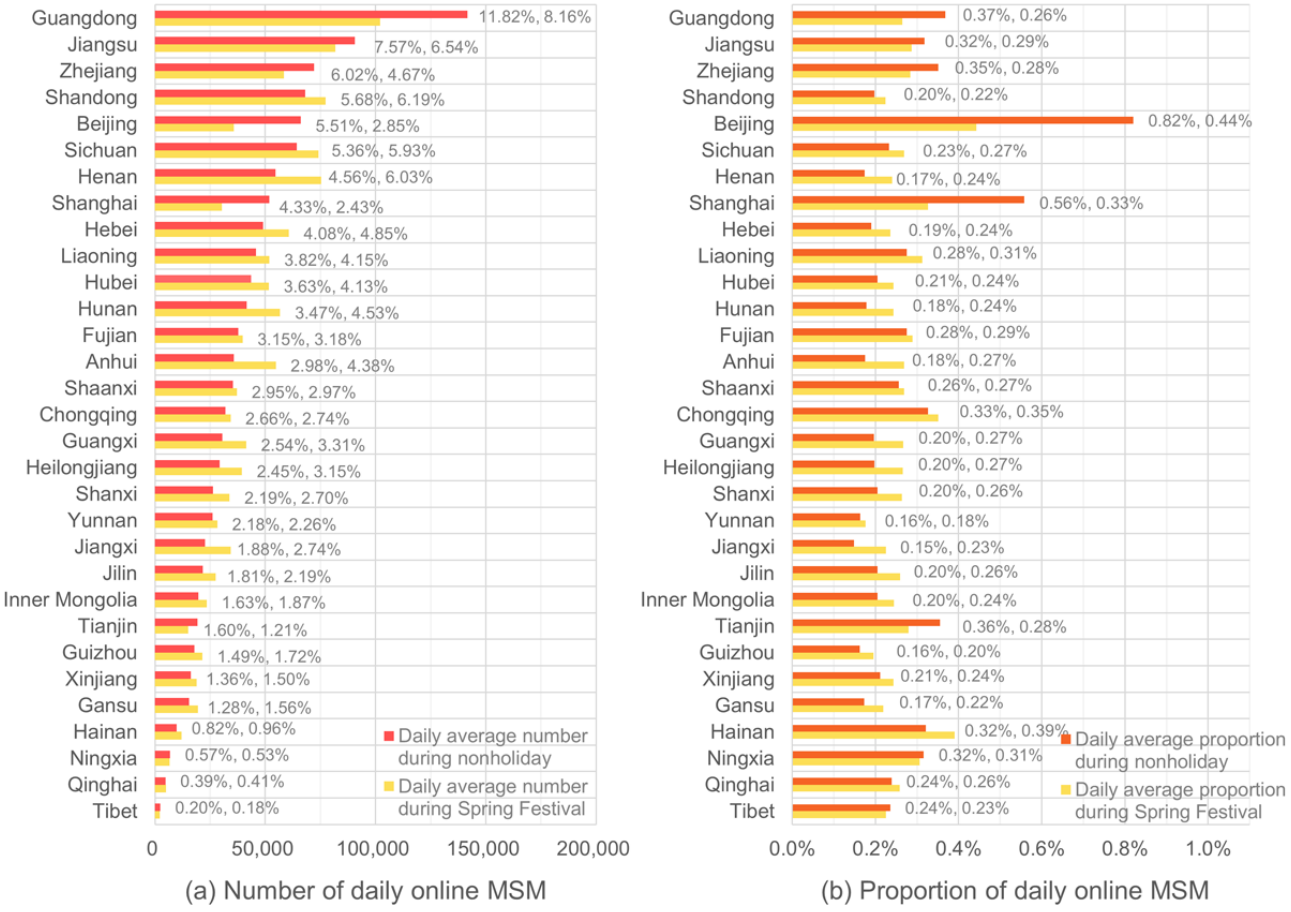
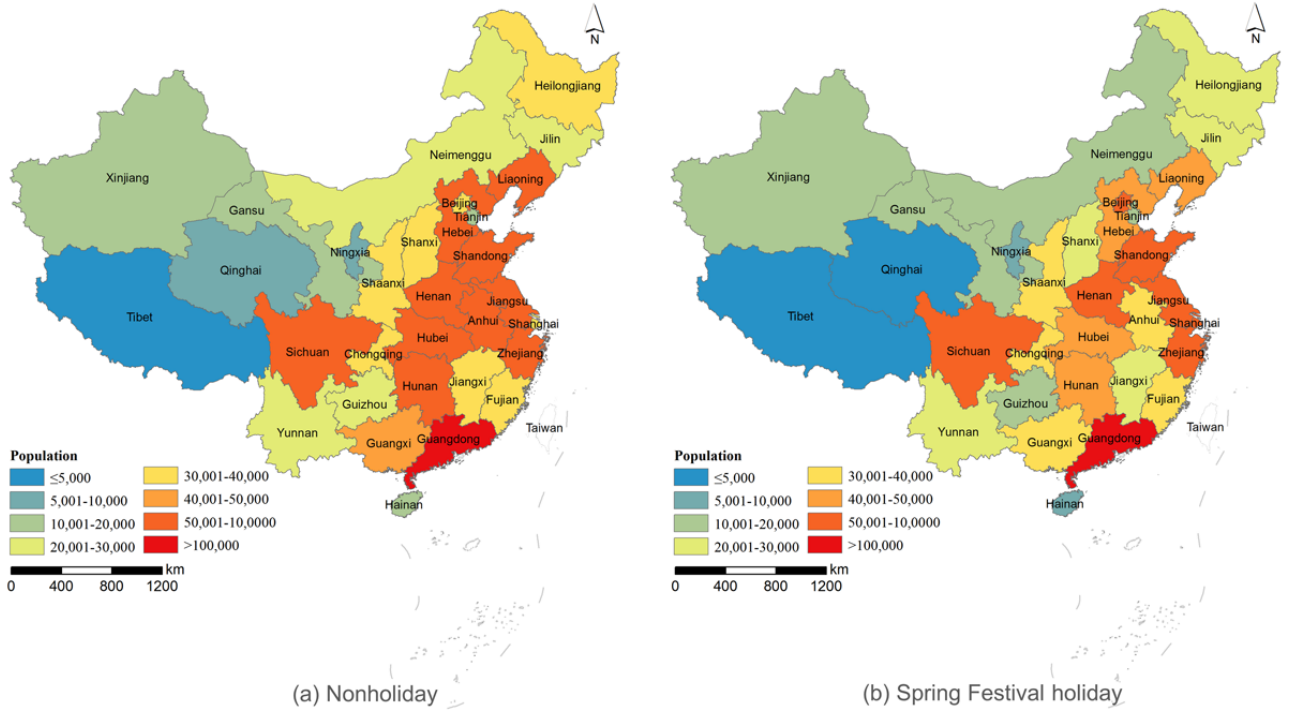


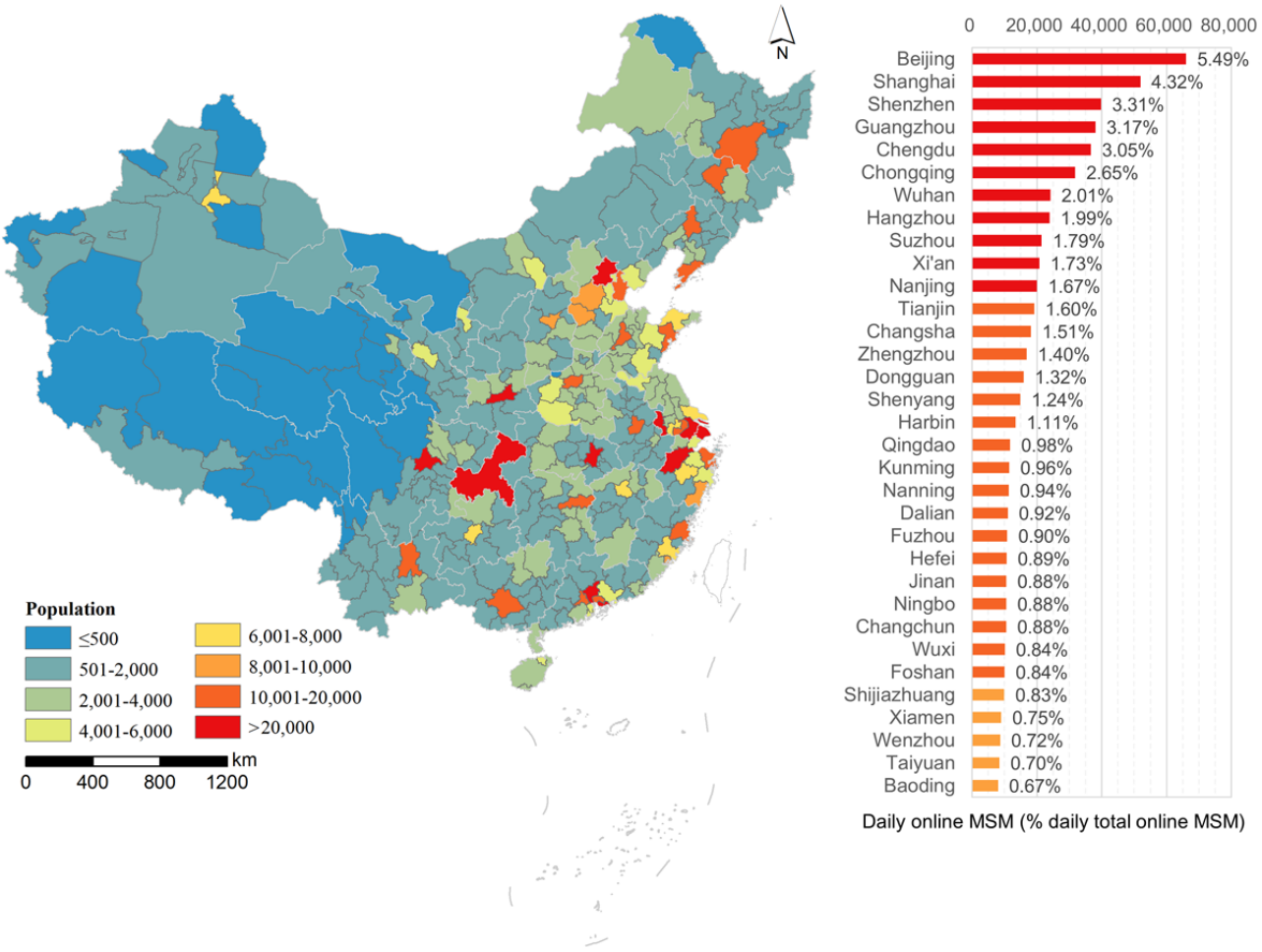
Figure 2. Spatial distribution patterns of daily online MSM from the Blued app.



Spatiotemporal Variation of City-Level Daily Social Networking MSM

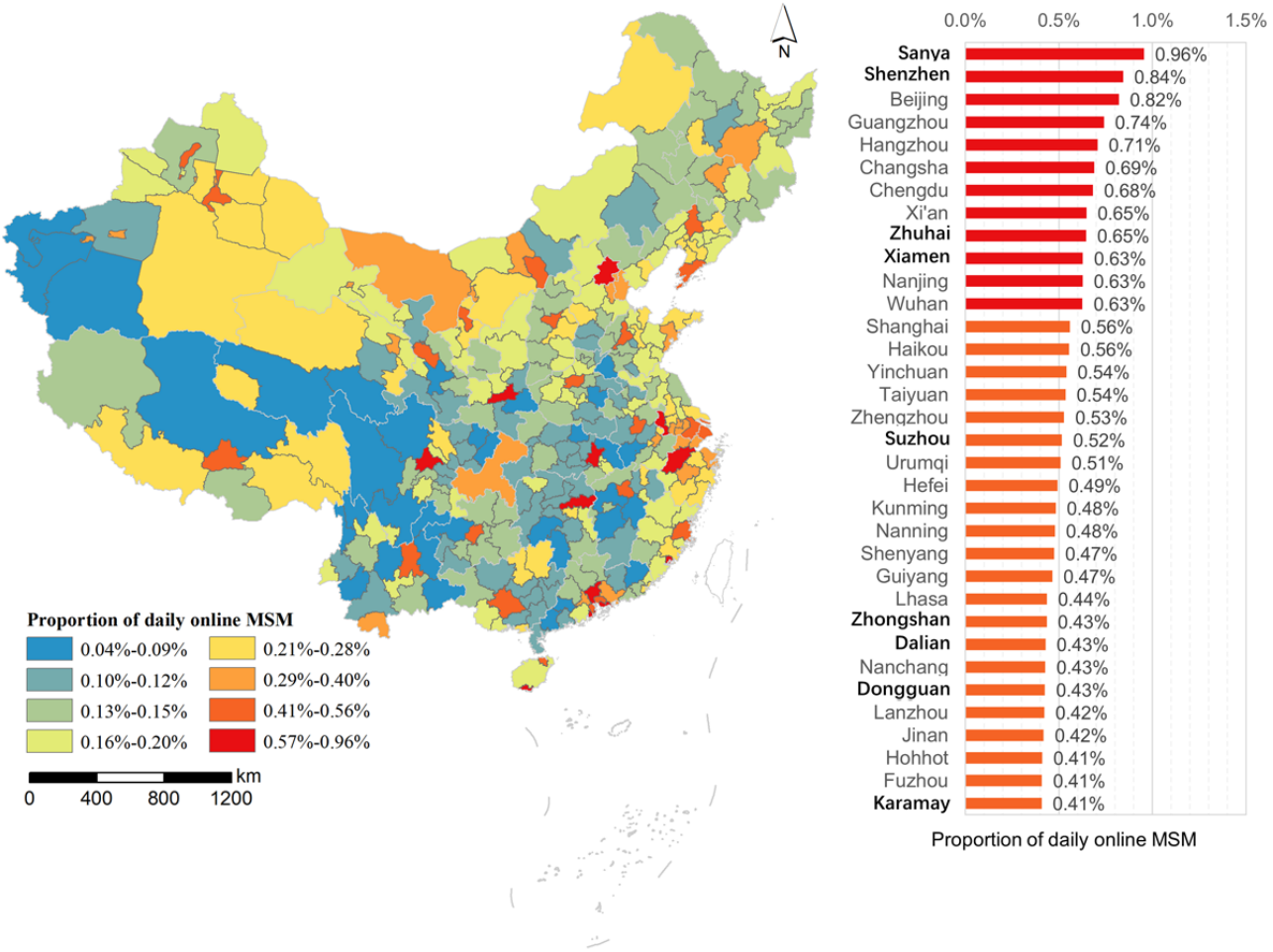
The number of daily online MSM varied greatly between different prefecture-level cities (Figure 3). Among 344 prefecture-level cities, 50.23% of nonholiday daily online MSM were in only 29 cities, whereas 28 cities had daily online MSM numbers greater than 10,000. In 11 cities (Beijing, Shanghai, Shenzhen, Guangzhou, Chengdu, Chongqing, Wuhan, Hangzhou, Suzhou, Xi'an, and Nanjing, in descending order), the number of daily online MSM exceeded 20,000. These cities accounted for 31.26% of daily online MSM in the country. The variation in social networking MSM numbers during the Spring Festival holidays was smaller than that during nonholidays: the coefficients of variation were 1.15 and 1.93, respectively. During the Spring Festival holidays, Chongqing had the second largest number of online MSM; Beijing and Shanghai had the largest and third-largest numbers of online MSM, respectively, and Chengdu replaced Guangzhou as having the fourth-largest number of online MSM.

Figure 3. City-level distribution of daily online MSM from nonholiday social networking.



The proportion of daily online MSM among adult men in different cities varied from 0.04% to 0.96%, with a mean of 0.20% and a standard deviation of 0.14% (Figure 4). Although the general distribution of high proportions of daily online MSM was similar to the distribution of high numbers of daily online MSM, the order of cities changed significantly. The top 10 cities, from high to low proportion, were Sanya, Shenzhen, Beijing, Guangzhou, Hangzhou, Changsha, Chengdu, Xi'an, Zhuhai, and Xiamen. Most of these cities are provincial capitals.

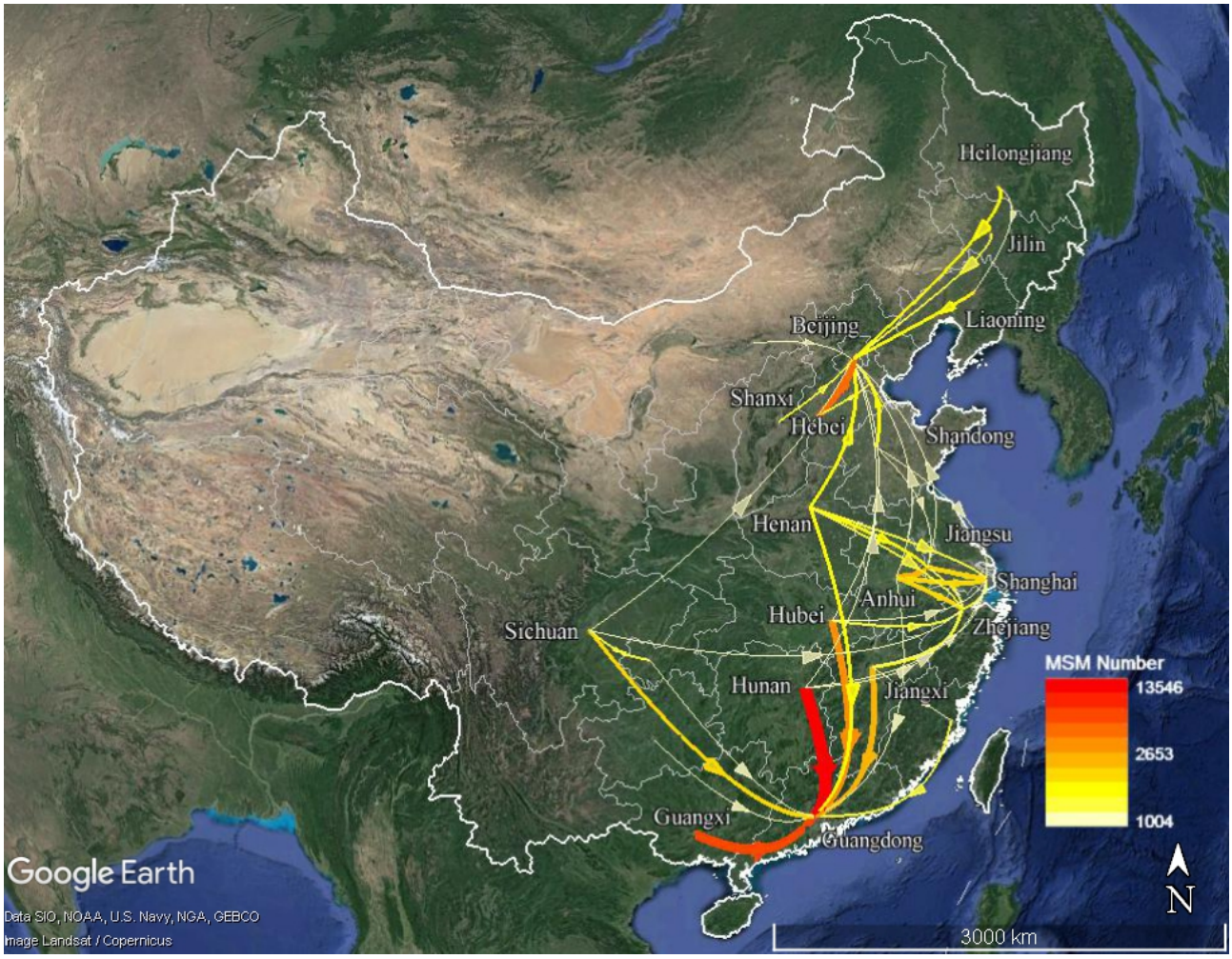
Figure 4. City-level distribution of the proportion of daily online MSM from nonholiday social networking. Cities in bold type are nonprovincial capitals.



Spatiotemporal Pattern of Social Networking MSM Migration Flow

A total of 1,705,456 MSM were online during both the Spring Festival holidays and the nonholidays. Origin-destination analysis based on co-occurring social networking MSM in the two periods showed that 391,915 social networking MSM migrated between provinces, accounting for approximately 22.98% of all social networking MSM. From the social networking MSM data, the top five MSM destinations were Guangdong, Beijing, Shanghai, Zhejiang, and Jiangsu (Figure 5), which accounted for 57.23% of migrants in mainland China. For Guangdong province, three provinces were the source of more than 10% of MSM migrants each: Hunan (19.05%), Guangxi (16.10%), and Hubei (10.70%). Jiangxi province was another important source province of MSM migrants for Guangdong, accounting for 9.36%. For Beijing, Hebei was the largest source of MSM migrants, accounting for 18.20%, which is much more than the second- and third-largest sources, Shandong (8.73%) and Henan (7.10%). Jiangsu and Anhui were the top two MSM migrant source provinces for Shanghai, accounting for 16.08% and 15.04%, respectively. The MSM migrants in Zhejiang were from three main source provinces, each accounting for more than 10% of MSM migrants: Anhui (17.79%), Jiangxi (12.53), and Henan (10.15%). Furthermore, Anhui (23.54%) and Henan (12.67%) were the two largest MSM migrant sources for Jiangsu province.

Figure 5. Interprovincial MSM migration flows (n≥1500) from the social networking data.



Total Number of MSM in China

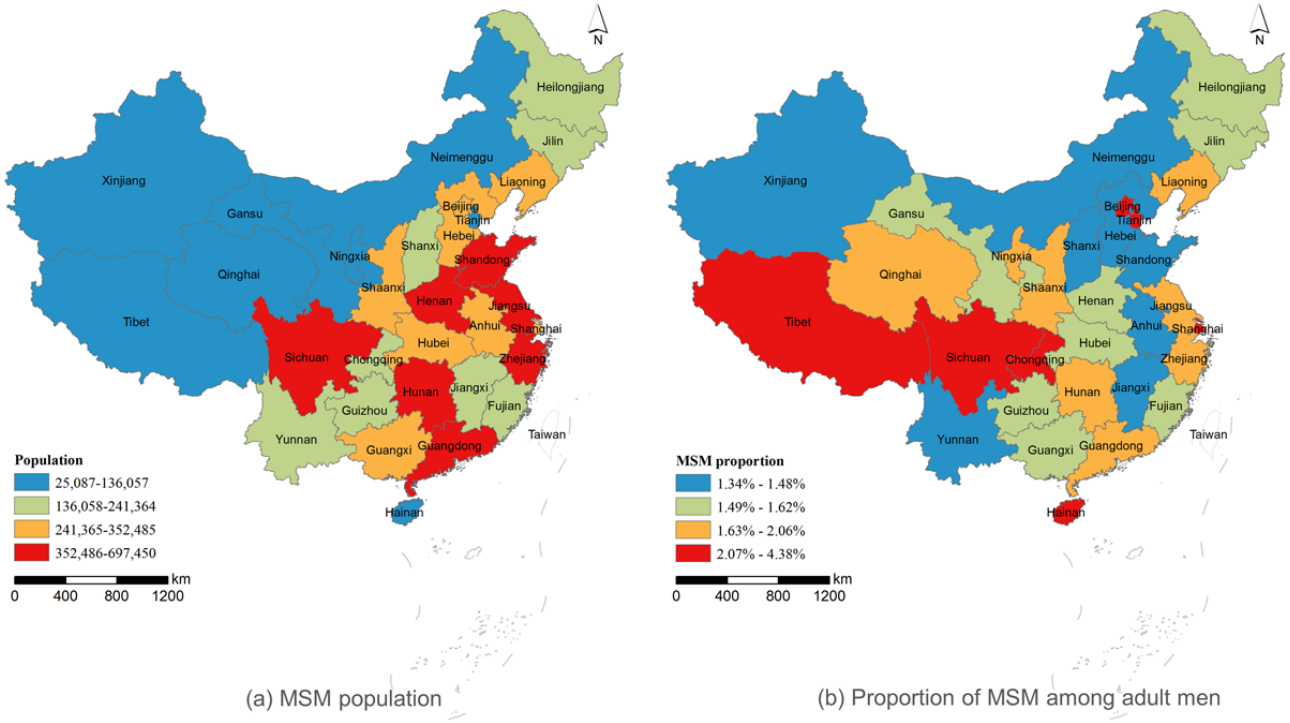
We recorded the profile IDs of 2,449,493 social networking MSM captured in the first sample period from March 12 to 28, 2018, and 2,474,293 social networking MSM in the second sampling from October 22 to November 4, 2018. According to the profile IDs from the two samples, 1,332,632 MSM were recaptured in the second sampling. The provincial numbers of social networking MSM were estimated by the capture-mark-recapture method and then adjusted by internet penetration to obtain the total number (Table 1). The sum of all provincial MSM number estimates was 8,288,536 (95% CI 8,274,931-8,302,141) in mainland China, accounting for approximately 1.732% (95% CI 1.729%-1.734%) of adult men aged between 18 and 64 years in China. The provincial number of MSM varied from 25,087 to 697,450, with a mean of 267,372 and a standard deviation of 163,061. The ratio of MSM to adult men also varied greatly by province, from 1.34% to 4.38%, with a mean of 1.85% and a standard deviation of 0.61%. The results are shown with quantile breaks in Figure 6. Seven provinces fell into the fourth quantile of MSM number, the highest level in Figure 6: Guangdong, Sichuan, Jiangsu, Henan, Shandong, Zhejiang, and Hunan (in descending order). For the ratio of MSM to adult men, the seven top provinces falling into the fourth quantile interval were Beijing, Shanghai, Tibet, Chongqing, Hainan, Tianjin, and Sichuan (in descending order). Sichuan was the only province in the fourth quantile with a large number of MSM and a high ratio, whereas Xinjiang and Inner Mongolia, in the first quantile, had both a small number of MSM and a low ratio. The similarity of the two spatial patterns was only 0.37 (P<.001), as measured by the Geodetector q statistic. This indicates that there was a significant difference between the spatial distribution of the MSM population and the proportion of MSM among adult men.

Table 1. Estimated provincial numbers and proportions of men who have sex with men (MSM) among adult men in mainland China.

Province	Internet penetration,[a] %	Social networking MSM, n	MSM, n (% of adult men)
Guangdong	74.0	516,113	697,450 (1.81)
Sichuan	43.6	248,679	570,365 (2.07)
Jiangsu	56.6	317,627	561,178 (1.97)
Henan	43.4	208,489	480,389 (1.53)
Shandong	52.9	249,935	472,467 (1.37)
Zhejiang	65.6	268,375	409,108 (1.99)
Hunan	44.4	174,478	392,968 (1.69)
Beijing	77.8	274,233	352,485 (4.38)
Hebei	53.3	184,049	345,308 (1.34)
Hubei	51.4	168,538	327,895 (1.55)
Anhui	44.3	131,758	297,422 (1.46)
Liaoning	62.6	176,804	282,435 (1.70)
Shanghai	74.1	204,844	276,443 (2.97)
Shaanxi	52.4	131,830	251,584 (1.82)
Guangxi	46.1	112,368	243,748 (1.57)
Chongqing	51.6	124,544	241,364 (2.47)
Yunnan	39.9	94,461	236,744 (1.48)
Heilongjiang	48.1	111,801	232,435 (1.57)
Jiangxi	44.6	96,776	216,987 (1.43)
Fujian	69.7	148,229	212,667 (1.55)
Shanxi	55.5	95,710	172,450 (1.35)
Jilin	50.9	87,452	171,811 (1.62)
Guizhou	43.2	71,265	164,965 (1.50)
Inner Mongolia	52.2	71,022	136,057 (1.42)
Gansu	42.4	57,249	135,021 (1.52)
Tianjin	64.6	77,784	120,409 (2.23)
Xinjiang	54.9	59,678	108,703 (1.41)
Hainan	51.6	39,051	75,680 (2.46)
Ningxia	50.7	22,611	44,598 (2.06)
Qinghai	54.5	17,610	32,312 (1.64)
Tibet	46.1	11,565	25,087 (2.49)

[a]Internet penetration was from the 39th China Internet Development Report [45].

Figure 6. Spatial distribution of estimated MSM number (a) and proportion (b) among adult men in mainland China.



(a) MSM population

(b) Proportion of MSM among adult men

Discussion

Compared with other members of the population, MSM have a significantly higher risk for HIV infection [1-3]. The MSM population and distribution are critical parameters for precision prevention of the deadly disease, to realize the goal of ending the AIDS epidemic by 2030 and to achieve the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets [46,47]. Our estimates are the first comprehensive estimation of the MSM population size, geographical distribution, and migration conducted in mainland China. These results will be an important contribution to accurately carrying out intervention for high-risk groups, expanding testing, and realizing the first 90% in China. For example, from the research result, we can identify provinces and cities with large MSM numbers, such as Guangdong, Sichuan, Jiangsu, Henan, Shandong, Zhejiang, and Hunan, which should have more resources allocated to them.

There is considerable spatiotemporal heterogeneity for social networking MSM in mainland China. The difference in the spatial distribution patterns of daily online MSM during nonholidays and the Spring Festival holidays might indicate that MSM are distributed rather evenly among all adult men. However, urbanization and economic development might be positive drivers of MSM accumulation. From the provincial social networking MSM distribution in Figure 2, it can be seen that provinces with large numbers of social networking MSM are mainly located in eastern China, and they usually have a large population and high gross domestic product. Thus, economic development level might be an important factor for the distribution of social networking MSM. Large or well-developed cities tend to have more social networking MSM because cities often have better network facilities and higher internet penetration. Provincial migration direction of MSM was from less-developed provinces to more-developed provinces, such as Guangdong, Beijing, Shanghai, Zhejiang, and Jiangsu. The social networking MSM migration flow was generally consistent with population migration flow in mainland China [37]. In recent decades, fast urbanization in China has brought large numbers of rural laborers flocking to cities to find jobs, which might increase the chance to use mobile apps to seek nearby friends for MSM coming from less-developed regions.

The study reveals that mainland China has approximately 8,288,536 MSM, approximately 1.8 times the number in the United States, although the percentage of MSM among adult men in mainland China (1.73%) is lower than that in the United States (3.9%) [12]. Our estimate of the percentage of MSM among adult men is also lower than the previous estimates of 2% to 4% in China [22,23]. The difference may come from different sampling designs. In traditional sampling-based studies to estimate the MSM population, the sample size was often limited to hundreds or thousands. Without enough a priori information on MSM distribution, it is hard to design an unbiased sampling to cover a country as large as China. Our estimates made use of social networking data, which have no sampling size limit and avoid potential bias due to sampling design. The estimate shows that 10 provinces have a percentage equal to or greater than 2%. More than one-half (51.66%) of the total MSM population reside in only nine provinces. The phenomenon of uneven distribution of MSM in mainland China is consistent with the distribution in the United States, where more than one-half of the total US MSM population is located in only seven states [12]. The estimated percentage of MSM among adult males is at the middle level compared with the range of 0.09% to 4.06% for Asia and Pacific countries [48].

The internet and mobile geosocial networking information technology have become not only the major tools for socializing and seeking same-sex partners for MSM populations in recent

years but they can also help with surveillance of the risk [30,31]. Compared with traditional offline approaches, online sex-seeking might lead to multiple sexual partners, a higher probability of having unprotected sex, and a higher possibility of being diagnosed with sexually transmitted infections, which is inevitably associated with a higher risk of HIV/AIDS infection [30,49]. However, online approaches can be used as an important window for health-related organizations to spread health protection messages, such as the location of the nearest testing center for sexually transmitted infections [31]. Online approaches should be used to help to control the incidence of HIV/AIDS for MSM in China.

To estimate the number of MSM in China, we had to make several assumptions that might limit the interpretation of our results. First, we assumed that the popular Blued app accounts for most social networking users in mainland China, but the proportion of MSM users might vary slightly across China. Second, we ignored population movement between the two samples in the capture-mark-recapture experiment, which might violate the closed population assumption. However, the total population movement would be small compared with the provincial population. Third, in the migration analysis, we did not consider that there might be a small portion of MSM who traveled to other locations as tourists during the Spring Festival. Although some limitations are associated with our results, we believe the results do provide a lower estimate of the MSM population in mainland China [50].

The study presents a promising and efficient method for estimating MSM populations in different areas of mainland China for the first time. We found that there are more than 8 billion MSM in mainland China, accounting for approximately 1.73% of adult men aged 18 to 64 years. The MSM population is unevenly distributed in different cities and provinces. The spatiotemporal distributions of MSM revealed by this study provide new opportunities for determining the burden of HIV and sexually transmitted infections among MSM in different areas. The nationwide estimates of MSM populations and geographical distributions could provide public health practitioners and policymakers with a useful tool for better resource allocation, intervention development, and service delivery. Provinces and cities with large MSM numbers and high proportions of MSM should be considered for allocation of more resources to control the potential HIV/AIDS risk.

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Authors' Contributions

All authors provided guidance on the concept and outline of the manuscript. MH and CX wrote different sections of the manuscript. MH, CX, and JW edited the various sections of the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

MSM: men who have sex with men

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Original Paper

Engagement and Participant Experiences With Consumer Smartwatches for Health Research: Longitudinal, Observational Feasibility Study

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Abstract

Background: Wearables provide opportunities for frequent health data collection and symptom monitoring. The feasibility of using consumer cellular smartwatches to provide information both on symptoms and contemporary sensor data has not yet been investigated.

Objective: This study aimed to investigate the feasibility and acceptability of using cellular smartwatches to capture multiple patient-reported outcomes per day alongside continuous physical activity data over a 3-month period in people living with knee osteoarthritis (OA).

Methods: For the KOALAP (Knee OsteoArthritis: Linking Activity and Pain) study, a novel cellular smartwatch app for health data collection was developed. Participants (age ≥50 years; self-diagnosed knee OA) received a smartwatch (Huawei Watch 2) with the KOALAP app. When worn, the watch collected sensor data and prompted participants to self-report outcomes multiple times per day. Participants were invited for a baseline and follow-up interview to discuss their motivations and experiences. Engagement with the watch was measured using daily watch wear time and the percentage completion of watch questions. Interview transcripts were analyzed using grounded thematic analysis.

Results: A total of 26 people participated in the study. Good use and engagement were observed over 3 months: most participants wore the watch on 75% (68/90) of days or more, for a median of 11 hours. The number of active participants declined over the study duration, especially in the final week. Among participants who remained active, neither watch time nor question completion percentage declined over time. Participants were mainly motivated to learn about their symptoms and enjoyed the self-tracking aspects of the watch. Barriers to full engagement were battery life limitations, technical problems, and unfulfilled expectations of the watch. Participants reported that they would have liked to report symptoms more than 4 or 5 times per day.

Conclusions: This study shows that capture of patient-reported outcomes multiple times per day with linked sensor data from a smartwatch is feasible over at least a 3-month period.

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KEYWORDS

medical informatics computing; mHealth; patient-reported outcomes; musculoskeletal diseases; mobile phone; smartwatch/wearable; self-tracking

Introduction

Background

Wearables, such as activity trackers, provide opportunities for frequent monitoring of chronic diseases. Their sensors can record behaviors of interest at high temporal and spatial resolution [1-4]. Wearables are widely used: in 2016 there were 325 million connected wearable devices worldwide, with half of the owners wearing their device every day [5,6]. In health care, sensor data from wearables would be even more relevant if combined with simultaneously collected patient-reported outcomes. This would enable symptom monitoring, adding context to the sensor outputs, and may aid clinical decision making and empower patients [7].

Consumer Cellular Smartwatches

A new technical innovation enables collection of sensor data alongside patient-reported outcomes. In 2017, the first *cellular* smartwatches came to market. Cellular smartwatches combine the functionalities of smartphones (touch screen, SIM card and cellular connection, and possibility to develop and install apps) with wearables (passive collection of sensor data, wrist-worn). This enables frequent collection of patient-reported outcomes (via touchscreen) alongside accurate and objective information on behavior or exposure (from sensors). Furthermore, these data can be collected in real time and automatically uploaded to remote servers without the need for pairing with a smartphone or another device for connectivity.

Physical Activity and Knee Osteoarthritis

An example of a clinical disease area where the pairing of symptoms and sensor data, especially on physical activity, could significantly advance research is arthritis [8]. Knee osteoarthritis (OA) is one of the most common types of arthritis: it affects 19% to 28% of men and women older than 45 years and is characterized by disabling knee pain and a reduction in mobility [9]. Physical activity is beneficial in reducing long-term pain severity and disability [10] and has cardiovascular and other benefits. However, the relationship between pain and activity is complex: pain can limit the amount of physical activity that is possible, while increasing physical activity beyond a certain level may further increase pain severity [11]. Wearable devices have been used to track physical activity in OA research [12], but frequent symptoms are rarely collected in parallel. Furthermore, proprietary algorithms from consumer fitness trackers are less accurate in arthritis patients because gait characteristics differ between healthy people and those with musculoskeletal conditions [13]. Understanding the interplay between physical exercise and symptoms would be an important step in helping to develop and target personalized interventions to support an appropriate level of physical activity. For example, encouraging more physical activity within an individual's personal threshold. This requires frequent, accurate, and granular data on pain symptoms and activity, which cellular smartwatches may be able to provide.

Objectives

The feasibility of collecting such data through cellular smartwatches remains uncertain. Knowledge of barriers and enablers of engaging with cellular smartwatches long term could inform the design of future studies. To address this, we conducted the KOALAP (Knee OsteoArthritis: Linking Activity and Pain) study. We developed a cellular smartwatch app for collection of patient-reported outcomes (multiple times a day) alongside continuous sensor data. The aim of this feasibility study was to investigate engagement patterns and acceptability of collecting health and behavior data using consumer cellular smartwatches daily for 3 months. Specifically, the study objectives were to report participant engagement, to investigate participant views and experiences, and to identify barriers and enablers to collecting data through cellular smartwatches.

Methods

Subjects and Data Collection From the Smartwatch

Men and women older than 50 years with self-reported knee OA were recruited in September 2017 for participation in a 90-day observational study. Detailed methods have been reported elsewhere [14].

In brief, participants received a Huawei Watch 2 preinstalled with the KOALAP study app (all other features and apps were disabled) developed by the study team and Google Android Wear. Participants were instructed to wear the watches for 90 days, from waking until going to bed, and answer the watch questions when prompted (Figure 1). At baseline, participants reported age, gender, and previous experience with health technology (see [14]), and, for the watch questions, the activity that caused most knee pain and the activity that was most important for them to do without knee pain. At study completion, participants received a Web-based questionnaire with questions about their experiences with the watch, for example, "I often forgot to charge the watch or wear it again after charging." The full questionnaire is available as an appendix to the published study protocol [14].

Figure 1. User interface of KOALAP app. Left: notification of an active survey; middle: data entry screen for survey "level of knee pain"; right: data are entered by swiping the numeric rating scale icon.

The KOALAP app triggered 4 or 5 questions on knee pain and quality of life per day. These questions had to be answered within a specific time window, which took around 10 seconds per question. The questions were:

- Level of knee pain (twice-daily at 12.22 and 18.22; window 4 hours)
- Knee pain affecting daily activities (daily at 17.00; window 7 hours)
- Knee pain during painful activity (as reported at baseline); daily at 17.00; window 12 hours)
- Pain interference with important activity (as reported at baseline); weekly on Wednesday at 12.00; window 12 hours)
- Impact of knee symptoms on quality of life (weekly on Sunday at 12.00; window 12 hours)
- 17 questions from the Knee Injury and Osteoarthritis Outcome Score [14,15] (monthly; window 7 days)

When a participant was wearing the watch, the KOALAP app collected raw sensor data. When participants took off the watch, *off-body detection* stopped sensor data collection. On the home screen of the watch, participants could see their heart rate and step count as calculated by the Android operating system. During recharging, data were uploaded to the study servers and deleted from the watch. If participants were abroad or had poor cellular signal at the charging location, the data upload failed, and the watch stopped collecting sensor data.

Participant Interviews

All participants were invited to take part in 2 separate interviews (1 shortly after baseline and 1 on completion of the study). A semistructured interview schedule (see Multimedia Appendix 1) was developed from the sociological research literature on self-tracking [16-21]. This literature is split between a techno-utopian approach and a critical approach. The techno-utopian approach suggests that self-tracking can empower and motivate individuals to adopt a healthy lifestyle. The critical approach has focused more on the implications of self-tracking for privacy, personal responsibility, surveillance, and changing views of the body and health. The interview schedule was also informed by factors known to affect attrition in digital health studies, including usability, feedback, perceived advantages of participation, time required, user experience, and external events such as health [22]. The interviews at baseline explored participants' experiences of living with OA, motivations and expectations of using a smartwatch, and previous experiences with health technology. We were interested if previous engagement with devices had changed health-related behaviors. At follow-up, interviews explored participants' experiences of using the watch and being monitored and whether the knowledge gained from using the watch (if any) had significant implications for their understanding of knee OA.

Analysis

Engagement With Smartwatch

The primary measures of engagement were the number of active participants per day, hours of wear time, and completeness of watch questions. Active participants were defined as participants who wore the watch for at least 30 min. Wear time per participant-day was defined as the total hours of available sensor data, rounded to the nearest hour. The completeness of watch questions was defined as the percentage of watch questions completed (per specific watch question over the study duration; per participant-day). For each study day, we calculated mean wear time and mean completeness of watch questions across all participants and across all active participants.

In addition, we determined temporary and permanent nonusage attrition and the mean clock time that participants put on and took off the watch. Temporary nonusage attrition refers to the participants that are not active for a period (ie, do not wear the watch for >30 min but later resume wearing the watch). Permanent nonusage attrition refers to participants that are not active and never again wear the watch [22]. Per participant over the study period, we determined the average clock time of the first and last sensor data record. When participants took off and put on the watch multiple times, we only considered the longest continuous episode per day for calculating these clock times.

End-of-Study Survey: Participant Experiences

Descriptive statistics were used to summarize responses to the baseline and end-of-study surveys.

Participant Interviews

Interviews were audio-recorded and transcribed verbatim and coded using NVIVO (QSR International). Transcripts were analyzed thematically, drawing on some of the key techniques

of grounded theory [23], including open coding, constant comparison, and memo writing**.** Verbatim quotes that illustrate the key themes were selected.

Case Studies

To illustrate how interview themes relate to individual levels of engagement, 2 case studies of participants were analyzed, combining quantitative engagement data with interview quotes.

This study underwent full review by the University of Manchester Research Ethics Committee (#0165) and University Information Governance (#IGRR000060).

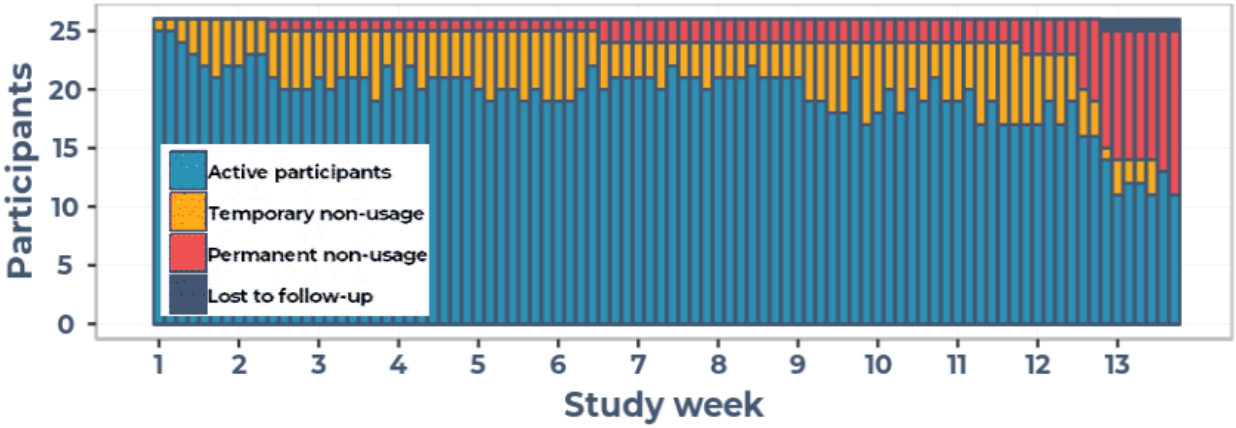
Results

Subjects and Baseline Survey

A total of 26 subjects took part in the study. Their mean age was 64 years, and 50% (13/26) were female (13/26). Before enrollment, 9 participants had used a smartphone only (n=3), wearable only (n=3), or both (n=3) for health or activity monitoring.

In total, 6894 watch questions and 643 gigabytes of sensor data were received over the 90-day study period. Participants wore the watch on 73% (81/90) of days. Over time, the number of active participants decreased (Figure 2): from 25 on the first day to 11 on the last day. Until the last study week, the main form of attrition was temporary nonusage attrition (participants not wearing the watch but later re-engaging). Permanent nonusage attrition (participants not wearing the watch again during the study) was low in the first 2 months: 1 participant stopped in the first month and 1 in the second month. In the last study month, 13 participants stopped using the watch (of which 8 in the last week), of which 1 was lost to follow-up after day 84 (ie, did not fill in the end-of-study-questionnaire and did not return the watch).

Figure 2. Active participants (blue) per study day, participants temporary nonusage (yellow), permanent nonusage (red) or lost to follow-up (dark blue).



Engagement With Smartwatch

The median daily wear time among active participants was 11 hours 12 min (interquartile range 9 hours 27 min-12 hours 6 min). The mean time-of-day at which sensor data collection started and stopped varied between participants: from 07.48 to 13.48 and 16.00 and 21.18, respectively (Figure 3). For most participants, this covered the trigger time for all watch questions from first (12.22) to the last (18.22). For 1 participant, average wear time started after the first trigger time, and for 8 participants average wear time stopped on or before the last trigger time. Some participants (eg, participant 14) recharged the watch and put it on again, resulting in a median wear time much higher than the clock times of the longest episode.

The completion rates of watch questions varied. On average, twice daily questions were answered by 60% (15/26; morning) and 52% (14/26; afternoon) of participants, the once daily questions by 66% (17/26), and the weekly questions by 69% (18/26) of participants. The longer, monthly questionnaires that remained open for 1 week were answered by 89% (23/26) of participants.

The median watch question completion rates and hours of sensor data decreased over the study duration (dark blue diamonds in Figure 4). Engagement of *active* participants remained roughly constant through time (light blue squares in Figure 4).

Figure 3. Average duration of continuous sensor data collection, per participant. Each bar corresponds to a participant. The bar starts at the average time of day that sensor data collection started and ends at the average time of day that sensor data collection ceased (duration in hours shown in middle of bar). On the right: the median wear time and number of days the participant was active. Median wear time can be higher than clock time duration of the longest wearing episode, as some participants recharged the watch and put it on multiple times.

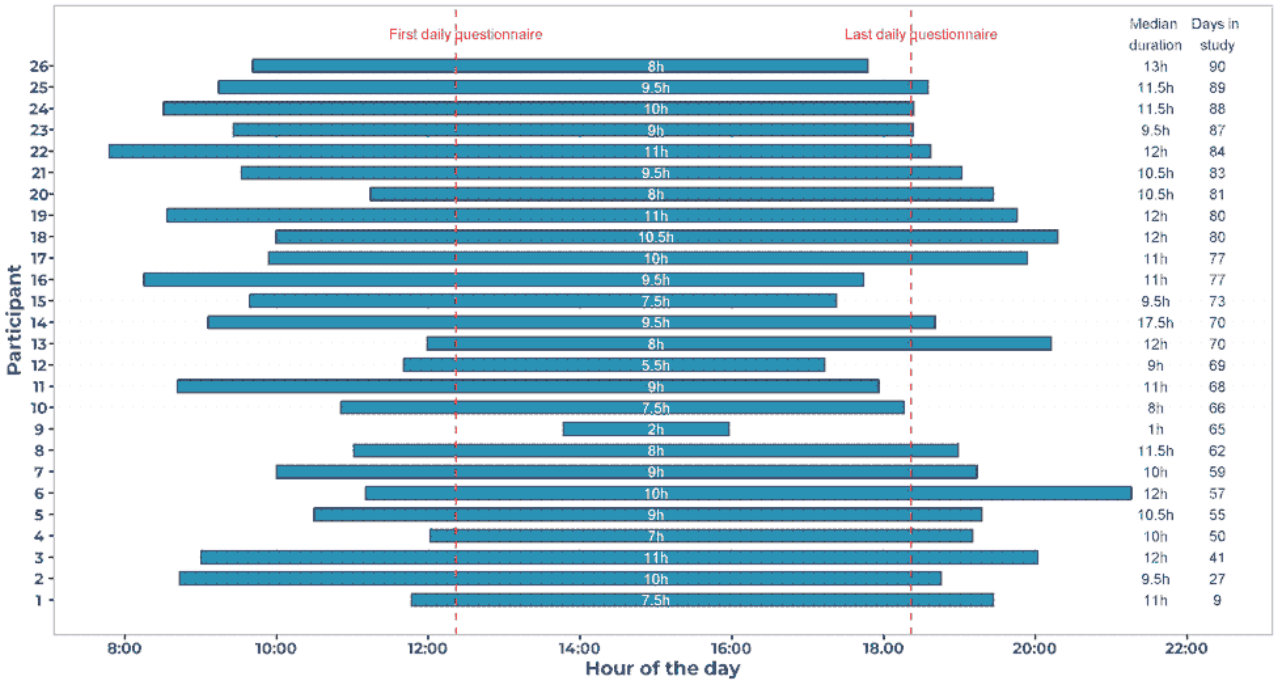
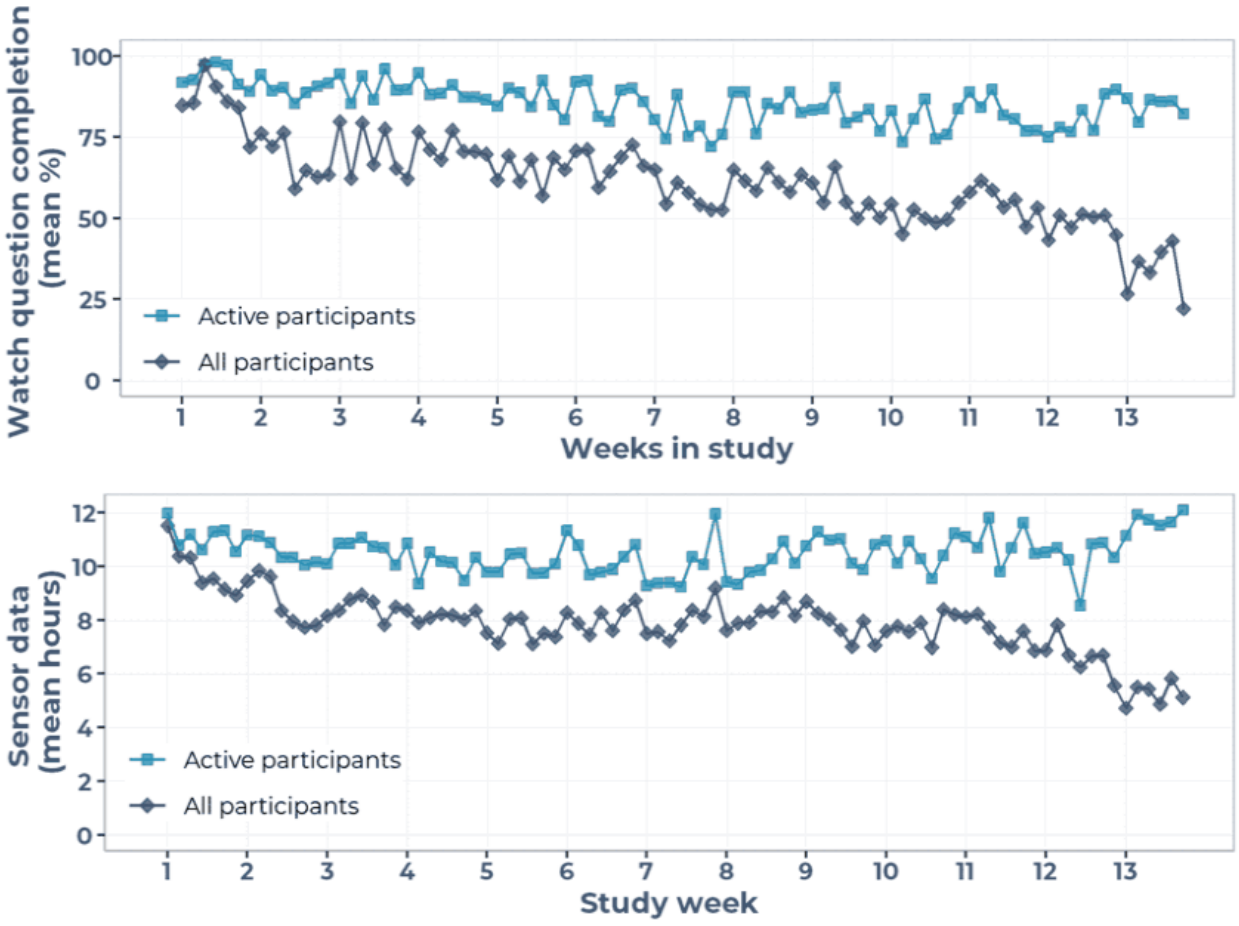


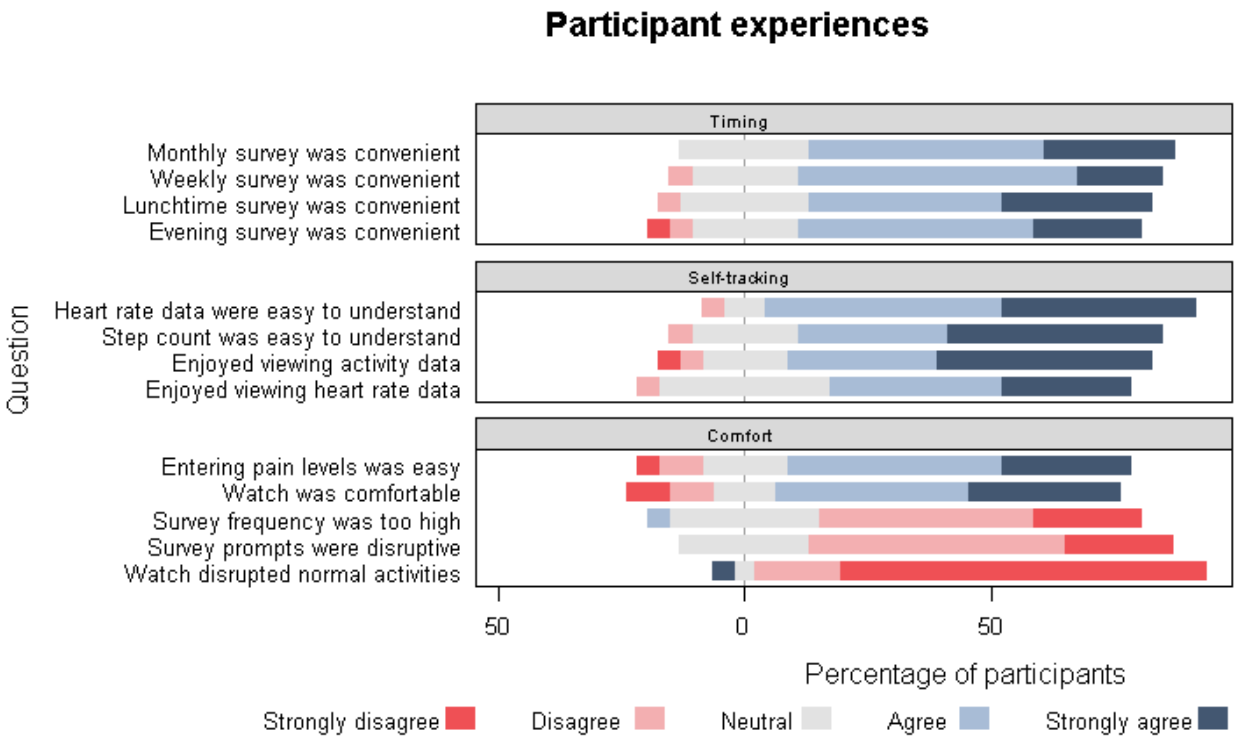
Figure 4. Engagement per study day, showing mean hours of sensor data (lower) and mean watch question completeness (upper). Dark blue diamonds correspond to median over all 26 participants; light blue squares correspond to median over all active participants.



End-of-Study Survey: Participant Experiences

A total of 23 participants completed the Web-based end-of-study questionnaire (Figure 5). Most participants found the watch comfortable, found it easy to enter pain levels on the watch, and found the timing of the various questions convenient. Only 1 participant found survey frequency too high, and 1 participant found the watch disrupted their normal activities.

Figure 5. End-of-study study survey—Comfort, convenience of prompts, and self-tracking. Proportion of participants (100%=23) that chose a specific answer; bars to the right of zero reflect positive experiences.



Participant Interviews

A total of 19 participants were interviewed at baseline, and 18 of these completed an end-of-study interview 3 months later (mean age 64 years; 10/19, 53% female). Analysis of the transcribed interviews identified themes around context, motivations, and expectations (section 1), interaction with the watch, experiences, and usability (section 2), and self-tracking (section 3).

Context, Motivations, and Expectations

The opportunity to learn more about the relationship between pain and activity was the primary motivating factor for the majority of interviewed participants (N=14). Some participants expected that participation would help them develop strategies to manage their pain better (Textbox 1, quotes 1.1 and 1.2). Others were motivated by the prospect of helping others and contributing toward improving knee OA research (Textbox 1, quotes 1.3 and 1.4).

Textbox 1. At baseline, most participants' motivation was to learn about their condition, whereas some enrolled to contribute to research.

1.1 I thought I might learn things from people...I might find out things that would help me. There was a degree of self-interest.

1.2 That's really why I'm taking part, to find out what I should do, what I shouldn't do, what I...when to rest, when not to rest, when to be active, when not to be active. Anything that could help me find out about the condition and how to maybe alleviate it

1.3 I saw this, I thought, well if it's anything that helps, even if it doesn't help me personally now, if it helps in the long term, it can't be a bad thing really, that was what attracted me.

1.4 I think if they can see some results from it, and it's going to improve knowledge and so on. Some people might want to be motivated by a bit of money or something like that, but I think the vast majority would do it because it's for the good of people, and hopefully improving the knowledge of people.

Interaction With the Watch: Experience and Usability

Although some participants expressed concerns in the preliminary interviews about successfully operating the smartwatch, all participants stated at follow-up that they found the watch easy to use (Textbox 2, quote 2.1). Participants did not consider answering the twice daily questions a burden. In fact, many participants suggested pain data should be collected

more frequently, for example, also in the evening (Textbox 2, quote 2.2). Participants were enthusiastic about recording pain levels, and some suggested to add a "pain button" to record pain in real time (Textbox 2, quote 2.3). Participants explained that their engagement with the watch was affected by other activities. Sometimes they were too busy to answer the question at the trigger time, or they removed the watch for activities (eg, writing, gardening, and swimming) and forgot to put it back on. Battery life significantly influenced patterns of engagement, particularly for those participants who worked full days (Textbox 2, quote 2.4). Sometimes, participants missed the evening questions because of limited battery life. There appeared to be an expectation that the battery should last from early in the morning to late in the evening without recharging (at least 15 hours). Step count was automatically reset to 0 after recharging, frustrating some participants (see case study 2).

Textbox 2. Participant experience with smartwatch and usability (quotes from follow-up interview).

2.1 It was easier than I thought really...When I came home, my husband went through it with me and I've been dead surprised how easy it was. I thought, I won't be able to do that… but I was surprised how easy I found it, yeah.

2.2 I think they could have asked a lot more, I think initially, I wouldn't say I was frightened by it, but I was a bit intimidated, God, what's this going to be like? When you got into it, and began to realise the sequences of questions, I think in a way it was a bit of a lost opportunity from your side, because I think there would have been the opportunity to ask quite a lot more.

2.3 I just felt I wanted to provide more information. I wanted to say that I'm in agony. So I think that maybe something that I could wear on that hand and I could say, right, that hurts now; that would be fine.

2.4 I think I struggled throughout with battery life and because I start work...I would be putting the watch on at about half past seven it didn't always make it through to the end of the day when I got home, which would be like five or six. And so, I'd have to recharge it to start it, you know, to do the survey, which is often why I ended up missing because I'd just plug it in rather than do the survey...I must admit, in the end I was relieved to get rid of the watch because the battery was doing my head in at work, you know?

Self-Tracking

Participants stated that being involved in the study had helped them to focus more on their activity levels and challenge existing assumptions regarding their activity and pain (Textbox 3, quote 3.1). For example, 1 participant had previously avoided walking long distances as she associated walking with pain. Once she started tracking her steps, she became aware of how far she could walk without causing pain, which led to greater confidence and increased activity (Textbox 3, quote 3.2).

Not all participants found the step counter or heart rate monitor useful. Participants already interested in self-tracking had concerns regarding the accuracy of the watch as the watch data were different to their personal devices (Textbox 3, quote 3.3). As the majority of participants were primarily motivated by the opportunity to learn more about their condition, feedback was an important issue. Some participants mentioned that they would have preferred to be more active in analyzing their own data on a daily basis. However, irrespective of the fact that participants had doubts concerning the accuracy of the sensor data, the majority of participants remained in the study for the 3-month period.

Textbox 3. Participant experience with self-tracking and watch feedback (quotes from follow-up interview).

3.1 It's made me very aware on a daily basis of where I am, what things I'm doing...because you are actually charting progress, lack of progress and whatever that may be, that journey that you're on. And the fact that you're focusing three or four times a day; it really does say yeah I felt okay today...I just really enjoyed the experience and I felt I was getting something out of it.

3.2 If someone said to me, let's go on a five mile hike, my absolute answer would be, no, my legs wouldn't let me do it. What the watch and the app rather than the phone, has told me, is that I can do that, 'cause I do that every day.

3.3 I don't think it was accurately recording footsteps. I have an app on my phone that does footsteps and I know that's pretty accurate because I've tested it against another app .I compared that against the watch and the watch was nowhere near.

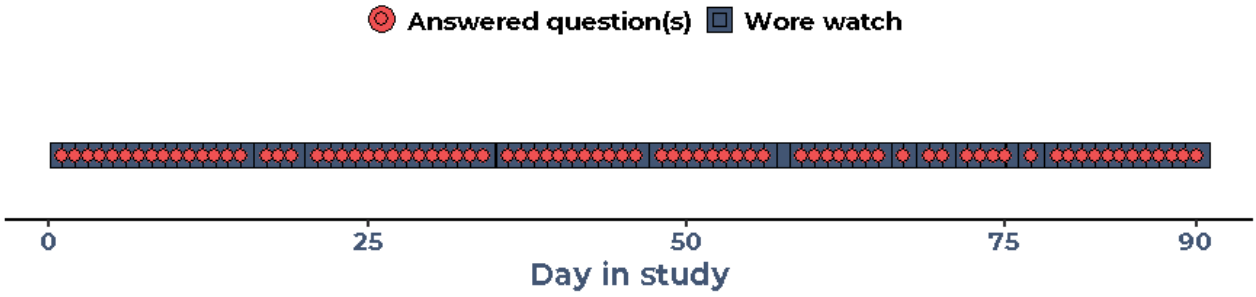
Case Studies

To illustrate how these themes interrelate to determine individual levels of engagement, we present 2 case studies: (1) a highly engaged participant despite no interest in self-tracking and (2) a participant that, in spite of interest in self-tracking, dropped out early. Each demonstrates how engagement results from a balance of the themes highlighted above, not always driven by the commonest themes.

Case Study 1—Highly Engaged

The participant was diagnosed with OA over 10 years ago. He wore the watch for 88 days and answered on average 73% (79/249 days; Figure 6) of the watch questions. He had no previous experience with self-tracking or wearables, meaning his high engagement in the study was not explained by any prestudy interest in self-tracking. In fact, at baseline, he considered self-tracking to be "narcissistic" (Textbox 4, quote 4.1).

Figure 6. Engagement of case study 1 over 90 study days.



The participant had no expectations that the study would benefit him personally. His reasons to participate were altruistic in nature as he emphasized that while the study may not benefit him, it could benefit others (Textbox 4, quote 4.2).

He occasionally missed questions on some days. He explained this was because of his daily routine, as he sometimes worked late, and he would forget to recharge the battery. He reported that he was glad to finish the study, as he did not particularly like the look of the watch (Textbox 4, quote 4.3).

Irrespective of a negative attitude toward self-tracking and the look of the watch, the participant had the highest level of engagement in the study. This paradox may be explained by the fact this participant had no expectations of personal benefit from participating in the study; hence, negative aspects of the watch did not disappoint him.

Textbox 4. Case study 1: experiences of high engager without previous self-tracking experience (4.1 and 4.2 from baseline interview; 4.3 from follow-up interview).

4.1 I've no desire, okay I'm sure there are uses of smartwatches but it doesn't have place in my way of life and I can't see how it would do...Well, its over-indulgence, over focus on your own...

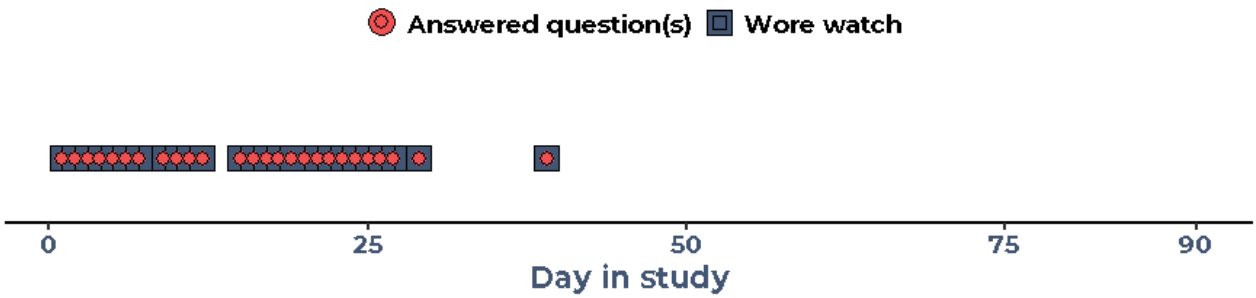
4.2 Whatever you learn will somewhere down the line, it'll be used. (...) I just wanted to find out what it's about, and also maybe help other people who might get it in the future.

4.3 I think a couple of days I forgot to wear it and I think it was probably I had to leave it in my slipper charging so that I wouldn't forget it. And I was glad when I didn't have to wear it anymore...wearing the watch was not a pleasure but we didn't sign up to look cool. Well it's a big ugly heavy rubber watch, there's nothing particularly aesthetic about it.

Case Study 2—Early Study Withdrawal

Some participants were highly engaged for the first part of the study but then started using the watch significantly less, or in some cases not at all. This participant was diagnosed with OA within recent years. She wore the watch for 27 days, answering 79% (26/88 days; Figure 7) of watch questions on average. At the beginning of the study, she was fully engaged and answered all the daily questions. In contrast to case study 1, this participant was motivated to participate in the study to learn more about how to deal with her pain and potentially avoid having surgery (Textbox 5, quote 5.1). She enjoyed the process of answering the daily questions at the beginning of the study as focusing on her pain challenged her previous assumptions regarding activity levels and pain (Textbox 5, quote 5.2). She had not done self-tracking before the study, but she did enjoy this at the beginning.

Figure 7. Engagement of case study 2 over 90 study days.



Over time, she increasingly became skeptical and frustrated with the technical aspects of the watch: the step counter reset when she recharged it, and she was not convinced of its accuracy (Textbox 5, quote 5.3). She was also concerned that nonambulatory triggers for her pain, such as standing and bending, were not captured by the watch (Textbox 5, quote 5.4). She found the size of the watch to be too big, and she mentioned that it got in her way when writing (Textbox 5, quote 5.5).

After this series of disappointments, the participant experienced technical problems. The watch would frequently turn itself off and eventually stopped recharging. The study team offered to send a new watch, but because of her overall frustrations with the watch, she declined this (Textbox 5, quote 5.6).

In conclusion, concerns about the data quality and problems with the size of the watch caused disengagement. Owing to the sequence of disappointments by the time the watch broke, she could not be persuaded to remain in the study.

Textbox 5. Case study 2: experiences of a participant that enjoyed learning from the self-tracking but dropped out after a series of unmet expectations (quote 5.1 from baseline interview; 5.2 to 5.6 from follow-up interview).

5.1 It's the idea of being better informed about what's causing the pain, and actually if anybody can find a way of helping with the pain, without having surgery, then that's got to be a good thing.'

5.2 "It's been brilliant because I was aware, for example, that some of my worst times can be when I'm at work, and I can be sitting there, and I stand up and I'm in agony...So whilst I can't see that I've contributed anything to kind of findings, if you like, from a personal point of view it's been good because I think it has helped me understand what hurts and what doesn't hurt, and I'm not as idle as I think. So that's quite good."

5.3 I just had some questions about the reliability; and although they said that it was still picking up steps, I didn't have confidence that it was providing an accurate reflection of the steps that I'd done I was frustrated because I don't think I ever had a complete day where I could be confident that actually I had walked quite a long way, and I thought I'd definitely walked more than the steps that it was showing, or it was cleared off, I couldn't ever tell how many I'd done.

5.4 It just raises lots of questions in my mind about, what do they really know about what I've been doing? 'Cause I was outside yesterday and I probably didn't do that many steps. But actually that's irrelevant, it's the fact that I'm bending. That is much more relevant to my knee pain...And the other thing is, standing. Just standing is a nightmare… And that wouldn't be captured, because I wouldn't have done any steps at all, 'cause literally, I was just standing there. And for me, that would have been a million times worse than walking loads of steps on the flat."

5.5 I can't write with it on, it was far too uncomfortable, the watch face is too big. And again I suppose that's a, you know, women generally have smaller watches, we're not used to it; but if I was writing it would pinch my skin, otherwise if I didn't have it reasonably tight it would flop around and the face would end up there, and then there'd be that bone there and I just couldn't get away with it.

5.6 I'd had a few problems with it; and then I had a little spell where it seemed to be better, so although I'd contacted the team and said I was having these problems, it then picked up; and then it just got really bad, so I contacted them again and said, I'm just not getting away with it because of...you know, because I always thought ''has that captured what I've said?', or if it was on charge the question didn't come back again. So although the team said you could still do it later, and they said that steps would still be captured, I didn't think it was reliable."

The case studies show that expectation of personal gain or learning about someone's condition alone does not explain engagement. Case study 1 shows that participants motivated by altruism may stay engaged even if they have little interest in self-tracking. Case study 2 shows that those with high interest in self-tracking also may have higher expectations, which, if not met, can be a reason for disengagement.

Discussion

Principal Findings

This study succeeded in collecting frequent sensor data and patient-reported outcomes using cellular smartwatches for 90 days. Participants wore their smartwatch on most days, with engagement declining most notably after week 12 as participants approached the study end date. Among participants who remained active, data completion remained high, and neither watch wear time nor completion rate of watch questions declined significantly over time. Most participants joined the study to learn more about the link between their pain and activity, in line with known benefits from symptom tracking [24]. They found the watch app technically easy to use even though most had no previous experience with self-tracking. Several participants found the watch somewhat big or cumbersome. Participant interviews showed that the main barriers to wearing the watch were battery life limitations, technical problems, and unfulfilled expectations of, or doubts about, the watch performance. The first case study illustrated that an interest in self-tracking (one of the commonest motivators) is not an essential requirement for high engagement. The second case study showed that being interested in self-tracking does not automatically lead to high engagement: this participant dropped out after recurrent small disappointments where the watch did not meet her expectations.

Strengths and Limitations

The study has a number of strengths. To our knowledge, it is the first to develop an app to collect both patient-reported outcomes and sensor data from this new generation of consumer cellular smartwatches. The combination of quantitative methods and qualitative methods provides important insights into motivations and barriers for participant engagement with the new technology. The case studies show how these motivations and barriers are weighed against one another. Although the app is not publicly available, lessons learnt about engagement are transferable to future consumer cellular smartwatch studies.

A limitation of this study is the small, self-selected sample. Participants had volunteered for the study, which means that they may have been more motivated than the nonvolunteering population with OA, resulting in higher engagement. Second, we may have underestimated watch wear time. We could not directly record wear time but instead defined this as "minutes of sensor data received." This definition excludes time that a participant wore the watch, but it was out of battery or out of internal memory. Third, we cannot draw conclusions about data collection for longer periods of time, as our feasibility study was limited to a 3-month period.

Comparison With Prior Work

High attrition rates are often a characteristic of mobile health studies [22] and even of activity trackers for personal use [25]. Until the last week of our study, attrition was relatively low. In a 6-week study of Fitbit activity trackers, most participants dropped out (75% attrition after 4 weeks, compared with 4% in our study) [26]. Despite asking participants to report symptoms 4 or 5 times per day, we retained higher completion rates than studies that requested information fewer times per day to OA patients [10,11] or other patient groups [22,27,28]. The possible burden of higher number of questions may have been offset by the speed of data entry per question: responding on a wrist-worn device took less than 10 seconds, compared with taking out a device or diary in other studies. The workload and time required to enter data are known to influence attrition [22], but it remains uncertain where the balance lies between frequency of entry and duration required per entry. A total of 12 participants stopped wearing the watch in the last week of the study but before their end date. Enrollment was staggered over 12 days, but participants received instructions for returning the watch on the day that the first participants had completed 90 days. This may have led to possible confusion for late enrollers, thinking the study had already ended for them.

Barriers and motivators that were identified in the interviews largely correspond with previous research. Our participants were primarily motivated to learn about their condition, a common motivation to engage with digital health apps [28]. Most barriers to engagement have also been described in other studies: forgetting to charge or put on the watch [26], physical design and aesthetics [26], issues with (expectations of) data accuracy [26,28], and preferring a competing intervention [22].

Receiving feedback from a digital health app has previously been identified as a motivator [28]. In our study, participants perceived wearing the watch as beneficial, even though they did not receive decision support and could not look back into previous pain or step count values. Many stated that using the watch still led to a better understanding of the relation between their pain and activity. We did not find "lack of previous experience with digital devices and health tracking" [28] as an important barrier to engagement, possibly because participants with limited digital literacy also found the watch and our app intuitive and easy to use.

This study focused on usage of consumer cellular smartwatches for research only, rather than for self-management or clinical care. Self-tracking using consumer devices has advantages for self-management such as giving participants a better understanding of their condition (an advantage also observed in this study) and identifying triggers [24]. Our app did not display visual feedback about recently tracked symptoms, which may have limited such benefits. Self-tracking also has the potential to transform clinical consultations by providing a clearer picture of symptoms while at home, improving shared decision making [29]. Integrating data from smartwatches into electronic health records in the future may well deliver similar advantages.

Recommendations For Future Studies

Future studies may increase engagement in a number of ways. Our interviews indicate that unrealistic expectations of watch performance (eg, battery life) and doubts about accuracy of the device or ability of researchers to derive relevant metrics caused participants to disengage. Better participant information upon enrollment might mitigate this source of attrition. Visualization of the participants' own data may increase engagement further, especially given the primary motivator of participants wanting to understand better their relationship between physical activity and pain. However, such a change needs to be balanced against concerns that feedback may influence subsequent reporting. Improvements in the technology, including longer battery life and lighter, more comfortable watches, may further reduce attrition.

Conclusions

This study suggests that it is feasible to use cellular smartwatches for collection of patient-reported outcomes 4 or more times per day alongside continuous sensor data collection. Indeed, participants felt self-reported data collection could be even more frequent than the 4 or 5 times per day in this study. Learning about symptoms was a prime motivator to use the watch, even though most participants had never self-tracked before. Technical issues rather than participant attitudes more commonly limited engagement with the smartwatches. Overall, cellular smartwatches were an acceptable and feasible new data collection tool to support health research.

Acknowledgments

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Conflicts of Interest

WGD has provided consultancy for Google and Bayer Pharmaceuticals.

Multimedia Appendix 1
Overview of interview topic guides.
[PDF File (Adobe PDF File), 72 KB - mhealth_v8i1e14368_app1.pdf]

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Abbreviations

KOALAP: Knee OsteoArthritis: Linking Activity and Pain
OA: osteoarthritis

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Original Paper

Making Self-Management Mobile Health Apps Accessible to People With Disabilities: Qualitative Single-Subject Study

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Abstract

Background: Over the past decade, a large number of mobile health (mHealth) apps have been created to help individuals to better manage their own health. However, very few of these mHealth apps were specifically designed for people with disabilities, and only a few of them have been assessed for accessibility for people with disabilities. As a result, people with disabilities have difficulties using many of these mHealth apps.

Objective: The objective of this study was to identify an approach that can be generally applied to improve the accessibility of mHealth apps.

Methods: We recruited 5 study participants with a primary diagnosis of cerebral palsy or spinal cord injury. All the participants had fine motor impairment or lack of dexterity, and hence, they had difficulties using some mHealth apps. These 5 study participants were first asked to use multiple modules in the client app of a novel mHealth system (iMHere 2.0), during which their performance was observed. Interviews were conducted post use to collect study participants' desired accessibility features. These accessibility features were then implemented into the iMHere 2.0 client app as customizable options. The 5 participants were asked to use the same modules in the app again, and their performance was compared with that in the first round. A brief interview and a questionnaire were then performed at the end of the study to collect the 5 participants' comments and impression of the iMHere 2.0 app in general and of the customizable accessibility features.

Results: Study results indicate that the study participants on their first use of the iMHere 2.0 client app experienced various levels of difficulty consistent with the severity of their lack of dexterity. Their performance was improved after their desired accessibility features were added into the app, and they liked the customizable accessibility features. These participants also expressed an interest in using this mHealth system for their health self-management tasks.

Conclusions: The accessibility features identified in this study improved the accessibility of the mHealth app for people with dexterity issues. Our approach for improving mHealth app accessibility may also be applied to other mHealth apps to make those apps accessible to people with disabilities.

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KEYWORDS

mobile app; self-management; accessibility; personalization

Introduction

Background

Currently, approximately 650 million people in the world live with a disability. In the United States alone, there are 61.4 million adults living with a disability, which is 25.7% of the US adult population [1]. The aging population in the United States has resulted in a steady increase in this percentage in the past several years because prevalence of any disability is higher among older age groups [2]. If there is no specific support provided to these people with disabilities, they will have serious difficulty taking care of themselves.

Mobile health (mHealth) apps offer one way to provide desired support to people with disabilities so that they can perform some health self-management tasks and achieve a certain level of independence. As of December 2017, 325,000 mHealth apps had been created [3]. The general purpose of patient-oriented mHealth apps has been to assist patients to manage their own health or receive desired health care services from their health care providers when a face-to-face meeting is not feasible [4-11]. A number of studies have been performed to evaluate the usefulness and effectiveness of these mHealth apps [12-19], and a number of apps have proven to be useful and effective in maintaining or improving people's health [12-20].

Only a small number of mHealth apps, though, have been specifically designed for people with disabilities, and an even smaller number of apps have undergone accessibility evaluation with people with disabilities [21-26]. In other words, although an enormous number of mHealth apps have appeared on the market, only a very limited number of them may be used by people with disabilities, thereby increasing health care service disparities between people with disabilities and the general population [27]. Therefore, more mHealth apps designed for people with disabilities that include features for self-management [17,28] of health care and that are highly accessible [29-31] are highly desirable.

People with different disabilities have different needs in terms of accessibility. For example, visually impaired people need magnifiers, audio alerts, or screen readers to access the information from a mobile app; people with hearing impairment may need flashing lights, vibration capability, or caption services to receive information from a mobile app. This difference in needs means it is important to work closely with target users when designing accessibility features in mHealth apps.

Previous Work

In the past two decades, although many accessibility studies have been conducted, many were related to Web accessibility on computers. Only a small number of accessibility studies investigating mobile app accessibility have been conducted, and only a few of these studies focused on mHealth app accessibility.

Among the studies on mobile app accessibility, authors have evaluated various approaches for improving the accessibility of their apps, for instance, creating different user interfaces for people with different types of disabilities such as visual [32,33], hearing, physical, and cognitive impairment [34]; designing user interfaces and information and communication technology systems for older adults [35,36]; building a customized mobile app for people with cerebral palsy (CP) [37]; and generating accessibility toolkits [38].

Several years ago, the first version of a novel mHealth system named iMHere 1.0 was created to help patients to manage chronic conditions [11]. The accessibility of the iMHere 1.0 app was evaluated in patients with dexterity impairment [29-31]. In iMHere 1.0, a number of accessibility features were implemented, for instance, simplified steps for entering information about medications, color-coded themes, a customizable app list, adjustable text and button size, and color-coded contents [30,31].

Recently, an updated version of the mHealth system, iMHere 2.0, was created to support a variety of self-management tasks for people with disabilities [28,39]. Moreover, a component of this updated mHealth system is an app used by people with disabilities (referred to as *client app* in the following descriptions). As this client app was implemented with cross-platform packages, it can run on all 3 major platforms: iOS, Android, and Windows phone systems. In the iMHere 2.0 client app, there are 12 app modules for different self-management tasks, such as medication management, mood self-assessment, and minor skin problem reporting. A usability study with 81 study participants from the general population was performed on the iMHere 2.0 client app, and the results indicated that the app had high usability for people in the general population [39].

Objectives

The objective of this project was to evaluate and improve the accessibility of the mobile client app in the iMHere 2.0 system to support self-management and personalized care. Our ultimate goal was to identify an approach for making mHealth apps accessible to people with disabilities.

Methods

Study Participant Recruitment

The study protocol (PRO18020101) was approved by the institutional review board (IRB) office at the University of Pittsburgh. The study participants were recruited via referral. The selection criteria were being a native English speaker aged between 18 and 65 years with CP, spina bifida (SB), or spinal cord injury (SCI) and with a disability in fine motor skills. A phone screening was conducted with each referred potential study participant to verify the information we had obtained from clinicians, such as the potential participant's willingness to participate in the study, their primary diagnosis, and their impairment in fine motor skills.

Study Procedure

Before the beginning of the study, each study participant was given sufficient time to read the IRB-approved consent form carefully and to sign the form if the contents were acceptable. The study participation was completely voluntary, and the participants could leave the study at any time. After the consent

form was signed, a general introduction to the study purpose and procedure was provided to these study participants.

Each study participant was then required to take a few standard tests to evaluate their vision, cognitive level, and dexterity. The Snellen eye chart was used for vision assessment, the Montreal Cognitive Assessment for cognitive level assessment, and the Purdue Pegboard Test (Model 32020A) for dexterity assessment.

Dexterity impairment level was determined based on the number of pins picked up from a shallow cup and plugged into holes on a board in 30 seconds, using his or her left and right hand, respectively. The smaller the values, the more severe the dexterity impairment. If the value was 0, it meant the study participant was not able to pick up any pin or plug it into a hole on the board.

After these standard tests, an interview was conducted to obtain a better picture of the situation of each participant, for instance, their disability, primary diagnosis, type of wheelchair used, difficulties in daily life, mobile devices used frequently, number of years using mobile devices, difficulties using mobile devices, and assistive technologies used in the past.

After the interview, a demonstration of 5 modules (skincare, mood, education, nutrition, and exercise) in the client app of the iMHere 2.0 system was provided to the study participants [39].

The study participants were then asked to use these app modules one by one and finish several tasks, one in each module. The following is a list of tasks they were required to finish:

- Reporting a skincare case in the skincare module.
- Performing a self-assessment on mood in the mood module.
- Adding records in the exercise module.
- Adding records in the nutrition module.
- Reading a few sections of education materials in the education module.

Study participants were also encouraged to use other modules offered in the app such as MyMeds for medication management and PHR for personal health records management. Their performance on all these modules was observed and noted, for instance, the number of attempts they needed to successfully click an indicated user interface component such as a button, whether they accidentally clicked a nearby button, and whether they had difficulties reaching the indicated button. Besides typical buttons, the indicated interface components in this study also included radio buttons, pictures, check boxes, icons in the app, text boxes, hyperlinks, keys on the soft keyboard, and arrows (eg, left, right, up, down, and back to the previous page).

An iPhone 6 plus, a 9.7-inch iPad Air 2, and a 9.7-inch Samsung Android tablet provided by the study team were used at this stage. Each study participant was only *required* to use one of these 3 devices according to their situation and the type of devices and the mobile operating systems they were familiar with. This arrangement was to remove any accessibility issues that could be introduced by having to use an unfamiliar mobile device or operating system. They were allowed to use the app on other devices as well if they chose to do so.

The study participants were interviewed to collect their feedback on the accessibility of the iMHere 2.0 client app and their desired accessibility features in the mHealth app. The accessibility features that the study participants expressed a desire to have were then summarized, analyzed, selected, designed, and implemented in the app.

As different people with disabilities have different requirements for accessibility, multiple types of accessibility features were made available and *customizable* in the app. People with disabilities then had the ability to customize the app interface according to their own needs.

During the accessibility feature selection stage, we evaluated each requested accessibility feature by asking 2 questions: (1) Is this request a need or preference? and (2) Will this feature improve the accessibility of the app for *this population*? If the feature was only a preference, not a need, it did not have high priority on the feature implementation list. If the feature could not improve the accessibility of the app for this particular population, we did not add it into the app.

It took us more than 3 months to discuss, design, and implement these accessibility features. After these features were added into the iMHere 2.0 client app, the 5 study participants were invited to use the same modules in the iMHere 2.0 app again and finish the same tasks with and without the newly implemented accessibility features. Their performance was again observed and noted.

After the study participants finished all the tasks, they were interviewed to determine whether the accessibility of the app had improved by orally giving a rating to the following 4 statements on a scale ranging from 1, strongly agree, to 7, strongly disagree.

These accessibility features make it easier for me to:

1. *click the desired buttons.*
2. *make selection in a list of options in the app.*
3. *understand the content in the app.*
4. *navigate different pages in the app.*

All 5 participants were also required to respond to the 10 usability statements in the System Usability Scale (SUS) via the Web-based Qualtrics system [40] to express their overall impression of the usability of the iMHere 2.0 client app. A brief and informal interview was performed to verify their answers on the questionnaire.

For study participants who used a power wheelchair and had a joystick on the wheelchair, a test was performed to determine whether they could use the joystick on their wheelchair to perform navigation and item selection in the iMHere 2.0 client app on the mobile devices.

All the data collected in these steps were summarized and analyzed to draw conclusions.

iMHere 2.0 Client App

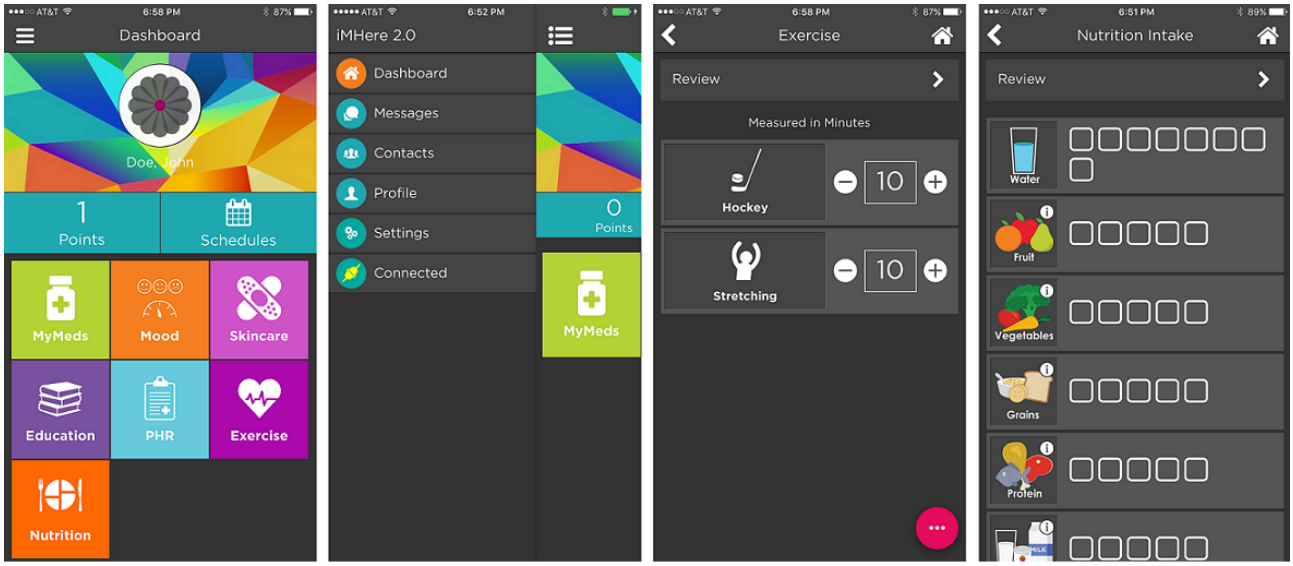
The iMHere 2.0 client app was designed to support patients' self-care tasks, send data to clinicians, and allow patients to receive personalized regimens from their clinicians [39]. This

app has 12 modules in total, 5 of which were used in this study: skincare, mood, exercise, nutrition, and education. The skincare module can be used to report minor skin problems by indicating the wound site, taking a picture, and sending it to the provider along with answers to a few questions about the wound situation. The mood module is used to perform mood self-assessment by answering the Patient Health Questionnaire-2 (PHQ-2) for depression screening and the Generalized Anxiety Disorder-2 (GAD-2) for anxiety assessment [41,42]. The exercise module can be used to track physical activities each day by having the user select the type of activities completed from an activity icon library and indicate the duration of each activity. The nutrition module is used to track types of food and drink consumed by the app user each day. The education module includes information on various topics related to the health of people with disabilities, such as background information on CP and SB. Each of these modules has unique user interface components.

Moreover, 2 other modules were made available during the study: MyMeds for medication management and PHR for personal health records management. They were not required in the study because they had useful features for users but did not include unique user interface components. These 2 modules were provided so that these study participants could explore the app further if they wanted.

As shown in Figure 1, the home screen of iMHere 2.0 consists of 2 main areas: one is the dashboard with a user name, reward points, schedules, and a list of modules (see the first diagram in Figure 1), and the other is a list of menu buttons, which appears after the list icon at the top-left corner is clicked (see the second diagram in Figure 1). One of the menu buttons is a link to the system settings page (not shown). All the modules shown in the dashboard can be launched by clicking on their icon. Once the icon of a module is clicked, the module takes the user to the corresponding app's main screen (the third and fourth diagrams in Figure 1 are for the main screen of the exercise and nutrition modules).

Figure 1. Screenshots of the iMHere 2.0 (a) dashboard, (b) menu buttons, (c) exercise module, and (d) nutrition module.



Results

Demographic and Basic Information

In this study, 5 participants were recruited from the Greater Pittsburgh area via referral. The ages of the 5 study participants were 18, 28, 33, 35, and 41 years; their average age was 31 (SD 8.63) years. All of them (5/5, 100%) were white Americans. The average number of years using smart devices was 8.8 (SD 1.10). Other demographic information is summarized in Table 1. Their standard test results, hand preference, and difficulty performing daily activities are shown in Table 2.

Table 1. Demographic characteristics of the study participants (N=5).

Characteristics	Value, n (%)
Gender	
Male	2 (40)
Female	3 (60)
Education	
High school	1 (20)
Bachelor's degree	3 (60)
Master's degree	1 (20)
Employment	
Employed	2 (40)
Not employed	3 (60)
Marital status	
Single	4 (80)
Married	1 (20)
Primary diagnosis	
Cerebral palsy	4 (80)
Spinal cord injury	1 (20)
Primary mobile device	
iPad	1 (20)
Android phone	2 (40)
iPhone	2 (40)
Wheelchair	
Power wheelchair with Bluetooth connection	3 (60)
Power wheelchair without Bluetooth connection	1 (20)
Manual wheelchair	1 (20)

Table 2. Standard test results, hand preference, and difficulty performing daily activities.

Prestudy evaluations	Value, n (%)
Standard test results	
Vision (both eyes)	
20/20	4 (80)
20/25	1 (20)
Cognitive level	
Normal	2 (40)
Below average	3 (60)
Dexterity (left/right)	
0/0	3 (60)
10/3	1 (20)
0/5	1 (20)
Hand preference	
Right	3 (60)
Left	2 (40)
Daily activity	
Feeding oneself	
Yes	1 (20)
Yes with special tools	1 (20)
No	3 (60)
Using restroom independently	
Yes	0 (0)
No	5 (100)
Needing reminder to take medications	
Yes	1 (20)
No	4 (80)

Subject-Specific Information

Participant 1 was an 18-year-old female high school student. Her primary diagnosis was CP. She also had experienced seizures and had type 1 diabetes. Her dexterity impairment was severe. The participant mainly used an iPad at home and in school. She strongly depended on her iPad to communicate with others and finish her schoolwork. Her spoken language could be understood by her family members, teachers, and friends but was difficult to understand for others. The joystick on her power wheelchair could be paired with other devices (such as a music player) via Bluetooth. She preferred to use her iPad and the soft keyboard on it to finish various tasks. She could use her fingers and the joystick on her wheelchair to finish those tasks. She could use her wheelchair to move around, but she needed others (eg, family members and school staff) to help her to finish many daily activities such as having a meal, taking a shower, and using a restroom.

Participant 2 was a 41-year-old male. He had a part-time job. His primary diagnosis was SCI. He used a power wheelchair. His spoken language was easy to understand for everyone. He commonly used a desktop computer and an Android phone. He did not own a tablet. He could use mobile apps on his Android phone. His power wheelchair had Bluetooth, but he had never tried to use it to pair with other devices. In most cases, he needed a dedicated caregiver to help him to finish daily activities. Sometimes, he used specially designed tools to feed himself. His dexterity impairment was moderately severe. He could use the back of his fingers to make selections on a mobile device. His arms had a very limited range of movement; therefore, he had significant difficulty using mobile devices with a bigger screen, such as a 10-inch iPad.

Participant 3 was a 35-year-old female. She had a bachelor's degree and a full-time job. Her primary diagnosis was CP, and she used a power wheelchair. Her dexterity impairment was moderately severe. Her wheelchair did not have Bluetooth. She was able to use a desktop computer, laptop, iPhone, iPad mini, and iPad. Her spoken language was sometimes difficult to understand.

Participant 4 was a 33-year-old male. He had a bachelor's degree and was looking for a job. His primary diagnosis was CP, and he had Parkinson disease as well. He had both a manual

wheelchair and a power wheelchair. He used the manual wheelchair at home. He used an Android cell phone and could use apps on the phone. His dexterity impairment was mild.

Participant 5 was a 28-year-old female. She had a master's degree and had a full-time job. Her primary diagnosis was CP. She used a power wheelchair with Bluetooth. She could use mobile apps on her iPhone and iPad. Her dexterity impairment was moderate.

All the study participants took multiple types of medications daily. Moreover, 4 of them (80%) needed other people's help to take the medications on time. They all had mobile devices and could use some apps on the mobile devices. They all had used smart mobile devices for a number of years. None of them could use the restroom independently. Most of them (4/5, 80%) could only use 1 hand to operate mobile devices.

Performance on iMHere 2.0 Without Accessibility Features

Overall, all the participants were able to follow the investigator's instructions, click the indicated buttons and options, take pictures, find the desired pages, and enter the information with different levels and types of difficulties. It was relatively easier for them to make selections at the left or right edge of a tablet or phone. It was difficult for them to perform selections when buttons or options were in the middle of a tablet or when they were only available on the left- or right-hand side instead of both sides, as most of them (4/5, 80%) could only use one hand to operate the mobile device.

Participant 1 had difficulty zooming in and out on a tablet using one hand or pinpointing a specific location for button clicking or typing. She made multiple attempts to finish tasks such as clicking a button, making selections of investigator-indicated options, or entering a word. She strongly depended on the word prediction feature of the soft keyboard to finish her word typing. If buttons were big and far away from each other, it was easier for her to make the selection. It was easy for her to swipe to move to different pages on the tablet.

Participant 2 had difficulty using the app on a 9.7-inch tablet as his arm had only a very small range of movement, and he could only use the back of his fingers of his left hand to make selections. His performance was much better when he used the app on the iPhone. On the phone, he was able to make the desired selections and type words into the app. He made multiple attempts before achieving success when a button only occupied a small area. He made a few mistakes when typing words.

Participant 3 could easily make selections when the buttons or options could be accessed from the left-hand side. Selections were especially easy for her when she was working on a large tablet. When she entered text on the app, she made many mistakes but could enter the correct text eventually. It was relatively difficult for her to select buttons located on the right-hand side or in the middle of the tablet screen, requiring multiple attempts. When she worked on the iPhone, the situation was better as she was able to access almost all the buttons and options from the left-hand side of the phone.

Participant 4 did not have any major difficulty finishing all the given tasks, whether on the iPhone or the tablets.

Participant 5 could make selections on both the iPhone and iPad using her right hand. She had difficulty when selecting some options, for instance, the pop-up menu in the skincare module. Sometimes, she experienced difficulty entering text. It was also difficult for her to select buttons located on the left-hand side or in the middle of the tablet screen.

All participants briefly explored the MyMeds and PHR modules after they finished the required tasks in the 5 modules. They all indicated that the availability of these 2 modules was very useful for their health management as the MyMeds module can remind them to take medications on time every day if needed, and the PHR module can store all their essential personal health records in one place.

Feedback and Desired Accessibility Features

The following is a summary of the feedback and desired accessibility features from these 5 study participants.

Font Size and Style

Although all the study participants could read the text contents of the app, multiple participants (3/5, 60%) expressed the desire for larger font sizes and bold style in certain cases. Some also expressed a desire for font size and style of text on the app to be adjustable according to their needs.

Spacing

Most of them (4/5, 80%) did not like dense reading material or buttons close to each other. They expressed a desire for the spacing between lines and buttons to be adjustable.

Button and Selection Option Arrangement

Most of the participants (4/5, 80%) had difficulty clicking buttons located in the middle of the screen, especially on a large tablet. Therefore, they preferred that buttons could be moved to the left edge and right edge, with multiple buttons aligned vertically. This also applied to options to questions. Instead of only allowing for radio button or check box selection, they desired that the option selection should be done anywhere from left to right as a long button.

Color and Contrast

All the participants liked the use of different colors for different pages in different app modules. At the same time, they pointed out that some colors were too light and that sometimes the contrast between the background and the text was not high enough. They felt that a simple white background and dark text or vice versa would be better. They also expressed a preference for the color of a button or option to change in acknowledgment of a selection having been made. Without that, they reported that they might keep trying and become frustrated because they thought they had not successfully clicked the desired button or option.

Alternative Approach for Data Input

Most of these participants (4/5, 80%) experienced some level of difficulty typing words using the soft keyboard on the app. These participants typically had to try multiple times to enter

one word. It was easier for them to select from among given options. Therefore, they expressed a desire that the app provides options for them to select instead of asking them to type in words to describe their situation, for instance, providing a picture or list of body parts to complete minor skin issue reporting in the skincare module.

Page Navigation

All the study participants noticed that some pages in the education module were longer than one screen and that there was no indicator of that. They reported that it would be better to have a scroll bar to indicate this fact. An alternative approach would be to split the page longer than one screen into multiple pages as all these participants were able to perform a swipe between pages easily. They also expressed that left and right arrows on a page were needed so that the page navigation could be performed using other approaches or tools than fingers, such as a paired joystick. Similarly, up and down arrows were requested as well for when the content was longer than one page on the mobile device screen.

Handedness

Most of these study participants (4/5, 80%) could only use one hand to operate the mobile devices, and it was easier for them to make selections on the side convenient for their hands. Therefore, they expressed the desire for an option for users to choose the handedness of the buttons and options.

Multimedia Contents

Some study participants (3/5, 60%) expressed a desire for screen reading, pictures, audio, and video content for the education materials.

They also desired to have *individual* accessibility setting changes (font size, font style, button size, spacing, and handedness) instead of choosing from a few built-in accessibility templates.

Accessibility Features Implemented

The iMHere 2.0 client app was modified to include the features participants had expressed a desire for. First, easily adjustable font sizes, font styles, line spacing, button sizes, button spacing, a scroll button, color and contrast preferences, and hand preferences were implemented in the app. In the modified app, all buttons and options, wherever possible, were shown as crossing one entire page from the left edge to the right edge. More than 20 sets of color themes were implemented to meet the variety of needs of different users. In addition, in response to participant suggestions, clickable pictures were implemented for body part selection instead of word typing, and to answer questions, options were provided for users to make selections from instead of typing words being required. Multimedia contents (pictures, audios, and videos) were added into text materials as well.

The first diagram in Figure 2 (top left) shows the accessibility feature settings page. The specific options for these accessibility features are listed in Table 3. The second and third diagrams in Figure 2 show the page difference in the education module before and after font size, font style, button size, and button spacing were changed. The second diagram in Figure 2 is the situation in the default setting, whereas the third diagram in Figure 2 demonstrates the situation when *large* font size, *bold* font style, *large* button size, and *large* button spacing have been applied. The fourth diagram in Figure 2 displays the situation in the mood module when only *large* button spacing has been applied. The fifth and sixth in Figure 2 are another comparison of a page in the education module before and after font size, font style, and line spacing were changed. These 2 figures also show the number of pages (using dots), current page (solid dot) in the selected section, and the left/right arrows, which can be clicked to go to the previous page or the next page, in addition to the typical page swiping.

The seventh diagram in Figure 2 shows the added human body part picture. One can simply click on the body part affected by a wound instead of using words to describe the location of wound. There are multiple pictures provided for this purpose, including the front and back of the human body (clicking the circle at the top right corner switches from front to back, not shown) and multiple pictures of a foot. One can also choose to select a body part from a list (clicking the square box icon at the top right corner to access the name list, not shown). The second, third, and fourth diagrams in Figure 2 show the edge-to-edge buttons, whereas the eighth diagram in Figure 2 shows the edge-to-edge options. The options in the eighth diagram in Figure 2 also make it possible for users to choose from among a list of answers to questions using a soft keyboard to describe the wound condition instead of having to type answers to those questions in text boxes. All figures also show the dark background and bright text.

By default, all customizable accessibility features are disabled. Once the accessibility features are enabled, users can choose the specific accessibility features according to their needs, and these features are then applied to the user interface components on the entire iMHere 2.0 client app. Users can determine whether their selections meet their own accessibility needs.

Figure 2. Accessibility features in the iMHere 2.0 client app. (a) List of customizable accessibility features. (b) A page in the education module without accessibility features. (c) A page in the education module with accessibility features. (d) One self-assessment question in the mood module with large button spacing. (e) A page in the education module with default settings. (f) A page in the education module with accessibility features. (g) A human body picture for body part selection in the skincare module. (h) A list of options for answering questions in the skincare module.

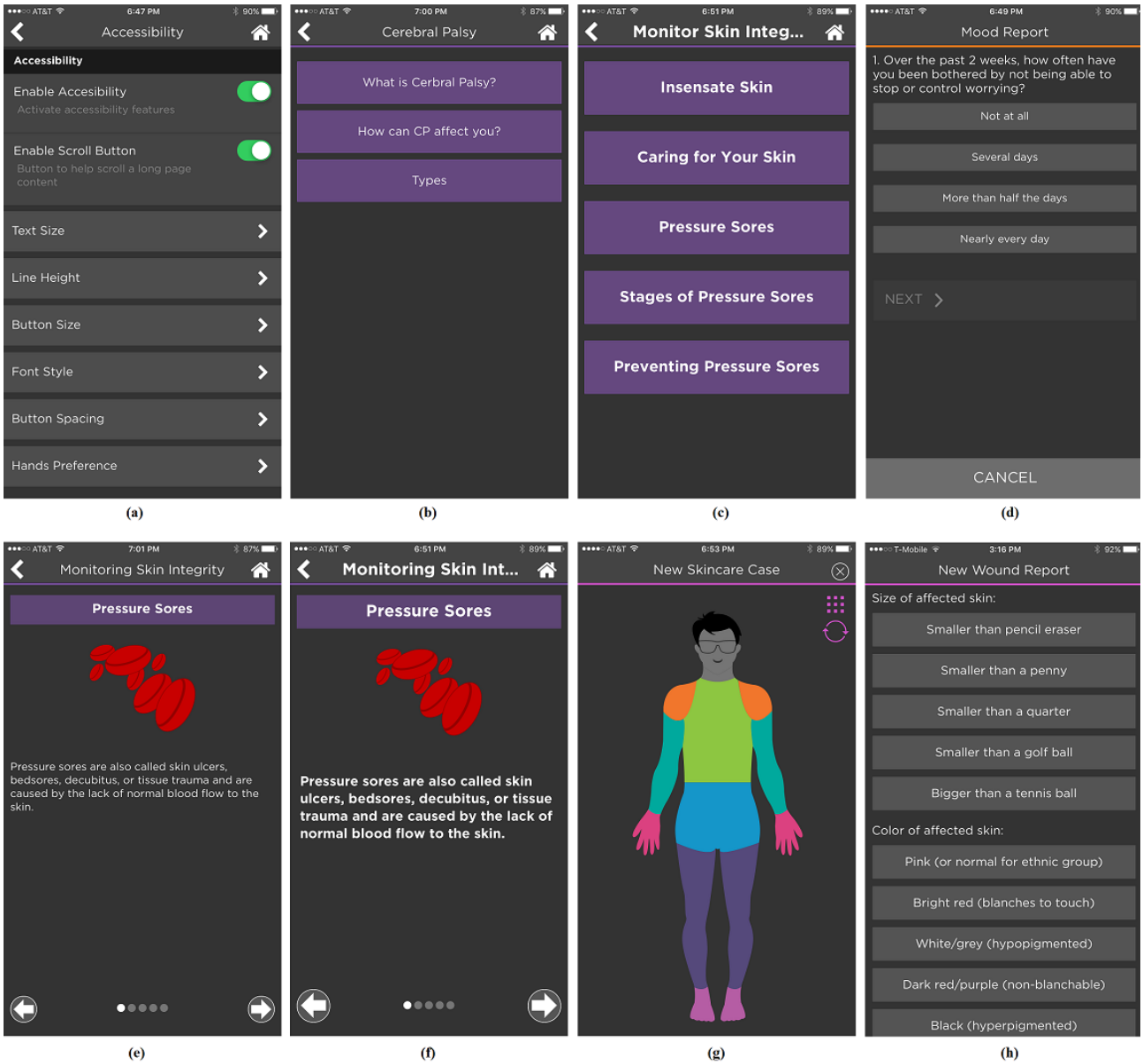


Table 3. Options for several accessibility features available in the iMHere 2.0 client app.

Accessibility features	Options
Font size	Small, medium[a], large, and extra large
Font style	Normal[a], bold
Line spacing	Narrow, medium[a], wide, and extra wide
Button size	Small, medium[a], large, and extra large
Button spacing	Small, medium[a], and large
Hand preference	Left, right[a]
Scroll button	False[a], true
Color themes	Multiple sets of color themes, such as colorful[a], black and white, frame, and bright

[a]Default options.

Performance on iMHere 2.0 With Accessibility Features

As mentioned earlier, all study participants in the first session of the study were able to finish the tasks given by the investigator with varying types and levels of difficulty. After the desired accessibility features were implemented into the iMHere 2.0 client app, the study participants were asked to complete the same tasks again. First, they were asked to use the app without the accessibility features (the original version of the app). Then, the study participants were given access to the accessibility features, and they made adjustments according to their needs. For instance, study participant 3 switched the hand preference from right to left because her left hand was better than her right hand, which moved all buttons listed on the right side of the screen to the left side.

Overall, when the original version of the app was used, these study participants still had the same difficulties experienced in the first session. After the accessibility features were turned on, however, not only did these study participants report that they believed that the new accessibility features were very helpful for them but their performance on the app was also consistent with their expressed beliefs. In many cases, they only needed 1 or 2 attempts to finish a task once bigger fonts and button sizes were applied instead of the several attempts required before the accessibility features were available. They could easily finish the mood self-assessment and minor skin issue reporting by clicking buttons or choosing options from either side of the mobile devices, no matter which of their hands was relatively better. For buttons that could not be changed to edge-to-edge bars, the adjustment of handedness could be used to allow the participant to move those buttons to the side easier for them to access. Therefore, it was much easier and faster for them to finish the required tasks in this study. Overall, none of the participants had any major difficulty finishing all the tasks.

All participants expressed that they were glad that they could make selections and adjustments on individual accessibility features, as this allowed them flexibility, and they felt they had some sense of control of the process.

After they finished all the tasks on the iMHere 2.0 client app with the desired accessibility features available, they orally indicated their agreement level with the 4 statements related to accessibility improvement (*These accessibility features make it easier for me to 1. click the desired buttons, 2. make selection in a list of options in the app, 3. understand the content in the app, 4. navigate different pages in the app*.). All of them chose 1 (strongly agree) in response to the 4 statements. In other words, they believed that those accessibility features made it easier for them to click buttons, make selections, navigate on pages, and read educational contents.

Usability

As these study participants had difficulty finishing tasks on the original iMHere 2.0 client app, they were quickly tired and became frustrated. Moreover, it is known that it is difficult for some people with CP to concentrate on 1 task for a long time. As a result of these issues, we did not ask participants to fill out any type of usability questionnaire in the first session. The main purpose of the first session was to observe their performance on the app and collect their desired accessibility features.

However, after the desired accessibility features were implemented, the study participants were able to finish the given tasks (same as the ones in the first session) easily and quickly. Therefore, they were capable of answering the usability questionnaire, the SUS, as well. The calculated SUS scores from the 5 study participants were 85, 95, 92.5, 77.5, and 100. The average SUS score was 90 (SD 8.84), which means they believed the usability of the app was excellent.

Typically, if the accessibility of an app is not high (users cannot use or have significant difficulties using the app), people with disabilities do not consider the usability of the app high. However, if the usability of an app is very good according to people with disabilities, its accessibility must be high as well. Therefore, the excellent usability of the iMHere 2.0 client app indicated that the accessibility of the app was also very good.

The feedback from the study participants was positive during the informal interview at the end of the second study session. All 5 participants said that they liked the app and believed that it was easy to learn and use; they also reported that the app could be very useful for their self-management and expressed a desire to download and use the app on their own mobile device.

Other Accessibility Features

Some accessibility features are already available in major mobile operating systems (eg, iOS and Android), for instance, VoiceOver, zoom, and bold font style. Utilizing the accessibility features offered by these mobile operating systems in a mobile app makes possible to improve the app's accessibility. Therefore, in this study, we encouraged the study participants to evaluate some of the accessibility features offered by mobile operating systems according to their needs as well. Most of them (4/5, 80%) indicated that they were glad to know the VoiceOver feature worked fine on the iMHere 2.0 client app and said that the feature was particularly useful for reading text contents in the education module. This feature could also be used to read the text for buttons and selection options. The remaining participant expressed that the accessibility features offered by these mobile operating systems were not as flexible as the ones offered in the iMHere 2.0 app.

Some power wheelchairs offer Bluetooth connection modules, and these modules can be used to wirelessly link (pair) the control systems of these wheelchairs (eg, joystick and switch) with various types of mobile devices, such as music players, smartphones, and tablets. Once they are paired, the wheelchair user can use the joystick or switch on the wheelchair to click buttons or type words by selecting letters on the soft keyboard on the mobile device.

In this study, 3 study participants had a power wheelchair with a Bluetooth connection module installed. These wheelchairs were successfully paired with the Android tablet used in the study. The 3 study participants with Bluetooth capable wheelchairs were able to make selections on buttons and options on the app using direction and selection buttons on their wheelchairs. For some people, this offers an alternative approach

to use the mobile app. For some people who could not directly operate on a mobile device because of very limited hand movement range, tremors, or another severe fine motor impairment, this could be their only way to use the app. The iPhone and iPad used in the study were not able to detect the Bluetooth signal because these power wheelchairs were missing the required module that serves as the interface between the wheelchair and Apple devices.

Discussion

Principal Findings

In this study, we worked with 5 study participants with different levels of dexterity impairment, collected their feedback on the accessibility of an mHealth app (iMHere 2.0 client app), implemented *customizable* accessibility features accordingly, and evaluated the mHealth app again (both accessibility and usability) to determine whether the implemented features improved the accessibility of the app and the level of usability of the updated app.

The study results indicate that before the desired accessibility features were available, these 5 study participants were able to use the app but experienced different levels of difficulty finishing some given tasks. However, after the customizable accessibility features were implemented in the app and selected by participants according to their specific needs, they were able to easily finish all the given tasks and expressed that they were highly satisfied with the updated version of the app. This indicates that our approach can be used to make mHealth apps more accessible to people with dexterity impairment.

There are multiple reasons for this satisfying outcome. First, we worked closely with these study participants to identify and analyze their needs before we designed the accessibility features for them, including taking into consideration their primary diagnosis, difficulties completing daily activities, information and communication technologies they had used in the past, mobile devices they had used in the past, and their desired accessibility features in general (including the iMHere 2.0 client app and other apps as well). The collected information was used to guide the design and implementation of accessibility features in the app. Second, we identified both the accessibility needs common among these study participants as well as the individual accessibility requests and designed those accessibility features accordingly; furthermore, we arranged these features into categories (eg, text, button, spacing, color, and handedness), which made it easy for the app users to select their desired accessibility features in the settings. Third, many of the accessibility features were implemented as *individually adjustable* components, allowing the app users to customize the user interface of the app according to their needs. This approach makes it possible to meet the needs of people with highly *diverse* types and levels of disabilities. Fourth, when we conducted the study, we took into account the device form factor (phone vs tablet) and possible uniqueness of different mobile operating systems (iOS vs Android) to make sure that the accessibility features would work well regardless of the size of mobile device or the mobile operating system.

As mentioned in the Methods section, we did not implement all the accessibility features requested by the study participants. We evaluated each requested feature first to determine the nature of the request (a need or a preference) and whether the feature could improve the accessibility of the app for this population. If the feature was only a preference, not a need, it did not have high priority on the feature implementation list. For instance, 1 participant requested very large text on buttons even though her vision was fine and she could read text contents in medium size. In this case, the request was a preference, not a need. It may be addressed in the future but not in this study. If the feature was determined to be a need, we further determined whether the feature could improve the accessibility of the app. For example, 2 study participants requested the ability to use their voice to make selections on the app because they had difficulty clicking on their desired option located in the middle of the iPad. This is a need rather than a preference. We still chose not to implement this feature in the app, however, because we believed that this particular feature would not improve the accessibility of the app and that there was a better way to make the option accessible to them (buttons crossing the page from edge to edge). We made this decision because all 5 study participants had issues with their spoken language being easily comprehensible. For 1 participant, most people who did not know her well could not understand her sentences, except for some very simple words. We actually needed her mother's help to understand her. Moreover, 3 other participants' spoken language was not very clear, either, including 2 who had requested this particular feature. Therefore, a natural language processing algorithm would have significant difficulties recognizing sentences generated orally by them. Most likely, the error rate of the algorithm would be very high, and hence, this feature would ultimately not improve the accessibility of the app for this group of people. This feature may be implemented in the future for a different group of people who can speak clearly but have significant difficulties using their hands to operate mobile devices.

Although these accessibility features were developed according to the needs of people with dexterity impairment, they can also be useful for other people with similar needs, such as elderly people, people with big hands, and people with visual impairment. For people who are not sensitive to color, the black and white theme (black background and white contents in most places) could be particularly useful and convenient.

Comparison With Prior Work

There have been some studies on improving accessibility of mobile apps for people with disability [34,37] or the elderly [43]; however, most of these studies were not related to health care but focused on making it feasible for the target users to use mobile apps or touch screen mobile devices [44].

Only a small number of studies on mHealth app accessibility have been conducted, including 1 study done by Silva et al [45] and our previous studies on iMHere 1.0 for patients with dexterity impairments [29,46]. The study by Silva et al only provided a design for an accessible mHealth system. It is not clear whether the usability study that was planned with the patients was performed. In this study, we continued our tradition

of user-centered development and evaluation of mHealth apps with target users of the app. In the iMHere 2.0 system, we utilized some good accessibility features identified in previous studies (eg, an adjustable app list, color-coded modules, and colored body parts) and added customizable accessibility features based on target users' feedback to meet the needs of people with a broad spectrum of disabilities.

Limitations

This was a small-scale qualitative study to explore the feasibility of improving accessibility of an existing app by adding customizable accessibility features into the app. This sample size may not have allowed us to identify all possible accessibility features needed by people with dexterity impairment, but the in-depth conversations with these study participants enabled us to identify several major accessibility features desired by people with dexterity impairment, which was sufficient for this study.

The study participants' performance on the app was observed but not timed. Therefore, there is no quantitative measure of the performance difference in terms of time. This was deliberate because the major purpose of the first session was to collect information on participants' needs, and they might have felt unnecessary pressure if they were timed. In the second session, as observed by the researchers and noted in the feedback from the study participants, it was very easy for them to finish those tasks (in seconds) after their desired accessibility features were turned on.

In the second session, study participants were asked to perform the same tasks both without and with accessibility features. Their performance when the version without accessibility features was used was the same as that in the first session. In other words, although these study participants obtained a certain level of familiarity with the app from the first session, as their difficulties were from the physical function of their hands and arms, the influence of the familiarity with the app was minimal with regard to their speed of finishing tasks.

In this study, we did not have any study participants who were color blind or had very weak vision, and therefore, the findings on color themes and contrast were not conclusive. These study participants made selections in the setting on color themes and viewed the content on the mobile app under different contrast ratios; however, they did not have significant difficulty in terms of reading the content. Therefore, to evaluate the color themes and contrast ratios, people who have color blindness and people who have weak vision should be recruited to participate in the study.

The study sessions were long (>2 hours), and the tasks were challenging (multiple attempts for a simple button click) for people with dexterity impairment when their desired accessibility features were not available. These study participants became tired and frustrated after they finished the given tasks before the accessibility features were available. Therefore, we did not ask them to complete any questionnaires in the first session. Therefore, there was no quantitative data available for comparison to show the improvement of app accessibility in the 2 sessions.

Some participants' cognitive ability in this study was lower than normal. Therefore, although they liked the app, it was overwhelming for them to learn multiple modules in a short period. It might be better to only show them 1 or 2 modules in each session and have multiple sessions.

In this study, the study participants' performance on the app was only observed during the study sessions. It would be beneficial to evaluate long-term use of the app and the impact of those accessibility features. A randomized clinical trial (RCT) with a group of people with disabilities, especially ones with CP, SB, SCI, is in the planning stage. The duration of the RCT will be 1 year, and the feedback from the study participants of this RCT may provide results about the app after long-term use of the app.

Conclusions

By collecting feedback from people with disabilities and introducing customizable accessibility features, the accessibility of a mobile app can be improved. More importantly, the accessibility features added to the app in this study can be introduced in other mobile apps. This would result in the desirable outcome of making many mobile apps more accessible to people with disabilities.

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Authors' Contributions

BP conceived the idea of the study. LZ, AS, and BP designed the study protocol. LZ and AS conducted the study with study participants and collected the data. LZ analyzed the data. All authors reviewed and interpreted the results. All authors discussed, selected, and designed the new accessibility features. IMAS implemented the accessibility features in the iMHere 2.0 app. LZ drafted the manuscript. All authors reviewed the draft and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CP: cerebral palsy
IRB: institutional review board
mHealth: mobile health
RCT: randomized clinical trial
SB: spina bifida
SCI: spinal cord injury
SUS: System Usability Scale

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Original Paper

An Ototoxicity Grading System Within a Mobile App (OtoCalc) for a Resource-Limited Setting to Guide Grading and Management of Drug-Induced Hearing Loss in Patients With Drug-Resistant Tuberculosis: Prospective, Cross-Sectional Case Series

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Abstract

Background: Tuberculosis (TB) affects millions of people worldwide and is treated with medication including aminoglycosides and polypeptides. Individuals respond differently to medications as a result of their genetic inheritance. These differences in genetic inheritance can result in the underdosing or overdosing of medication, which may affect the efficacy or, in the case of aminoglycosides and polypeptides used in the treatment of all forms of TB, result in ototoxicity. When ototoxicity is detected, physicians should adjust dosages to minimize further ototoxicity and hearing loss; however, there are no suitable grading systems to define significant hearing loss.

Objective: The aim of this study was to develop a standardized grading system by making use of an electronic health (eHealth) platform to ensure that a user-friendly method was available to interpret hearing test results, calculate significant hearing loss, and provide recommendations with regard to dosage adjustments and management. It further aimed to establish the sensitivity of the newly developed grading scale.

Methods: This grading system was developed in South Africa based on data that were obtained from an audiology and pharmacokinetic study on patients with drug-resistant TB (DR-TB) at two DR-TB units at state-run hospitals. This feasibility study employed a prospective, cross-sectional, exploratory, descriptive case series research design, with a total of 22 participants. Participants underwent audiological and pharmacological assessments at baseline and every 2 weeks for the first 3 months of treatment. Various professionals (8 in total) were subsequently involved in the development of the eHealth system, including a software engineer, four audiologists, a pharmacist, a medical doctor, and a nurse. The app underwent 14 modifications that involved aspects of data storage, ease of usability, grades, and the risk factor checklist.

Results: An ototoxicity grading system within a mobile app for use by doctors, nurses, and audiologists was developed for patients with DR-TB. The purpose of this user-friendly ototoxicity calculator, *OtoCalc*, is to (1) assist health professionals in assessing patients for ototoxicity, (2) establish the clinical significance of ototoxicity by calculating the grade of hearing loss, (3) monitor the progression of hearing loss, and (4) enable systematic referral and management of patients according to their needs.

Conclusions: This newly developed system is more sensitive than the existing grading methods for determining ototoxicity in patients with DR-TB. This app needs to be trialed in a larger sample to establish data security, ease of use, and suitability within this population.

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KEYWORDS

drug-resistant tuberculosis; ototoxicity; grading system; eHealth; OtoCalc

Introduction

Background

Tuberculosis (TB) is a contagious, potentially lethal airborne disease [1]. The overall burden of TB has been declining at an annual average of 2% [2], yet the number of patients with drug-resistant TB (DR-TB) is increasing [3]. In 2016, there were an estimated 600,000 new multidrug-resistant and rifampicin-resistant TB cases [2].

Aminoglycosides, such as kanamycin, and some polypeptides, such as capreomycin, are used in the treatment of DR-TB. Although the guidelines are being re-evaluated and many less toxic drugs have been introduced [4], aminoglycosides are still used in countries that do not have access to these more expensive drugs [5]. Aminoglycosides are inhibitors of prokaryotic protein synthesis at commonly accepted therapeutic concentrations. However, they may also affect the protein synthesis of cells at larger concentrations, leading to toxicity such as ototoxicity, vestibulotoxicity, and nephrotoxicity [6]. The toxicity profile of capreomycin is similar to that of aminoglycosides [7].

The prevalence of cochlear damage because of aminoglycosides ranges from 7% to 90% [7]. This variability could be because of a potential underreporting and the lack of distinct parameters for examining ototoxicity [7,8]. Different studies also detail different dosages and methods of monitoring hearing loss, which could account for the different results in terms of incidence [9].

Monitoring and management of ototoxicity are concerns [10], and currently, no comprehensive protocols for monitoring ototoxicity in this population exist; different methods are used worldwide. Interdisciplinary communication with monitoring and management is rare. Monitoring allows for intervention, which permits the patients and their families to maintain effective communication, should the hearing loss worsen, in cases where alternative treatment may not be a suitable or viable option [11]. Hence, there is a need for a detailed and descriptive monitoring tool to guide this interdisciplinary input, specifically in the DR-TB population.

A grading system provides a systematic framework to classify the loss of hearing from baseline. It allows a clear understanding of the degree of this loss and assists with methodical and uniform management. However, existing ototoxicity grading systems, namely, the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) ototoxicity grades [12], the grading system by Theunissen and colleagues (TUNE) [13], Brock Hearing Loss Grades [14], the Chang and Chinosornvatana grading scale [15], and the International Society of Pediatric Oncology Boston Ototoxicity Scale [16], do not seem relevant, as they were not developed for this DR-TB population and frequencies between 12.5 kHz and 20 kHz. Furthermore, the interpretation of audiological results seems to differ among individuals. This difference makes the management of the DR-TB difficult for physicians, as there are various opinions of a *significant change* in hearing to motivate a change in the drug regimen of these patients. There are also no grading scales that correspond to management recommendations, where audiologists may not be present for the skilled interpretation of the grades. There has been a need identified for ototoxicity grading systems to allow clinicians to understand the severity of ototoxicity and standardized treatment based on the grades [7]. In addition, it is unclear as to which frequencies tested actually dictate clinical hearing loss. Textboxes 1 and 2 describe the existing grading scales in adult and pediatric populations, respectively, but these are not specifically developed for this DR-TB population.

It is generally the audiologists' role to interpret audiograms; however, audiologists are often not available at all TB management clinics in developing countries. If a trained nurse conducts audiological testing, a grading system will assist in the interpretation and guide the management protocol. Ototoxicity monitoring can only be successful when a fixed regimen is followed and involves numerous health professionals (oncologists, ear-nose-throat specialists, audiologists, nurses, and clinical pharmacists) as well as the patients [17].

Textbox 1. Existing ototoxicity grading scales according to National Cancer Institute's Common Terminology Criteria for Adverse Events and TUNE for adults.

National Cancer Institute's Common Terminology Criteria for Adverse Events (grades up to 8 kHz) [11,12]

- Originally developed for children yet has adult applications
- Grade 1: Threshold shift or loss of 15-25 dB relative to baseline, averaged at two or more adjacent frequencies in at least one ear
- Grade 2: Threshold shift or loss of >25-90 dB, averaged at two adjacent test frequencies in at least one ear
- Grade 3: Hearing loss sufficient to indicate therapeutic intervention, including hearing aids. Adults: >25-90 dB, averaged at three adjacent test frequencies in at least one ear
- Grade 4: Indication for cochlear implant and requiring additional speech–language-related services. For adults, a profound hearing loss is *at* >90 dB HL

TUNE by Theunissen and colleagues (grades up to 12.5 kHz) [13]

- Developed for adults
- Grade 0: No hearing loss
- Grade 1a: Threshold shift ≥10 dB at (8-10-12.5) or subjective complaints in the absence of a threshold shift
- Grade 1b: Threshold shift ≥10 dB at (1-2-4)
- Grade 2a: Threshold shift ≥20 dB at (8-10-12.5)
- Grade 2b: Threshold shift ≥20 dB at (1-2-4)
- Grade 3: Hearing level ≥35 dB HL at (1-2-4) de novo
- Grade 4: Hearing level ≥70 dB HL at (1-2-4) de novo

Textbox 2. Existing ototoxicity grading scales for children.

Brock (1991; grades up to 8 kHz) [14]

- On the basis of absolute hearing level rather than change from baseline and bilateral loss
- Grade 0: <40 dB at all frequencies
- Grade 1: ≥40 dB at 8 kHz only
- Grade 2: ≥40 dB at 4 kHz and above
- Grade 3: ≥40 dB at 2 kHz and above
- Grade 4: ≥40 dB at 1 kHz and above

Scale by Chang and Chinosornvatana (grades up to 12 kHz) [15]

- On the basis of absolute hearing levels and a modification to the Brock scale. It detects milder degrees of hearing loss rather than change from baseline and is based on bilateral loss
- Grade 0: ≤20 dB at 1.2 and 4 kHz
- Grade 1a: ≥40 dB at any frequency 6-12 kHz
- Grade 1b: >20 dB and <40 dB at 4 kHz
- Grade 2a: ≥40 dB at 4 kHz and above
- Grade 2b: >20 dB and <40 dB at any frequency below 4 kHz
- Grade 3: ≥40 dB at 2 or 3 kHz and above
- Grade 4: ≥40 dB at 1 kHz and above

Objectives

The mobile health (mHealth) trend, which uses mobile devices and associated technology for health interventions, provides an unprecedented opportunity to transform health services available to people across the globe, specifically in developing countries where the public health system is often described as dysfunctional [18]. mHealth care can become widely available and assist health care at the regional, community, and individual levels [19]. The aim of this study was to develop a standardized grading system by using an electronic health (eHealth) system to ensure a user-friendly method was available to interpret hearing test results, calculate significant hearing loss, and provide recommendations with regard to dosage adjustments

and management. It further aimed to establish the sensitivity of the newly developed grading scale.

Methods

App Design and Development From an Audiology and Pharmacokinetic Study

A mobile app was developed as part of a project conducted in 2016 in South Africa. This mobile app was based on data that were obtained from an audiology and pharmacokinetic study on patients with DR-TB at two DR-TB units at state-run hospitals. The study was a joint study among the Audiology Department at the University for the Witwatersrand, Division of Clinical Pharmacy at Sefako Makgatho Health Sciences University, Wits Health Consortium Clinical HIV Research Unit, and the South African Medical Research Council. The medical ethics boards of the University of the Witwatersrand and various hospitals approved this study.

The intention of this app was to propose a standardized grading system; enhance the utilization of eHealth; and develop a user-friendly mobile app to interpret hearing test results, calculate significant hearing loss, and provide recommendations with regard to dosage adjustments and management for adult patients with DR-TB. The app was designed to streamline the protocol for testing adult patients treated with aminoglycosides for DR-TB and to assist with a uniform interpretation of a significant hearing loss and consequently the collection of reliable statistics based on a similar method of collection and grading of the hearing loss. Furthermore, its aim was to assist a variety of health care professionals who are not necessarily trained in audiology, to guide with recommendations and counseling, particularly when audiologists are not available in poor-resource contexts.

Data from a feasibility study that employed a prospective, cross-sectional, exploratory, descriptive case series research design were used in the development of the app. A total of 22 participants participated in this multisite study at Helen Joseph and South Rand Hospitals (two of the three main hospital-based TB focal points that treat patients with DR-TB in the Johannesburg area of the Gauteng province in South Africa). This study used purposive sampling, a nonprobability sampling strategy to select participants [20], whereby specified inclusion and exclusion criteria were determined. Inclusion criteria included males and females; HIV-positive and HIV-negative patients; those who anticipated treatment with an injectable (either kanamycin or capreomycin) for at least 3 months; those who had proficiency in English, isiZulu, and isiSotho (to ensure study procedures could be performed accurately); those who were aged between 18 and 55 years to exclude presbycusis [21]; those who had normal middle ear status at baseline, as determined by otoscopy and tympanometry; and those who had hearing loss no greater than 70 dB at three or more frequencies bilaterally. The study excluded patients with diabetes mellitus [22] and a history of significant substance abuse.

The sample size was initially calculated as 60 based on a power calculation. However, 12 months after the initiation of recruitment, enrollment ceased as saturation (after adequate enrollment for a feasibility study) was reached. Only 22 participants were enrolled owing to various reasons such as refusal to participate, being transferred elsewhere, and not fitting within the inclusion/exclusion criteria. Although this study had a small sample size, it is essential to place the sample size in the broader context of TB treatment adherence, where adherence is often poor [23].

Data collection included several hospital standard-of-care procedures such as weight, height, HIV status, creatinine level, CD4 count, potassium level, thyroid-stimulating hormone level, liver enzyme levels, and a full blood count. Study-related procedures included a detailed case history as well as audiological and pharmacological assessments at baseline and every 2 weeks for the first 3 months of treatment. Audiological procedures included otoscopy [24], tympanometry [25], pure-tone air-conduction audiometry (up to 16 kHz), and distortion product otoacoustic emissions (up to 12 kHz) [25]. Pharmacological measures included kanamycin or capreomycin elimination rate (ke) and half-life ($t_{1/2}$) from peak and trough concentrations (C_{max} and C_{min}, respectively), volume of distribution (Vd), and calculation of the creatinine clearance (CrCl). Finally, the overall outcome of treatment was evaluated in relation to the pharmacokinetics.

From observation and individual consultation with medical doctors in the field, through this feasibility study, many are unable to interpret audiograms when provided. Hearing loss guides the motivation for changes in the treatment regimen. These changes in the treatment regimen may involve the doctor changing the drug and, perhaps, reducing the days of therapy. Thus, it is essential that the doctors and nurses understand the correct interpretation of audiograms to implement these changes and counsel the patients.

Although audiologists generally interpret audiograms, they are often not employed at TB management clinics. If a trained nurse, as recommended above, conducts audiological testing, a grading system will assist in the interpretation. This will guide the management protocol.

In addition, many audiologists are unsure of how to classify a significant ototoxic hearing loss and when to advise the medical doctor to adjust the medication regimen.

Need for Mobile App Development

The intention of this app was to propose a standardized grading system; enhance the utilization of eHealth; and develop a user-friendly mobile app to interpret hearing test results, calculate significant hearing loss, and provide recommendations with regard to dosage adjustments and management for adult patients with DR-TB. Patients in poor countries generally have less access to health services than those in more developed countries. Key solutions to assist these people can involve innovations in the delivery of services and the regulation of health services. The use of eHealth can assist the vulnerable population in accessing the required services [26]. Thus, this app was designed to streamline the protocol for testing adult patients treated with aminoglycosides for DR-TB and to assist with a uniform interpretation of a significant hearing loss, and thereby the collection of reliable statistics based on a similar

method of collection and grading of the hearing loss. The study aimed to assist a variety of health care professionals who are not necessarily trained in audiology, to guide with recommendations and counseling, particularly when audiologists are not available in resource-poor contexts.

Mobile App Development and Accessibility

Data from the audiology and pharmacokinetic study were analyzed and yielded information regarding high and ultrahigh frequency hearing loss within the first 3 months of treatment. Hearing loss did not extend to the lower frequencies, which is likely because of the short duration of data collection. However, various cultural, social, and context-specific issues need to be considered, including the acknowledgment of patients defaulting on their treatment, the influence of African traditional healers on many patients, the 11 official languages spoken in South Africa that can contribute to communication difficulties, and the limited number of audiologists available in South Africa to implement and manage an ototoxicity monitoring protocol.

The app was primarily developed by a software engineer and piloted by various health professionals. Data security was specifically considered. The mobile app allows for patient data entry directly into the app via any mobile device connected to the Web. Despite the capability for data transmission over wireless networks, we elected only to allow users involved in the field of TB to participate. Collected data were stored on the mobile devices in field and in a password-protected cloud, where only two users (developers) had access. All users' phones required to be password protected, and the passwords needed to be entered upon opening the app. Patient-specific data could only be obtained with the patient's identity and hospital numbers to ensure only authorized personnel had access. Both Android and iOS operating systems were selected to reach as many users as possible.

The data backups comprised both active and manual backups. Both the active backup and archives used the same encryption as the database. To minimize the risk of data mitigation failure, the data were stored in different geographic locations. The infrastructure was powered by a small Google Cloud. All access to the data can be logged and time stamped, and a log file can be provided in unlikely cases. The raw data can be exported in .csv, .txt, and .json formats to Microsoft Excel for data analysis and statistical purposes.

The cost of the app was equal to the data costs involved in the original download of the app. The developers tried to ensure Wi-Fi availability where possible to reduce these charges.

Process Flow for the App-Based Data Collection Tool

Data collection via the app involved a user using the app as either a one-off user (ie, as an ototoxicity calculator) or a continued user, whereby he or she would require permission to *reaccess* patient data for more than a one-off use. Once the user had signed up as a continued user, their application was vetted and access was either denied or granted.

Subsequently, they could begin using the app by selecting *New Patient*, whereby they would enter basic identifying data, data on more in-depth variables such as weight and medication, and then a risk factor checklist. Baseline audiometric data could be entered, following which the session could be saved. Upon a subsequent patient visit, new data could be updated and new audiometric results could be entered. Upon entering a follow-up audiogram, the app automatically calculated the *grade* of hearing loss and provided explanations and recommendations. These explanations can be shown to the patient, with a management plan. Figures 1-3 display a few screenshots of the various stages of *OtoCalc*.

All results are stored in a central database; hence, if the patient were to be transferred to another treatment facility, their results and management plans could be accessed and continued. Figure 4 illustrates this process.

Figure 1. *OtoCalc* home page.

Figure 2. Screenshot depicting the new consultation page.

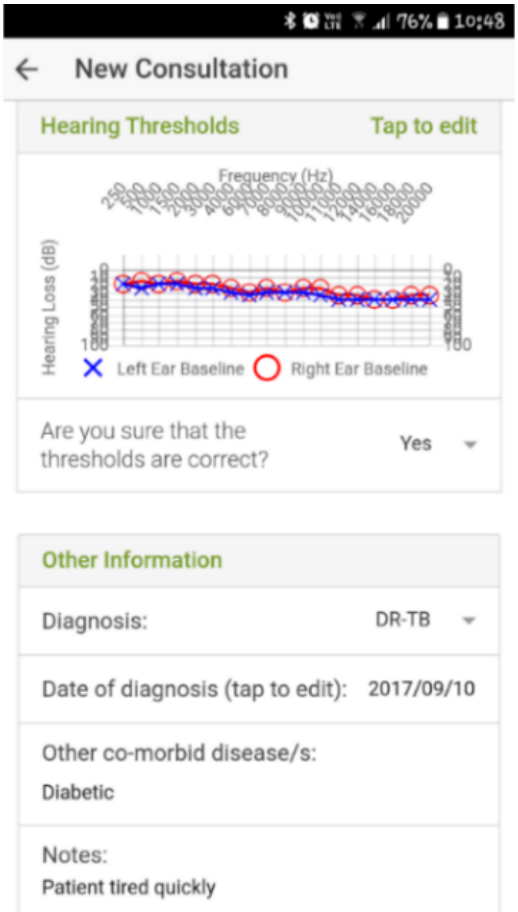


Figure 3. Screenshot of the page when follow-up consultation has been entered and results are calculated.

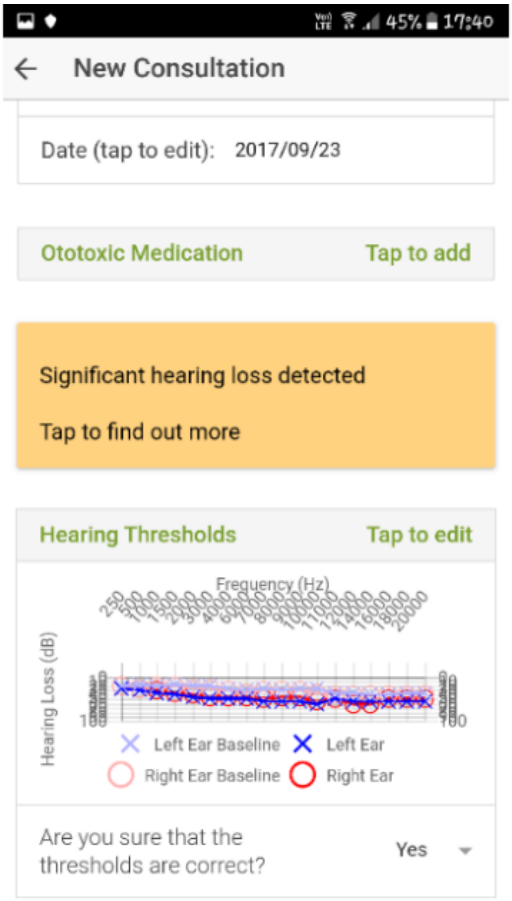
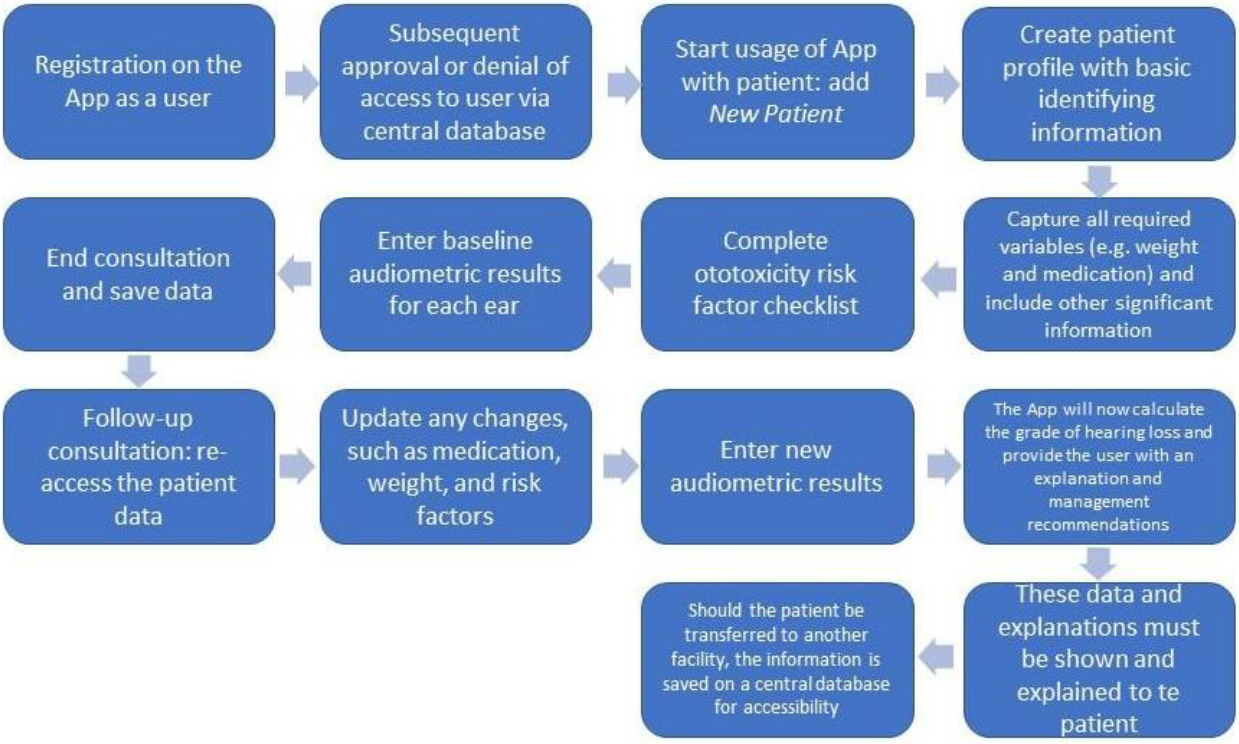


Figure 4. Process for the app-based data collection tool.



Usability and Piloting of the App

Various professionals were involved in the piloting of the app, namely, a software engineer, four audiologists, a pharmacist, a medical doctor, and a nurse.

Each professional was asked to evaluate seven aspects on a scale from 1 to 10 (10 is the highest score). When there was one or more ratings of ≤7, the app was modified by the developer. The aspects evaluated were (1) ease of use, (2) ability to reaccess the data for follow-up consultations, (3) coverage of relevant aspects of the app (ie, risk factors), (4) accessibility in terms of usage when there is no internet connection, (5) ability to follow through with the recommendations as detailed in the app, (6) ease of implementing a variety of test protocols within the app (not all frequencies are always tested at various sites), and (7) relevance of the grading scale to the DR-TB population.

The changes required included multiple user accessibility modifications and changes with the *recommendations* framework as well as additions and deletions of aspects such as the risk identification checklist, storage of the data on the database, and grading descriptions. From initial development, the app underwent 14 modifications until it was ready for upload on the Android and iOS stores for download.

All eight professionals and data collectors were confident in using the app and found the tool easy to use. Most of the data collectors found the functions of the app to be well integrated and consistent. All eight data collectors agreed that the app could be useful in future ototoxicity management.

Validation of the App

This newly developed app needs to be trialed and further piloted by various health care professionals, such as doctors, nurses, pharmacists, and audiologists, within the DR-TB population.

Results

OtoCalc Description

The app allowed two-fold usage. It was predominantly used as an *ototoxicity calculator* to assist the health professional in assessing the patient for ototoxicity and establishing the clinical significance of this ototoxicity. This can be used for a *one-off* calculation, and the patient details are not stored on the system. The user does not need to register for this option. The second use of the app was as an ototoxicity monitoring app that would be available to those working within the field of TB, specifically DR-TB management. It can be used for ongoing care by the health care professional who will update the variable component of the app at each visit to monitor the progression of hearing loss. This system provides a systematic basis for referral and management of patients according to their needs.

In total, the grading system comprises eight grades, with each grade containing specific information regarding the description of the class (Multimedia Appendix 1). This entails the decibels, specific frequencies, and whether it would be unilateral or bilateral. The description of this grade is provided to the *layperson*, describing the clinical difficulty that a patient would experience. This would involve explanations of whether the patient will likely notice a deterioration in hearing; whether the speech sounds are affected; the clinical symptoms the patients would experience in everyday life, for example, as a result of the loss of specific frequencies; and whether the current drug regimen may cause progression in speech frequencies when it has not already. It also details when the patients may start to experience social and emotional difficulties as a result of deterioration in hearing.

The mobile app then correlates the grade to management recommendations for the multidisciplinary team, including the medical doctor, nurse, and audiologist. This would include dosage adjustments or motivation for dosage adjustments; the use of an alternate drug or motivation for alternate drugs; appropriate and relevant referrals for the medical doctors, nurses, and audiologists; and audiological recommendations including diagnostic assessments, implementation of communication strategies, and amplification.

Finally, for each grade, counseling recommendations are listed for the treating team to cover. This is specifically important for the patient and family to understand hearing loss as well as its possible management in the future. It is important for patients to not only understand that DR-TB treatment is imperative, despite the hearing loss, but also to know that they are not alone and management is possible. The aspects to cover are listed as points, if the medical or allied professional is unskilled and not knowledgeable in this field (Multimedia Appendix 1).

Grades 1 and 2 involve frequencies in the range of 9-20 kHz. As ultrahigh frequencies (above 8 kHz) are often not conducted, most individuals present with either a grade 3 and above or hearing that is not gradable (no ototoxicity). When the hearing presents as grade 3, the loss in hearing is likely interfering with daily functioning, as it involves the speech frequencies (Multimedia Appendix 1).

Sensitivity of OtoCalc

The data from the feasibility study were used to establish the sensitivity of *OtoCalc*. The sensitivity of *OtoCalc* was compared with the existing grading/classification systems, namely, TUNE, CTCAE, and the American Speech-Language-Hearing Association (ASHA) system (Table 1). When using *OtoCalc*, ototoxicity was identified in all but two ears (participants 2 and 4). This is more than the number for the other scales, namely, TUNE and CTCAE, as well as the ASHA system. Table 1 exhibits the sensitivity of the *OtoCalc* scale and its ability to identify a change in hearing more often than the other scales. The specific grades further depict changes in certain frequencies; for example, grade 3 indicates a loss in the high frequencies and not ultrahigh frequencies, whereas grades 1 and 2 indicate ultrahigh frequency hearing loss. The results for patients 3, 11, and 13 were not included, as only a baseline assessment was conducted for them.

Table 1. Sensitivity of *OtoCalc* (N=15).

Patient	Weeks in the study and ear		Grade according to different scales			Presence of ototoxicity
			OtoCalc	TUNE[a]	CTCAE[b]	ASHA[c]
1	4	Right	2	2a	N/A[d]	Yes
		Left	2	1a	N/A	Yes
2	2	Right	2	0	N/A	No
		Left	0	1a	N/A	No
4	12	Right	3	1a	N/A	Yes
		Left	0	0	N/A	No
5	12	Right	1	1a	N/A	Yes
		Left	3	2a	N/A	Yes
6	4	Right	1	0	N/A	Yes
		Left	2	0	N/A	Yes
7	12	Right	2	2a	N/A	Yes
		Left	1	0	N/A	Yes
8	12	Right	2	2a	N/A	Yes
		Left	1	1a	N/A	Yes
9	12	Right	3	1a	N/A	Yes
		Left	1	1a	N/A	Yes
10	12	Right	3	2a	N/A	Yes
		Left	1	2a	N/A	Yes
12	2	Right	3	2a	1	Yes
		Left	1	1a	N/A	Yes
14	8	Right	1	1a	N/A	Yes
		Left	3	1a	N/A	Yes
15	2	Right	3	1a	N/A	Yes
		Left	4	1a	N/A	Yes
16	8	Right	1	2a	N/A	Yes
		Left	3	1a	N/A	Yes
17	8	Right	5	2a	N/A	Yes
		Left	3	1a	N/A	Yes
18	10	Right	1	1a	N/A	Yes
		Left	2	2a	N/A	Yes

[a]TUNE: Theunissen and colleagues.

[b]CTCAE: Common Terminology Criteria for Adverse Events.

[c]ASHA: American Speech-Language-Hearing Association.

[d]N/A: not applicable.

Discussion

Principal Findings

This study led to the development of *OtoCalc*, a detailed and sensitive ototoxicity grading system specifically to be used as a mobile app to assist in hearing loss grading and management resulting from the treatment for DR-TB.

Hearing loss can affect one's quality of life by affecting the ability to communicate. This hindered or lack of communication can affect socialization and professional opportunities.

Hearing loss can also further result in emotional and social difficulties, including loneliness, decreased self-esteem, and various other difficulties [27]. This can impact an individual's ability to function and obtain work. Severe depression can become a comorbid disability resulting in the need for further

disability grants, again placing financial burden on the country. An individual's mental state also impacts his/her family and their entire unit's well-being.

A robust ototoxicity-monitoring protocol requires synergistic relationships among all the involved health care professionals, including positive patient-clinician relationships [17]. This mobile app includes a team approach that can foster patient-centered/family-centered rehabilitation. Improvement in the understanding of the cellular and molecular underpinnings of ototoxicity is critical to developing individualized preventive and rehabilitation strategies, thus minimizing chronic morbidities and optimizing health-related quality of life [17]. As this app was developed through an in-depth pharmacokinetic study, it attempted to develop a family-centered approach while still understanding the intricate pharmacological aspects. However, as this was a feasibility study, pharmacokinetic models were not yet incorporated in detail.

Throughout the feasibility study, the need for a standardized and user-friendly method to interpret hearing results was identified. It was evident that doctors, audiologists, and nurses experienced difficulty in identifying a significant hearing loss and the need for dosage adjustments based on these audiologic results. Therefore, an ototoxicity monitoring protocol for DR-TB and mobile ototoxicity calculator app, *OtoCalc*, was developed. *OtoCalc* assists health care workers with the calculation of a significant hearing loss, its equivalent grade, and recommendations for management. In addition, it is specifically useful when audiologists may not be available to interpret data and can be used as an eHealth system.

This grading system is still in the premature phase and needs validation in an independent group of patients. This newly developed app needs to be trialed by various health care professionals such as doctors, nurses, pharmacists, and audiologists within the DR-TB population. It has the potential to standardize monitoring and dosage adjustments based on hearing while also allowing for reliable statistics and follow-up of the patients on a single database throughout the country.

Limitations and Recommendations

Various aspects still need to be evaluated, such as costs (free Wi-Fi is not always available), user satisfaction, efficiency after implementation, and data security. A multisite study is required in at least two provinces in South Africa.

Contribution to the Field

Despite the challenges and limitations that have been noted through this study and within the app itself, this app is the first of its kind and has the potential to make significant contributions to ototoxicity monitoring and management as well as the collection of more consistent and reliable statistics from uniform classification and measurement. The app provides a practical solution using existing infrastructure and technology (ie, smartphones) to assist various types of health care professionals dealing with patients with DR-TB to understand hearing loss and to assist with the appropriate management, specifically in cases where an audiologist is not present.

Conclusions

OtoCalc is a potential tool to be used in monitoring ototoxicity in both resource-limited and resource-abundant countries. It has proven to be user friendly and time saving. *OtoCalc* has been tested in various settings and will continue being used as a vehicle to monitor ototoxicity. This technology could pave the way for future guidance and prevention of ototoxicity.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Mobile app grading system.
[DOCX File , 18 KB - mhealth_v8i1e14036_app1.docx]

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Abbreviations

ASHA: American Speech-Language-Hearing Association
CTCAE: Common Terminology Criteria for Adverse Events
DR-TB: drug-resistant tuberculosis
eHealth: electronic health
mHealth: mobile health
TB: tuberculosis
TUNE: Theunissen and colleagues

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Original Paper

A Smartphone App Designed to Empower Patients to Contribute Toward Safer Surgical Care: Community-Based Evaluation Using a Participatory Approach

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Abstract

Background: MySurgery is a smartphone app designed to increase patient and carer involvement in behaviors that contribute toward safety in surgical care.

Objective: This study presents a pilot evaluation of MySurgery in which we evaluated surgical patients' perceptions of the app in terms of its content, usability, and potential impacts on communication and safety.

Methods: A participatory action research (PAR) approach was used to formulate a research steering group consisting of 5 public representatives and 4 researchers with equal decision-making input. Surgical patients were recruited from the community using multiple approaches, including Web based (eg, social media, recruitment websites, and charitable or voluntary organizations) and face to face (via community centers). Participants referred to MySurgery before, during, and after their surgery and provided feedback via an embedded questionnaire and using reflective notes.

Results: A diverse mix of 42 patients took part with good representation from 2 "seldom heard" groups: those with a disability and those from a black, Asian, or minority ethnic group. Most were very supportive of MySurgery, particularly those with previous experience of surgery and those who felt comfortable to be involved in conversations and decisions around their care. The app showed particular potential to empower patients to become involved in their care conversations and safety-related behaviors. Perceptions did not differ according to age, ethnicity, or length of hospital stay. Suggestions for improving the app included how to make it more accessible to certain groups, for example, those with a disability.

Conclusions: MySurgery is a novel technology-driven approach for empowering patients to play a role in improving surgical safety that seems feasible for use within the United Kingdom's National Health Service. Adopting a PAR approach and the use of a diversity strategy considerably enhanced the research process in terms of gaining diverse participant recruitment and patient and public involvement. Further testing with stakeholder groups will follow.

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KEYWORDS

patient safety; surgery; smartphone; mobile phone; patient empowerment

Introduction

Background

Optimizing patient safety remains a key priority for health care systems across the world, including the United Kingdom's National Health Service (NHS). When looking at the frequency of patient safety incidents, surgical care settings typically emerge as the most *risky*, with higher rates of adverse events than other hospital departments or specialties [1-3]. This is likely attributable to the complexity of surgical environments and the

risk profile of surgical patients, but it may also reflect higher incident reporting rates by surgical teams.

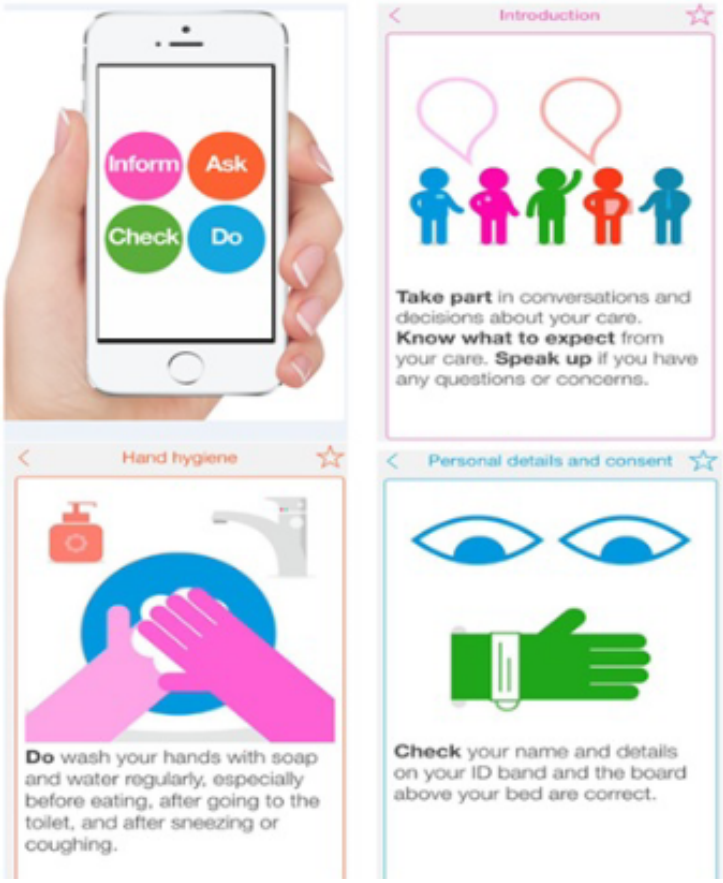
Numerous tools have been introduced to surgical settings to increase reliability and improve safety, ranging from safety checklists to electronic devices for counting swabs [4,5]. Although these clinical and team-based interventions are critical, the call to deliver more patient-focused interventions in health care is equally important. This is set in the context of an ongoing movement across the NHS and internationally, toward greater patient and public involvement (PPI) and empowerment, working on the concept that, where appropriate, patients should be encouraged to take an active role in the management of their own health and facilitated in participating more meaningfully in their care [6-8]. This focus on patient involvement extends into the world of health care research and evaluation, with patients and the public increasingly being included in all phases of research, from conception, through design and data collection, to dissemination [9]. However, the evidence suggests that PPI efforts, particularly in the world of patient safety, have tended to be atheoretical, exclusive, and tokenistic in nature, with few addressing issues of equality and diversity in their involvement strategies [10-12].

In parallel to the patient empowerment movement, the *industry* of health care is being called to take on another challenge—to better embrace the potential of digital technology for transforming care. In 2016, the Nuffield Trust released a report highlighting the possibilities offered by digital technology and how best to grasp them, putting health care at least a decade behind other industries in terms of incorporation and use of information technology [13]. Smartphones, with their ever-increasing accessibility, have emerged as a key device for communicating knowledge at scale and for improving patient empowerment [14]. Around 85% of the UK population own or have access to a smartphone, including 71% of 55 to 75-year olds, and between 45,000 and more than 300,000 medical health apps are available to download (depending on the platform used) [15-17]. In the context of surgical safety, given their accessibility, smartphone apps could constitute an effective means of mobilizing knowledge to patients about risk and empowering them to play a role in optimizing the safety of their care.

In 2017, the NHS released an online *App Library* with the aim of providing "trusted digital tools to patients and the public to manage and improve their health." To be listed on the library, an app must meet the NHS quality standards for clinical effectiveness, safety, usability, and accessibility and have evidence to support its use. Therefore, it should be tested with the relevant stakeholder groups [18]. There are currently 76 apps available in the library, falling into the following categories: first aid; living with cancer; mental health and well-being; pre- and postnatal care; welfare and lifestyle; advice, management, and support for long-term conditions; and prescription and appointment management. Although all the apps aim to empower and educate patients in some manner, none of them have a specific focus on involving patients in the effort to improve patient safety. Outside of the NHS, there are apps available that have a greater focus on patient safety. The majority are designed for clinicians or hospital management, for example, digital patient safety manuals, or patient safety solutions for hospitals (eg, the *Patient Safety Solutions* app). Others, designed for patients, have a broad focus on patient education and empowerment (eg, eg, providing information about procedures, conditions, complications, and processes of care; keeping track of upcoming appointments; and informing patients about how to interact and ask questions; eg, the *Empowered Patient*, *Manage my Surgery*, and *Patient Aider* apps) and include some safety-relevant information as part of this. With their broader scope, these apps do not focus specifically on the key evidence-based safety risks present in any particular specialty or pathway.

MySurgery is a smartphone app that aims to empower patients to help optimize the safety of their care when having a surgical procedure. The app was developed for the context of the United Kingdom's NHS and was created by a multidisciplinary team of clinicians, patient safety experts, and patient/public representatives. It has been available for free download on the Apple App Store since 2015 (located under apps for iPhones)—to date, it has been downloaded by more than 6000 people. MySurgery mobilizes evidence around safety in surgery into a format that is easily digestible by patients and their carers. It is an animated app combining simple, jargon-free information and is structured around 10 specific areas of risk to safety: preparing for surgery, personal details and consent, hand hygiene, deep vein thrombosis, falls, pressure ulcers, medications, wound care, nutrition, and going home. For each area of risk, MySurgery provides practical step-by-step advice on the actions that patients and their carers can take—including warning signs to look out for, information to provide, and questions to ask. The app also includes a short introduction (to inform users of its objectives and how it was developed), a *Top 10 Things to Remember* tab (highlighting 10 key behaviors that patients should always aim to engage in), and a link to a survey for evaluating the app (Figure 1) [19]. Until now, formal evaluation of the MySurgery app has not been possible because of funding cessation. However, new funding has recently been secured from the National Institute for Health Research (NIHR), United Kingdom, to evaluate the app over a 3-year program of work. On completion of this work, MySurgery would offer a novel contribution to the NHS App Library and an approach to improving patient safety that is both patient focused and embraces the call for better digital technology solutions to care problems.

Figure 1. Screenshots from the MySurgery app.



Objectives

This study represents the first phase of this program of work, in which we present results from some pilot testing of MySurgery with surgical patients. To further strengthen the study design, the research was also conducted in partnership with a study being carried out by JO who was funded by the Health Foundation and aimed to understand how best to incorporate diverse PPI into the testing of patient safety interventions. The research objectives are 2-fold:

1. To assess the views relating to MySurgery with a cohort of diverse surgical patients recruited from the community and to understand perceptions of the app, perceived impacts on care and safety, and areas for improvement.
2. To describe and evaluate the approach and impact of incorporating diverse PPI into the project design, planning, and delivery.

Methods

Research Approach

The research team was formulated using a participatory action research (PAR) approach, which is appropriate when seeking to solve problems and effect improvement [20,21]. PAR is particularly relevant to the development of PPI as it is a methodology that seeks to empower its research *subjects* and to create more equal partnerships in the research process [22,23]. We used PAR to enable collaborative working within the project by creating a *research steering group*. This consisted of 5 public representatives (AL, HO, JOT, JT, and SW), alongside 4 researchers (SR, ZL, NS, and JO). The public representatives were recruited following attendance at a focus group on the design of the app. They all had some experience of surgery and were selected to represent a diverse range of backgrounds (1 male/4 females; 2 white British/3 black, Asian, or minority ethnic [BAME] group British; 1 with a disability/4 with no disability; and 2 aged <55 years/3 aged >55 years). Steering group members attended face-to-face meetings at 3 key time points across the project and maintained regular communication via email and telephone. In line with PAR, all steering group members were treated as coresearchers and were involved equally in decision making around the design and planning of the project (including development of research tools and recruitment strategy), analysis of the findings (extraction of themes from qualitative data), and write up and review of this manuscript (4 of the 5 public representatives are involved as authors; 1 public representative chose to opt out of authorship but is acknowledged). Owing to time limitations in gaining Disclosure and Barring Service approval, we were not able to involve the public members in collecting the data.

Study Design

To evaluate MySurgery, the steering group agreed upon a prospective mixed methods design. Both quantitative (survey) and qualitative (reflective notes) methods were used to evaluate patient perspectives of the app with a sample of individuals undergoing surgery recruited from community networks across England. The study ran as a pilot to test the feasibility of the procedure and research tools before future evaluation of

MySurgery with a larger cohort of patients. Ethical approval was granted by the King's College London Research Ethics Review Board (Reference LRS-17/18-5697).

Participants

Individuals meeting the following inclusion criteria were eligible to participate:

1. Those awaiting surgery between May and June 2018. (Surgery refers to any hospital-based surgical procedure involving an incision, including cesarean sections and tooth extractions, emergency and elective procedures, and day surgery as well as surgery requiring a hospital stay).
2. Those older than 18 years.
3. Those with a good understanding of written English.
4. Those with the capacity to provide informed consent.
5. Those with access to an Apple iPhone or iPad.

Given the narrow time frame and inclusion criteria, we recruited participants using an opportunistic approach via a range of channels, including social media (Facebook and Twitter); bimonthly *calls for research participants* generated by King's College London; the *Call for Participants* open Web-based platform ; specialist and nonspecialist local community centers; community-based networks of the steering group; and other community voluntary and charitable organizations, including disability groups. We also formulated a structured diversity approach as this objective was central to the study (Textbox 1).

Textbox 1. Participant recruitment: diversity approach.

Steps taken to achieve a diverse sample:

- By striving for diversity, we would be able to analyze the relationship between participant characteristics and perceptions of the app in a more comprehensive way.
- We used the Equality Act 2010 to inform our conceptualization of diversity [24]. Although all individuals awaiting surgery were eligible to take part, we targeted (via the research advert—Multimedia Appendix 1) 2 groups with protected characteristics who are frequently underrepresented in this type of research—those with a disability and those from a black, Asian, or minority ethnic (BAME) group [12,25]. We hoped that approximately one-third of our participants would have 1 of these characteristics.
- We also aimed to capture diversity in procedure type (all types of hospital-based surgery were included) and geographical location (individuals having surgery at any National Health Service Trust in England were invited to participate).
- A multimethod approach was used to recruit diverse population groups. This included placing our study advert in patient charity newsletters, patient-centered Facebook groups, and specialist and nonspecialist community centers working with local communities across England and with disability groups.
- We monitored diversity of our sample using an Equal Opportunities Monitoring form and via the study questionnaire (see the Outcome Measures section).
- The research team was made up of 2 researchers (JO and ZL), who were culturally competent in developing practices and appropriate, relevant, and sensitive strategies in working with individuals from different cultures and backgrounds.
- We targeted community centers located in areas with a high and diverse BAME population. Individuals working at the centers helped us access specific groups and introduced the study to potential participants. These workers have, over time, developed trusting respectful relationships with their service users and are aware of cultural and religious sensitivities.
- Although all BAME participants recruited to the study spoke fluent English, an amount of code switching [26]—alternating between 2 or more languages during conversations—enabled the researcher to build a rapport with individuals from South Asian backgrounds—this encouraged participation and completion.

Outcome Measures

Research participants completed the following:

- Equal Opportunities Monitoring (EOM) form: a standardized form used to capture demographic information including ethnicity, gender, age, disability, and sexuality.
- MySurgery feedback questionnaire: a bespoke questionnaire designed to capture attitudes toward MySurgery, which was embedded into the app itself. This captured views regarding the usability, content, impact, acceptability, and appropriateness of the app, alongside suggestions for improvement. It also captured information specific to the individual, including the type of surgery, hospital attended, previous surgeries, and 3 items relating to views about being involved in health care decisions and conversations more generally (Multimedia Appendix 2). Attitude-based questions were answered on a 5-point scale ranging from 1 (completely disagree) to 5 (completely agree). Although the questionnaire was intentionally bespoke and specific to MySurgery, items from Weiner's standardized implementation outcome measures were included to assess acceptability, appropriateness, and feasibility [27] (Multimedia Appendix 2, items 13, 14, 15, and 20).
- Reflective notes regarding MySurgery: open-ended written reflections regarding patients' experience of using MySurgery and how it impacted their surgical experience using a bespoke template (Multimedia Appendix 3). The template prompted participants to reflect on how MySurgery affected their relationship with clinical staff and their own involvement in their care, how applicable MySurgery was to them, their thoughts around its content and usability, whether it affected their safety, any improvements they felt were needed, and anything else relevant. (Participants were also given the option to provide these reflections over the phone.)

All members of the research steering group completed a written self-reflection tool as part of the research process to enable

critical thinking both about the research process and their involvement in it (findings are highlighted in the Results section).

Procedure

A study advert (Multimedia Appendix 1) outlining the study aims and inclusion and diversity criteria was distributed via email (to the community networks and organizations), face to face (at community centers), and via social media promotion. Eligible individuals expressed their interest to the research team and received a Participant Information Sheet (that detailed the study procedure), a consent form, and an EOM form to complete by email or in the post. On receipt of the completed forms, they were offered a phone call to explain the procedure further and answer questions. Consenting participants were assigned a unique identifier and were asked to download and refer to the MySurgery app before (preferably before their preoperative appointment), during, and up to 2 weeks following their surgery. They were asked to keep their reflective notes throughout the time they were using the app and to complete the embedded questionnaire following their surgery. On completion and return of the questionnaire and reflective notes, they received a £25 shopping voucher. Data collection took place in May and June 2018.

Data Analysis

Quantitative analyses were completed using Statistics 24 Software (IBM). Participant characteristics and survey data were summarized using descriptive statistics. To examine the relationship between perceptions of MySurgery and participant characteristics, independent-samples *t* tests were computed—the sample was split according to sex (male/female), disability (yes/no), ethnicity (white/BAME), age (either side of median), length of hospital stay (day surgery/1 or more nights), and general perceptions of patient involvement in hospital care for the 3 relevant questionnaire items (agree/other).

Participant's reflective notes were divided randomly between members of the steering group for inductive thematic analysis. At the final face-to-face steering group meeting, emergent themes were discussed and cross-checked before collectively agreeing on a list of themes that represented the reflections as a whole. Furthermore, 2 of the researchers (SR and JO) analyzed the steering group self-reflections in a similar manner to extract themes regarding perceptions of the research process and involvement strategy. No software was used for the qualitative analyses.

Results

Diversity of Sample

A total of 42 participants took part in the study. Their age ranged from 20 to 70 years (mean age=40 years), with a good split between males and females. Participants were treated at 27 different hospitals across England for 25 different kinds of surgical procedures under a total of 11 surgical specialties, with the majority (31/42, 74%) staying in hospital for a night or longer. Just under half of the participants were from a white background—the remaining were from a BAME background. In addition, 41% (17/42) of the sample reported having a disability (Table 1).

Table 1. Summary of participant characteristics (N=42).

Characteristics	Value, n (%)
Sex	
Male	17 (41)
Female	25 (59)
Age (years)	
18-24	6 (14)
25-34	11 (26)
35-44	8 (19)
45-54	8 (19)
55-64	5 (12)
≥65	4 (10)
Ethnicity	
Asian/Asian British	14 (23)
Black/African/Caribbean/black British	6 (14)
Other ethnic group (Arab)	2 (5)
White (British)	10 (24)
White other (Eastern European)	10 (24)
Disability[a]	
Yes	17 (41)
If yes, type of disability[b]	
Visual	8 (47)
Hearing	4 (24)
Mobility	3 (18)
Learning difficulties	2 (12)
Other	5 (29)
No	21 (50)
Type of surgery	
General surgery	8 (19)
Orthopedics	7 (17)
Obstetric	5 (12)
Eye surgery	5 (12)
Gynecological	3 (7)
Other	14 (33)
Previous surgical procedures	
None	24 (58)
1-2	10 (24)
≥3	7 (17)
Length of stay	
Day surgery	11 (26)
Overnight or longer	31 (74)

[a]Missing n=4.

[b]5 participants reported more than one disability.

Perceptions of MySurgery: Questionnaire Data

One participant failed to complete the questionnaire. The sample as a whole was positive about MySurgery (Table 2). A large majority agreed that it was acceptable and appealing, it was useful and informative, it was easy to use, it provided new information, it made them better able to become involved in conversations and ask questions about their care, it changed the way they behaved, it should be recommended to patients, it would make surgery more successful, and that they intended to use it in future. Participants were more unsure about the potential impact the app could have on *safety* per se and whether or not it was applicable to all surgical patients. In general, patients felt the app contained the right amount of information, but of those who disagreed with this statement (7/41, 17%), all but 1 felt it contained too little information. A third (14/41, 34%) of the sample encountered technical difficulties when using the app, which were all related to problems downloading it onto an iPad. Over half of the sample (25/41, 60%) said that they would support an option to incorporate audio into the app and availability of an *easy-read* version, and more patients (30/41, 71%) said that they would like to know how to access support in using MySurgery.

Table 2. Summary of survey responses for the 18 items relating to perceptions of MySurgery (N=41).

Questionnaire item	Completely disagree, n (%)	Disagree, n (%)	Neither agree nor disagree, n (%)	Agree, n (%)	Completely agree, n (%)
MySurgery meets my approval	0 (0)	4 (10)	9 (21)	24 (57)	4 (10)
MySurgery is appealing to me	0 (0)	3 (7)	8 (19)	26 (62)	4 (10)
MySurgery seems applicable to all surgical patients	0 (0)	13 (31)	18 (43)	9 (21)	1 (2)
I found MySurgery useful and informative	1 (2)	2 (5)	5 (12)	29 (69)	4 (10)
MySurgery provided me with new information	1 (2)	4 (10)	4 (10)	31 (74)	1 (2)
The content of MySurgery is appropriate	1 (2)	3 (7)	10 (24)	24 (57)	3 (7)
I felt the right amount of information was provided	2 (5)	5 (12)	9 (21)	23 (55)	2 (5)
MySurgery was easy to use	1 (2)	3 (7)	6 (14)	29 (69)	2 (5)
I found it difficult to navigate through the information on the MySurgery app	4 (10)	19 (45)	11 (26)	6 (14)	1 (2)
MySurgery made me feel better able to ask questions	0 (0)	4 (10)	5 (12)	31 (74)	1 (2)
MySurgery will help patients to become more involved in conversations around their care	0 (0)	2 (5)	7 (17)	31 (74)	1 (2)
Using MySurgery changed the way I behaved	1 (2)	1 (2)	7 (17)	30 (71)	2 (5)
It is unrealistic to expect patients to use the information provided in the app	2 (5)	9 (21)	22 (52)	7 (17)	1 (2)
MySurgery should be recommended to all patients awaiting surgery by their doctor or nurse	0 (0)	2 (5)	10 (24)	24 (57)	5 (12)
I would recommend MySurgery to other people having surgery	1 (2)	1 (2)	8 (19)	25 (60)	6 (14)
Using MySurgery would make me safer when having an operation	1 (2)	3 (7)	15 (36)	20 (48)	2 (5)
Using MySurgery would make surgery more successful	0 (0)	2 (5)	2 (5)	25 (60)	12 (29)
I intend to use MySurgery for any future surgeries I have	0 (0)	4 (10)	6 (14)	29 (69)	2 (5)

Relationship With Patient Characteristics

There were no significant differences in perceptions of MySurgery according to sex, participants' age, ethnicity, or length of stay.

Those with a disability were significantly less likely to agree that MySurgery was easy to use (t_{39}=2.22; *P*<.04) and that they would recommend it to others having surgery (t_{39}=2.45; *P*=.02).

Those who had experienced at least one previous operation were significantly more positive about MySurgery for 5 of the 18 questionnaire items that related to perceptions of the app than those who had not had a previous operation. They were more likely to approve of it (t_{39}=2.27; *P*=.03), to find it appealing (t_{39}=2.48; *P*=.02), to feel it contained the right amount of information (t_{39}=2.87; *P*<.001), suggest that it should be recommended to all patients (t_{39}=2.69; *P*<.001), and suggest that it would make them feel safer (t_{39}=2.56; *P*=.01).

Participants' views about being involved in conversations and decisions around their care in general had the most striking impact on their views of MySurgery. Those who agreed that they were confident to play an active role in conversations around their care (n=15), that they could help to reduce errors by being involved (n=23), and that it is best for patients to be involved in decisions around treatment and safety (n=30) were

significantly more positive about the app for a large number of questionnaire items than those who disagreed or neither agreed nor disagreed with these statements (*t*s range: 1.0-4.3; *P*s range <.001-.04).

Perceptions of MySurgery: Participant Reflective Notes

Overall, 8 themes were extracted from the analysis of participants' reflections (Table 3).

Content/Usability of MySurgery

The app content was deemed to be useful and pitched at the right level. Many commented on how it served as a useful reminder of things they needed to do and helped them to prepare for their surgery. Some picked out particular sections they had found helpful, for example, hand hygiene. However, there were some conflicting comments—for example, although many found it refreshingly simple, others commented that is was too basic and they wanted more information. In terms of usability, comments again were largely positive, for example, easy to use, nice graphics, and easy to navigate. All negative comments in this respect were related to problems with downloading the app.

Empowerment and Involvement

This was a significant and positive theme. Most felt that MySurgery had empowered them in some way and had enabled them to become more involved in conversations and decision making relating to their care. Predominantly, this was reflected in feeling that they were able to prepare and ask more relevant questions and that the app promoted self-agency, proactivity, and confidence. Some commented on how it helped them to prepare before consultations when they were less stressed and distracted.

Encouraging Self-Care

A significant number of patients commented on how the app had provided them with new information that enabled them to care better for themselves, particularly after surgery, for example, wound care, hygiene, and nutrition. Requests were made for more of this information (eg, in relation to returning to work).

Improved Emotional Well-Being

A large majority of patients felt that using MySurgery had helped them to cope emotionally, for example, promoting confidence, providing a sense of security, reducing anxiety and worry, and making them feel less alone.

Patient Involvement in Safety

This was an interesting theme given the objective of MySurgery. Almost half (20/41, 48%) of the sample was unsure about the concept of *safety*—assuming safety meant better surgical outcomes rather than reduced risk of error. Others were unsure about how an app could affect safety and stated explicitly that keeping patients safe was the responsibility of the clinical staff alone. These views were not specific to patients with any particular demographic profile, that is, ethnicity/age/disability. The remaining patients were able to demonstrate specifically how the app might enhance safety and provided examples, for example, increasing awareness of risk, of complications to look out for, and of the role patients can play in flagging inconsistencies in care. One patient gave an example of how the app triggered them to identify a drug error.

Diversity and Inclusivity

Some of the BAME and Eastern European participants and those with a disability highlighted how MySurgery was not currently ideally suited for certain groups or suggested adaptations that would improve the utility of the app for them. For example, comments were made around the difficulties those with mental health problems or learning difficulties might have in accessing the app or working with the information provided. Others highlighted the need to tailor the app to be more inclusive of different cultures, for example, to refer to different cultural diets or alternative therapies and to make MySurgery available in different languages. Others highlighted a lack of information around vegan and vegetarian diets or information for those with certain allergies. Some highlighted where certain elements of the content were not relevant for particular procedures, for example, dental surgery, eye surgery, or other basic procedures.

Improvements

More generally, participants were forthcoming with various suggestions for improving MySurgery. Some related to technological issues with the app, for example, improving the ease of downloading on to iPads and making MySurgery available on Android devices. Others related to improving the content, for example, adding links to more specific procedure-related information or websites, providing more detail in general, and adding audio/videos to make it more interactive.

Unintended Consequences

Although this was not a strong theme in the data, it was considered important to be aware of the potential for unintended consequences of MySurgery. A small minority of patients (3/41, 7%) found the app anxiety provoking, in that it made them aware of risks they had not previously considered and increased their level of worry. One other patient commented that staff appeared irritated with the number of questions being asked, raising the question as to whether MySurgery could create tension with staff in certain circumstances.

Table 3. Themes extracted from reflective notes with illustrative quotes (N=42).

Theme	Illustrative quotes
Content and usability: comments relating to the content of MySurgery, including its acceptability and appropriateness, and comments relating to ease of use, interface, or technological issues	• "The medical language makes no sense. MySurgery app explained medical language and I understood it" • "The dos and don'ts list (top 10 things to remember) was incredibly helpful alongside deconstructing myths surrounding surgery in general which I liked" • "It reminds you of all the things the doctors tell you but you forget to do" • "It was well laid out, nice visually and easy to navigate through the steps" • "My wife and I are old. We've never used a phone app but used this one because it was easy to use"
Empowerment and involvement: influences on patients' ability to become involved in their care and their feelings around this	• "I was proactive and I think the clinicians thought I was a good patient" • "I was able to share information with the midwives who found the app useful too" • "It made me feel more positive about asking questions" • "I came prepped with questions and was able to get these answered" • "I felt empowered by having the information earlier when I was less stressed" • "Before my preop appointment I was able to use the app to help me make decisions and consider certain aspects of my surgery and recovery" • "I sometimes go into my appointments with a list of question I don't ask. Doctors think I'm complaining. The app helped with these feelings."
Encouraging self-care: reflections around how the information within MySurgery influenced the ability to care for one's self before or after surgery	• "After surgery I learnt how to care for the wound" • "Gives good information about preparing for surgery and caring after surgery" • "It made me less agitated about looking after my surgical wound- in terms of how to take care of it" • "I think the app was particularly useful for aftercare of an operation and this could be expanded upon"
Improved emotional well-being: positive reflections about how using MySurgery made patients feel	• "It did help with my confidence and general sense of security as I was quite scared to be on my own in hospital" • "Living alone and having access to support after surgery were important for me. With the app I did not feel alone" • "The app was helpful as it made me feel in control of what was happening" • "I had major surgery and this app helped to calm my nerves as I knew what to expect" • "I found the information very useful and it made me feel less worried about what was going to happen"
Patient involvement in safety: comments around the impact of MySurgery on surgical safety, whether it was conceptualized to be related to safety and in what way	• "Surgeons are involved with safety, not patients" • "Doctor and nurse should check everything, that's not my job" • "Safety up to the doctors not patient. Doctors/nurses are paid to make sure the operation is carried out properly" • "I did not know about all the risks after surgery – the app helped me to understand these" • "Yes it made you aware that your recovery is in your hands as well as the surgeon's" • "It made me think to check everything because hospital very busy" • "It made me more cautious towards potential complications that I could keep an eye out for" • "Of course it improved safety. Patients can't expect staff to do everything, the NHS is over-burdened as it is" • "When patients are involved in their surgery, they can help to improve safety. Things like preventing infections"
Diversity and inclusivity: reflections around areas or groups to whom MySurgery may be less accessible, acceptable, or relevant	• "It is a good app but it needs to be made more user friendly for people with learning difficulties or mental health problems" • "Maybe needs to be in different languages" • "More dietary information for vegans" • "What about people who don't have access to the internet?" • "More detail in the nutrition section for ethnic backgrounds is needed"
Unintended consequences: potential unintended consequences of using MySurgery that may conflict with the objectives of the app	• "Staff felt I (was) asking too many questions but I felt happy to ask them after using App" • "I normally worry about everything and this app made me worry if my surgery will be successful. I come from another country where we leave everything to the doctors. As patients we do not get involved in our care. I like this" • "I did not like it, information made me scared to have operation"

Theme	Illustrative quotes
Improvements: suggestions for improvements and additions that could be made to MySurgery, whether in terms of content, design, or usability	• "I think it would be really good to eventually have some sections addressing specific types of surgery, and/or resources linked to the hospital/Trust or location were the surgery is taking place" • "Maybe it could give information on the most common operations" • "Would like to see the ability to add individual bullet points in a page rather to my favourites list as opposed to the whole page" • "Signpost to other websites/services for more information" • "Maybe if you added videos to make it interactive and more person centred" • "There needs to be more detail—it is very basic" • "Please make it available for other smartphones"

Steering Group Self-Reflections

Key themes that emerged from the self-reflections of the steering group were as follows:

- The importance of using a research strategy based on coproduction that allowed public members to feel like equal partners in the research and to gain key research skills and knowledge.
- The fact that having diverse public involvement allowed a much richer contribution of perspectives and ideas to emerge in the research.
- Having strong public involvement meant that there was an important and critical challenge to the formal expertise of the lead researchers, which was invaluable in shaping the design and implementation of the work and cross-checking the validity of the research strategy.
- A reflective tool was useful in enabling people to think more about their own subjectivity either as a researcher, layperson, or current patient or as someone from a particular ethnic or professional background and how this might influence the research process.

Discussion

Principal Findings

MySurgery is a novel smartphone app that works on the premise of educating and involving patients and their carers in behaviors that are known to contribute toward surgical safety and to increase resource in the health care system for preventing safety incidents. It has the potential for inclusion in surgical care pathways in the NHS and the NHS App Library should the data be there to support its use and effectiveness.

We gathered views regarding MySurgery from a diverse group of patients undergoing a range of surgical procedures in hospitals across England. Using a survey combined with reflective notes, we were able to conduct a critical analysis of participants' perceptions of the app that can inform improvements to the app itself and areas to probe in the next phase of evaluation. Overall, the feedback was positive, and there was a strong sense of support for MySurgery. It was reported to act as a useful reminder of steps to take in preparing for surgery, it empowered patients to engage in conversation with clinicians and prompted questions to ask, it promoted confidence in caring for surgical wounds, it reduced anxiety about the surgical process, it was reported to be easy to use, and it would be recommended to others in its current form by 76% (31/41) of participants. This feedback, particularly in relation to promoting greater patient empowerment, shows that the perceived impact of MySurgery was in line with the objectives of the app.

Those who had undergone previous surgery were more positive about MySurgery in a number of respects. Perhaps having more knowledge and experience of the surgical process, and reflecting from previous as well as current experience, allowed participants a greater appreciation of the potential virtues of the app. However, the strongest predictor of perceptions was individuals' views about whether they personally felt confident to be involved in conversations around their care and whether they thought patients *should* be involved in health care conversations and decisions making. Those who felt uncomfortable to engage in health care conversations and did not feel that they could have an impact on the occurrence of error were less supportive of the app (although not entirely unsupportive). This suggests that MySurgery will likely be more appealing to those who already feel that they are able to play a role in their care or think it is appropriate to do so. It also highlights how some patients are unclear about the role patients *can* play or may need more support becoming involved.

Reflections about the impact of MySurgery on safety were also interesting. Almost half of the patients were unclear what was meant by *safety*, assuming we were referring to procedural success as opposed to reduction in risk of error, and the same proportion felt strongly that safety was a matter for clinicians alone. Many recognized that they had become more involved in safety-relevant behaviors after using MySurgery (eg, checking medication and providing a more thorough history), but they did not describe this in terms of *safety* per se. This seems to reflect both a lack of awareness about safety issues in health care in general and a lack of insight into the role a patient might be able to play, which highlights a challenge for those working in the area of patient empowerment in terms of how best to promote the scope for patient involvement in safety and how to encourage the formation of working partnerships between clinicians and patients. Interestingly, in this sample, we did not find any difference in the willingness to become involved in safety between those from different backgrounds (in terms of ethnicity and disability), which is an important finding to explore further, given how often these groups are excluded from involvement processes in quality and safety.

There was evidence to suggest that MySurgery may be currently less suited to certain patient groups, which was highlighted by the theme of diversity and inclusivity. Those with a disability reported more issues in using the app and were a key group that would be less likely to recommend it to others. The suggested

additions of audio, videos, signposting, easy-read versions, and support in using the app may help here. Likewise, although ethnicity was not related to views of the app in general, there were some limitations identified with regard to a requirement for more nutrition-related information for different cultures (as well as those with restricted diets) and availability of the app in different languages. Finally, a few suggested that MySurgery is likely to be less relevant for certain procedures (eg, dental, eye, or minor procedures with fewer inherent risks).

When introducing a new intervention, it is critical to analyze the potential for unintended consequences. Although MySurgery was deemed to have a beneficial emotional impact by most, 3 participants reported that it made them feel *more* anxious about their surgery as they became more aware of potential risks/complications. The content of MySurgery was designed to be intentionally nonanxiety provoking; however, this should be explored in future evaluations. One participant inferred that clinicians might be resistant to patients asking more questions, and it would be interesting to explore this further with clinicians. Both potential issues might also highlight areas that will need to be addressed during implementation.

Strengths, Limitations, and Next Steps

A key strength of the project was the PAR approach taken in setting up the research steering group. Through a process of self-reflection, we were able to demonstrate a number of beneficial impacts, including a richer contribution of perspectives to project design and data analysis and validation of the approach from a more diverse group of decision makers. A second strength was the diversity achieved in the sample. By implementing a structured diversity approach, we were able to include good representation (17/42, 41% and 22/42, 52% of the sample, respectively) from 2 groups with protected characteristics (disability and BAME background) who are often described as *seldom heard* in health care research. As a result, we have identified steps that can be taken to adapt the app to make it more suitable to these groups.

In terms of limitations, this was a pilot sample totaling 42 participants. Accordingly, although the sample was diverse, the subgroups were relatively small, and formal cross-groups analyses will not be definitive as they lack statistical power. Therefore, any subgroup effects reported in this study (eg, with regard to ethnicity or disability) should be interpreted with caution and will be followed up in the next phase of the study with a larger patient cohort. We did not assess the impact of socioeconomic status or geographic region, which may impact the ability to access the app; this should also be addressed going forward. In addition, we did not assess actual use of MySurgery in real time (eg, via observation) because of the methodological challenges inherent in doing so, and we did not assess clinicians' views of the app at this stage.

Next steps are to evaluate MySurgery with surgical staff and a larger cohort of patients, using themes identified here to refine the research questions and outcome measures and to test subgroup effects more robustly. Feedback from this pilot study and the next phase of the research will then be used to make improvements to the app. We will also be more formally exploring the design and interface of MySurgery, focusing on user experience, with Mindwave Ventures—UK experts in the design and implementation of digital technology solutions to health care problems. Following improvements to the app, the final objective will be to work with NHS Trusts to explore the best approach to implementing MySurgery into surgical care pathways and to include it on the NHS Apps Library.

Conclusions

MySurgery is a smartphone app that brings together efforts to empower patients and their carers to become involved in their care and, specifically, to play a role in enhancing surgical safety, with the movement to embrace the potential of digital technology to transform health care. Our findings show that MySurgery has particular potential to empower patients to become involved in health care conversations, shared decision making, and safety-related behaviors. Adopting a PAR approach and the use of a diversity strategy also considerably enhanced the research process in terms of gaining diverse participant recruitment and PPI in the process. Further research is needed to explore why some patients felt less comfortable with their involvement in safety issues and to look more closely at how particular groups of patients, such as those with disabilities, can be empowered through use of the MySurgery app.

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Authors' Contributions

All authors formed part of the research steering group and contributed toward the study design, development of outcome measures, data analysis, and preparation of the manuscript.

Conflicts of Interest

NS is the director of the London Safety and Training Solutions Ltd, which offers training in patient safety, implementation solutions, and human factors to health care organizations. The other authors have no conflicts of interest to declare.

Multimedia Appendix 1
Study advert.
[PDF File (Adobe PDF File), 238 KB - mhealth_v8i1e12859_app1.pdf]

Multimedia Appendix 2
MySurgery feedback questionnaire.
[PDF File (Adobe PDF File), 141 KB - mhealth_v8i1e12859_app2.pdf]

Multimedia Appendix 3
Template for reflective notes.
[PDF File (Adobe PDF File), 83 KB - mhealth_v8i1e12859_app3.pdf]

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Abbreviations

BAME: black, Asian, or minority ethnic
EOM: Equal Opportunities Monitoring
CLAHRC: Collaboration for Leadership in Applied Health Research and Care
NHS: National Health Service
NIHR: National Institute for Health Research
PAR: participatory action research
PPI: patient and public involvement

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Original Paper

Testing Consultation Recordings in a Clinical Setting With the SecondEars Smartphone App: Mixed Methods Implementation Study

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Abstract

Background: Health care systems are increasingly looking to mobile device technologies (mobile health) to improve patient experience and health outcomes. SecondEars is a smartphone app designed to allow patients to audio-record medical consultations to improve recall, understanding, and health care self-management. Novel health interventions such as SecondEars often fail to be implemented post pilot-testing owing to inadequate user experience (UX) assessment, a key component of a comprehensive implementation strategy.

Objective: This study aimed to pilot the SecondEars app within an active clinical setting to identify factors necessary for optimal implementation. Objectives were to (1) investigate patient UX and acceptability, utility, and satisfaction with the SecondEars app, and (2) understand health professional perspectives on issues, solutions, and strategies for effective implementation of SecondEars.

Methods: A mixed methods implementation study was employed. Patients were invited to test the app to record consultations with participating oncology health professionals. Follow-up interviews were conducted with all participating patients (or carers) and health professionals, regarding uptake and extent of app use. Responses to the Mobile App Rating Scale (MARS) were also collected. Interviews were analyzed using interpretive descriptive methodology; all quantitative data were analyzed descriptively.

Results: A total of 24 patients used SecondEars to record consultations with 10 multidisciplinary health professionals. In all, 22 of these patients used SecondEars to listen to all or part of the recording, either alone or with family. All 100% of patient participants reported in the MARS that they would use SecondEars again and recommend it to others. A total of 3 themes were identified from the patient interviews relating to the UX of SecondEars: empowerment, facilitating support in cancer care, and usability. Further, 5 themes were identified from the health professional interviews relating to implementation of SecondEars:

changing hospital culture, mitigating medico-legal concerns, improving patient care, communication, and practical implementation solutions.

Conclusions: Data collected during pilot testing regarding recording use, UX, and health professional and patient perspectives will be important for designing an effective implementation strategy for SecondEars. Those testing the app found it useful and felt that it could facilitate the benefits of consultation recordings, along with providing patient empowerment and support. Potential issues regarding implementation were discussed, and solutions were generated.

Trial Registration: Australia and New Zealand Clinical Trials Registry ACTRN12618000730202; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373915&isClinicalTrial=False

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KEYWORDS

mHealth; cancer; mobile apps; implementation; pilot; consultation audio recording

Introduction

Using Mobile Health to Strengthen Patient-Centered Care

Mobile health (mHealth) describes health care facilitation or delivery via mobile devices such as smartphones or tablets [1]. Hospitals are increasingly looking to mHealth and electronic health (eHealth) innovations to improve safety and quality [2-4]. Benefits can include low-cost health system integration and improved engagement, communication, and care delivery, particularly for low income and other disadvantaged patient populations [1,3,5,6]. In addition, patients are increasingly becoming interested in accessing technological solutions designed to empower them to effectively and independently manage their care [7]. Furthermore, the increasing availability of smartphones has allowed for the development of mHealth interventions to reduce inequities in health care service delivery and barriers such as poor health literacy [5].

Consultation Audio-Recordings

Consultation audio-recordings are one such technological solution. Patients report difficulty remembering and understanding information in the health care context, with these difficulties exacerbated by shock or stress [8]. Research has demonstrated that providing recordings of medical consultations can be a useful tool to combat this. With the help of recordings, patients' report improved understanding and recall of key medical information and improved engagement and satisfaction with their doctor and health service [9-15]. Previous consultation-recording research using technologies such as Dictaphones or cassette tapes identified numerous potential barriers to health service implementation including lack of sustainability, data security, poor sound quality, and high clinical burden [13,14,16].

The SecondEars App

The SecondEars smartphone app was developed by our team as an evidence-based mHealth solution to overcome barriers described, and to facilitate implementation of consultation audio-recordings into routine clinical care [17]. An experience-based co-design methodology [18] was used to develop the app, with patients, doctors, nurses, health information management, and information technology representatives involved in all facets of the project from concept creation to design and development [17].

The Need for Pilot Testing and User Experience

Nevertheless, even evidence-based mHealth technologies such as SecondEars are not easily integrated into everyday clinical care. Most mHealth interventions fail to be implemented after pilot-testing [19,20] with the term *pilotitis* created to describe this phenomenon [21,22]. This is likely due to a number of reasons. It is well documented that the foremost barrier to acceptance and use of a new technology is poor attention to user experience (UX), or *usability* [23], and pilot trials have typically done a poor job of collecting the information needed to remedy usability problems before implementation [20]. UX in this context refers to the dynamic, context-dependent, and subjective singular and accumulated experiences a user has as a consequence of interaction with a technology [24]. Positive UX and subsequent user decisions regarding acceptability, satisfaction, and feedback regarding the intervention have been found to be directly linked to whether an innovation will be adopted by its target population [4,23,25].

mHealth apps are also often not piloted in the actual environment where they will be used [20], meaning that barriers to feasibility or use in *real-world* settings cannot be adequately identified. Implementation and system development issues need to be identified and understood as part of comprehensive pilot testing [3,26,27]. mHealth innovations tend to be more complex than other technologies as they often require integration with multiple existing systems and must be appropriate for a variety of users [21]. Effective communication between stakeholders regarding application function, underlying public health improvement purpose, and function within the health system is also optimal for implementation [28]. Many unsuccessful pilot projects have in common a lack of consideration of this complexity, poor stakeholder engagement, and a failure to investigate and collect the requisite data regarding key elements essential for sustainable and scalable system implementation [21,29].

Objectives

This study aimed to pilot the SecondEars app within a real-world clinical setting to identify factors to optimize implementation. As identified in the literature, the following elements were deemed essential for consideration before implementation:

1. Patient UX and subsequent decisions regarding acceptability, utility, and satisfaction of SecondEars app
2. Health professional perspectives about issues, solutions, and strategies for effective implementation of SecondEars.

Methods

About the SecondEars App

SecondEars was designed so that patients can record conversations during appointments they think will be most helpful and with whichever health professional they wish (providing the health professional gives their permission). Appointments may include (but are not limited to): one-on-one doctor consults, nurse-led treatment or symptom education sessions, and appointments with allied health professionals. SecondEars also includes features (see Multimedia Appendix 1) which allow patients to write and associate notes with each recording, such as questions for their next appointment. Each recording can be labeled, or *tagged*, according to a particular health professional, the consultation type, or any other association the patient wishes to make, for example, diagnosis information and treatment plan.

Data Management and Security

Audio files made by patients can be uploaded from the SecondEars app and stored within a secure cloud server prior to playback. This storage facility was designed so that the audio-recordings can be accessed by the health service's patient health information services and information technology teams. Once uploaded, patients can share their audio files via the SecondEars app using any of the standard services on their smartphone (eg, email and messaging services with the exclusion of social media apps such as Facebook).

Version Details

Version 1.0 of SecondEars was pilot tested in this study. This version was only available through the Apple testing service TestFlight. Version 1.0 was operated by all participants as no revisions or updates were implemented during the study period.

Theoretical Framework

The Consolidated Framework for Implementation Research (CFIR) was chosen as the theoretical framework for this study. The CFIR is a taxonomy of health implementation theories and the associated constructs that have been shown to be effective for facilitating successful implementation of health innovations [30]. The following CFIR domains were used to inform development of study processes: (1) the characteristics of the intervention being implemented, (2) characteristics about individuals who are involved in the implementation process, (3) inner setting refers to the features of the context where the technology is to be implemented, that is, hospital, and 4) the process by which implementation is undertaken [30].

Pilot Testing, User Experience, and Implementation Data Collection

A mixed methods implementation study was employed to collect data regarding the feasibility and UX of the SecondEars consultation audio-recording app in a clinical setting. Combining qualitative and quantitative data is recognized as the optimal approach to describe and understand user perceptions of mHealth interventions for cancer patients' self-management [4]. Data were collected concurrently, with the greatest weighting on the qualitative data, in line with the study's focus on description and exploration.

The study was conducted at the Peter MacCallum Cancer Centre (Peter Mac) in Melbourne, Australia. Written informed consent was obtained from all study participants, and the study protocol was approved by the Peter MacCallum Cancer Centre Human Research Ethics Committee (study number: 16/07L). This study was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12618000730202).

Participants

Patients and Family

Patients with a scheduled out-patient consultation at Peter Mac were invited to test the SecondEars app by downloading and using it to audio-record a consultation with a participating health professional. To be eligible, patients needed to be aged ≥18 years; able to read, write, and speak English; and have access to and ability to operate an iPhone or iPad.

Clinical Staff

Oncologists, nursing, and allied health staff working in the following departments were invited to take part: Nutrition, Physiotherapy, Speech Pathology, Skin and Melanoma, Urology, and Lung outpatient clinics. All staff in these departments were made aware of the study via presentations at staff meetings and email circulations. Staff who expressed interest were then invited to participate via email.

Measures

Patient Demographic Questionnaire

A customized, self-report measure was used to gather patient demographic, appointment, and technological ability characteristics comprising age, postcode, sex, consultation information, and self-reported skill with smartphone technology.

Patient Mobile App Rating Scale

The Mobile App Rating Scale (MARS) was used to collect data regarding the CFIR construct: intervention (app) characteristics [30,31]. The MARS uses a 5-point scale to assess app quality (from 1=inadequate to 5=excellent). Researchers can select to use only the categories of the MARS that are relevant to their application; this study used aesthetics (3 items), functionality (4 items), and subjective app quality (4 items) [31].

Patient and Health Professional Interviews

Semistructured interviews were used to collect data about the UX of the SecondEars app in a clinical setting (patients and health professionals) and at home (patients only), and perspectives regarding implementation and stakeholder engagement (health professionals only). Patient interviews were designed to elicit responses regarding user perspectives and experiences of each feature and function of the app, and how the app was integrated into their overall health care experience. Health professional interviews were designed to investigate

perspectives on implementation barriers, facilitators, and strategies for effective implementation. Most questions in both interview schedules were open-ended, but some were closed to provide quantifiable data about app use (eg, *How many times have you listened to the audio-recording?*).

Procedures

Pilot Testing

Health professionals were informed of the pilot study at multidisciplinary team meetings. Those who volunteered to take part in the study provided consent to have consultations audio-recorded and complete an interview. Patients scheduled to attend outpatient appointments with consenting health professionals were screened for eligibility between February 19 and July 31, 2018. Eligible patients were approached via telephone before their appointment; those interested were emailed an information sheet and consent form and instructions on how to download the SecondEars app using TestFlight. TestFlight is part of the iOS development program, which allows users to test mobile apps before they are listed on the Apple App store. A member of the research team met the patient in the waiting room before their consultation to collect the signed consent form, provide assistance with downloading and setting up the app if required, and collect demographic information. If any family or friends were attending the appointment with the patient, they were also given information about the study and asked to provide consent to the consultation being audio-recorded. App use was not directed by the researchers during or after the consultation; it was up to the patient participants to use the app as they chose.

Interviews

One week after their recorded consultation, patient participants completed an interview and the MARS via telephone. A copy of the MARS was emailed to each patient participant before the interview, and responses were provided verbally by participants, at the end of the interview. Some participants had chosen to ask a family member to manage the app for them. These participants had the option of nominating their family member to participate in the interview with them, or on their behalf. Participating health professionals completed a face-to-face, audio-recorded interview with a researcher at the conclusion of the study.

Data Analysis

Quantitative Data

The MARS was scored using published guidelines [31]. Responses to items from the MARS aesthetics and functionality categories were averaged separately to provide subscale scores. Descriptive statistics were used to summarize data collected using the customized, self-report survey, the MARS and closed-ended interview questions. Nominal data were summarized using counts and percentages. Continuous data were summarized using means and standard deviations.

Qualitative Data

Patient, carer, and health professional interviews were analyzed using interpretive description methodology, which is designed to be used in addressing questions of clinical utility in health care [32,33]. Transcribed interview data were sorted into codes, then categories and themes using QSR International's NVivo 11 software [34]. A total of 2 members of the research team analyzed the data. RLS analyzed the patient interviews, and AH analyzed the health professional interviews. Group discussions were held with the project team to review the categories and themes. If there were differences in opinions, discussion would continue until a consensus was reached regarding interpretation of the data [35].

Results

Pilot Testing Sample

Patients

Of the 51 patients who were eligible for the study, 30 consented to participate (59% consent rate). Of those who declined, a majority (n=12) were not interested in participating in research, 2 were not confident with technology, 2 were scheduled to have their appointment via telehealth, 2 did not want any distractions from their consultation, and 3 listed personal reasons (eg death in family and having nurse as partner).

Recorded Their Consultation

Of the 30 patients who consented to participate, 6 did not record their consultation. In all, 3 had their appointment changed or cancelled, 2 were unable to download the app as the hospital WIFI was not working or they had forgotten their Apple ID password, and 1 forgot to press record. The total number of patient participants included in the study was therefore 24 (see Table 1).

Health Professionals

A total of 18 health professionals volunteered to take part in the trial; however, 8 of these did not have any eligible patients agree to take part. Therefore, the total number of health professionals included in the study was 10 (see Table 1).

Table 1. Participant demographic information (N=24).

Characteristics	Value
Patients	
Age (years), mean (SD, range)	58 (10, 39-75)
Sex, n (%)	
Male	17 (71)
Female	7 (29)
Cancer type, n (%)	
Lower gastrointestinal	5 (21)
Lung	3 (13)
Melanoma	7 (29)
Urology	8 (33)
Head and neck	1 (4)
Consultation type, n (%)	
Surgical oncologist	6 (25)
Medical oncologist	15 (63)
Oncology nurse and physiotherapist (joint consult)	2 (8)
Speech pathologist	1 (4)
Tech ability, n (%)	
Beginner	2 (8)
Intermediate	17 (71)
Advanced	5 (21)
Device used, n (%)	
iPhone (own)	15 (63)
iPhone (partner's or family's)	7 (29)
iPad	2 (8)
Health professionals (n=10)	
Sex, n (%)	
Male	5 (50)
Female	5 (50)
Specialty, n (%)	
Surgical oncologist	1 (10)
Medical oncologist	5 (50)
Oncology nurse	1 (10)
Physiotherapist	1 (10)
Speech pathologist	2 (20)

Interviews

Of the 24 participants who recorded their consultation, 21 patients and 4 carers completed the interview (2 carers completed the interview on behalf of the participant, 2 carers completed an interview in addition to the participant, and 1 participant was lost to follow-up). One health professional did not complete a follow-up interview due to extended leave; therefore, a total of 9 health professionals completed the interview. Closed-ended interview data are summarized in Table 2.

Table 2. Participant and family use of the SecondEars app

App and recording use	Patients (n=21)[a], n (%)	Carers (n=4), n (%)
Number of participants who listened to all or part of audio-recording		
All	11 (56)	3 (75)
Partial	8 (36)	1 (25)
Did not listen	2 (8)	0 (0)
When listening to the audio-recording, was anybody else present[b]		
No, listened to it alone	9 (39)	1 (25)
Yes, listened with a spouse/partner	11 (48)	3 (75)
Yes, listened with another family member	3 (13)	0 (0)
Number of participants who used the share function		
Used function to share recording	4 (19)	2 (50)
Intended to use function to share recording	2 (10)	0 (0)
Did not use share function	15 (71)	2 (50)
The audio-recording was shared with		
Self	2 (50)	1 (50)
Child	1 (25)	1 (50)
Partner	1 (25)	0 (0)
Intended to share with		
Child	1 (50.0)	0 (0)
General practitioner	1 (50.0)	0 (0)
Number of participants who used the notes function		
Did use	2 (10)	0 (0)
Did not use	19 (90)	4 (100)
Number of participants who used the labeling function		
Did use	6 (29)	2 (50)
Did not use	15 (71)	2 (50)

[a]Including two patients that completed only the interview, not the Mobile App Rating Scale.

[b]Does not add up to 19 for patients because some people listened to it with more than one person.

User Experience and Acceptability, Utility, and Satisfaction

Patient and Carer Qualitative Interviews and the Mobile App Rating Scale Results

UX interviews were completed with 21 patients, 4 family members, and 9 health professionals. Quantitative app utility data collected via the MARS are displayed in Table 3. The themes that emerged from the qualitative interviews with patients and carers are described below. A total of 3 themes summarize the usability, acceptability, utility, and satisfaction that patients and family members identified and described as relevant to their experience testing SecondEars (see Figure 1 for a summary of the results).

Empowerment and Reassurance

Patients described the SecondEars app as a *safety net* that helped them to feel secure and in control. Having the app on their own smartphone gave the participants flexibility and choice about how and when to make and listen to the recordings. Participants liked that they could choose to listen to the recording in an environment where they felt comfortable, as this helped to control the emotional aspects associated with relistening to health information, and provided an antidote to rumination. Using SecondEars to confirm that their interpretation or recall was correct gave participants confidence and reassurance—the app was literally at their fingers.

> *If something sort of goes over your head a little bit during the meeting you've got it [the app] there you know and you can actually listen to that audio at any time and it will sort of clear what's going on in your head... it really does take a load off your mind because you can hear everything back.* [Female patient, aged 55, P22]

Table 3. Results from the Mobile Application Rating Scale (participants, N=23).

Subscale[a]	Value, n (%)
Functionality[b]	
Performance: How accurately/fast do the app features and components work?	
App is broken; no/insufficient/inaccurate response (eg, crashes/bugs)	0 (0)
Some functions work, but lagging or contains major technical problems	0 (0)
App works overall. Some technical problems need fixing, or is slow at times	0 (0)
Mostly functional with minor/negligible problems	6 (26)
Perfect/timely response; no technical bugs found	17 (74)
Ease of use: How easy is it to learn using the app?	
No/limited instructions; menu labels, icons are confusing; complicated	0 (0)
Takes a lot of time or effort	0 (0)
Takes some time or effort	1 (4)
Easy to learn (or has clear instructions)	6 (26)
Able to use app immediately; intuitive; simple (no instructions needed)	16 (70)
Navigation: Does moving between screens make sense, all links present?	
No logical connection between screens at all/navigation is difficult	0 (0)
Understandable after a lot of time/effort	1 (4)
Understandable after some time/effort	2 (9)
Easy to understand/navigate	4 (17)
Perfectly logical, easy, clear, and intuitive screen flow throughout and/or shortcuts	15 (64)
Gestural design	
Completely inconsistent/confusing	0 (0)
Often inconsistent/confusing	1 (4)
Okay with some inconsistencies/confusing elements	1 (4)
Mostly consistent/intuitive with negligible problems	5 (22)
Perfectly consistent and intuitive	16 (70)
Aesthetics[c]	
Layout: graphic design, overall visual appeal, color scheme, and stylistic consistency	
Very bad design, cluttered, options impossible to select, locate, see, or read	0 (0)
Bad design, random, unclear, some options difficult to select/locate/see/read	0 (0)
Satisfactory, few problems with selecting/locating/seeing/reading items	2 (9)
Mostly clear, able to select/locate/see/read items	5 (22)
Professional, simple, clear, orderly, logically organized	16 (70)
Graphics	
Appears amateur, very poor design, disproportionate, stylistically inconsistent	0 (0)
Low quality/low resolution graphics; low quality visual design—disproportionate	0 (0)
Moderate quality graphics and visual design (generally consistent in style)	2 (9)
High quality/resolution and visual design, mostly proportionate, consistent in style	11 (48)
Very high quality/resolution and visual design, proportionate, consistent in style	10 (43)
Visual appeal	
Ugly, unpleasant to look at, poorly designed, clashing, mismatched colors	0 (0)
Bad: poorly designed, bad use of color, visually boring	1 (4)

Subscale[a]	Value, n (%)
OK: average, neither pleasant, nor unpleasant	5 (22)
Pleasant: seamless graphics, consistent and professionally designed	9 (39)
Beautiful: very attractive, memorable, stands out; use of color enhances app	7 (30)
App subjective quality	
Would you recommend this app to people who might benefit from it?	
Not at all I would not recommend this app to anyone	0 (0)
There are very few people I would recommend this app to	0 (0)
Maybe there are several people whom I would recommend it to	1 (4)
There are many people I would recommend this app to	2 (9)
Definitely, I would recommend this app to everyone	20 (87)
How many times would you use the app in the next 12 months if it was relevant to you?	
None	0 (0)
1-2	3 (13)
3-10	9 (39)
10-50	10 (44)
>50	1 (4)
Would you pay for the app?	
No	7 (30)
Maybe	6 (26)
Yes	10 (44)
What is your overall star rating of the app? (number of stars)[d]	
1 (one of the worst apps I have used)	0 (0)
2	0 (0)
3 (average)	2 (9)
4	15 (65)
5 (one of the best apps I have used)	6 (26)

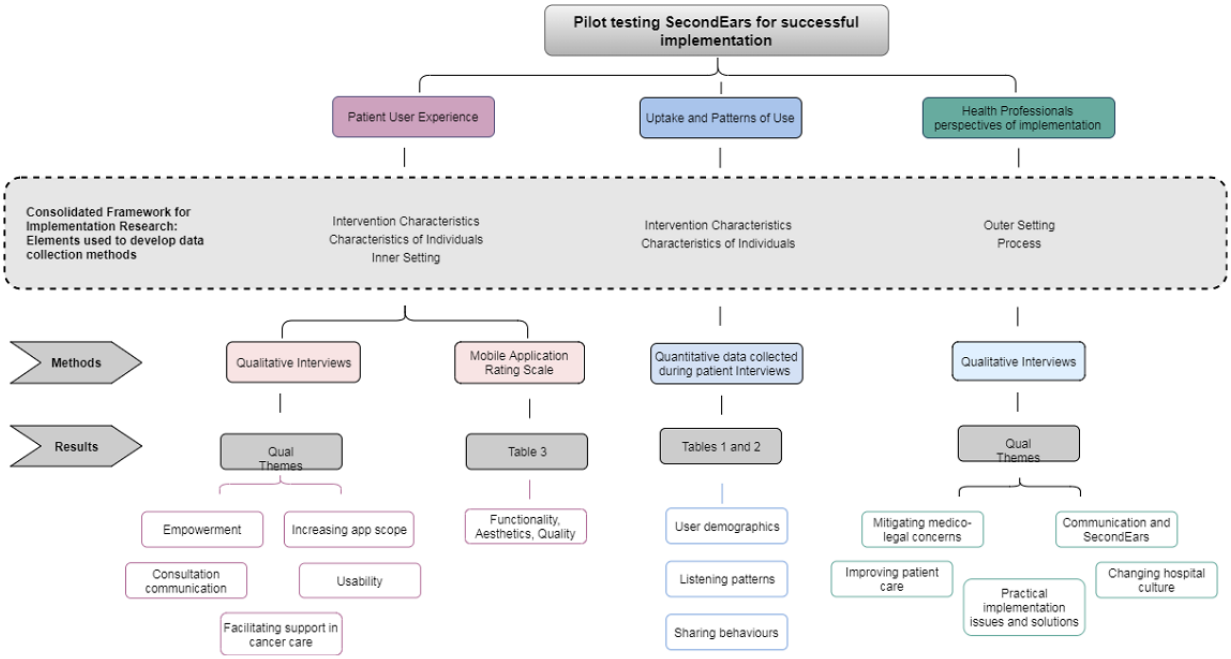
[a]The Mobile App Rating Scale (MARS) was only offered to patients who recorded their consultation. In addition, 2 patients did not complete the MARS as had delegated the operation of the app to their carer; therefore, their carers completed it instead.

[b]The mean functionality subscale score was 4.6 (SD 0.7).

[c]The mean aesthetics subscale score was 4.3 (SD 0.8).

[d]Overall star rating (mean [SD]) was 4.2 (0.6).

Figure 1. Synthesis of results.



The design of the app allowed participants to skip over sections of the audio-recording that they found less relevant. Some participants took the initiative to test the app before their consultation or to use the app in ways unintended by the app developers, for example, sharing the recording to their own email address so that they could store a back-up copy.

Facilitating Support in Cancer Care

Patients felt that SecondEars facilitated support from family and health professionals. Participants often used the app collaboratively, as it made it easier for their family members and friends to be involved in their care. Participants operated the device with help from family, chose to listen to the audio-recording with others, or to share the recording via the share function. One participant mentioned that his wife might use the app to record his future appointments, even though he did not plan to do so. Being able to relisten to the consultation facilitated discussion with family and helped to settle disagreements.

> *It really satisfied us that we could revisit the conversation we had with [health professional]. For example we would talk to our daughter and she was quite impressed with it too, you know, in 15, 20 minutes you can do an awful lot of talking... we sent [shared recording of health professional appointment via app] through to our daughter in Shepparton and as I said she was quite impressed with it.* [Male patient, aged 75, P11]

Participants also suggested that SecondEars could be used to share consultation audio-recordings with other members of their treatment team, including health professionals external to the hospital (such as GPs), to keep everyone informed. However, some participants described feeling apprehensive or reluctant to burden others with information by sharing recordings.

Ease-of-Use

SecondEars was described as functional and user-friendly, with good sound quality, even when there were multiple people speaking in the room. In one of the testing situations, the recording was made in a lecture theatre education session with many patients and carers attending, with this also reported as having adequate sound quality. Particularly, participants liked the simple design and scope, which they felt would enable access for a wide range of people, including older adults. Almost every participant commented on how simple and easy it was to use SecondEars, even when in a busy and emotional clinical environment.

> *Very simple just the layout and graphics very simple. Probably very good for people who are not technologically savvy... there's a big record button in the middle of the screen you just press it and away you go... just about anybody could use without sort of stuffing it up [laughs].* [Male patient, aged 64, P04]

Most participants reported no technological issues, and they liked the convenience SecondEars provided by enabling them to record and relisten on their own phone. Some participants reported feeling worried that uploading the audio-recording would be time consuming if the internet or mobile reception was poor; however, this was not the case in practice as most participants found recordings easy to upload. Some participants relied on family to use the app for them. Patient participants who mentioned in the interviews that they were frightened of technology were all part of a patient/carer dyad where the carer primarily operated the app. One nontech-savvy participant reported that he did not skip through irrelevant sections of the consultation recording because he was worried about accidentally deleting something. One participant suggested adding some frequently asked questions to the instructions.

Others felt it was important to be able to ask a member of staff for help with the app if needed.

> *Like I said I'm not very adventurous on that [technology]. I wouldn't do that [tagging] without one of the kids being around.* [Female carer for male patient, aged 71, P20a]

The *core* functions of the app (audio-recording, uploading, listening, and sharing the audio-recording) were used by most participants, however few used the other functions, such as the labeling feature or the note-taking function. Participants made suggestions to make the app more functional, such as allowing patients to *bookmark* certain sections of the recordings. People also expressed surprise the system had not already been implemented into usual care given how useful and easy they had found SecondEars. Furthermore, 1 participant emphasized the importance of involving clinicians in the implementation process and ensuring the app had full support of the hospital before rolling it out.

Changing Communication

Participants reported being conscious of SecondEars during the consultation, but that, on the whole, they did not find it obtrusive. However, 3 participants speculated whether having SecondEars in the consultation may result in clinicians being more cautious or guarded because they know they are being audio-recorded. In all, 2 of these participants felt this may improve the quality of the consultation for the patient, whereas the other was not so sure. One participant thought that being able to use SecondEars on their phone with clinician permission solved the dilemma of having to ask the clinician to record the consultation and having a Dictaphone prominently displayed between them, or with the alternative of covertly recording.

> *We were all quite conscious of it being there during the consultation but at the same time you know it didn't distract us from what we were talking about... I mean we were conscious in the sense that we just put it in between us so that we'd both be heard.* [Male patient, aged 58, p28]

Increasing App Scope

A participant (as quoted below) suggested that using the app could help them to be a more informed and engaged health consumer. A total of 2 participants mentioned that they, or a member of their family, could use the audio-recording to take notes after the appointment. Some participants suggested other uses for the app beyond its original scope, such recordings being used for communication skills education and training for clinicians, or as a form of preparation for new patients to learn what to expect. One participant mentioned that the app could be used to play recordings to other health professionals to correct inconsistencies in information provided. Although some participants felt that the app would be most useful at initial diagnosis, others felt they would use it for all their medical consultations at Peter Mac and elsewhere, and with other types of health professionals such as physiotherapists. They felt that SecondEars would be most useful if all clinicians were on board and if the app was available at other health care organizations and for other illnesses besides cancer.

> *I'm very much process person and um I ask lots of questions um because I believe in being a responsible health consumer and an informed health consumer and it strikes me that your app helps me to do exactly that…um I would say what would I say, I would say look if you want to make an informed choice about your treatment um then this app will help you to do that.* [Female patient, aged 67, P27]

Mobile App Rating Scale

All participants rated that they would use the app again, with a large proportion (10/23, 44%) selecting that they would use the app 10 to 50 times (see Table 3 for a summary of the MARS results). When asked whether they would recommend SecondEars to others, 100% of participants stated they would, with the majority confirming that they would definitively recommend to everyone they knew (20/23, 87%). Participants predominantly rated the app highly according to functionality, aesthetics, and subjective quality, with mean subscale scores all greater than 4 (out of a possible 5). A small minority of participants found the app often or sometimes confusing (2/23, 4%); or thought the design was bad (1/23, 4%). Interestingly, 44% (10/23) of participants indicated they would pay to use SecondEars.

Implementation

Health Professional Qualitative Interviews

Although health professionals were not direct users of the app themselves, the app design and purpose means that their involvement and engagement are essential for successful implementation. Health professionals were asked to focus on issues, solutions, and strategies for effective implementation of the SecondEars app. A total of 5 themes emerged from these qualitative interviews.

Changing Hospital Culture

All health professional participants supported the idea of SecondEars being made available to all patients, and that it should remain under patient control. Health professionals recognized that not all patients would have the need or capacity to use SecondEars; therefore, patients should self-identify for the service. Maintaining patients' control over SecondEars also ensures that the app would not incur additional demands on clinical staff.

> *I absolutely 100% think it [SecondEars] should be part of usual care. End of the day, see more patients, help more people um it's only a good thing. I think this is this is where health care is going. I think it just needs to be embraced as much as it can be and rolled out.* [C1]

Many health professionals felt that patients were already leading the way in this area, as requests to use smartphones to record consultations were already common. Patients already realized the benefits of recording important information. Some health professional participants also reported having discovered patients recording appointments covertly in the past, with this seen as further impetus for the health service to embrace the technology.

> *Patients will sometimes do this anyway... they'll say: "would you mind awfully if I recorded this?" you know?* [C3]

Health professionals discussed strategies that could be employed to begin culture change within the hospital. Clinical champions or change agents were seen as being useful in driving group acceptance of new technology for both health professionals and patients. Nurses were suggested as hospital-wide change agents, as they are the largest group of health professionals in the hospital and carry lots of influence with patients and staff alike. Having a SecondEars champion or representative in each clinical service to assist with implementation was also suggested. Likewise, marketing and social campaigns for both health professionals and patients were suggested as good methods to employ to change hospital culture, including: promotions at multidisciplinary team meetings, an internal marketing campaign, with patient stories, and engaging with the communications team for both internal and external media.

> *I think you need champions for sure and I think if you're going to roll out you'd need clinical champions and you need patient champions as well.* [C4]

One doctor likened the potential for mHealth culture change to the ubiquity to which apps are accepted and used by customers in the airline industry. People boarding a plane automatically search for entertainment apps, and so likewise, patients could become accustomed to investigating what mHealth services are available upon arrival at a hospital.

Mitigating Medico-Legal Concerns

Health professionals felt that early and open discussion and planning for medico-legal concerns would assist hospital culture change. SecondEars was thought to have the potential to improve transparency and communication, and this could be reflected in discussions about legal issues, and how this is protective for both parties.

> *Have people... point out [to health professionals] some of the legalities associated with the system and to say that yeah that it's going to be actually in some ways protecting you rather than it being something that can be um be a risk.* [C5]

Health professionals briefly discussed the potential for consultation recordings to form part of legal proceedings. However, the concerns about recordings being used in legal settings were predominantly discussed in the context of 'other health professionals may potentially be worried about this;' all clinical staff interviewed were comfortable with the process in their own practice and saw only the benefits of recordings for both themselves and patients.

> *...people's mind often go to medico legal things whereas to me that's the least of worries you know. Yeah I mean I've been working 15 years I've never been you know called up for anything um... you know and... you know ninety nine point nine percent of people do a very good job within their roles so I don't think necessarily that's the issue. I think the benefit is more around for us I would see it more for the patient. Getting a better understanding of what their treatment is and being able to share it rather than ah protecting ourselves or covering ourselves.* [C10]

Health professionals also thought that having a recording of the consultation would prove beneficial in this context, particularly when using something like SecondEars, which also ensures a copy is saved within the hospital medical record.

> *From a kind of legal reassuring point of view I suppose to know that if the patient is unhappy or thinks you said something that wasn't true or you know…any of those things that you kind of worry about as a health professional yourself…to know that [the hospital] holds a copy of [the recording]* [C1]

Improving Patient Care

Health professionals also felt that SecondEars could facilitate family involvement in patient care. Echoing the sentiments of patient participants, health professionals also felt that it would be reassuring for both health professionals and patients to know that a copy of all information was saved and could be relistened to. The ability of health professionals to listen to and share recordings among themselves was also seen as valuable for numerous reasons: to reduce duplication of information provided to patients, improve continuity of care, remind themselves of what information they had communicated to patients, and to assist during sudden transfer of care. Patients having recordings was thought to potentially reduce questions about forgotten information, but conversely, also increase patient engagement and discussion about information provided. Several health professionals also mentioned that SecondEars could be beneficial during informed consent procedures for treatment and/or clinical trials.

> *I absolutely think it would be a big improvement to patient care. It's something they'd [patients] really value and staff would value too. For me I like to know that they had that information at home they could listen to with someone else. It's a big thing for patients to come and hear all this and hear the word cancer, meet loads of people and it's reassuring to know they've got it all with them somewhere when they get back [home].* [C1]

Communication and SecondEars

The most common opinion expressed by health professionals was that recording their consultations had not changed how they spoke or behaved toward patients, despite this being an initial concern. Instead, the health professionals felt that they could use SecondEars to identify areas where communication could be improved. It was also thought that having SecondEars in the appointment would encourage patients to ask more questions.

> *It can be difficult for patients to speak out and ask questions at the time and then if they don't ask those questions, recalling their questions or recalling the prompt to those questions can be difficult. So for my groups specifically um knowing that they could listen to what was said and then come back to me with their questions was really good.* [C1]

Participating health professionals hypothesized that while they were comfortable with SecondEars, this may not be the case for all health professionals. They felt that some people may be uncomfortable with being audio-recorded, and that there may be some initial reluctance owing to concerns that lack of knowledge or poor communication skills could be *shown up*.

> *You know perhaps they feel a bit insecure in their clinical skills (laughs) or something and so they feel like being recorded might... could be used against them at some point or other or... I don't know.* [C9]

Having a phone active in the consultation was discussed as potentially being a distraction or increased awareness of being recorded and so impact on establishing patient rapport (at least initially). However, participants reflected and felt that this had not occurred in practice during the study. It was also felt that recordings should not be used deliberately by either health professionals or patients to *prove* each other wrong about information discussed or missed within an appointment. Overall, it was thought that very few health professionals would be opposed to SecondEars being implemented, and that any initial discomfort regarding the app or recordings would diminish in time.

Practical Implementation Issues and Solutions

Important considerations regarding facilitation of use included how to ensure that interpreters were comfortable being recorded if non-English speaking patients were to download and use the app, or how to manage patients who do not own a smartphone or who struggle with using technology. Health professionals also raised process concerns, such as potential technical issues increasing already busy clinic times and the sustainability of the app. Data security was also discussed.

> *My other concern would be um if it adds time onto the consultation [for example] so if you've got 15 minutes to speak to your consultant about um... ah your illness it's the first seven minutes of it wasted while you say oh where's my phone, hang on my wife had it, it's in a bag... you know you don't want to lose that precious time with the consultant. They don't want to lose that precious time with the patient* [C1]

One doctor also raised the potential for recordings to be shared inappropriately via social media; however, they themselves were comfortable with standing by whatever they had said in a consultation and felt that this was going to be a potential issue regardless of the patient using SecondEars to make a recording or not.

> *Literally any time you speak to a patient or any time you email somebody you have to... ah have an expectation that this could appear on Twitter or you know or the front page of the Herald Sun and am I prepared to stand over what you might have thought was, is still a confidential conversation but I think that's just the way we... the society we live in.* [C3]

Solutions to these concerns were readily supplied. Health professionals suggested that written information about SecondEars be provided to patients upon admission or registration at the hospital, including detailed instructions on how to download and use the app. Hospital volunteers were proposed as appropriate persons to assist patients with app installation and use to reduce any technical issues and/or delays by ensuring that installation is completed before attending a consultation to. Information about SecondEars displayed prominently in clinic waiting rooms and consultation rooms to prompt patients planning to record to obtain consent from all persons in the room, reminders to start and stop recording, and details outlining patient responsibilities were suggested. Furthermore, several health professionals suggested using implementation strategies previously employed by other new technologies, such as telehealth or even other nontech strategies, such as health screening tools, as it was felt that these successful examples were implemented effectively and collaboratively. Finally, including communication skills training with implementation was seen as essential, as this would help mitigate health professionals' concerns relating to communication, inappropriate sharing, or medico-legal issues.

> *So we could develop some pretty concise—not you have to go to a communications skills training workshop for the next weekend—but here's some techniques that other people say are useful you know and then you can go OK I'm gonna try that so. It feels like there could be some training with the rollout.* [C6]

Discussion

Clinical Pilot Testing

To facilitate successful implementation, information about the functionality and suitability of new technologies is required. This study used patient, family, and health professional feedback to identify factors for optimal implementation.

Piloting SecondEars in a clinical setting was useful for determining how both patients and health professionals interacted with the app in conjunction with balancing their needs as a patient or role as a health professional. Importantly, not all patients chose to use SecondEars. This information is essential for planning appropriate infrastructure to support data management and storage of recorded files within the medical record. Although the app worked well for the majority of participants, some process issues were identified, such as issues with Wi-Fi or passwords. Implementation would require supportive frameworks and governance to ensure that users are able to access and use the app at the appropriate times, or that the app is adapted to address any identified barriers [36]. Most patient participants used the app to relisten to recordings or share with family and friends, validating the needs assessment, and mapping of use identified in the co-design process [17]. Integration of SecondEars into the current health care system is likely to be effective in overcoming some of the previous technological challenges seen with older consultation audio-recording research, as it has the potential to be sustainable, have strong data security, good sound quality, and low clinical burden [17].

User Experience and Acceptability, Utility, and Satisfaction

Data from both the MARS and the patient interview provided a comprehensive indication of UX, and decisions or perspectives of acceptability, utility, and satisfaction of SecondEars. Comments about design and function focused on how simple the functions were, and how easy people found the app to use. Every participant confirmed that given the opportunity they would use SecondEars again, and recommend it to others, indicating that patients who want to audio-record consultations feel the app delivers this service well. Perceived usability, usefulness, and design quality have been identified as key criteria for uptake and continued use of technological innovations [23,30,36-38], and the results of this pilot suggest that SecondEars meets these criteria. Findings from this study underscore the benefits provided by involving end users in the design of mHealth solutions [38], as the final product aligns with patient needs and resulted in improved patient experience.

Moreover, SecondEars was specifically designed as a tool to improve communication, patient empowerment, and health care quality [17], while simultaneously overcoming one of the more significant barriers identified in previous consultation recording studies, sustainable facilitation, patient audio file provision, and storage of consultation recordings [16]. Our results suggest that SecondEars helps patients to feel empowered, and using their own phone to be in control of the audio-recording process gives them agency and flexibility. Health service interest in mHealth technologies is related to realigning service delivery to embody patient-centered care [5]. Health consumers likewise are looking to mHealth tools to assist with self-management of their care [7]. UX data from this pilot suggest that the app facilitates patient health care engagement and self-management, indicating that SecondEars will meet both health system and patient requirements.

Implementation Strategy

Results from this pilot study suggest that health professionals support the implementation of SecondEars as an optional component of usual care. This indicates that mHealth is beginning to be accepted as a norm in routine health care, which will prove a positive driver for implementation [39]. For health professionals who participated in this study, this change in perspective extended to commonly discussed barriers to consultation recordings such as medico-legal concerns. Feedback from our sample reflected an attitude of acceptance, pragmatism, and focus on patient benefit, which deviated from the wariness that has been raised by health professionals in other studies [13,16,40]. Health professionals reported previous experience of both covert and permissive use of smartphones to record consultations, replicating previous research [11,41,42]. The ubiquity of smartphone use was seen as an additional driver for hospital culture change, and an argument for implementation to ensure the hospital has oversight of this process.

While our sample of health professionals may not reflect the majority of health care workers, reflections were made about other colleagues and peer perspectives regarding audio-recordings. Potential concerns were acknowledged, particularly that people may feel uncomfortable with being recorded. Possible unintended consequences recording consultations may have on doctor-patient communication emerged in this study, something which has been discussed at length in the literature [13,16,40,42]. However, again, the dialogue changed, as health professionals reported that anticipated negative side-effects of recording (disruption of rapport building) did not eventuate in practice, or if they did occur, they diminished rapidly with time, findings which have been supported by research demonstrating that recording does not affect clinical practice [43]. Furthermore, medico-legal and communication concerns were thought to stem from doubt or insecurity about communication skills. Several health professionals interviewed therefore recommended a communication skills training program to be designed and coimplemented with SecondEars to alleviate these barriers.

As noted above, both health professionals and patients volunteered to take part in this study. As per the CFIR framework, this is likely due to a complex interplay between the domains investigated (see Figure 1) such as characteristics of individuals, the intervention, inner settings of the organization (such as organization culture), and features of the intervention itself [30]. It could be postulated that our sample represents individuals who are *early adopters* of technology [44], and therefore, their perspectives are representative only of this group and not those who may be more wary or less enthusiastic about new technology in general, or of SecondEars in particular. An important aspect for future evaluation of integration of SecondEars into a clinical setting will be to understand in more detail which factors drive uptake and ongoing use of the app by patients and health professionals alike. While smartphone apps have been used specifically to improve health access and equity for disadvantaged populations [5,45], further investigation into whether SecondEars use improves health literacy or whether low health literacy is a barrier to use is needed.

Overwhelmingly, health professionals viewed SecondEars as a tool which enabled them to improve patient care and to improve the efficiency and quality of their work; 2 key facilitators for mHealth uptake noted in previous implementation studies [26,46]. As previously noted, new technologies are more likely to be taken up if they improve care delivery and do not impede or slow existing processes [36]. Implementation of SecondEars will therefore benefit from harnessing health professionals' desire to provide the best possible patient care as a key driver for acceptance and uptake. Likewise, information regarding how the app can facilitate health professional role efficiency will also be useful. Health professionals in our study referred to implementation of other successful implementations of eHealth technologies, such as telehealth. Incorporation of implementation protocols which have already met with eHealth professional approval could also be a useful lever for acceptance.

Limitations

Pilot testing was only conducted in 1 location, with a small sample of patients and health professionals. Pilot testing in health services other than a specialized oncology service would help identify and understand differing organizational processes which would require consideration for implementation. An evaluation of patterns of use with a larger sample of patients

and health professionals would also provide more information regarding uptake, use, and those who do not elect to use the app. Furthermore, the SecondEars app was only available for testing in iOS and not in Android, which limited the sample of eligible patients. The mean age of participants (58 years) was slightly younger than the mean age of Australians at cancer diagnosis (66.3 years) [47]. It is possible that our younger sample may reflect a propensity for younger people to participate in mHealth research, however only 9% (2/23) of the patients who declined participation cited lack of confidence with technology as their reason for declining. In addition, the majority of participants were male, which was most likely a consequence of participating clinicians working in cancer specialties which typically have greater numbers of male patients (Urology, Gastrointestinal, and Lung). SecondEars is currently only available with English prompts; therefore, the study excluded people who could not speak English. Future versions of SecondEars are intended to include other languages to increase equity of access.

Future Research

While clinical testing indicates positive responses from health professionals and patients alike, the next step will involve longer term implementation and evaluation of SecondEars. Integration of this solution within usual care would additionally provide a data collection platform to facilitate a range of additional research opportunities in doctor-patient communication, health literacy, and treatment/medication adherence.

Conclusions

Data collected from pilot-testing SecondEars, in conjunction with patient and health professional perspectives, will be useful for developing a comprehensive strategy to implement SecondEars within a hospital setting. In particular, the app was met with support from the participants in this study and was seen by participants as useful in improving patient care and self-management and health service delivery. mHealth innovations which are most likely to succeed are those which focus on improved patient communication or supporting patient-centered care and those which improve patient empowerment and self-management [38,44]. Given the extensive research conducted on the benefits of consultation recordings [13,48,49], SecondEars as an mHealth solution has the potential to effectively deliver these benefits, and use patient and health professional experience to assist in developing a robust implementation strategy.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the SecondEars app design.
[PDF File (Adobe PDF File), 3256 KB - mhealth_v8i1e15593_app1.pdf]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
eHealth: electronic health
MARS: Mobile App Rating Scale
mHealth: mobile health
Peter Mac: Peter MacCallum Cancer Centre
UX: user experience

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Review

Benefits of Mobile Apps for Cancer Pain Management: Systematic Review

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Abstract

Background: Pain ratings reported by patients with cancer continue to increase, and numerous computer and phone apps for managing cancer-related pain have been developed recently; however, whether these apps effectively alleviate patients' pain remains unknown.

Objective: This study aimed to comprehensively evaluate the role of mobile apps in the management of cancer pain.

Methods: Literature on the use of apps for cancer pain management and interventions, published before August 2019, was retrieved from the following databases: MEDLINE, Embase, Cochrane, CINAHL, Scopus, and PsycINFO. The effects of apps on cancer pain were evaluated using RevMan5.3 software, and the rates of adverse drug reactions were analyzed using the R Statistical Software Package 3.5.3.

Results: A total of 13 studies were selected for the analysis: 5 randomized controlled trials (RCTs), 4 before-after studies, 2 single-arm trials, 1 prospective cohort study, and 1 prospective descriptive study. The 5 RCTs reported data for 487 patients (240 patients in the intervention group and 247 patients in the control group), and the remaining studies reported data for 428 patients. We conducted a meta-analysis of the RCTs. According to the meta-analysis, apps can significantly reduce pain scores (mean difference [MD]=–0.50, 95% CI –0.94 to –0.07, I^2=62%, P=.02). We then used apps that have an instant messaging module for subgroup analysis; these apps significantly reduced patients' pain scores (MD=–0.67, 95% CI –1.06 to –0.28, I^2=57%, P<.01). Patients using apps without an instant messaging module did not see a reduction in the pain score (MD=0.30, 95% CI –1.31 to 1.92, I^2=70%, P=.71). Overall, patients were highly satisfied with using apps. Other outcomes, such as pain catastrophizing or quality of life, demonstrated greater improvement in patients using apps with instant messaging modules compared with patients not using an app.

Conclusions: The use of apps with instant messaging modules is associated with reduced pain scores in patients with cancer-related pain, and patient acceptance of these apps is high. Apps without instant messaging modules are associated with relatively higher pain scores. The presence of an instant messaging module may be a key factor affecting the effect of an app on cancer pain.

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KEYWORDS

mobile apps; cancer pain; meta-analysis; instant messaging

Introduction

Cancer Pain Management

According to the 2018 global cancer statistics, there were approximately 18.19 million new cases of cancer [1]. The number of new cancer cases is increasing rapidly every year and is expected to exceed 20 million by 2030 [2]. Further, the incidence of persistent cancer pain during treatment has also increased [3]. According to reports, approximately 69% of patients with cancer worldwide experience pain during their daily activities, which may have serious psychosocial consequences, including anxiety and depression [4].

Due to differences in treatment levels, cancer pain that is not adequately controlled is still widespread in developing countries [5]. According to reports, only 25% of patients with advanced cancer have pain that can be relieved, especially out-of-hospital patients, who have a lower pain relief rating than patients in the hospital. This is primarily caused by disjointed management of patients after discharge, resulting in reduced patient compliance, poor control of side effects, and outbreaks of pain [6].

Apps for Cancer Pain Management

With the development of the Internet, the number of health-related apps is growing rapidly, including apps for monitoring and managing diseases [5,7-9]. Apps for pain management are also gradually entering the market [10-12]. There are currently 283 pain-related apps in China and abroad, but only 8.2% of these apps include medical professionals in the development process, and none are scientifically proven to be effective. Therefore, whether apps can improve pain relief for patients remains unknown. Among the available pain apps, none are comprehensive for pain management, and most only contain a pain diary module [13,14].

Aim of the Study

It is not clear whether using an app to manage cancer pain can improve pain relief rating or which module type is the most effective in terms of app usability and pain management. Therefore, we conducted a systematic review and meta-analysis of studies of apps intended to manage cancer-related pain to explore whether these apps can improve pain relief ratings for patients with cancer and identify which modules increase the app's effectiveness for managing pain.

Methods

Literature Search

Eligible studies were identified by searching Medline, Embase, Cochrane, CINAHL, psycINFO, and other relevant databases, and the results were combined using the literature traceability method. Searches were conducted on August 1, 2019. Search keywords included "cancer pain+," "cancer pain management+," "mobile phone," "+," "Mobile Devices," "Mobile Apps," and "mHealth." Search strategies are detailed in Multimedia Appendix 1. Only articles written in English were considered. There were no restrictions regarding publication date.

Inclusion and Exclusion Criteria

Inclusion Criteria

Studies were included when they (1) focused on patients with cancer pain, (2) involved an intervention using apps downloaded and registered on either a mobile phone or computer for the management of cancer pain, (3) used the numeric rating scale to assess pain, (4) included patients that were followed up for more than a week, and (5) reported the results in English.

Exclusion Criteria

Studies were excluded when (1) the study type was a review, model study, literature review, or conference summary; (2) the results of the study used scales other than the numeric rating scale or did not report the pain score; (3) the study intervention was a telephone conversation; or (4) the study was a duplicate report.

Document Screening and Data Extraction

All reference titles and abstracts were initially screened for relevance by two reviewers. Afterward, full-text analysis for eligibility was independently performed by Caiyun Zheng and Lizhu Weng. Disagreements were resolved by discussion and consensus or third-party arbitration.

The required data were extracted by a researcher using a literature data extraction table, and another researcher confirmed the accuracy and authenticity of the data. The extracted content included study information (research topic, author, date), baseline characteristics of the study subjects (sample size, median age), specific details of the app intervention, pain scores for up to 12 months of intervention, and other outcome indicators (quality of life, side effects).

Literature Quality Evaluation

Risk assessment of the included RCTs was performed using the Cochrane risk of bias tool based on the Cochrane Systematic Review Manual's literature evaluation criteria.

Statistical Analysis

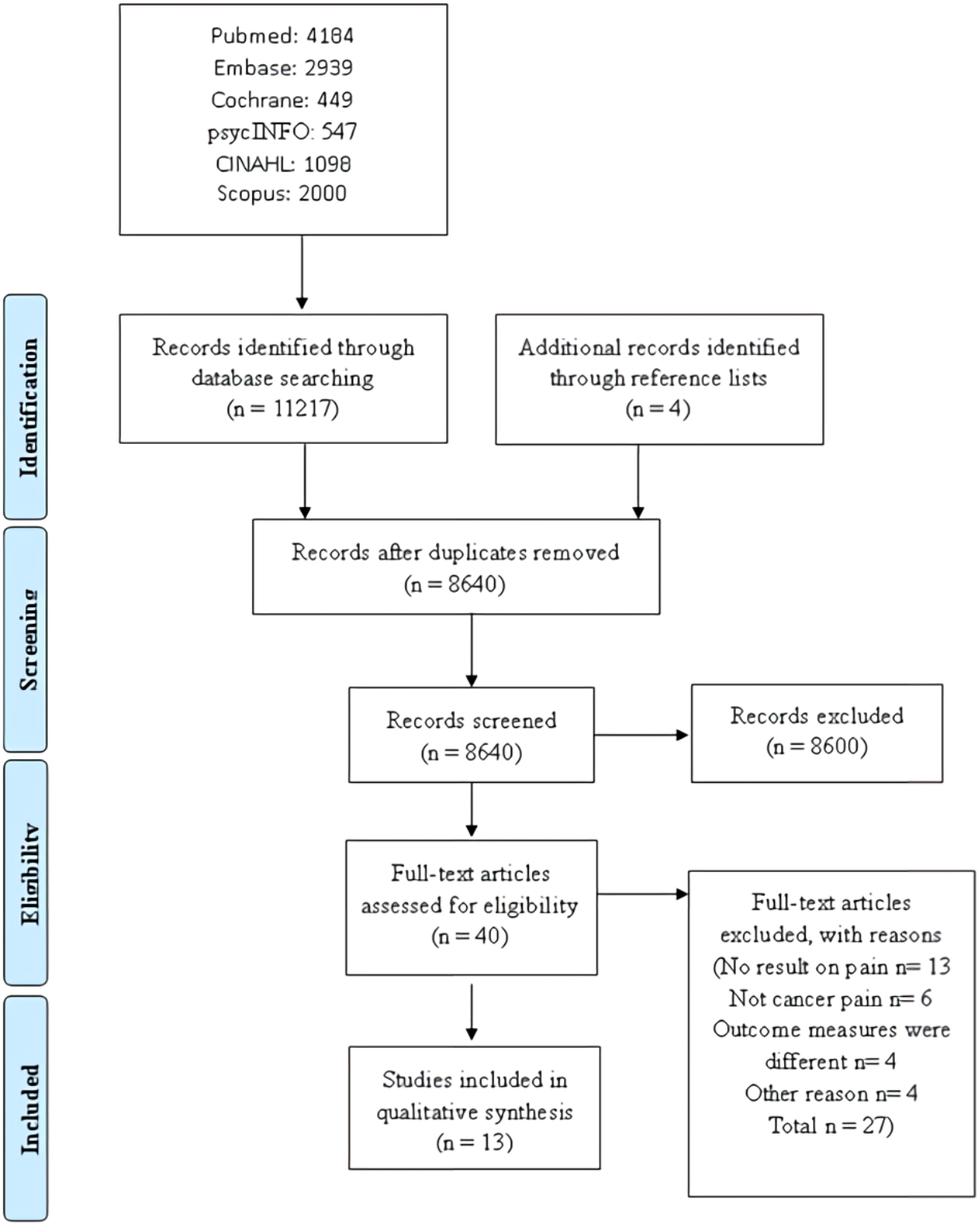
Meta-analysis of RCTs was performed using RevMan5.3 software. Heterogeneity was assessed using the chi-squared test, and quantitative analysis was performed using I^2. Values of $P \geq .05$ and $I^2 \leq 50\%$ were considered to represent no heterogeneity, and a fixed-effect model was used. If $P < .05$ and $I^2 > 50\%$, a random-effects model was used, followed by subgroup analysis to identify the cause of heterogeneity [15].

Results

Search Results

A total of 11,217 articles were retrieved from the systematic literature search, and 4 articles were retrieved by other means, totaling 11,221 articles. After removing duplicate studies, the remaining 8640 were screened. After reading 40 eligible full-text articles, 27 were excluded, and 13 were selected [16-28]. The systematic search results are shown in Figure 1.

Figure 1. Literature screening and selection flow chart.



Basic Characteristics and Quality Evaluation of the Literature

The 5 RCTs included a total of 487 patients: 240 patients in the intervention group and 247 patients in the control group. The remaining studies reported data for 428 patients. General information from the studies is shown in Table 1. The Cochrane systematic evaluation method was used for quality evaluation, and overall, the included literature had a low risk of bias, as shown in Figure 2.

Table 1. Summary of the characteristics of the included studies.

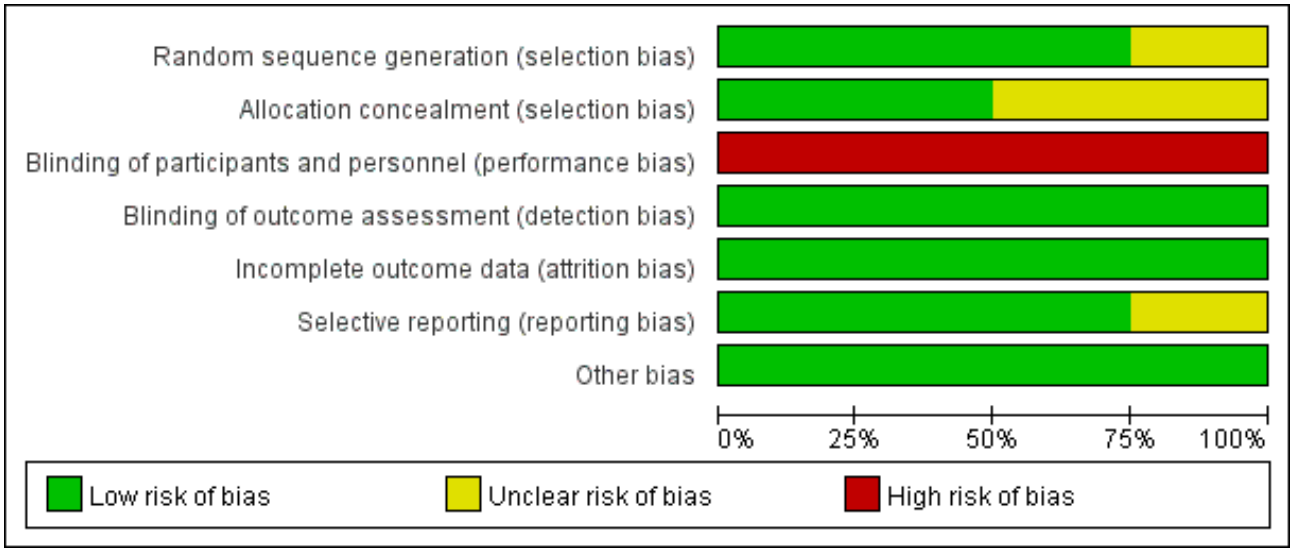
Study	Study design	Number of participants	Follow-up (weeks)	Age (years), mean (SD)	Description of modules within the app	Instant messaging module
Yun, 2012 [17]	RCT[a]	273	12	Unknown	Five modules: self-assessment and graphic reports, health advice and online education, enhanced and short message services, caregiver monitoring and support, monitoring by a health professional	Yes
Somers, 2016 [23]	RCT	23	1	60.00 (11)	Skype	No
Sun, 2017 [21]	RCT	46	2	67.50 (Unknown)	Four modules: life quality self-evaluation, cancer pain self-evaluation, real-time messaging, standard medication	Yes
Smith, 2018 [28]	RCT	87	18	56.70 (8.7)	Four modules: Web-based content, required activities including attending one online introductory group meeting, viewing videos to complete cognitive reframing, mind-body exercises	No
Yang, 2019 [16]	RCT	58	4	52.53 (8.78)	Four modules: pain education, consultation, cancer pain self-evaluation, soothing music	Yes
Somers, 2015 [18]	BAS[b]	25	1	53.88 (12.59)	Videoconferencing on a tablet computer, eg, Skype	No
Jibb, 2017 [24]	BAS	40	4	14.20 (1.7)	Questionnaires, real-time self-management recommendations, email alerts	Yes
Bae, 2017 [26]	BAS	100	4	57.00 (Unknown)	PHR[c] data gathering, PHR gateway, Web service	No
Lengacher, 2017 [25]	BAS	13	6	57.00 (9)	iBooks on an iPad	No
Stinson, 2015 [22]	Prospective, descriptive study	92	2	13.10 (2.9)	Assessment items	No
Oldenmenger, 2017 [27]	Prospective, cohort study	48	6	59.00 (11)	Three modules: a pain diary, eConsult, patient education	Yes
Dorfman, 2018 [19]	Single-arm pilot study	20	Unknown	57.85 (11.72)	Daily access to session content, video clips modeling coping skills, stories about pain experiences from example participants, other materials (eg, relaxation audio)	Yes
Parks, 2019 [20]	Prospective, single-arm study	90	12	55.10 (8.7)	Three modules: to-do list, individual health information, in-app chat service	Yes

[a]RCT: randomized controlled trial.

[b]BAS: before-after study.

[c]PHR: personal health record.

Figure 2. Bias risk map from the Cochrane systematic evaluation method to evaluate the quality of the included randomized control trials.

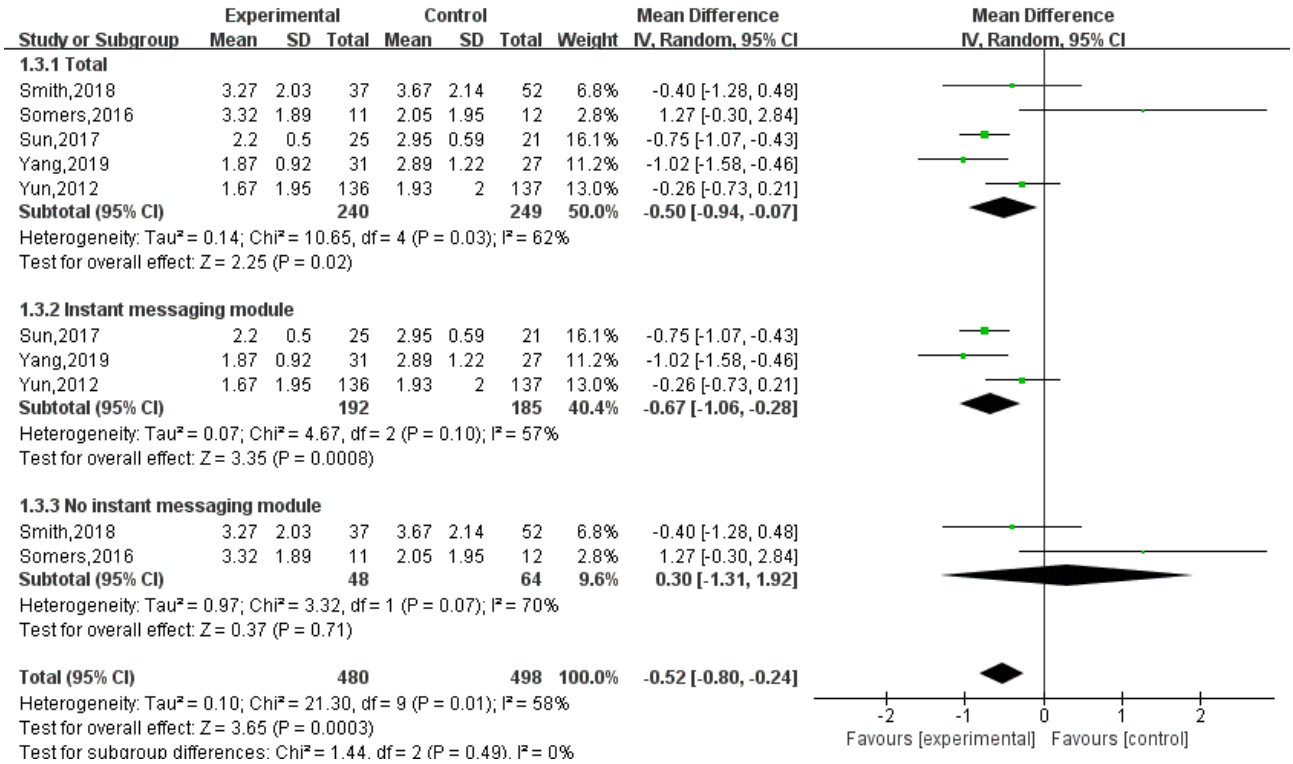


Meta-Analysis

Pain Relief Rating

A random-effects analysis model was used for the meta-analysis of the RCTs. The pain scores of the intervention group were lower than those of the control group (mean difference [MD]=–0.50, 95% CI –0.94 to –0.07, I^2=62%, *P*=.02). Subgroup analysis was performed for apps with instant messaging modules. Instant messaging modules are a channel for real-time communication between patients and medical staff. Patients who used apps with instant messaging modules had lower pain scores (MD=–0.67, 95% CI –1.06 to –0.28, I^2=57%, *P*<.01) than patients who used apps without an instant messaging module (MD=0.30, 95% CI –1.31 to 1.92, I^2=70%, *P*=.71; Figure 3).

Figure 3. Subgroup analysis of the effects of apps with instant messaging modules on pain in patients with cancer.



Sensitivity Analysis Results

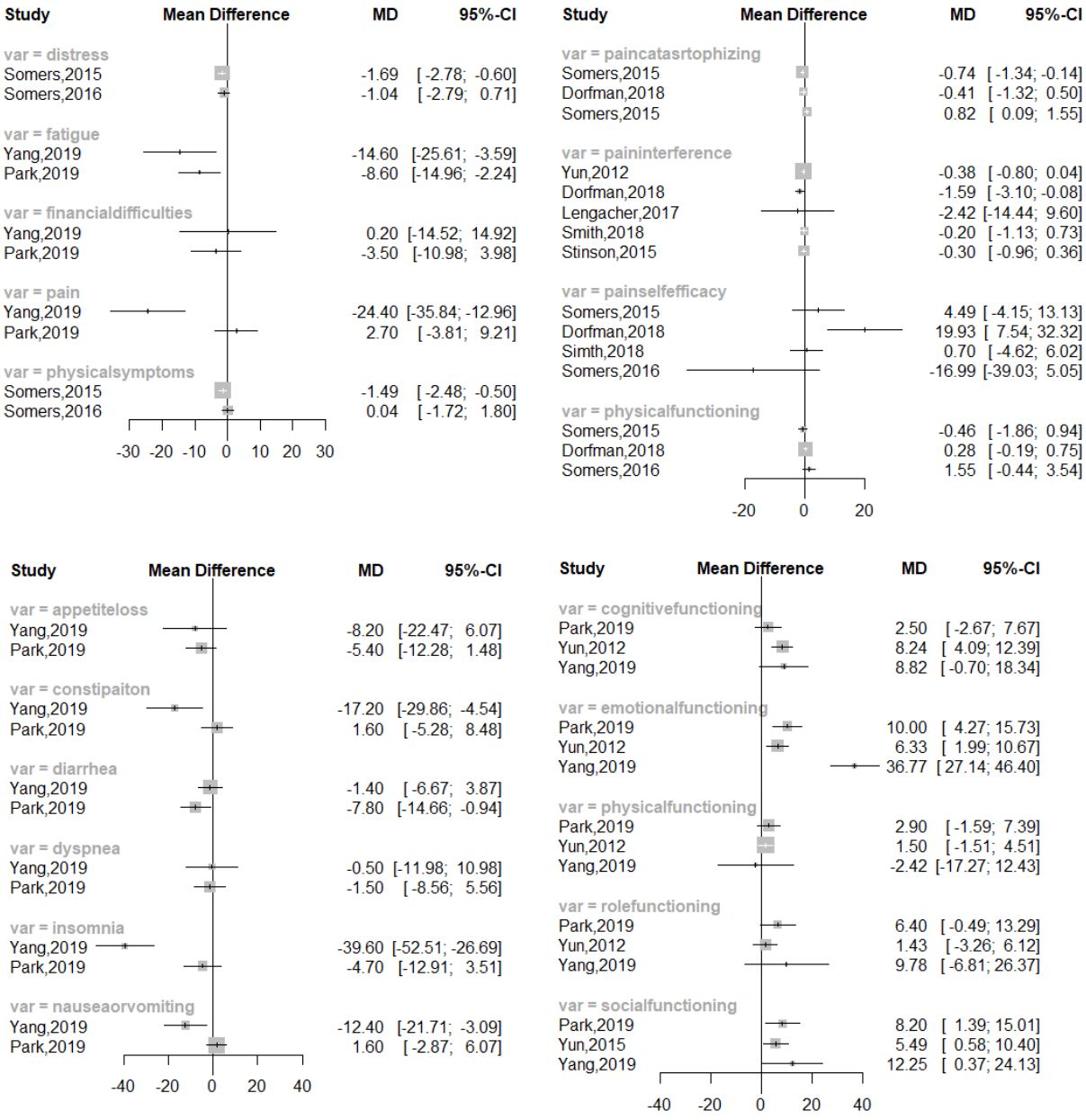
The data were analyzed with the fixed- and random-effects model, and the consistency of these results reflects the reliability of the combined results to some extent. The two effect models were used to analyze the combined effect of each risk factor and calculate 95% CIs. The results were similar, indicating that the results of this study are stable.

Impact of Apps on Other Outcomes

Two studies reported that the number of side effects in patients using apps is statistically significantly lower than in the control

group, whereas Bae et al reported no reduction in the number of adverse reactions [16,26]. All studies evaluating changes in quality of life and anxiety showed significant improvement in groups using apps [16,17,20,25,28]. In addition, in 3 studies, pain catastrophizing was lower, and pain self-efficacy was higher in the intervention group when compared to the control group [18,23]. However, Smith et al [28] reported no significant difference in pain catastrophizing or self-efficacy between the intervention and control groups, only a significant improvement in fatigue. Seven studies reported high levels of satisfaction with the ease of use of the app [16,18,20,21,25,28], and 5 studies showed that patients using apps had a higher intervention completion rate [18-20,25,28]. We created a forest plot to show the effects of apps on other outcomes (Figure 4). Most of the studies had no significant differences in results, apart from those for fatigue, emotional functioning, and social functioning.

Figure 4. Forest plot of the effect of app use on other cancer-related outcomes.



Discussion

Principal Findings

The purpose of our study was to assess the effectiveness of apps for pain management in patients with cancer and to explore which modules influence pain relief ratings. A total of 13 studies were included in this study, and most of the studies reported that pain apps are effective. Patients who use the apps have less pain than patients who do not use the apps. Other results, such as quality of life, pain catastrophizing, and pain self-efficacy, significantly improved in patients using apps. Due to the lack of reported data and heterogeneity, a synthesis of the other results using statistical methods was not performed.

The apps used to manage cancer pain typically have multiple modules, including common records, training, and real-time feedback. These types of apps can be installed on a computer

or mobile phone or accessed directly from a website. They can effectively teach patients about pain and provide the ability to record pain and provide feedback. To determine which modules have the greatest impact, we further conducted a subgroup analysis of the RCTs, which showed that, the use of an app that has instant messaging modules significantly improves pain relief ratings. Furthermore, the use of an app without instant messaging modules had no significant effect on the pain relief ratings of patients with cancer. Therefore, instant messaging modules in apps may be a key factor for pain relief. This may be because the patient can report their condition to the medical staff in a timely manner.

When using an app with an instant messaging module, patients with cancer can notify doctors or pharmacists of a pain outbreak or persistent pain, allowing pharmacists or doctors to intervene in real time. Additionally, a physician can give advice on the dosage of prescribed medication, manage the patient's pain and adverse drug reactions in real time, or recommend that the patient see a doctor immediately, thereby improving compliance with pain treatment and pain relief ratings [27,29]. A pharmacist can relieve stress by discussing how the patient is feeling or suggesting suitable alternative pain management methods. Studies have shown that yoga, proper exercise, or listening to soothing music can relieve pain [30,31]. These activities effectively allow patients to control their pain outside the hospital setting without panic or confusion [32]. Therefore, an instant messaging module could provide patients with both technical support and a sense of security when outside the hospital, which is an important part of pain management apps.

Limitations

There are some limitations to our study. The included literature had relatively small sample sizes and varying follow-up times, some as short as 14 days. Despite these limitations, this study is the first to comprehensively analyze the effect of app modules on the ability of the app to effectively intervene. Therefore, larger samples and longer clinical RCTs are needed to further evaluate the impact of app intervention on pain relief ratings.

Comparison With Prior Work

To the best of our knowledge, this is the first systematic review of the effectiveness of mobile apps for pain management in cancer patients. In published systematic reviews, the evaluation of the effects of apps focus on other chronic pain [6,13,33,34] or explore the impact of an app on quality of life and other symptoms for a single cancer type. They generally provide qualitative descriptions without an assessment of the overall effectiveness of the app as a tool for managing pain. These studies have also not identified which app modules are critical for the effectiveness of the app-based intervention [2,35].

The authors of 3 previous reviews reported that apps were not effective for the following reasons: The participation of health care workers was too low, the apps could not find resources in the online store, and the apps that could be downloaded did not pass scientific verification [14,36,37]. Rincon et al [2] pointed out that strict clinical trials are lacking for most apps. Three other reviews assessed multiple app types, which cannot quantitatively analyze the overall effectiveness of the apps on pain [35,38,39]. Martorella et al [38] and Fridriksdottir et al [39] studied the effects of multiple intervention types on pain, with a variety of intervention models, mainly based on the network that includes the app. Thurnheer et al [12] studied the benefits of an app for chronic pain. Of the 15 studies, 4 included in-hospital management, and 11 involved out-of-hospital management. Most preliminary reports suggest that an app is beneficial for relieving pain in patients, but all require additional scientific verification and analysis to determine which module is key for improving usability [12]. Silva et al [33] studied the effectiveness of self-management via an app for improving pain, psychological distress, fatigue, and sleep in cancer survivors. Only 6 studies were included, and the quality of the included literature was poor. Only 2 studies reported that the intervention group had a lower mean pain score at follow-up, but neither result reached statistical significance [33].

Other studies that did not meet our inclusion criteria (eg, studies that included patients with non-cancer pain and studies of different types) showed similar results to the studies included in our analysis. Schatz et al [40] used smartphone-based cognitive-behavioral therapy in children with sickle cell disease. The results suggested that smartphone-supported cognitive-behavioral therapy coping methods can reduce pain intensity in children with sickle cell disease. Sundberg et al [41] used an interactive smartphone app (Interaktor, Health Navigator, Sweden) to detect and treat symptoms during early prostate cancer radiotherapy, and the intervention group had significantly lower levels of fatigue and nausea at the end of radiotherapy. Therefore, it is an effective mobile health tool to promote supportive care during cancer treatment. Uhm et al [42] studied breast cancer patients using mobile health smartphone apps and pedometers, which resulted in greater improvements in quality of life than with traditional exercise manuals.

Conclusions

This study found that patients with cancer might benefit from the use of apps for cancer pain management, especially those with instant messaging modules, which can reduce pain scores in cancer patients. Patient acceptance of these apps is high. At the same time, the app has a palliative effect on patients' cancer pain and other cancer-related symptoms. Pain management apps with instant messaging modules provide the ability to connect patients and medical professionals with a convenient learning channel, especially in outpatient clinics and for patients living in remote areas with less access to doctors and medical support. Therefore, the findings of this study can guide the development of cancer pain apps, help optimize app modules, and narrow the gap between doctors and patients to achieve better control of cancer-related pain.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy to find literature on the use of apps for cancer pain management and interventions.
[DOCX File , 20 KB - mhealth_v8i1e17055_app1.docx]

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Abbreviations

BAS: before-after study
MD: mean difference
PHR: personal health record
RCT: randomized controlled trial

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Original Paper

Mobile Clinical Decision Tools Among Emergency Department Clinicians: Web-Based Survey and Analytic Data for Evaluation of The Ottawa Rules App

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Abstract

Background: The Canadian CT Head Rule (CCHR), the Canadian Transient Ischemic Attack (TIA) Score, and the Subarachnoid Hemorrhage (SAH) Rule have all previously demonstrated the potential to significantly standardize care and improve the management of patients in emergency departments (EDs). On the basis of user feedback, we believe that the addition of these rules to the *Ottawa Rules App* has the potential to increase the app's usability and user acceptability.

Objective: This study aimed to evaluate the perceived usefulness, acceptability, and uptake of the enhanced *Ottawa Rules App* (which now includes CCHR, TIA, and SAH Rules) among ED clinicians (medical students, residents, nurses, and physicians).

Methods: The enhanced *Ottawa Rules App* was publicly released for free on iOS and Android operating systems in November 2018. This study was conducted across 2 tertiary EDs in Ottawa, Canada. Posters, direct enrollment, snowball sampling, and emails were used for study recruitment. A 24-question Web-based survey was administered to participants via email, and this was used to determine user acceptability of the app and Technology Readiness Index (TRI) scores. In-app user analytics were collected to track user behavior, such as the number of app sessions, length of app sessions, frequency of rule use, and the date app was first opened.

Results: A total of 77 ED clinicians completed the study, including 34 nurses, 12 residents, 14 physicians, and 17 medical students completing ED rotations. The median TRI score for this group was 3.38, indicating a higher than average propensity to embrace and adopt new technologies to accomplish goals in their work or daily lives. The majority of respondents agreed or strongly agreed that the app helped participants accurately carry out the clinical rules (56/77, 73%) and that they would recommend this app to their colleagues (64/77, 83%). Feedback from study participants suggested further expansion of the app—more clinical decision rules (CDRs) and different versions of the app tailored to the clinician role. Analysis and comparison of Google Analytics data and in-app data revealed similar usage behavior among study-enrolled users and all app users globally.

Conclusions: This study provides evidence that using the *Ottawa Rules App* (version 3.0.2) to improve and guide patient care would be feasible and widely accepted. The ability to verify self-reported user data (via a Web-based survey) against server analytics data is a notable strength of this study. Participants' continued app use and request for the addition of more CDRs warrant the further development of this app and call for additional studies to evaluate its feasibility and usability in different settings as well as assessment of clinical impact.

(JMIR Mhealth Uhealth 2020;8(1):e15503) doi:10.2196/15503

KEYWORDS

emergency departments; mHealth; clinical prediction rule; decision aids

Introduction

Background

Clinical decision rules (CDRs) are useful tools in emergency departments (EDs) as they can objectively guide clinicians in making critical decisions regarding patient care. There is evidence that the appropriate application of CDRs can aid in standardization of practice and improve patient care, leading to a reduction in ED wait times and significant health cost savings [1-3]. These findings, combined with the growing ubiquity of mobile phone technology in health care settings [4], have provided clinicians with a means of improving patient care by rapidly and easily accessing CDRs and reducing health care costs. Our previous work to make CDRs more accessible by developing the *Ottawa Rules App* was evaluated in phase I of the *Ottawa Rules Study* [5]. Phase I work was centered around development and evaluation of the *Ottawa Rules App (version 1.0.0)*, which housed 3 validated ED clinical rules—The Ottawa Knee Rule [6], Ottawa Ankle Rules [7], and Canadian C-Spine Rule [8], collectively known as The Ottawa Rules. *The Ottawa Rules App (version 1.0.0)* was well received; it was found to be helpful in applying the rules, and the large majority of participants would recommend the app to colleagues.

Objectives

Phase I user feedback indicated that that the addition of The Canadian CT Head Rule (CCHR) [9], the new Canadian Transient Ischemic Attack (TIA) Score, and Subarachnoid Hemorrhage (SAH) Rule [10] to the app had the potential to increase the app's usability and user acceptability. These rules have previously demonstrated the potential to significantly standardize care and improve the management of patients in EDs [9] and thus further reduce unnecessary radiographic imaging at The Ottawa Hospital (TOH) and beyond. In this study, we sought to develop and add the CCHR, TIA Score, and SAH rules for use in the app, as well as evaluate the enhanced app.

The Ottawa Rules Study: Phase II aims to pilot *The Ottawa Rules App* (Version 3.0.2) among ED clinicians (physicians, residents, nurses, and medical students) at TOH in Ottawa, Canada, and evaluate the perceived usefulness, acceptability, and uptake of the enhanced *Ottawa Rules App* (version 3.0.2).

Methods

Mobile App Improvements

Primary development of the CCHR, TIA Score, and SAH rules for use in the *Ottawa Rules App* (Version 3.0.2) was completed in the middle of 2018. The enhanced app underwent internal user testing and iteration among a small group of ED physicians before the app's public release. The app's mechanism for feedback and user support, where users were permitted to provide suggestions for app improvements, to report bugs, and to request for technical assistance remained unchanged from phase I [5]. The final enhanced version of the *Ottawa Rules App* (version 3.0.2), which was used for this study, added CCHR, TIA Score, SAH rules, and new user interactive features and updated Nursing Directives. This version was completed in November 2018.

App Release and Promotion

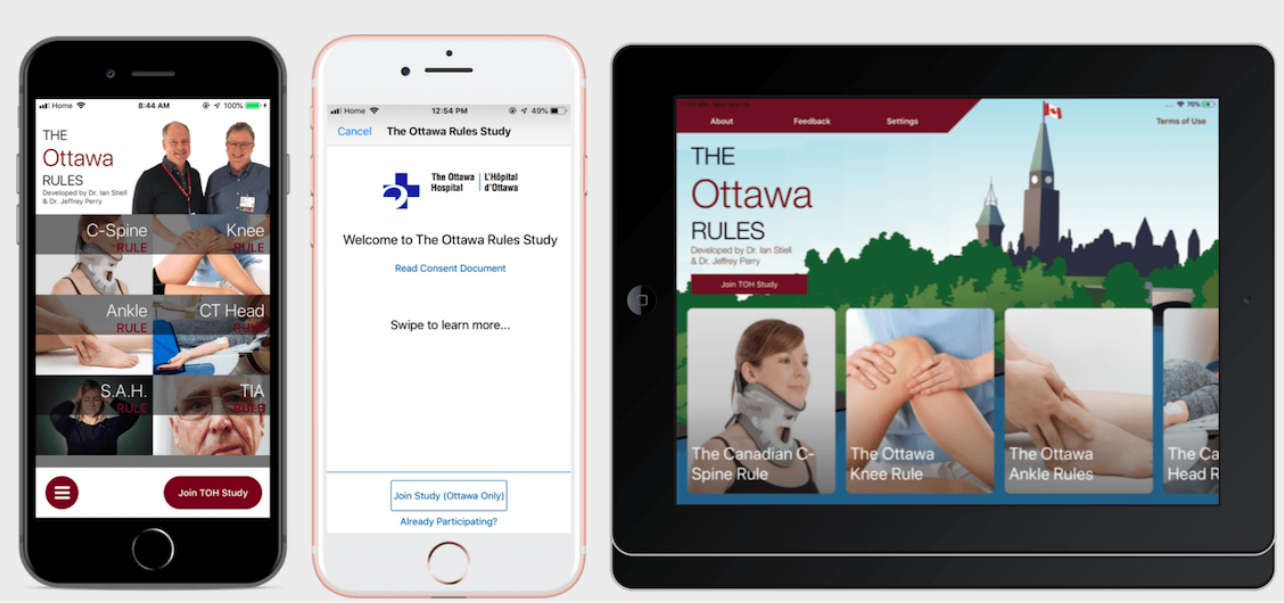
The enhanced *Ottawa Rules App* (version 3.0.2) was publicly released for iOS devices via the App Store, for Android devices via Google Play, through TOH Research Institute (OHRI) app portal, and on the Ottawa Rules website [1]. On the basis of the success of the phase I app release and its associated promotional activities, the enhanced *Ottawa Rules App* was promoted through institutional, local, and national channels. Institutional emails were circulated to all ED medical students, residents, nurses, and physicians, and the app's public release was featured in the weekly TOH news release, "What's Happening." Additional promotional efforts were made across social media channels, including Twitter and Facebook.

Study Enrollment

During the enrollment period (November 15, 2018-May 15, 2019), various recruitment strategies were used to enroll participants from the 2 campuses (Civic and General) that comprise TOH. These strategies included posters, direct enrollment (study coordinators approaching eligible ED clinicians during work hours), snowball sampling, and emails. Study inclusion criteria were as follows: above 18 years of age, working as a clinician (medical student, resident, nurse, or physician) or be on rotation in a TOH ED, possess an institutional email (TOH, OHRI, or University of Ottawa email address), and own a personal or institutional iOS or Android smartphone onto which they could download the enhanced *Ottawa Rules App* (version 3.0.2).

Individuals' study eligibility was assessed as part of the in-app informed consent process. Figure 1 provides screenshots of the *Ottawa Rules App* (version 3.0.2) landing page where the "TOH Study" button would then consecutively lead participants through study information screens and study enrollment and consent forms. Consenting participants then had to verify their institutional email by clicking a verification link sent to the institutional email provided, before being enrolled. Individuals who did not meet the study inclusion criteria were notified as such and were unable to move further through the enrollment process. Participants had in-app access to the consent documents and contact information of study staff throughout the duration of the study. The Ottawa Health Research Network Research Ethic Board (#20150405-01H) approved the study.

Figure 1. The *Ottawa Rules App* (Version 3.0.2) interfaces on iOS. The Ottawa Rules is available as a free download for mobile and tablet devices. A 'TOH Study' button was available on the app homepage for interested participants who were then prompted to review an in-app consent document before enrolment.



Data Collection

The methodology used to collect in-app analytics and user evaluation of the app did not differ much from phase I of *The Ottawa Rules Study.* In brief, user analytics (ie, number of app sessions, frequency of rule use, and the date the app was first opened) were collected and encrypted instantaneously before being sent to a secure cloud server in Canada, administrated by TOH mobile health Lab at OHRI. Feasibility, perceived user acceptability, and usability of the app were evaluated 1-month postenrollment via a Web-based survey. The survey was sent to participants' verified institutional email and comprised 3 multiple-choice, 20 5-point Likert scale, and 2 open-ended questions. The Web-based survey used for this study can be viewed in Multimedia Appendix 1. Participants who completed the 1-month poststudy survey received an electronic coffee gift card worth Can $10 (US $8), the same amount as phase I. To assess participants' "propensity to embrace and use cutting-edge technologies for accomplishing goals in home, life and at work," the Technology Readiness Index (TRI) 2.0 was administered in the second half of the Web-based survey (Questions 10-25) [11].

Google Analytics (GA) was also used to obtain app usage statistics and understand how users globally utilize the *Ottawa Rules App* (version 3.0.2). GA's behavior flow feature also allowed us to track and visualize the path users traveled through the app—from the home page to the rules or other TOH resources. Having GA data (external data), in-app analytic data, and survey data (internal data) allowed for data triangulation [12]. This comparison was used to establish degree of compatibility and generalizability of results.

Results

Participants

A total of 132 participants from the 2 TOH campuses (Civic and General) met the eligibility criteria and provided electronic consent to join the study (Figure 2). Study participants were excluded from the final study cohort if they did not submit the 1-month poststudy survey or if their survey was incomplete. The final study cohort comprised 77 participants (Figure 1). Nurses constituted the largest proportion of study participants (34/77, 44%), followed by physicians (14/77, 18%), medical students (17/77, 22%), and residents (12/77, 16%). Participant characteristics are summarized in Table 1.

Figure 2. Study flow diagram.

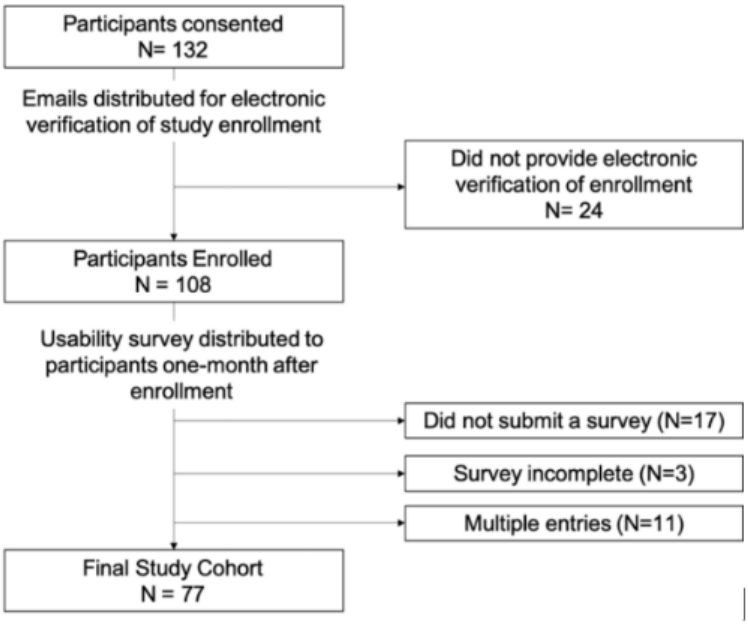


Table 1. Descriptive characteristics of survey respondents (N=77).

Characteristics	Respondents
Level of training, n (%)	
Medical student	17 (22)
Nurse	34 (44)
Physician	14 (18)
Resident	12 (16)
Age range (years), n (%)	
18-24	10 (13)
25-34	41 (53)
35-44	17 (22)
45-54	7 (9)
55-64	2 (3)
Years of service, n (%)	
<1	12 (16)
1-5	42 (55)
6-10	11 (14)
11-15	5 (7)
16-20	2 (3)
≥21	5 (7)
Sex, n (%)	
Female	51 (66)
Male	26 (35)

Usability Survey

A total of 72% (56/77) of the participants agreed or strongly agreed that the app helped participants accurately carry out the clinical rules, and more than 75% (58/77) of the participants agreed or strongly agreed that they would recommend this app to their colleagues. In addition, 84% (65/77) of the participants agreed or strongly agreed that they would continue using the app. More than half, 55% (42/77), of the study participants reported that they used the app weekly, 34% (26/77) of the

participants said they used the app monthly, 3% (2/77) of the participants said they used the app daily, and 9% (7/77) of the participants said they never used the app. Only 1% (1/77) users reported difficulty using the app. Although there was favorable reception of the app by ED clinicians, only 39% (30/77) of the participants agreed or strongly agreed that they used the app for the majority of the cases that required use of the clinical rules. The C-Spine rule was reported as the most useful rule by users. See Multimedia Appendix 1 for full survey results.

Participants provided numerous positive comments regarding the usability of the *Ottawa Rules App (*Version 3.0.2), and they generally had little difficulty using the app. A participant commented, "Just keep on expanding the app as more CDRs arise." Participants liked the app and several of them suggested that the app should be built into "Epic," TOH's "1 patient-1 record" electronic health information system. Being able to quickly move through the rule inclusion and exclusion checklist and recommended clinical strategies was beneficial and described as "[This app is] perfect for triage nurses." Participants also reported that the app could be beneficial for those who are still learning the rules. For example, a participant mentioned, "Great for teaching. Consider pushing the app out to learners" and another said, "…as a new medical student it was convenient and comforting to have that information at my fingertips." Users also suggested that rule feedback should be modified, as they found it to be more physician focused; a nurse explained "…nursing cannot order a CT, we are most interested in whether the patient needs a collar or not. Using the app with a colleague the other day, once I reworded it for her as 'can we say that the patient is unlikely to have an injury (no collar) or are they likely and will need a CT to make the diagnosis (collar)?."

Technology Readiness Index

As part of the survey, we also measured participants' innate propensity to adopt and utilize a new technology to achieve a goal at home or in their work life by using the TRI 2.0 [11]. The mean TRI score among the final study cohort was 3.38 (IQR 0.69, SD 0.47) on a 1 to 5 scale. The mean overall TRI score of the US population was reported as 3.02 in 2014 [11]; thus, our study participants demonstrated relatively higher than average propensity to embrace/adopt new technologies to accomplish goals in their work or daily lives. A Pearson chi-square test revealed significant correlation (χ^2_{104}=12.4, *P*=.42) between TRI scores and participant age, with younger participants having higher scores.

In-App Activity

Over 7 months, study-enrolled participants accessed the app 489 times. Most participants returned to the app multiple times over the 8-month period: 40% (31/77) of the participants used the app on between 2 and 4 days, and 14% (11/77) of the participants used the app on 5 or more days. Server data showed that some participants did not engage with any specific app features—15 participants (15/77, 19%) did not venture beyond the home screen, which is slightly higher than self-reported nonuse. The newly added rules (CCHR, TIA score and SAH rules) were collectively accessed a total of 197 times (40% of total app uses). Participants' app engagement stratified by content accessed and clinician role is presented in Table 2. Nurses were the most active users; they accounted for 44% of all users and 37% of all app uses.

Table 2. Study user app engagement stratified by content accessed and clinician role.

Rules	All clinicians, n (%)	Students, n (%)	Residents, n (%)	Nurses, n (%)	Physicians, n (%)
All Rules Total	489 (100)	120 (24.5)	110 (22.5)	181 (37.0)	78 (16.0)
The Ottawa Rules Total	187 (100)	51 (27.3)	41 (21.9)	71 (38.0)	24 (12.8)
Ankle Rules	63 (33.7)	13 (20.6)	11 (17.4)	34 (53.9)	5 (7.9)
Knee Rule	42 (62.7)	17 (40.4)	7 (16.6)	12 (28.6)	6 (14.3)
C-Spine Rules	82 (43.9)	21 (25.6)	23 (28.0)	25 (30.5)	13 (15.6)
Newly added rules Total	197 (100)	51 (25.9)	51 (25.9)	52 (26.4)	43 (21.8)
Canadian CT Head Rule	89 (45.2)	23 (25.8)	27 (30.3)	18 (20.2)	21 (23.6)
Transient Ischemic Attack	48 (24.4)	9 (18.8)	6 (12.5)	15 (31.3)	18 (37.5)
Subarachnoid Hemorrhage Rule	60 (30.5	19 (31.7)	18 (30.0)	19 (31.7)	4 (6.7)
Other TOH resources[a]	105 (100)	18 (17.1)	18 (17.1)	58 (55.2)	11 (10.5)

[a]Refers to the Ottawa Hospital (TOH) nursing directives, antibiotic guidelines, and triage algorithms.

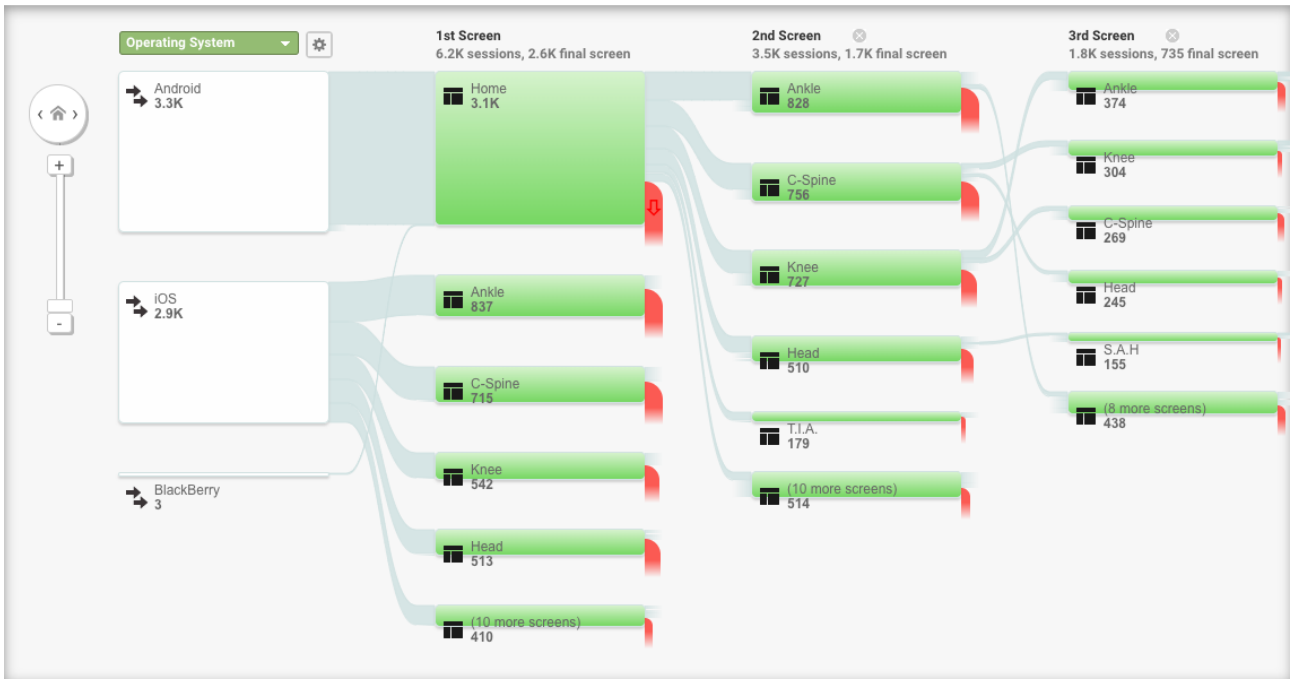
Triangulation With Google Analytics Data (Global App Use)

GA was used to obtain app usage statistics and understand how all users utilized the *Ottawa Rules App* (Version 3.0.2) during the study period (Figure 3). Aggregated app usage data among all users between November 15, 2018, and May 1, 2019, were retrieved. During this time, 48,349 app sessions were recorded among 42,225 app users. A large majority of users, 94.5% (40,096/42,225), are based in the United States. The app was visited by a minimum of 44 users and a maximum of 669 users per day, with a minimum of 45 sessions and a maximum of 695 sessions per day. The average app session length was 59 seconds.

In-app data revealed that among study-enrolled users, CCHR, C-Spine, SAH Rule, and Ankle rules (in order of most use) were the most frequently accessed rules on the app (Table 2). GA

data revealed similar usage trends among users globally—the Ankle, C-Spine, Knee, and CCHR rules were the most frequently used rules.

Figure 3. Behaviour flow diagram stratified by user operating system.



Discussion

Principal Findings

This study generated evidence on acceptability and feasibility of operationalization of a CDR app, the *Ottawa Rules App* (version 3.0.2), among ED clinicians to guide patient care. Quantitative and qualitative findings suggest that participants believed the app facilitated accurate use of the CDRs. Whether participants used the app for the majority of their cases where the CDRs were applicable is unclear. Overall, survey data suggest that the app was useful in guiding clinical decision making, and it is a tool that clinicians would use in the future and would recommend to colleagues. These findings are consistent with the positive reception and usage patterns reported in phase I [5]. Analysis and comparison of GA data and in-app data revealed similar usage behavior among study-enrolled users and all app users globally. The addition of the CCHR, TIA, and SAH rules to the app proved to be beneficial, as these rules were collectively accessed just as much as the Ottawa Rules (Table 2).

The wide adoption of smartphones by health care professionals for use in medical practice has been widely documented in recent years [13]. Implementation studies have demonstrated that the use of CDRs in the ED can result in a relative reduction of radiography for ankle, knee, and cervical spine injuries [14] by 26.4%, 26%, and 15.5%, respectively [15,16]. Uptake and implementation of CDRs has been less optimal, but mobile apps provide a unique opportunity to increase and improve CDR use by facilitating access. This study demonstrated feasibility and acceptability of using a mobile app to access and use 6 validated CDRs. Our findings are consistent with previous studies that have shown that smartphone-based apps are an acceptable and effective modality for quickly and easily accessing electronic resources to support and guide patient care [17,18]. The ability to verify self-reported user data (via Web-based survey) against server analytics data is a notable strength of this study. In addition, global app usage as monitored by GA demonstrates some generalizability. Our methodology and findings add to a growing body of literature on how evaluation and validation of smartphone apps for medical care provider use can be done [19,20].

Limitations

This study has some limitations. First, as with many studies of this nature, limitations related to generalizability exist. The use of GA data to demonstrate similar app usage trends compared with our analysis and in-app data partially addresses this issue. Further work comparing the usage data between the hospital users and the global users could further address the issue of generalizability; however, hospital users only make up about 0.5% of all users worldwide. Second, response bias, as well as familiarity bias, may exist, as all the rules housed in the piloted version of the app were developed by clinicians at TOH, and clinicians who participated in this study may have also participated in phase I piloting. To overcome these biases, future work to evaluate feasibility and acceptability of the *Ottawa Rules App* (version 3.0.2) should be done externally among clinicians who are less likely to be familiar with the CDRs housed in the app. Given the well-documented impact of CDR use and potential for cost savings, improving CDR accessibility is important. Mobile technology offers the opportunity to facilitate access and use of CDRs; this study demonstrates that this is feasible. Future research should weigh the potential advantages of integrating CDRs into electronic medical record (EMR) systems and adding more CDRs to the app. A formal study evaluating the impact of CDR use, facilitated by a mobile app, on clinical care is needed to establish validity. In addition,

more evidence is needed to support whether CDR use in EDs, facilitated by mobile apps, will translate into real reductions in unnecessary diagnostic imaging and health care costs. Future work should explore the use of the app in other settings and its impact on health services utilization and patient outcomes from a system or macro-level perspective. Integration of the digital tool into EMRs may also facilitate use and would be worth evaluating.

This study provides evidence that the use of *Ottawa Rules App* (version 3.0.2) to improve and guide patient care would be feasible and widely accepted. The addition of CCHR, TIA score and SAH rules for use in the app had favorable reception. Participants' continued app use (as reported by the Web-based survey) and demand for the addition of more CDRs warrant the further development of this app and call for additional studies to evaluate its feasibility and usability in different settings. Uptake and implementation of CDRs has not been optimal; this app offers a way to make use of mobile apps to facilitate use of CDRs to standardize patient care in EDs and reduce unnecessary radiographic imaging.

Conflicts of Interest

None declared.

Multimedia Appendix 1
One-month post enrolment usability survey questions and response data.
[DOCX File , 104 KB - mhealth_v8i1e15503_app1.docx]

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Abbreviations

CCHR: Canadian CT Head Rule
CDR: clinical decision rule
ED: emergency department
EMR: electronic medical record
GA: Google Analytics
OHRI: Ottawa Hospital Research Institute
SAH: Subarachnoid Hemorrhage
TIA: Transient Ischemic Attack
TOH: The Ottawa Hospital
TRI: Technology Readiness Index

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Original Paper

A Tablet App Supporting Self-Management for People With Dementia: Explorative Study of Adoption and Use Patterns

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Abstract

Background: Assistive technology (AT) is rapidly emerging within dementia care and support. One area of AT application is support of people with dementia in compensating for cognitive symptoms and thereby promoting their self-management. There is, however, little evidence for the applicability, usability, and effectiveness of AT for people with dementia, and there is a need to identify factors that can promote adoption.

Objective: This study aimed to (1) evaluate the applicability and usability of an app, tailor-made for people with dementia; (2) explore factors affecting adoption; (3) explore the possible influence of caregiver involvement; and (4) contribute to process evaluation of the intervention.

Methods: The ReACT (*Rehabilitation in Alzheimer's disease using Cognitive support Technology*) app was designed as a holistic solution to support memory and structure in daily living. Persons with dementia had access to a personal user account, and family caregivers were given a parallel login. Written and Web-based materials were provided to support self-applied implementation. A mixed methods design was applied to explore adoption and use patterns, including background and disease-related data, qualitative data from a survey, and log data. Adoption was defined as the use of the app over a period of ≥90 days.

Results: Data from 112 participants and 98 caregivers were included. Shorter time from diagnosis (U=595; P=.046; r=0.19) and caregiver activating the app (P=.02) had a significant impact on the participant adoption status. Logistic regression analysis showed that if caregivers had activated the app, the participant was five times more likely to become an adopter (odds ratio 5.1, 95% CI 1.29-19.99; P=.02). However, the overall predictive power was low, and there was a wide variation in background and disease-related characteristics among adopters. The level of experience and skills in tablet use were not significantly different between adopters and nonadopters. Adopters generally rated the app high on usefulness, satisfaction, and ease of use (rated on the USEdem questionnaire). Their scores were significantly higher compared with nonadopters (U=5.5; P=.02; r=0.64). Analysis of use patterns showed that all functionalities of the app were used among adopters.

Conclusions: For participants who became adopters, the ReACT app and the methods for self-applied implementation were applicable. However, the results were also in accordance with the well-known challenges of nonadoption and nonadherence to digital health interventions. The study provided insight into the importance of timely introduction and caregiver support for

adoption of AT among people with dementia. It also underlined the high complexity of personal and contextual factors that influence adoption. These complex factors need to be considered when designing and implementing AT for people with dementia.

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KEYWORDS

dementia; technology; information technology; self-help devices; app; self-management; rehabilitation; memory; caregivers

Introduction

Globally, the number of people living with dementia is increasing rapidly [1], and it is a global concern that in the near future, we may not have enough resources to meet their need for support and care [2]. These challenges call for efficient and flexible solutions, and the progressive digitalization and use of technology are seen as promising solutions [2,3]. In the last decade, there has been a steadily growing emphasis on assistive technology (AT) in dementia care and support, both from the industry, governments, and organizations and in research [4-6]. It is assumed that AT has great potential to support cognition and can be used to compensate for cognitive decline, which is a core symptom across dementia diseases, and thereby promote self-management of people living with dementia [7-9].

AT comprises a variety of solutions, ranging from basic everyday low-technology devices to advanced technology devices [10]. In the field of dementia, AT based on information and communication technology (ICT), such as apps applied on touchscreen devices, has expanded [6]. The focus of this study is ICT-based AT, and for the remainder of the paper, this will be the kind of AT referred to.

The optimism on the potential of AT to support people with dementia is unfortunately not based on strong evidence. There is a great need for research addressing applicability, usability, and effectiveness of AT for people with dementia [8,11,12], and when designing and conducting research within this field, a complex set of preconditions must be considered. First, this field of research is subject to the same challenges as other digital health interventions. The relatively high rate of nonadoption and nonadherence, referred to as *the law of attrition* [13], is a natural and typical feature of digital health interventions in all medical fields [14,15]. Consequently, the pattern of dropout rates in research addressing these kinds of interventions is quite distinct from other types of research, such as drug trials or studies of psychosocial interventions. This requires a different approach to research methodology, for example, by including detailed log data analysis to explore user patterns and analyze characteristics of individuals who successfully adopt and adhere to the technology [13]. Such perspectives and methodologies are often not included in research addressing AT for people with dementia, where more traditional quantitative and qualitative outcome measures have often been applied to assess usability and impact [8]. Another challenge is the progressive cognitive symptoms of dementia diseases that reduce the ability of people with dementia to adopt and adhere to AT. Therefore, it is essential to explore factors (for instance, caregiver support and tailor-made interventions) that can support and promote their adoption and adherence. Consequently, to explore the potential of AT for people with dementia and to provide evidence for specific solutions, study designs have to incorporate these complex preconditions. An essential step is the use of mixed methods when assessing applicability, usability, and effectiveness, including log data analysis.

This paper has presented data from the third substudy of the research project, *Rehabilitation in Alzheimer's disease using Cognitive support Technology* (ReACT). In the first substudy, the ReACT app was created through an iterative user-centered design process [16]. The app was tailor-made to support self-management of people with dementia, mainly by supporting various aspects of prospective and retrospective memory and structuring of daily activities. People with early stage Alzheimer disease were considered the main group of end users during the design phase, and the applicability and usability of the app for people with Alzheimer disease have been investigated in a second substudy [17]. This third substudy was conducted to investigate the applicability and usability of the app in a large mixed cohort of people with dementia, representing various etiologies and backgrounds. To the best of the authors' knowledge, this paper is the first to present detailed data, including an analysis of log data, from a study where AT tailor-made for people with dementia has been disseminated to a large heterogeneous group of people with dementia.

Accordingly, the aims of the study were to (1) investigate the applicability and usability of the ReACT app to a mixed population of people with dementia, (2) investigate user patterns and factors influencing adoption and nonadoption, (3) explore the possible influence of caregiver involvement on participants' adoption of the app, and (4) contribute to process evaluation of the app and methods used for deployment and adoption to guide future adaption of the app and methods of implementation.

Methods

Participants

Participants were recruited from 9 Danish memory clinics. The aim was to recruit a broad variety of people with dementia, and therefore, few inclusion criteria were specified. Participants were eligible if they (1) were patients in the memory clinics, (2) were motivated to try using the app, and (3) had access to a tablet where the app could be installed (iPad). It was not mandatory to have a caregiver as coparticipant, but if they were accompanied by a family caregiver when visiting the clinic, the caregiver was invited as coparticipant. There were no inclusion criteria related to age, language, or other personal or disease-related characteristics, and participants were not required to have had a final diagnosis at the time of inclusion. As the intervention addressed people with dementia as primary participants, they are referred to as participants in this paper, and the coparticipating caregivers are referred to as caregivers.

Information about the study was presented to patients in the memory clinics. Posters and flyers presenting the app and the study were available in waiting areas and introduced by staff. Eligible participants who showed interest in the study were given a detailed oral introduction and additional written material describing the details of the study. Participants and caregivers were then given an opportunity to deliberate before deciding whether to participate in the study.

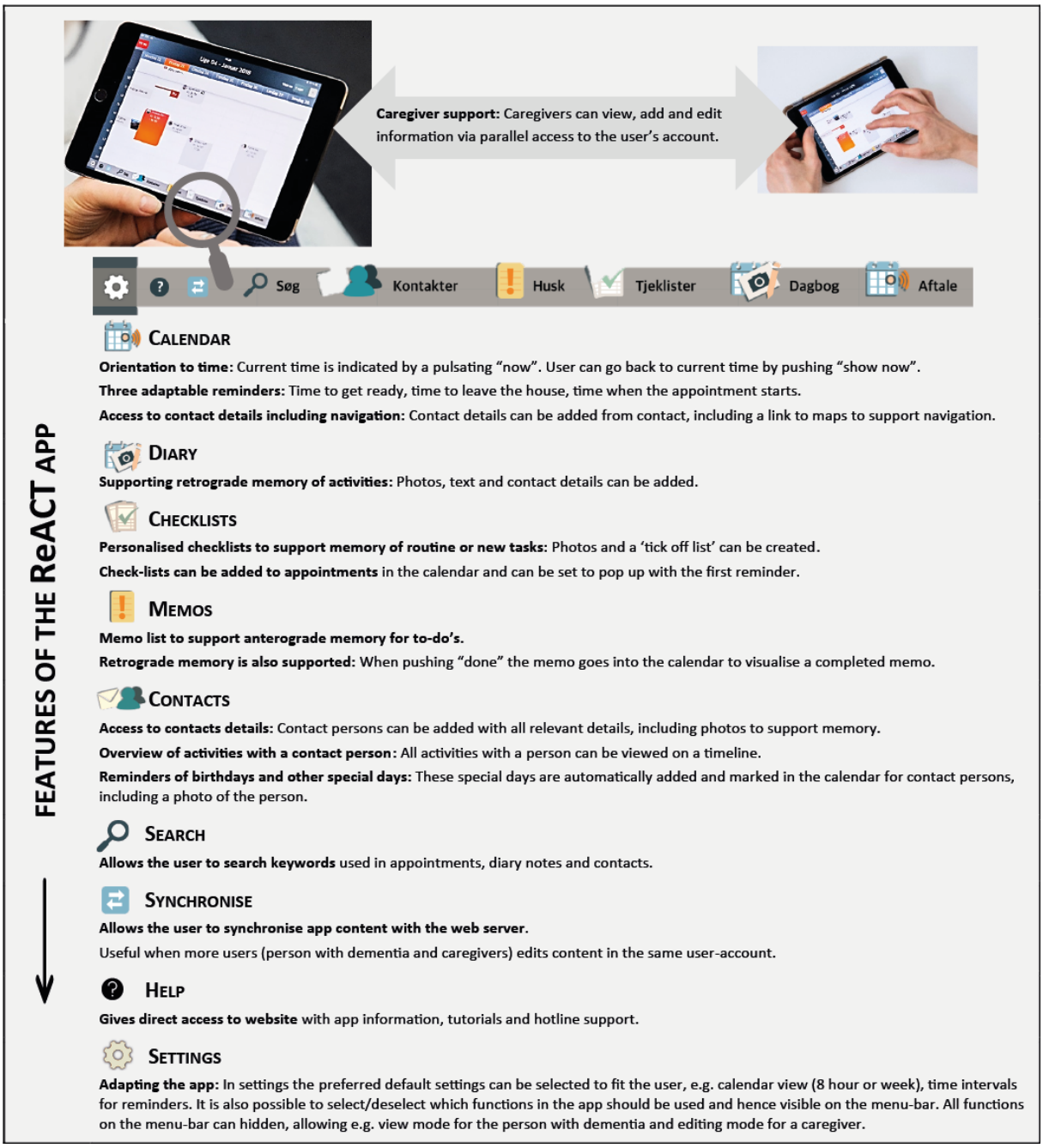
Participants were recruited from June 2017 to February 2018, and during this period, 116 participants and 98 caregivers were enrolled.

The regional scientific ethical committees of the Capital Region of Denmark (protocol number H-15005558) evaluated the study protocol and decided that the study did not need approval because it was not considered to be within the framework of biomedical research. All participants received oral and written information about the study objectives and methods, and all participants gave written informed consent.

Intervention

Participants and caregivers were given access to the ReACT app after being included in the study. The specific features of the ReACT app are illustrated and specified in Figure 1. As described, the app was a holistic solution, comprising a calendar that interacts with other features (eg, diary notes, contacts, checklists, and memos). It was designed as a cloud-based native app for a tablet computer and could be accessed from an iPad.

Figure 1. Features of the ReACT app.



As described in Figure 1, the participants had access to a personal user account, and caregivers could support the use of the app via a parallel login to this account, allowing them to add and edit content. Usernames and access codes were provided separately to participants and caregivers to enable monitoring of log data from both. For data protection, these codes were provided in sealed envelopes to the participant and caregiver, and staff at the memory clinics had no access to this information. In case of need for backup information on usernames and access codes, these could only be provided if a participant or caregiver contacted the principal investigator of the study directly.

Participants and caregivers were provided written material to support their self-applied implementation of the app. This written material had been validated as applicable for a person with early stage dementia during the second substudy of the ReACT research project [17], where people with early stage Alzheimer disease and caregivers were consulted when developing these materials. Two leaflets were provided: one leaflet gave instructions on how to download and activate the ReACT app on a tablet, whereas another leaflet gave a brief introduction to the functionalities of the app and gave advice on how the app could be used in various everyday situations, including how caregivers could support the use of the app. Details on telephone and email hotline support were also included. Hotline support was accessible within working hours throughout the study period.

A help feature was also built into the app, as illustrated in Figure 1. When tapping this icon on the app's menu bar, the user was directed to a website with information, video tutorials, and hotline details.

Assessments

Baseline Characteristics

Demographic information for both participants and caregivers was collected at the time of inclusion. Data included participant's age, gender, and education; caregiver's gender; and the relation between participant and caregiver. In addition, data from participants' medical records were included to document diagnosis, time of diagnosis, and the most recent score on the Mini-Mental State Examination (MMSE) [18], a brief assessment of cognitive function.

Log Data

App usage was monitored through data logs from each participant's and caregiver's use of the app. The log files provided data on participant's and caregiver's actions in the app and provided information on action types and timestamps for these actions. The action types that were logged were activating the app; using adaptive features; and activities related to appointment, diary note, memos, checklist, and search features.

Adoption of the app was defined as a minimum period of 90 days between the first and last use of the app. This criterion was set based on results from the previous substudy [17], showing that a person with early stage dementia could adopt the app and use it independently after a period of 90 days of introduction and familiarizing with it.

Survey

A Web-based survey was conducted to collect additional background information and to collect feedback on the app. It was distributed via email 3 to 4 months after inclusion in the study. In cases where email correspondence was unsuccessful, a printed version of the survey was sent out by mail.

Two versions of the survey were distributed: one for participants and another by-proxy version for caregivers. It was constructed in an adaptable manner, enabling specific questions being directed at those who had used the app and those who had not. The survey included questions with a fixed set of possible answers. For nonusers, the questions addressed the level of skills to use a tablet and reasons for not using the app. For users, the questions addressed methods used when learning how to use the app and the level of skills to use a tablet. Moreover, 2 optional text boxes were also included, allowing additional comments on reasons for not using the app and general feedback on the app. The general feedback mainly addressed specific technical and functional issues of the app, which is not within the scope of this paper.

In those cases where the participant had tried using the app, the USEdem questionnaire [17] was included in the survey, and a by-proxy version was delivered to caregivers. The USEdem questionnaire is a modified version of the Usefulness, Satisfaction, and Ease of Use Questionnaire [19], which was designed to assess usefulness, satisfaction, and ease of use of technology. The USEdem questionnaire was designed and applied in a previous substudy of the ReACT research project [17]. This modified version contains 12 items and was adapted to be applied to people with dementia [17]. Scores on each item range from 1 to 5 on a Likert scale, with a total score between 12 and 60, higher scores indicating higher ratings.

Data Analysis

Quantitative data were analyzed using IBM SPSS Statistics version 22. Baseline characteristics and log data from adopters were explored with descriptive statistics. Possible between-group differences on baseline characteristics, log data, and data from the surveys were analyzed using nonparametric chi-square tests for categorical variables, and for continuous variables, Kruskal-Wallis tests, Mann-Whitney U tests, or Fisher exact tests were used as appropriate. Logistic regression was conducted to explore whether baseline characteristics predicted adoption status.

Tests of significance were performed 2-tailed, with a significance level of .05. Imputed values for missing data on background characteristics were calculated following standard procedures for multiple regression modeling.

Qualitative data from surveys, from the textbox allowing feedback on reasons for not using the app, were processed and summarized in themes, as outlined in constant comparison analysis [20].

Results

Principal Results

Data from 112 participants and 98 caregivers were included in data analysis. No participants or caregivers withdrew their consent to participate in the study, but because of insufficient background information from 4 participants, these were excluded from the original sample of 116 participants.

Log data monitoring the use of the app were collected for all participants and caregivers for a maximum of 90 days; hence, the intervention period for this study was 90 consecutive days after activating the app or 90 days from the inclusion of those who did not activate the app. Additional follow-up data are not within the scope of this paper.

Data from the surveys were obtained from 35 participants and 30 caregivers, and 19 of these cases were overlapping, with a reply from both. Of 35 participants, 14 had support from a caregiver when answering the survey, and in 2 cases, a caregiver had answered the participant survey on behalf of the participant; these 2 were excluded, leaving 33 participant and 30 caregiver replies for data analysis. Included in this were data on the USEdem questionnaire from 14 participants and 9 caregivers from cases where the participant had tried using the app were included.

Participants' Characteristics

The characteristics of participants and caregivers are summarized in Table 1. These data show that participants were quite heterogeneous with regard to age, education level, months since diagnosis, and most recent MMSE score. Most participants had a diagnosis of Alzheimer disease. People with diagnoses of vascular dementia and other less common dementia, such as frontotemporal dementia, were also represented. Those with a diagnosis of mild cognitive impairment were also a part of the participants. A fairly large group of participants were categorized as other and included, for example, participants with an unspecified dementia diagnosis or cognitive symptoms caused by stroke. Gender was almost equally represented, but with a slightly greater proportion of men among participants. A dyad of participants and caregivers were included in 87.5% (98/112) of the cases, and most of these caregivers were spouses.

Table 1. Characteristics of participants and caregivers and differences between adopters and nonadopters.

Characteristics	All participants (N=112)	Adopters[a] (N=18)	Nonadopters[a] (N=94)	*P* value
Age (years), mean (SD; range)	68 (8.8; 39-86)	69 (10; 52-82)	68 (8.6; 39-86)	.86
Gender, n (%)				
Women	49 (43)	9 (50)	40 (43)	.51
Years of education, n (%)				.36
≤10	16 (14)	3 (17)	13 (14)	
11-12	23 (20)	3 (17)	20 (21)	
13-14	25 (22)	2 (11)	23 (25)	
15-16	29 (25)	8 (44)	21 (22)	
≥17	19 (16)	2 (11)	17 (18)	
Diagnosis, n (%)				.29
Alzheimer disease	65 (58)	12 (67)	53 (56)	
Vascular dementia	2 (1)	0	2 (2)	
Dementia with Lewy bodies	1 (0)	1 (6)	0	
Frontotemporal dementia	3 (2)	0	3 (3)	
Mild cognitive impairment	9 (8)	2 (11)	7 (8)	
Other[b]	27 (24)	2 (11)	25 (26)	
Unresolved[c]	5 (4)	1 (6)	4 (4)	
Months since diagnosis, mean (SD; range)	12 (15; 0-73)	6 (7; 0-25)	16 (14; 0-73)	.046
Mini-Mental State Examination score[d], mean (SD; range)	25 (4.2; 11-30)	25 (5; 11-30)	25 (4; 11-30)	.69
Caregiver included, n (%)				
Yes	98 (87)	15 (83)	83 (88)	.70
Caregiver gender, n (%)				
Woman	58 (59)	8 (44)	50 (60)	.78
Caregiver relation, n (%)				.30
Spouse	81 (83)	11 (73)	70 (84)	
Son or daughter	13 (13)	4 (27)	9 (11)	
Other	4 (4)	0	4 (5)	
Caregiver adopter or nonadopter of the app[a], n (%)				
Adopter	7 (6)	3 (17)	4 (4)	.08
Caregiver activated the app[e], n (%)				
Yes	21 (19)	8 (44)	13 (14)	.02

[a]Adoption was defined as the use of the app for ≥90 days.

[b]For example, stroke, Huntington disease, and unspecified dementia diagnosis.

[c]Participants who were not diagnosed at the time of inclusion.

[d]Higher scores indicate higher attainment. The scores on Mini-Mental State Examination (MMSE) are the most recent score documented in the participants' medical record. Data on months between the latest MMSE score and study inclusion showed MMSE were, on average, conducted 9 months before inclusion (SD 10; range 0-47), and 89 (89/112, 79.4%) of the MMSEs were conducted less than 12 months before inclusion.

[e]Includes all levels of caregiver adoption status.

Adoption

The details of adoption status and period of adherence are specified in Table 2, showing that 18 (16%) participants and 7 (7%) of the caregivers became adopters. Overall, 47 (42%) participants and 78 (80%) caregivers never activated the app. However, if adoption status was based only on those who had activated the app, 28% of participants and 35% of caregivers

were adopters. The aim of this study was to explore nonuse, abandonment, and adoption of the app, and therefore, data from the entire population were included in data analysis when applicable.

Caregivers had also activated the app in 44% of the 18 cases where the participants became adopters, and in 3 of these cases, both the participant and caregiver were adopters. In 4 additional cases, the caregiver became adopter without the participant becoming adopter.

As summarized in Table 1, when comparing adopters with nonadopters, results showed that time from diagnosis was significantly lower for adopters (median 4 months) than for nonadopters (median 8 months; U=595; *P*=.046; *r*=0.19). There was also a significant association between participants' adoption status and whether caregivers had activated the app (*P*=.02; FET). There were no significant associations for other characteristics.

An exploratory logistic regression analysis was performed to assess the impact of baseline characteristics and caregiver's app activities on participant adopter status. As shown in Table 3, caregivers having used the app was a significant predictor of a participant's adoption status (odds ratio 5.1, 95% CI 1.29-19.99; *P*=.02). Results indicated that a participant was 5 times more likely to become an adopter when a caregiver had engaged in activating the app.

Data from the survey provided additional information on adopters and nonadopters. As summarized in Table 4, there were no significant differences in either disease-related or background characteristics between participants who replied to the survey and those who did not reply. However, months since diagnosis was close to significance (*P*=.06).

The survey gave opportunity to further explore reasons why participants did not use the app or become an adopter. As outlined in Table 5, there were no significant differences between adopters and nonadopters regarding their level of experience, skills, and need for help when using a tablet, both when rated by the participants and caregivers.

Table 2. Adoption status and period of adherence among participants and caregivers.

Participants and caregivers	Participants (N=112)	Caregivers (N=98)
Adoption status, n (%)		
Never used the app (0 days)	47 (42)	78 (80)
Activated the app, n (%)		
Short use (1-10 days)	19 (17)	7 (7)
Early abandonment (11-31 days)	11 (10)	2 (2)
Late abandonment (32-89 days)	17 (15)	4 (4)
Adopter (≥90 days)	18 (16)	7 (7)

Table 3. Logistic regression: Impact of baseline characteristics and caregiver's app activities on participant adoption status.

Included	Beta (SE)	*P* value	Odds ratio (95% CI)
Participant's age	−.03 (0.03)	.29	0.97 (0.91-1.03)
Participant's gender	−.27 (0.60)	.65	0.76 (0.24-2.47)
Months since diagnosis	−.01 (0.02)	.74	0.99 (0.96-1.03)
Mini-Mental State Examination score	−.09 (0.06)	.17	0.92 (0.81-1.04)
Caregiver adoption status	.13 (1.01)	.90	1.1 (0.16-8.24)
Caregiver activated the app	1.6 (0.70)	.02	5.1 (1.29-19.99)
Constant	2.5 (2.83)	.29	12.4

Table 4. Baseline characteristics of participants who replied to the survey compared with participants who did not reply to the survey.

Characteristics	Participants who replied to survey (N=35)	Participants who did not reply to survey (N=77)	*P* value
Age (years), mean (SD), range	68 (9.7), 52-86	69 (8.5), 39-83	.65
Gender, n (%)			.84
Women	15 (46)	33 (43)	
Years of education, n (%)			.92
≤10	6 (18)	10 (13)	
11-12	6 (18)	16 (21)	
13-14	6 (18)	19 (25)	
15-16	9 (27)	19 (25)	
≥17	6 (18)	13 (17)	
Diagnosis, n (%)			.33
Alzheimer disease	21 (64)	43 (56)	
Vascular dementia	0	2 (3)	
Dementia with Lewy bodies	1 (3)	0 (0)	
Frontotemporal dementia	0	3 (4)	
Mild cognitive impairment	4 (12)	5 (7)	
Other[a]	6 (15)	21 (27)	
Unresolved[b]	2 (6)	3 (4)	
Months since diagnosis, mean (SD), range	9 (12), 0-61	14 (15), 0-73	.06
Mini-Mental State Examination score[c], mean (SD), range	26 (4.1), 11-30	24 (4.4), 11-30	.12

[a]For example, Huntington disease or stroke.

[b]Participants who were not diagnosed at the time of inclusion.

[c]Higher scores indicate higher attainment. The scores on the Mini-Mental State Examination are the most recent scores documented in participants' medical records.

Table 5. Data from survey: participant's and caregiver's rating of the participant's level of experience, skills, and need for help when using a tablet.

Participants' and caregivers' by-proxy rating[a]	Adopter[b]	Nonadopter[b]	*P* value
Participant			
Level of experience as tablet user, n (% within group)			.49
Much experience	2 (15)	5 (28)	
Some experience	7 (54)	5 (28)	
Little experience	1 (8)	4 (22)	
Novel user	3 (23)	4 (22)	
Skills as tablet user, n (% within group)			.15
Uncomplicated	7 (54)	7 (44)	
A little difficult	5 (38)	2 (12)	
Quite difficult	1 (8)	5 (31)	
Very difficult	0	2 (12)	
Help from others when using a tablet, n (% within group)			.54
No help	5 (38)	6 (33)	
A little help	6 (46)	5 (28)	
Some help:	1 (8)	3 (17)	
A lot of help	1 (8)	4 (22)	
Caregiver by-proxy			
Level of experience as a tablet user, n (% within group)			.41
Much experience	3 (38)	4 (19)	
Some experience	3 (38)	7 (33)	
Little experience	1 (12)	7 (33)	
Novel user	1 (12)	3 (14)	
Skills as a tablet user, n (% within group)			.38
Uncomplicated	3 (37)	6 (30)	
A little difficult	3 (37)	3 (15)	
Quite difficult	2 (35)	6 (30)	
Very difficult	0	5 (25)	
Help from others when using a tablet, n (% within group)			.28
No help	2 (25)	3 (14)	
A little help	4 (50)	8 (36)	
Some help	2 (25)	4 (18)	
A lot of help	0	7 (32)	

[a]Ratings cannot be compared between participants and caregivers because participant's and caregiver's rating does not refer to parallel cases.

[b]Answers were not complete to all questions; hence, the total number of answers on each question varied for both participants and caregivers.

In those cases where the app had not been activated by the participant or the person had stopped using it, the survey gave opportunity to comment on reasons for not using or adopting the app. These comments are summarized in themes (Textbox 1). The results indicated that both among participants and caregivers, common reasons were that the app did not fit their needs, some indicated the using the app was too early from the perspective of living with a progressive dementia disease, and others found it too difficult to use. Some indicated that they preferred using standard off-the-shelf software (eg, the calendar app that is preinstalled in the device), and others preferred to continue using a paper diary. Reasons for not using the app were, in some cases, also related to cognitive symptoms caused by the dementia disease (eg, some participants forgot to use the app or had lost the ability to use a tablet), indicating that this kind of AT was introduced too late for the person with a progressive disease.

Textbox 1. Participants' and caregivers' reasons for not using the app.

Theme: participant intends to start using the app

- Participant quotes
  - I want to use the app, I just need to learn how to use it.
  - I will try to install the app.
  - I think I will start using it, the calendar would be nice to have.

Theme: using the app was found premature

- Participant quotes
  - It's not relevant for me...yet.
- Caregiver quotes
  - It was too simple for him
  - I think we will wait until it is the right time to use it.

Theme: participant does not use the app because of dementia symptoms

- Participant quotes
  - I forget to use it.
  - I don't think about using it...I forget.
  - Frankly, I have forgotten that I have ever heard of it.
- Caregiver quotes
  - He is not able to use the iPad anymore.
  - She has opened the app a few times, she but does not understand how to use it. It is too late to introduce it.
  - The problem is my wife forgets to use it.
  - Our dad probably got the app too late.
  - She feels under surveillance when using the app.

Theme: participant prefer to use other technology solutions

- Participant quotes
  - I am happy with the things I use already.
  - I use a computer for e-mails, calendar and things like that...I have an iPad, but I haven't started using it yet.
  - When I read more about what the app could do I realised that I was covered by the things I already use, and I like using the things that I already know.
  - I prefer to use the calendar that is installed on my phone.
  - When I read more about what the app could do I realised that I was covered by the things I already use, and I like using the things that I already know.
  - I prefer to use the calendar that is installed on my phone.
- Caregiver quotes
  - He prefers to use the calendar which is installed on the iPad.

Theme: participant prefer to use nontechnology solutions

- Participant quotes
  - It is easier for me to use a paper diary.
  - I prefer my paper diary.
- Caregiver quotes

- She finds it easier to use an ordinary paper diary.

Use Patterns and Usability

To enable a more detailed analysis of use patterns of those participants who activated the app (N=65), they were split into 4 groups based on the number of days they had been users of the app (number of days from the first to last activity in the app, with a maximum of 90 days): short use (1-10 days), early abandonment (11-31 days), late abandonment (32-90 days), and adopter (≥90 days). These are summarized in Table 2.

The number of activities in the app for the 4 groups of participants who had activated the app is summarized in Figure 2, which illustrates a clear tendency that a longer period of using the app generated more activities in the app; however, there was a large within-group variation.

To further assess if the content of the app was relevant to users or if adaptions were needed, data from adopters were further analyzed. The number of times each functionality was used by a participant or caregiver is illustrated in Figure 3.

Figure 2. Number of activities in the app (maximum 90 days) for all participants who activated the app.

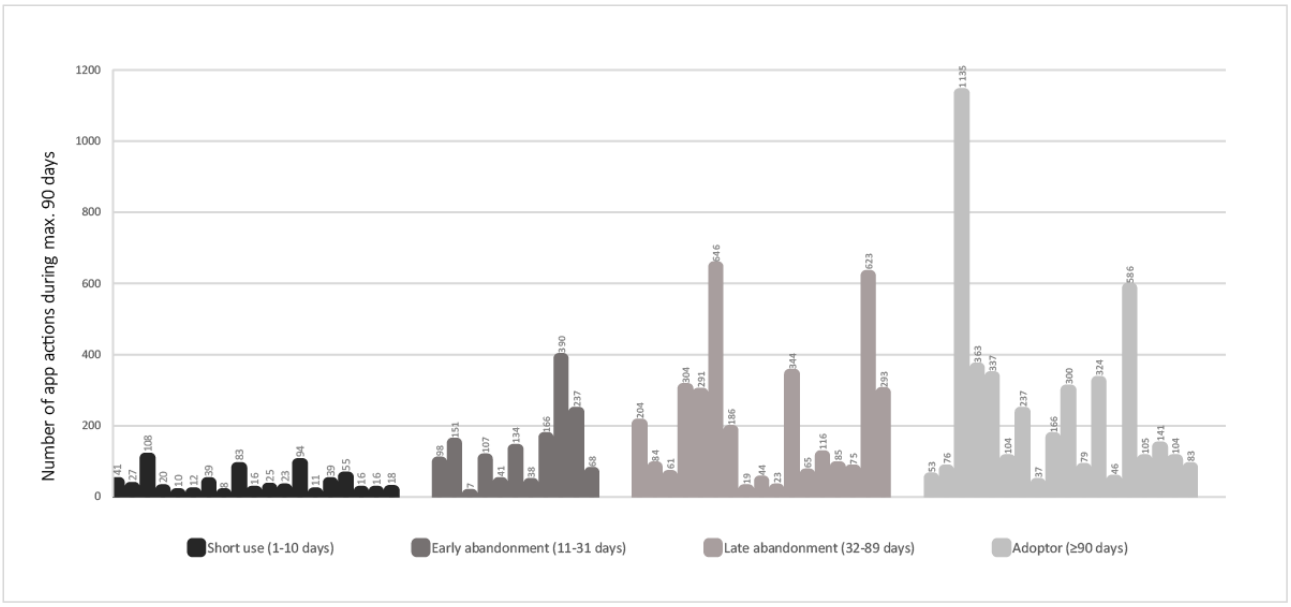
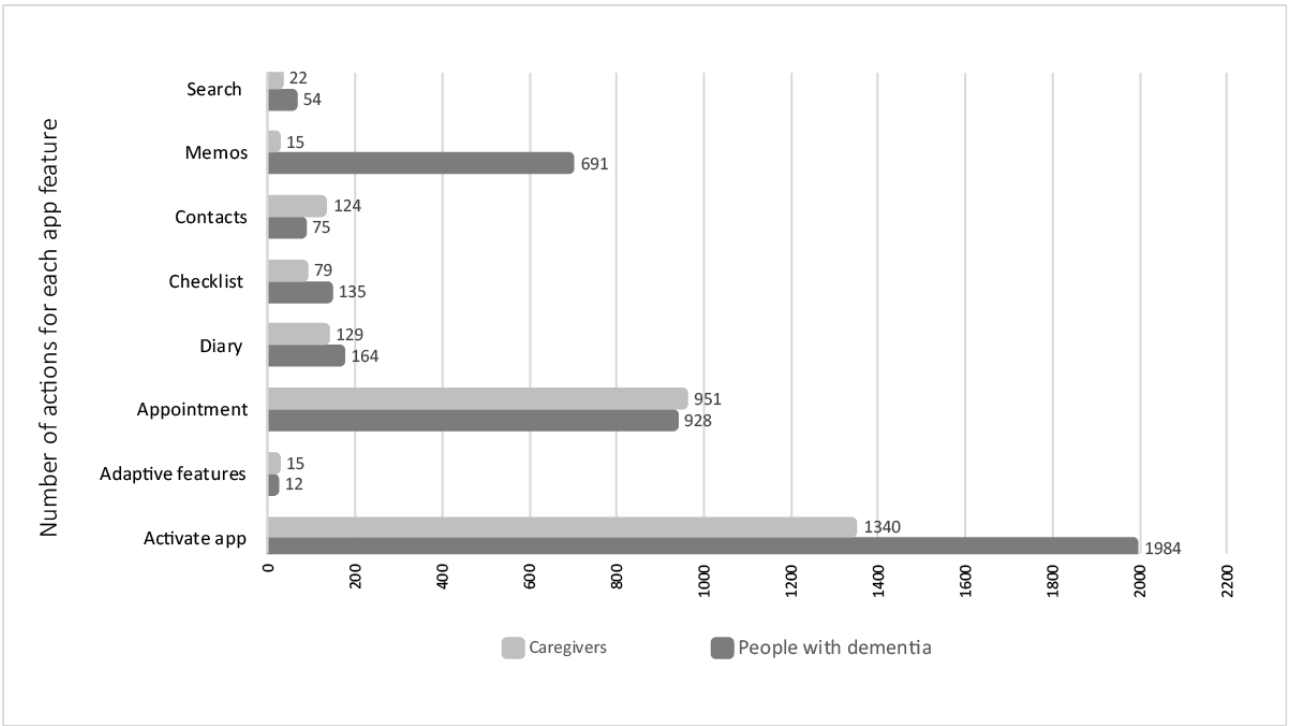


Figure 3. Log data from adopters illustrating what app functionalities were used.



The level of satisfaction with the app could be analyzed based on data from the USEdem questionnaire. Analysis of results (not illustrated) showed an overall average score of 40 (SD 9.4; range 21-55) for participants and 34 (SD 12; range 18-51) for caregivers, which indicated a generally positive rating of the app with regard to usefulness, satisfaction, and ease of use, but with large variation. For the participants, the score on the USEdem questionnaire was significantly higher for adopters (median 46) compared with nonadopters (median 38; U=5.5; *P*=.02; *r*=0.64). There was also a tendency toward higher scores on by-proxy replies from caregivers to participants who became adopters, but this difference did not reach statistical significance (*P*=.14).

Discussion

Principal Findings

The aims of this study were to investigate the applicability and usability of the ReACT app in a mixed group of people with dementia and to investigate user patterns, factors influencing adoption, and possible impact of caregiver involvement. The study also served as a process evaluation of both the app and methods for implementation.

The overall adoption rate was not high in this study, and whether it can be considered a successful adoption rate or not is hard to estimate since, to the best of the authors' knowledge, no previous comparable studies have been conducted within the field of dementia research. The relatively low adoption rate is in line with the well-known challenge of nonadoption and nonadherence for digital health interventions across all medical fields, referred to as *the law of attrition* [13] as described in the Introduction section.

Participant Profiles

According to the study objectives, a heterogeneous sample of people referred to a memory clinic were included in the study. As expected from a mixed population of people with dementia, most of the participants had a diagnosis of Alzheimer disease; however, the prevalence was higher among participants in this study compared with a general Danish population of people referred to a memory clinic [21], and participants were also, on average, younger compared with a general population of people referred to a memory clinic [21].

The relatively young age of participants could reflect an age or generation-related higher frequency of using tablets and apps among middle-aged and younger seniors compared with older generations [22]. However, it is also important to notice the relatively wide age range among participants, and there was no significant age difference between adopters and nonadopters, underlining the importance of not letting age be a determinant when presenting AT to people with dementia.

Disease-Related Factors Had Influence on Adoption

The MMSE scores, indicating the level of cognitive function, were generally higher among participants than in a general Danish population of people referred to a memory clinic [21]. These results indicate that participants who were interested in using the app, and hence included in the study, were generally at an early stage of dementia, and this was consistent with the target group of the app. There was no significant difference in MMSE scores for adopters and nonadopters, indicating that results from the cognitive screening tests should not guide introduction of AT to people with dementia. However, time since diagnosis was statistically significant and can be considered a pseudo marker for disease severity. This finding shows that timely introduction of AT can be of great importance for successful adoption. Comments from the survey indicated that reasons for nonadoption in some cases were that it was considered too early to use AT tailor-made for people with dementia and standard off-the-shelf software met the participant's current needs. This preference to use off-the-shelf technology among people with dementia and family caregivers has also been observed in other studies [23,24]. In other cases, comments revealed that the app was introduced too late at a stage where the participant was no longer able to learn how to use it or had lost the ability to use a touchscreen device. This notion of timely introduction of technology is in line with the general emphasis on the importance of timely delivery of support and interventions for people with dementia [25,26], and it underlines the importance of providing clear and user-centered labeling of AT for people with dementia, enabling users and caregivers to choose a solution that fits their current needs and resources and professionals to give individualized advice on the use of AT, and thereby provide genuinely person-centered AT to people with dementia.

As illustrated in Figure 1, the app was designed to be adaptable and could be tailored to fit individual preferences and skills. The idea was the app could either from the start be adapted to a person with a more advanced stage of dementia or over time gradually be adapted to fit the changing needs because of progressive cognitive symptoms. As summarized in Figure 3, analysis of log data from adopters showed that adaptive features of the app were in total only activated 12 times by participants and 15 times by caregivers, indicating that, perhaps, there is a need to promote these features more strongly. Future studies will be needed to explore if these adaptable features are suitable to fit the changing needs of a user or if such features should be further adapted.

In general, research is needed to explore how long-term adherence to technology can be supported among people with dementia and to define realistic goals for long-term adherence among this group. It is also important to consider whether progressive cognitive symptoms might imply that aiming for long-term adherence is too ambitious. Various models and frameworks have been proposed for successful innovation, design, and implementation of AT [27] and electronic health (eHealth) solutions [28,29]. The holistic framework to improve the uptake and impact of eHealth technologies proposed by van Gemert-Pijnen et al [29] has been applied within the field of dementia [30]. In future studies, it is essential to explore how such frameworks can be further integrated into the innovation and implementation of lifecycles of AT for people with dementia. It is, for instance, important to consider the progressive nature of dementia diseases and how it affects AT needs and skill over time and to include such variable disease-related factors in these frameworks.

Caregiver Involvement

Our results clearly indicated that caregiver involvement in using the app could influence participants' adoption of it. These results are in line with other studies finding caregiver engagement important for the everyday use of technology among people with dementia [23]. The benefits of caregiver involvement have implications for the design and implementation of AT for people with dementia. AT should be designed to promote convenient and flexible caregiver support in a way that is feasible and acceptable for both the person with dementia and the caregiver. There are, however, important issues of privacy and ethics that need to be addressed when designing and implementing AT [31]. The ReACT app was designed as a Web-based app, it could be accessed from several devices simultaneously, and this allowed flexible caregiver support. Our design also allows the person with dementia to decline caregiver's support because caregiver's access could be deactivated; this option was never used during the study. In many cases, the caregiver undoubtedly also supported the use of the app alongside the participant without accessing their parallel login, but our data do not provide enough insight into this use pattern.

The benefits of caregiver involvement also highlight the need to provide information and guidance to caregivers on how they can best support people with dementia in using AT. In this study, this was done by providing written and Web-based material giving advice on caregiver involvement. The need to consider methods to support caregiver involvement has also been discussed by others [23], stressing the need to address both the person with dementia and caregivers and their mutual cooperation on AT use when designing methods for the implementation of AT.

It is important to acknowledge, however, that in some cases, participants adopted the app and were high-frequency users with minimal or no caregiver involvement, again indicating a large variation among adopters and stressing that the person with dementia should be addressed as the main user of AT for people with dementia.

The regression analysis showed that none of the participants' background characteristics could predict participants' adoption status, and overall, the regression to predict adoption was relatively low in predictive power (Nagelkerke R^2=0.173) underlining that a complex set of personal and contextual features influence adoption of AT, making it difficult to predict adoption and adherence. It also underlines the limited applicability of models trying to predict the use of AT among this group of users, which have been proposed by others [32].

Usability and Use Patterns

Data from the surveys revealed that there were no significant differences between adopters and nonadopters when it came to how much experience they had using a tablet, their skills when using it, and how much help they needed to use it. Some of the adopters were even characterized as novel users, indicating that the app is applicable for a varied group of users and can be used despite having a low level of tablet skills, which has also been demonstrated in a previous pilot study [17]. This finding is similar to other studies demonstrating the accessibly and user-friendliness of tablet computers and app-based interventions for people with dementia [33,34].

Use patterns among all participants who activated the app are illustrated in Figure 2, showing considerable variation in how intensively the app is used in all groups. Interestingly, among nonadopters who abandoned the app late (after 32-89 days of use), there were users who used the app quite intensively. The reasons for their late abandonment of the app were not revealed by our data because most were lost to follow-up in the survey. These log data indicate that it can be of great importance that both people with dementia and caregivers are provided support not just at the beginning of a self-applied intervention similar to this but also during the intervention to support the continued use of the app. Further studies are needed to address what kind of support is needed and how it is best delivered.

The results from the USEdem questionnaire revealed a relatively high satisfaction with the app among participants and caregivers, but with some variation, and participants who became adopters rated it significantly higher than nonadopters. Results from caregivers were generally less positive, and this should, of course, be investigated further. However, data quality on this questionnaire was limited because of the small number of replies.

Log data showed that all functionalities in the app were used, as illustrated in Figure 3. There was, of course, variation, reflecting that some functionalities, such as appointment and memos, were by nature more frequently used compared with others (eg, search). Consequently, this part of the process evaluation did not imply major changes of the app.

Limitations

This study has several limitations that should be acknowledged. Participants were recruited from memory clinics, and consequently, only people who have sought an examination and had contact with a memory clinic were included. This limitation will be addressed in a subsequent study with open access to the app. In addition, staff could have been biasing inclusion. Although information on the study was generally available in the clinics, inclusion was also promoted by staff, and they could have been directing information to subgroups of participants, based on common ideas of who can benefit from using AT (eg, younger participants or those with mild cognitive symptoms).

In addition, a number of participants did not have a dementia diagnosis; hence, describing participants as a group of people with dementia could be considered imprecise. There was also a quite large proportion of participants who were categorized as *other*, some had a nonspecific dementia diagnosis or stroke, and many of these did not become adopters. This could indicate a risk of bias from participants being included whose needs did not match the design and functionalities of the app. The study did, however, aim to apply the intervention to a broad group of potential end users, allowing their own need and motivation to guide inclusion, rather than specific disease-related factors. The relatively large proportion of *others* who were nonadopters underline the need for clear and user-centered labeling of AT for people with dementia as discussed previously.

Another limitation was that the app could only be used on a series of tablets (iPads) during this study, and this, of course, excluded potential participants who had access to other kinds of tablets. For practical and financial reasons, a specific type of tablet had to be selected when designing the app for this study, and the selection was based on various factors (eg, the iPad was the most common tablet in Denmark) [35].

Data included in this study were generally rich and provided interesting results and observations, but there were also limitations in relation to data quality and quantity. Disease-related information was only obtained from medical records, and no pre-post measures were applied. This could be changed in future studies. However, as shown by previous studies [36,37], it is difficult to capture the essence of such interventions by applying traditional outcome measures addressing, for instance, cognition, daily activities, or quality of life. In line with the broader field of psychosocial interventions, there is a great need to develop outcome measures that are more appropriate for the specific intervention [38]. In addition, applying a survey to this group of end users causes limitations. Completing a survey can be challenging for a person with dementia and impossible for those more severely affected by their disease. Our results showed that months since diagnosis was close to significance (P=.06) when comparing participants who replied to the survey with those who did not reply, indicating a risk that data could be biased by being collected from participants who were less severely affected by their disease. In addition, the amount of survey data obtained from caregivers was limited. Although data quantity was low, the survey did contribute valuable data. In future studies, we suggest that feasibility of surveys must be considered, but not generally abandoned as a method for data collection among this group of participants.

The study was designed to provide separate log data from participants and caregivers; however, this does not reveal all details on how the app is used in real life, for example, caregiver support could be more intense than revealed by current data. In future studies, richer data can be obtained by including more qualitative data (eg, by interviewing participants and caregivers). The aim of the study was, however, to obtain detailed data from a large group of potential users of the app, and this could be obtained by the mixed method design, which is also used to evaluate the use of apps in other fields of health care [39]. Analysis of extensive log data from participants and caregivers brings an important new methodology to this field of research.

Conclusions

The results from this study were in line with the general well-known challenges of nonadoption and nonadherence to digital health interventions. However, for those who adopted the app, results showed that the ReACT app was applicable and useful for a mixed population of people with dementia and that the methods used for deployment and self-applied implementation were applicable for this group of end users. The study clearly demonstrated the benefits of applying mixed methods when accessing applicability, usability, and effectiveness of AT. The analysis of detailed log data contributed valuable insights into use patterns and allowed a detailed analysis of factors influencing adoption. In addition, it provided detailed data used in the process evaluation and validation of the ReACT app. To the best of the authors' knowledge, this study is the first to include such a large and rich dataset from the everyday use of AT among people with dementia and their family caregivers.

The results from the study revealed factors that could influence the adoption of AT among people with dementia. Timely introduction of AT and support from caregivers had significant influence on whether participants adopted the ReACT app. However, data also revealed great variation among adopters when it came to personal, disease-related, and contextual factors, and the predictive value of caregiver involvement was small. This underlines that adoption of AT among people with dementia is influenced by a complex set of personal and contextual factors, which is made even more complex by the changing needs imposed by living with a progressive dementia disease. This complexity and variability restrain the extent to which adoption and adherence to AT can be predicted and emphasize the importance of incorporating this wide range of changeable factors when designing and implementing AT for people with dementia.

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Conflicts of Interest

None declared.

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Abbreviations

AT: assistive technology
eHealth: electronic health
ICT: information and communication technology
MMSE: Mini-Mental State Examination
ReACT: Rehabilitation in Alzheimer's disease using Cognitive support Technology

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Original Paper

Development of a Living Lab for a Mobile-Based Health Program for Korean-Chinese Working Women in South Korea: Mixed Methods Study

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Abstract

Background: Korean-Chinese (KC) women make up the largest group of female migrants in South Korea. To prevent and manage chronic diseases in middle-aged KC women working full time, it is necessary to develop health promotion programs that utilize an online platform because such a platform would allow individuals to participate in health promotion interventions at their convenience.

Objective: This study aimed to develop a living lab for a mobile-based health (LLm Health) program focused on improving the physical activity and cultural adaptation of KC women workers.

Methods: We used a mixed methods design. Living lab principles were factored into the LLm Health program, including the use of multiple methods, user engagement, multistakeholder participants, real-life settings, and cocreation. The program was developed using the 4 steps of the intervention mapping method: needs assessment, setting of objectives, identification of intervention strategies, and intervention design. Needs assessment was conducted through a literature review, focus group interviews with a total of 16 middle-aged KC women, and an online survey related to health promotion of migrant workers given to 38 stakeholders. KC middle-aged women participated in the early stages of program development and provided the idea of developing programs and mobile apps to enhance physical activity and acculturation. The mobile app developed in the program was validated with the help of 12 KC women and 4 experts, including 3 nursing professors and a professor of physical education. They were asked to rate each item based on content, interface design, and technology on a 4-point scale using a 23-item Smartphone App Evaluation Tool for Health Care.

Results: The LLm Health program comprised a 24-week walking program using Fitbit devices, the mobile app, and social cognitive interventions. The mobile app contained 6 components: a step counter, an exercise timer, an online chat function, health information, level of cardiovascular risk, and health status. The cultural aspects and lifestyles of KC women were accommodated in the entire process of program development. The content validity of the mobile app was found to be 0.90 and 0.96 according to the 12 KC women and 4 experts, respectively.

Conclusions: The mobile app was found to be valid and acceptable for KC women. The living lab approach was a useful strategy for developing a culturally adaptive LLm Health program for KC women workers, leading to their active participation in the overall research process, including needs assessment, program composition, and pre-evaluation.

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KEYWORDS

mHealth; living lab; intervention mapping; health promotion

Introduction

Background

Migrant workers have health disparities because of language, cultural barriers, and difficulty accessing medical services [1] and are categorized as a vulnerable group in terms of health care access and treatment [2]. In particular, a study of Korean-Chinese (KC) migrant workers in South Korea showed that the percentage of KC workers with poor perceived health was higher than that of native Koreans [3].

KC migrants make up almost 31% of all migrants in South Korea, with a total population of about 680,000. Moreover, 70.4% of KC women are middle-aged [4]. The most common health issues among middle-aged KC women residing in South Korea are musculoskeletal symptoms, depression, cultural adaptation stress, and cardiovascular risk factors (obesity, hypertension, and diabetes) [5,6]. As middle-aged women make up such a large proportion of KC migrants and are experiencing a profound health transition because of menopause, health promotion interventions targeting this group in particular should be developed and delivered in an accessible manner.

Physical activity is highly recommended for health promotion among middle-aged individuals [7]. Previous studies have shown that walking for about 30 min per day for 5 days a week is effective for reducing the risk of cardiovascular disease [8,9]. It may also help prevent musculoskeletal disorders by reducing joint pain and enhancing muscle strength [10].

Therefore, walking exercise may be an effective intervention for addressing the primary health problems of KC women workers. However, although women tend to recognize that a lack of physical activity is a health risk factor, their actual exercise practice remains low [7]. KC women reported that it is difficult to maintain regular exercise because of a lack of time, motivation, and social support or an unfamiliar working environment [11]. To ensure the sustainability of physical activity promotion programs, and thereby maximize their benefits for disease prevention and health promotion, these programs should be both culturally acceptable and easily accessible for KC women. Given the aforementioned barriers, on-site exercise programs may be inappropriate for KC women workers; home-based or mobile-based interventions seem most suitable, as they can be delivered at a convenient time and place. There is evidence for their efficacy: coaching using SMS (including feedback and facilitation) and app-based health promotion programs aimed at facilitating communication between participants and providers have been found to contribute to improved health performance in various community-dwelling populations [12,13].

In South Korea, almost 91% of the population uses smartphones. Smartphone users install more apps than users of other types of mobile device [14]. Moreover, 88% of migrant workers in Seoul have smartphones [15]. In accordance with the high rates of smartphone and app usage, mobile health (mHealth) has been rapidly gaining attention in the field of health promotion. Researchers have defined mHealth as the use of various apps, such as GPS and Bluetooth technology, as well as the basic utilities (voice calling, SMS) of mobile or wireless devices for the purposes of health and health care [16]. Mobile-based interventions are increasingly being adopted to increase migrants' access to health services. Such interventions have proven useful for expanding information provision and peer and resource support [17-19].

For exercise interventions to be effective for migrants, activities should be tailored to their particular level of experience and demands. One approach to ensuring such tailored interventions is a living lab. In a living lab, participants and stakeholders conduct research to best represent their needs; it is an innovative activity in which users and stakeholders all actively participate in the research process, even while at home, for the betterment of community problem solving or services [20]. In an integrative review study [21], the living lab approach was identified as an appropriate way to identify and address the health needs of vulnerable groups for whom health care services are economically and locally less accessible. The living lab approach is useful for developing culturally specific health promotion programs centered on KC women through the application of its core principles, namely, user participation, the use of multiple methods, stakeholder participation, basis in real-life settings, and cocreation.

Objectives

The purpose of this study was to apply the living lab approach to KC women (who are, in this context, the users) to enable their direct participation in the development of a culturally sensitive mobile app–based health promotion program (living lab for a mobile-based health [LLm Health]), alongside community stakeholders. We hope that the program will help contribute to the health promotion activities of middle-aged KC women and establish a culture of health promotion in the community.

Methods

Overview

This study used a mixed method design to develop a mobile app–based health promotion program using the living lab approach [22]. Living labs emphasize a multimethod approach, user engagement, multistakeholder participants, real-life setting, and cocreation. In this study, the process of program development was, through the intervention mapping approach [23], as follows: needs assessment, setting of objectives, identification of intervention strategies, and intervention design. This study was approved by our institutional review board (IRB-2017-1641-001).

Needs Assessment

The needs assessment comprised a literature review, focus group interviews, and a stakeholder analysis.

Literature Review

We searched the PubMed, EMBASE, and CINHAL databases for studies published in English up to November 2017. The search terms were “mobile applications and health promotion” OR “smartphone applications AND health promotion” OR “app-based intervention AND health promotion.” We ultimately analyzed 12 out of 191 studies, after excluding those that did not meet the criteria. More specifically, we considered only the studies on health interventions for adults in peer-reviewed journals, having excluded studies that used only SMS text messaging or Web-based interventions.

Focus Group Interviews

The focus group interviews were conducted between November and December 2017. A total of 3 interviews were conducted with 16 middle-aged KC women; each interview lasted between 60 and 90 min. The participants were from Seoul and Gyeonggi-do, aged between 40 and 65 years, had been working full time for the last 6 months, were able to communicate in Korean, understood the purpose of the study, and agreed to participate. The interviews were conducted in a church education center in the K district of Seoul, which has a large population of KC women. The interviews were carried out by researchers trained in conducting focus group interviews.

The focus group guideline was developed by the researchers according to the guidelines of Krueger and Casey [24]. Before each interview, participants were informed of the necessity of the research, its purpose and methods, that the data would be anonymous, and that they could withdraw from the interview at any time. The questions asked in the interviews focused on the health information necessary for health promotion of KC women workers and the difficulty of adapting to everyday life as a foreign worker. The interviews were recorded and transcribed and then subjected to content analysis. A researcher repeatedly read the transcripts; identified and verified meaningful words, sentences, and paragraphs; and categorized them into themes.

Stakeholder Analysis

An online questionnaire was conducted for the stakeholder analysis, from November to December 2017. In total, 38 people were surveyed as community stakeholders, including those in national institutions (public health centers), local community organizations (Korean support center for foreign workers and KC church), KC merchant society (Koreans who employed KC women), and KC women who participated in the focus group interview. We provided the survey participants with the same information on the study that we provided to the focus group participants (eg, necessity, purpose, and anonymity of data) via SMS text message and obtained their voluntary consent to participate. Stakeholders were provided a URL to the online survey system at the bottom of the explanation comment sent by email. To protect the rights of the participants, the purpose and procedures of the research, privacy protection, and withdrawal from research participation were presented on the start screen before they began the online survey. The online survey was set up so that the survey would proceed step by step only if participants agreed to participate in the survey. The participants completed the online questionnaire, which included 10 items, each rated on a 5-point Likert scale, evaluating the health promotion of migrant workers in terms of interest, importance, influence, and position of stakeholders. The data obtained through the online questionnaires were assigned IDs and stored in an encrypted computer, accessible only to researchers trained in research ethics.

The collected data were analyzed using the Beeye of stakeholder analysis tool.

Settings of Objectives

The LLm Health program was based on the Interaction Model of Client Health Behavior (IMCHB) by Cox [25]. There are 3 main elements of Cox’s IMCHB: client singularity, client professional interaction, and health outcome. Cox considered that the individual characteristics of subjects, including their socio-psychological factors, are necessary to understand their practice of positive health behaviors, and emphasized the importance of interaction between the participant and provider in determining health behaviors. The element of client singularity is determined by background variables, internal synchronization, cognitive appraisal, and emotional responses. The element of client professional interaction is determined by emotional support, health information provision, decision control, and professional and technical competence. Finally, the element of health outcomes included the use of health care services, clinical health status indicators, health problem severity, and service satisfaction. In this study, we designed various social cognitive interventions that considered the cultural characteristics of participants for inclusion in the LLm Health program. We then examined the effects of intervention on health outcomes to compare the enhanced group with the control group.

Identification of Intervention Strategies

In this study, we decided on intervention strategies using the behavior change technique (BCT) taxonomy of Michie et al [26]. This taxonomy describes 40 BCTs that have proven effective in producing behavior change, through an analysis of previous studies on behavior change interventions. This strategy is based on a variety of social psychological theories, including social cognitive theory. The main contents of BCTs involve providing information related to the results of the health behavior, setting goals, self-monitoring, overcoming obstacles, feedback, and social support.

Intervention Design

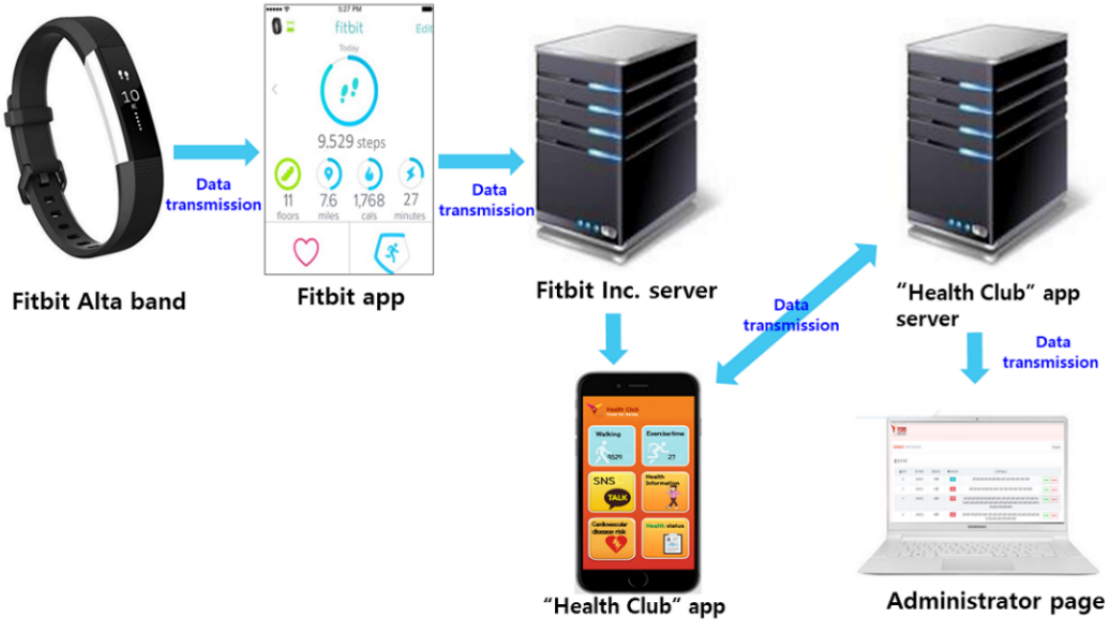
The LLm Health program was designed to improve the physical activity and cultural adaptation of KC middle-aged women workers. The program consisted of 12-week adaptation and 12-week maintenance phases. Enhanced intervention was designed to strengthen social-cognitive factors related to physical activity for the adaptation phase only. The mobile app was a core intervention tool used through the 24-week period by the participants.

Development of the Mobile App

A total of 10 meetings were held with app developers from November 2017 to February 2018. The mobile app was designed to measure the number of steps and exercise duration of users

using smart bands, and we attempted to encourage users to self-monitor their walking adherence through the development of a mobile app linked with the smart bands (Fitbit Alta). The app was designed for the Android operating system based on the resolution of a Samsung Electronics Galaxy S5. Data, such as the number of steps and exercise duration of participants wearing the smart bands, were collected by the app from the Fitbit company server. These data were sent to the mobile app "Health Club" and linked with the administrator Web page for the research team. The data transmission process is shown in Figure 1. To develop a mobile app that suited the participants, we referred to the findings of the needs assessment. Moreover, we consulted with KC participants for help designing the app, color, and logo from the initial development process.

Figure 1. The process of mobile app development.



Validity Test of the Mobile App

The app was evaluated using the Smartphone App Evaluation Tool for Health Care [27], which contains 23 items in 7 domains: content (accuracy, understanding, and objectivity), interface design (consistency, design suitability, and vocabulary accuracy), and technology (security). Each item was rated on a 4-point Likert scale. The content validity of the app was also evaluated based on the recommendations of at least three experts [28]—specifically, 3 nursing professors with multicultural research experience and a professor of physical education. The content validity was deemed appropriate if the average of the scale-level content validity indexes (the ratio of responders who rated an item with 3 or 4; Scale Content Validity Index/Average) was 0.90 [29].

Development of the Enhanced Intervention

The 24-week period was divided into a 12-week adaptation period for providing an intervention and a 12-week maintenance period without the intervention. During the 12-week adaptation period, the following interventions were applied to strengthen the social psychological factors affecting the change in health behavior and social-cognitive capabilities (self-efficacy, social support, etc) of the enhanced treatment group: sending SMS to improve self-efficacy, setting exercise goals, providing feedback, and social networking service (SNS) interaction. In addition, a photovoice activity was planned to represent the exercise promotion factors of community and the sense of local community that KC participants perceive.

The self-efficacy SMS was constructed according to the questionnaire items of the Barrier Self-Efficacy Scale of McAuley et al [30] and the self-efficacy tool of Marcus et al [31].

To help acculturation, offline cultural workshops were planned to provide information about Korean life according to the needs of KC women.

Results

Needs Assessment

Literature Review

According to the 12 studies on mobile app–based health promotion programs, the primary goals of these programs were physical activity promotion, weight and diet management (8 studies), and establishment of a healthy lifestyle (4 studies). The primary purposes of the apps in these studies were to provide feedback on personal health status (9 studies), behavior change monitoring (9 studies), and health information provision (8 studies). Overall, the mobile app–based interventions for adults without disease were found to be effective for improving health promotion behavior [32].

Focus Group Interviews

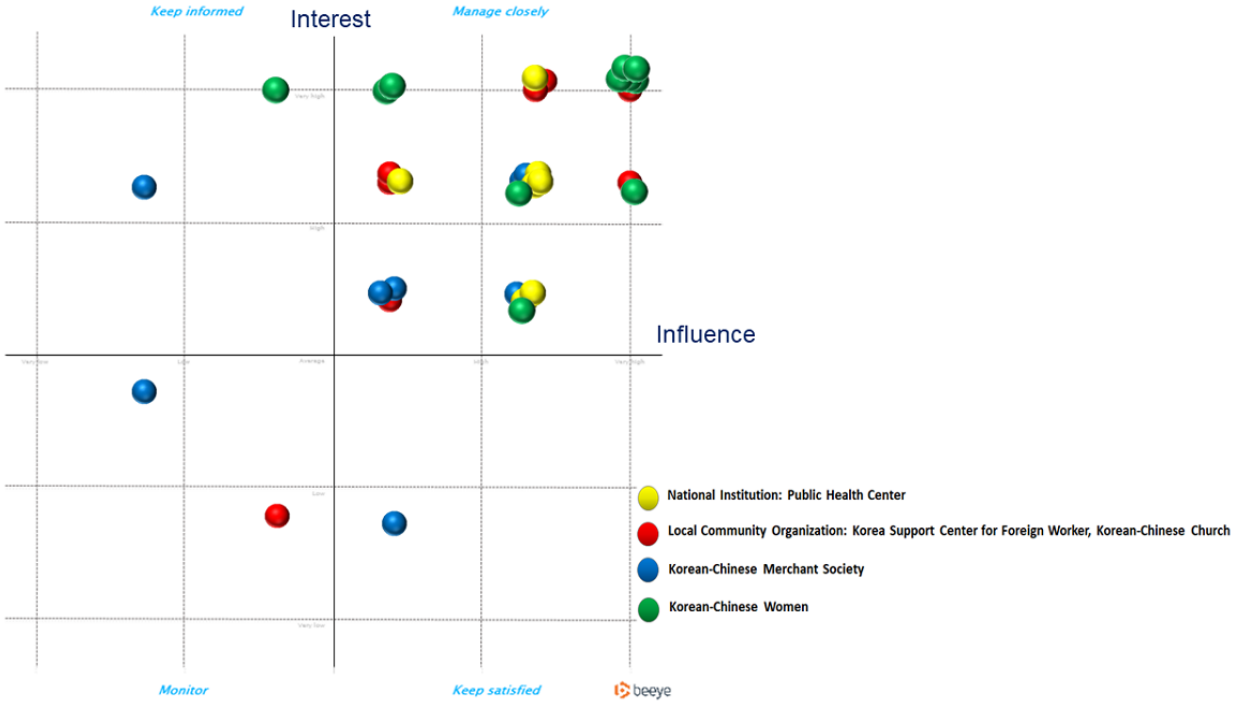
The analysis of the focus group interviews of middle-aged KC women workers identified the following main topics related to their health management: nutrition management (nutrient proportion and calorie confirmation method), information about chronic diseases, and exercise methods at home. These were,

therefore, selected as contents of the LLm Health program. KC women workers also expressed the need for education related to cultural discrimination, such as nonpersonal treatment because of cultural differences in South Korea, the need to learn a newly coined term, and their language restrictions in using English and foreign words. In addition, we confirmed that KC women actively seek health information using smartphones and share this information through online interactions.

Stakeholder Analysis

Analysis of the stakeholder questionnaire data revealed that the type of participation desired by most stakeholders was a partnership (n=20) in program planning, implementation, and evaluation. Offline health education (n=19), app-based health promotion information (n=11), health information booklets (n=6), and cultural competence training for community practitioners (n=6) were also noted as helpful activities in designing health promotion programs for migrant workers. An analysis revealed that stakeholders from national institutions, local community organizations, and KC women in Korea were highly influential and interested in health promotion of foreign workers, whereas Korean employers showed little interest in it (Figure 2).

Figure 2. Stakeholder analysis: interest and influence.



Setting of Objectives

Drawing on the IMCHB of Cox [25], we designed the interaction elements of the participants and experts in the LLm Health program. We decided to deliver health information through health booklets and exercise skills coaching. We used SMS text messages to encourage participants and to motivate them to continue the program as a form of emotional support. Decision control was established by enabling users to identify and implement step-by-step goal setting and monitor the results of follow-up tests in the app. Participants were also encouraged to apply the health information acquired in the offline cultural workshops in their daily life. We ensured access to expertise and technical ability by having the research team be available for counseling regarding the results of participants' health tests and by providing participants with information on improving and preventing cardiovascular diseases. These interventions were expected to help participants achieve social-cognitive competence (eg, exercise self-efficacy, social support, and community consciousness), leading to an increase in walking adherence.

Identification of Intervention Strategies

In this study, we applied the BCT taxonomy of Michie et al [26] to the adaptation period (12 weeks after participation in the program) in the enhanced treatment group to strengthen self-efficacy and social support for exercise performance (Table 1). Self-monitoring of walking adherence was encouraged by providing participants with walking exercise results and through goal setting. In addition, a photovoice intervention was employed to overcome obstacles to exercise and to identify promotive factors using community resources (eg, parks and sports facilities). To encourage cultural adaptation in participants, we provided useful information about life in South Korea. In offline cultural classrooms, participants were encouraged to announce their willingness to practice the contents of education and encourage each other to induce positive behavior changes. Finally, we designed a strategy to provide personal counseling on the results of health exams and to provide nursing prescriptions for lifestyle improvement.

Table 1. Behavior change theory methods and practical strategies for the living lab for a mobile-based health program.

Determinants	Behavior change technique methods	Strategies
Exercise adherence	Prompt review of behavioral goal behavior modeling; prompt specific goal setting; set graded tasks; prompt self-monitoring of behavior; provision of feedback on performance	Setting step goal (3 times); sending a medal image (3 times); guiding in possible muscular and stretching exercises indoors
Social support	Setting graded tasks; prompt specific goal setting; environmental restructuring; social support; provide general encouragement; prompt self-talk	Setting goal of walking steps (3 times); sending medal image (3 times); photovoice; SNS[a] interaction
Self-efficacy	Prompt intention formation; environmental restructuring; social support	Exercise self-efficacy SMS (12 times)
Sense of community	Environmental restructuring; social support; provision of general encouragement; prompt self-talk	Photovoice; SNS interaction
Acculturation	Use of imagery; provision of general encouragement; prompt self-talk	Cultural adaptation contents (6 times); offline cultural workshops (3 times)
Health outcome	Provision of general information on behavior	Personalized face-to-face counseling after health examination

[a]SNS: social networking service.

Design of Intervention

Mobile App "Health Club"

The developed mobile app was named "Health Club." In the cocreation process of the "Health Club" mobile app, the first task for KC women and stakeholders was to give the mobile app a name that could be easily understood and suitable for KC women. Simple and familiar terms were chosen as better than those that were less familiar. Consequently "Health Club" was selected over "Healthy Program" or "Healthy Heart." In addition, the researchers and KC women jointly reviewed and revised the mobile app menu design and health topics of interest, giving due consideration to KC women's preference and lifestyles.

Users could search for and download it from the Google Play Store after registering with a Google email address. To encourage participation in the study, we set up automatic transmission of Fitbit Alta data and Health Club app synchronization notifications once a day on the registered participants' mobile phones.

The app had 6 main functions, all listed on the main screen: number of walking steps, duration of exercise, chatting, health information, cardiovascular disease risk, and health status. The daily number of steps and moderate-intensity exercise time were obtained via synchronization with the Fitbit Alta, and participants were able to input their strength exercise and stretching time during the day. The group chat feature of the app was linked to an SNS (eg, KaKao talk) to encourage information sharing among participants, leading to an increase in emotional and network support. The health information covered 12 topics, including cardiovascular disease, musculoskeletal disease, menopausal symptoms, aging prevention, stress management, pharmacy and hospital available on weekends, weight control, healthy eating, stretching, strength exercise, and cancer screening for women. This information could be accessed as a PDF file or by linking users to related websites when participants pressed the relevant information icon.

Users' 10-year cardiovascular risk was calculated using an algorithm presented in the Framingham Heart study [33]; it was assessed at baseline and at 12- and 24-week blood tests. The health status menu was designed to check changes in health test results 3 times (baseline, 12 weeks, and 24 weeks) using numerical data and graphs (Figure 3).

Figure 3. Components of the Health Club mobile app.

Pilot Test of the Mobile App "Health Club"

After developing the "Health Club," we recruited 12 KC middle-aged women for a pilot test of its usability. They were selected as health leaders and were provided with educational materials, the mobile app, and a smart band to play a promotional role in recruiting participants in the following research. After health leaders used the Health Club app for 2 weeks, they were given the app evaluation tool. The content validity of the app was found to be 0.90 according to the 12 KC women. The validity based on responses of the 4 experts to the mobile app was 0.96.

The validity of 7 subitems evaluated by 4 experts and 12 KC middle-aged women were as follows: accuracy=0.90, understanding=0.91, objectivity=0.92, consistency=1, design suitability=0.96, vocabulary accuracy=0.98, and security=0.86. The mobile app was revised and supplemented to reflect opinions on "adding the source of the information" and "adding statements regarding user privacy protection."

Enhanced Intervention

To encourage exercise adherence during the 12-week adaptation period, step goals were set 3 times every 4 weeks, and encouragement with a medal image was sent via SMS whenever participants reached the goal. The app was designed to send a self-efficacy SMS once a week, so that participants could overcome the barriers to exercise and recognize the benefits of exercise. A total of 12 self-efficacy SMS messages were designed, all with less than 60 characters that focused on mood, lack of time, lack of interest, physical discomfort, lack of social support for exercise, limitations because of appearance, limitations of place, fatigue, lack of exercise skills, negative perception of migrant worker exercise, and lack of awareness regarding the benefits of exercise.

The offline cultural classes covered 3 topics: "personal color and makeup," "low sodium healthy diet," and "practical English." These classes emphasized what users could do in real life, and individuals shared their action plans at the end of each class. To confirm the motivational factors and sense of community, participants were encouraged to post 2 pictures taken on the themes of "good exercise in our neighborhood" and "exercise experience with local people" using photovoice.

Discussion

Principal Findings

This study developed a culturally appropriate mobile app–based health promotion program for KC women by applying the living lab principles, entitled "LLm Health program." We also incorporated BCTs [34], which are based on the social cognitive theory of changing health behaviors, as main components of the health promotion program. The app was developed based on the characteristics of KC women—who often experience social isolation [35] and social and cultural challenges (eg, language barriers, changes in socioeconomic status, and emotional difficulties with loneliness and belonging) because of their international migration—to enable them to easily access health information and social support. The Fitbit Alta is a device that can be worn on the wrist by KC women who work in the household and service industries; it allows participants and researchers to monitor real-time exercise adherence.

Implications

This study is meaningful in that it is the first to apply the living lab approach in the migrant population. The participants were involved in the early stages of program development, proposing ideas for promoting physical activity and cultural adaptation. We believe that participants' acceptance of the program was enhanced through their participation in deciding the app name,

interface design, contents, etc. Moreover, some KC women were selected as community health leaders, who voluntarily participated in the overall research process including program composition, pre-evaluation, and leading living lab–based active participation and cocreation. Through this study, we have involved various community stakeholders, including national institutions and religious facilities, in planning, development, and the implementation of this migrant health promotion program. According to previous studies, the participation of various stakeholders, such as health and welfare agencies, hospitals, clinics, companies, patient associations, and local governments, has been found to be a successful strategy for developing a patient-centered health management model for patients with chronic conditions [36]. In community-based health research, living labs appear to be useful for promoting active health behavior changes, especially among vulnerable social groups who often need to solve their health problems on their own [21]. The LLm Health program was designed to improve middle-aged KC women's self-efficacy and social support in relation to physical activity, as well as promote their physical, mental, and social health, while considering their specific cultural features. The living lab approach was applied as a platform to help these women solve their health problems by reflecting on their own point of view. In future research, it would be useful to incorporate the living lab principles into existing behavior change theories.

The main component of the LLm Health program was its use of BCTs. Previous studies have found that BCTs can promote the active participation of the vulnerable population. For instance, Sidhu et al [37] applied BCTs to improve the self-management ability of low-income individuals of various races with chronic conditions in the United Kingdom. Mathews et al [38] developed a type 2 diabetes prevention program for low-income individuals in India using BCTs at the individual, interpersonal support, and community levels. A therapeutic intervention using BCTs—primarily goal setting and social support—was an effective strategy for people from low social and economic backgrounds to engage in health promotion behavior [34]. We also applied goal setting [39] (setting a goal for the average number of steps every 4 weeks) in the LLm Health program, as it is well known to help reduce physical activity withdrawal and increase adherence. Developing health programs based on BCT to enhance the capacity of social-cognitive factors, such as the health information provision and SNS interaction used in this study, might be useful in planning effective intervention strategies for groups with different cultural and social backgrounds.

Although this study adopted several BCTs from the list of commonly used BCTs, such as goal setting and behavior modeling used in top-ranked physical activity apps [40,41], it is necessary to thoughtfully consider further BCTs that have been found to be effective for behavior changes in migrant populations.

This study developed a mobile app–based health promotion program that considers the characteristics of middle-aged KC women. Programs to promote migrants' participation in physical activity should consider the cultural beliefs and constraints of the participants [42]. Middle-aged KC women living in South Korea often live in low-income areas. Moreover, they have poor access to systematic health services [3] or good quality health care and tend to have difficulties with the early detection of illness [5]. They comprise a "culturally and linguistically diverse" population group [43] and experience considerable stress in adapting to Korean society [5]. High acculturation stress is associated with lower physical activity [44]; conversely, efforts to acculturate migrants can positively influence their physical activity levels [45]. It is, therefore, essential to consider the cultural aspects and lifestyles of immigrants when developing intervention programs so that they can best adapt to their new cultures.

From the perspective of convenience—particularly considering that KC women often perform housework and are employed in the service industry—our program relied on data from smart bands (Fitbit Alta), wearable devices that synchronized with the app to allow participants to check their exercise progress directly. Being able to constantly monitor their exercise might have increased their motivation to adhere to the exercise. The use of a smart band, which records objective real-time step counts and moderate-to-vigorous physical activity, overcomes the limitation of a previous study [46] measuring the effects of walking exercise, which relied on self-reported step counts.

This study has several limitations. First, owing to budget constraints, we could not develop an iPhone operating system version of the mobile app; it is only available on the Android operating system. Second, to enable examination of the effect of walking exercise on health, objective data on the number of steps and moderate-to-vigorous intensity exercise time were collected through the Fitbit Alta. However, there is limitation in that strength exercise and stretching had to be self- reported. Third, further efforts are necessary to educate middle-aged KC women on the terminology and technical aspects of wearable and mobile devices, to increase their ease of use. Therefore, it is essential to repeatedly train users in adopting a new technology during the initial adaptation stage.

Conclusions

We developed a mobile app–based program for the health promotion of middle-aged KC women using the living lab approach, which focuses on expanding participation and strengthening community health capabilities. This approach appears to be useful for creating health promotion program content and intervention strategies. It is recommended that future research examines the effectiveness of mobile app–based health promotion programs on physical and mental health outcomes for KC women.

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Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change technique
IMCHB: Interaction Model of Client Health Behavior
KC: Korean-Chinese
LLm Health: living lab for a mobile-based health
mHealth: mobile health
SNS: social networking service

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Original Paper

A Mobile Phone App to Improve the Mental Health of Taxi Drivers: Single-Arm Feasibility Trial

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Abstract

Background: Psychological distress among taxi drivers is 5 times higher than that in the general population, and more than half of all drivers have experienced 3 or more potentially traumatic events in their lifetime. Nevertheless, help-seeking for mental health problems in this male-dominated, predominately immigrant workforce is low. Mobile technologies have the potential to increase mental health awareness, teach self-help skills, and encourage help-seeking in this hard-to-reach population.

Objective: This study aimed to assess the feasibility, acceptability, and potential efficacy of *Driving to Health*, a mobile phone–friendly mental health website app designed for people working as taxi drivers.

Methods: Drivers (n=46) were recruited from the Melbourne Airport Taxi Holding Yard to participate in a single-arm trial. Self-reported, paper-based assessments were completed at baseline and at 1 month. Feasibility was measured by completion rates, representativeness of study participants, and levels of use. Acceptability was assessed by measuring users' perception of the quality of the app and anticipated levels of future use. The efficacy of *Driving to Health* to increase awareness, self-help behaviors, and intentions to seek help was assessed using the user version of the Mobile App Rating Scale (uMARS) and the General Help-Seeking Questionnaire (GHSQ). Psychological symptoms were measured using the short form of the Depression, Anxiety, and Stress Scale (DASS-21). Data were analyzed using complete case analysis.

Results: In total, 42 participants comprising drivers from 10 different countries of origin, and 14 different languages, completed pre- and poststudy measures (42/46, 91% completion rate). Just under half (45%) of all users used the app more than once with an average visit of 4 min 8 seconds. Responding to the uMARS, 62% (26/42) of the participants said that they would recommend the app to many people. Nearly all (40/42, 95%) participants said that *Driving to Health* increased awareness of their own mental health; 86% (36/42) said that it increased their mental health knowledge; and 76% (32/42) said that it increased their self-help behaviors. Increases in help-seeking intentions on the GHSQ were not significant, and increases on all 3 scales of DASS-21 were not reliable or meaningful.

Conclusions: This study suggests that *Driving to Health* is an acceptable and feasible electronic health intervention for a hard-to-reach population. Our findings also suggest that *Driving to Health* results in increases in mental health awareness, behaviors, and willingness to seek help.

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KEYWORDS

mental health; eHealth; taxi drivers; immigrant; help-seeking behavior; self-help

Introduction

Background

The need for mental health support in high-risk industries, such as the military and emergency services, is well known. However, another large occupational group that has received relatively little attention is that of taxi drivers. A recent Australian study found that 61% of urban taxi drivers reported high or very high levels of psychological distress compared with just 12% of the general population [1]. The origin of such distress among taxi drivers is multifaceted and includes poor working conditions characterized by long hours, night shift, low pay, lack of physical activity, high rates of verbal assault and physical violence, and increased competition from ride-sharing services [2-6]. A recent spate of suicides among taxi drivers working in New York dramatically illustrates the vulnerability to mental health issues among taxi drivers [7]. Despite their substantial mental health needs, relatively few taxi drivers access health services, especially mental health services [1,8].

Nearly all taxi drivers are male, and over 90% of drivers working in urban areas are immigrants [1,9-11]. Previous studies show that immigrants tend to use health services less often than the locally born population, a phenomenon attributed to lower mental health knowledge and awareness, higher rates of mental health stigma, and difficulties in navigating an unfamiliar health system among people from culturally and linguistically diverse communities [12-16]. Lack of time may be an additional barrier to help-seeking for men working as taxi drivers who typically work long hours [1].

These long hours are characterized by extensive periods of waiting between jobs, and drivers can find themselves idle for up to 8 hours of a 12-hour shift. They pass this time using their mobile phone to socialize with friends, search the internet, and play games [17]. Our research shows that 97% of drivers use a mobile phone during their working day [1], which suggests that mobile phones may provide an avenue to address some of the disparities experienced by drivers in accessing mental health care [18-21].

Evidence suggests that individuals from minority populations access web-based health information at a greater rate than majority populations [22] and that electronic health (eHealth) interventions delivered via mobile technologies such as mobile phone apps and mobile-enabled websites can support skills acquisition and symptom monitoring [23], promote health behavior-change [24], and increase intentions to seek help from professional services [25]. Importantly for taxi drivers, mobile phone-delivered eHealth care can be accessed at any time and often at a relatively low cost, which is important for drivers on a low income who work long hours, often during the night when traditional health services are unavailable. Accessing eHealth services also offers anonymity, which may appeal to drivers whose cultural background r personal beliefs include a high degree of mental health stigma [22,26].

Clearly, taxi drivers are a hard-to-reach population for whom targeted mental health support is urgently needed. The synchronicity between drivers' ownership and use of mobile phones and the utility of mobile phones in delivering health services make them an especially promising mode of mental health intervention for this hard-to-reach population [27].

The Driving to Health App

Based on our research into the mental health needs and technology use among people working as taxi drivers [1,17], we designed and developed *Driving to Health*. *Driving to Health* is a self-guided, smartphone-friendly website app that can be used on both iOS (Apple) and Android (Google) mobile devices. The app was designed to provide taxi drivers with psychoeducation, self-help strategies, symptom assessment, and links to health professionals. Consistent with previous work on designing culturally relevant health apps for minority populations, the design phase was based on an iterative action process which included taxi drivers and a team of mental health experts comprising psychologists, primary care physicians, posttraumatic stress specialists, and human-computer interaction researchers [28].

The website underwent 2 rounds of user experience testing with taxi drivers, resulting in the version tested in this study. Designed with a culturally and linguistically diverse user group in mind, text in the website is limited, and most of the information is delivered via video demonstrations and audio explanations. All text and audio are presented in English. Local taxi drivers were employed to be the actors in the videos, and a professional voice actor was employed to provide the narration. All written information in the website has a Flesch readability score between 60 and 70 and a reading grade level between 7 and 8 [29,30].

Driving to Health has 4 main components that can be accessed in any order from the home screen (Figure 1):

1. The How This Can Help component was designed to engage drivers by presenting images and words capturing the essence of what it is like to work as a taxi driver and to introduce users to the purpose of the tool.
2. Symptom awareness is facilitated by the Check Your Health component which includes the 10-item Kessler Psychological Distress scale (K10) [31] and psychoeducational information about stress, mental health disorders and treatment options. The K10 was selected as it provides a measure of general distress that is not tied to a particular disorder or classification system. At the same time, it is highly predictive of formal diagnosis and has excellent psychometric properties [31]. The K10 is widely used and validated in Australia and internationally in national health surveys [32]and is the most frequently used outcome measure in Australian primary health care [33], providing the potential for Driving to Health scores in the future to be used by health care providers to inform treatment and referral decisions. When users complete the K10, they are provided with feedback based on their score. For example, users who score in the high or very high range on the K10 are presented with feedback that they may be experiencing depression or anxiety and are advised to book an appointment with a primary care doctor. User experience testing found that the K10 was the most popular feature of the website.

3. The core (and the largest) component of Driving to Health is the self-help component which is called Healthy Activities. This component includes 31 individual activities designed to provide drivers with skills and techniques to reduce symptoms of stress, depression, and anxiety and to improve overall well-being. Activities include cognitive behavioral strategies, mindfulness and relaxation exercises, and physical health activities (see examples in Figure 2). These activities were selected by our team of experts on the basis of current mental health and occupational health literature [34-36]. Our previous research indicated that drivers use their mobile phone during the frequent breaks in their workday, but that they are unlikely to use computers at home. This finding informed our decision to include activities that drivers can do during the breaks in their working day and to not include longer, homework style activities.
4. The Find Help Now component provides phone numbers for crisis services, telephone counseling, and a link to a government website that can be used to find a doctor in the desired area.

Figure 1. *Driving to Health* home screen.

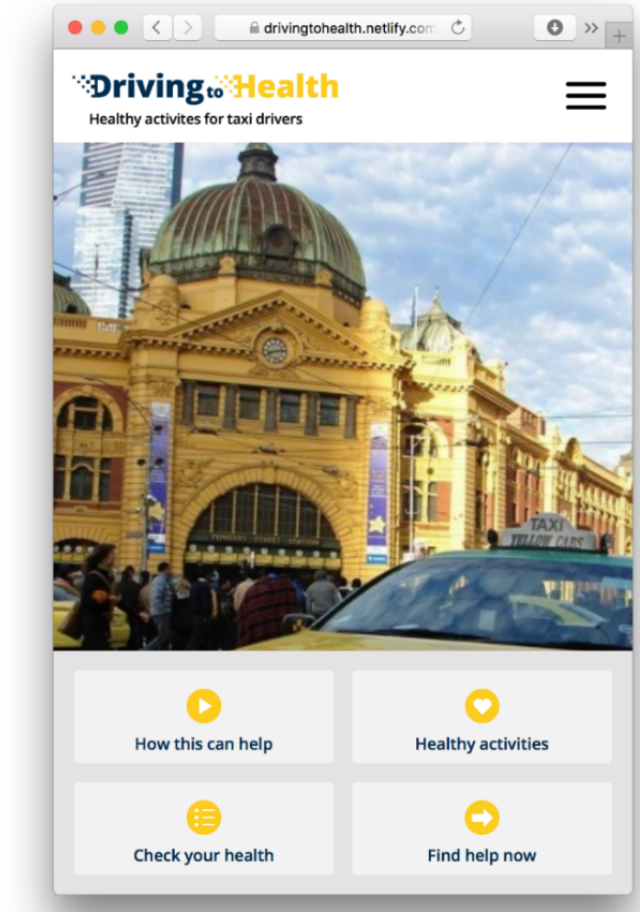
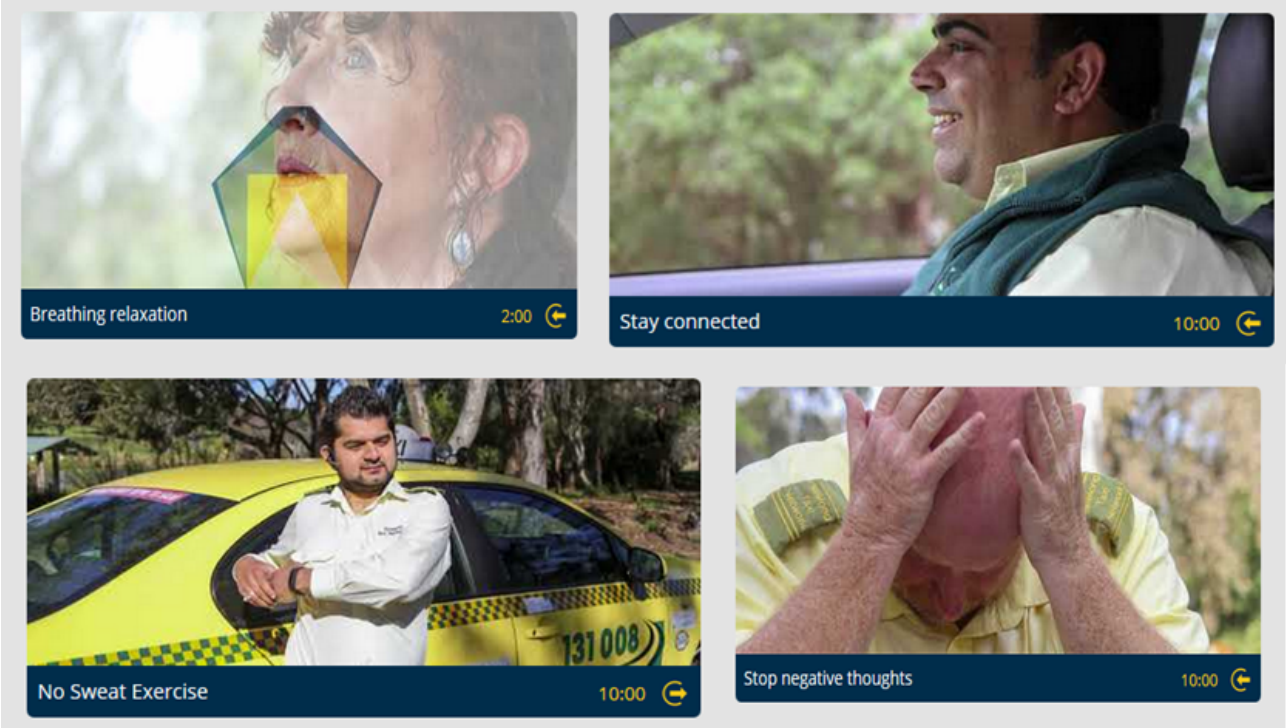


Figure 2. Examples of self-help activities in *Driving to Health*.



Aim

The aim of this study was to determine the feasibility and acceptability of *Driving to Health* and to assess its potential efficacy to increase mental health awareness, self-help behaviors, help-seeking intentions, and reduce psychological symptoms among taxi drivers. The results of this study will inform decisions around whether to proceed directly to a larger randomized controlled trial testing whether the intervention is effective or whether to modify the intervention and/or study design before proceeding to trial.

Methods

Design

This study was designed as a single-arm trial. Participants completed a suite of paper-based questionnaires at baseline, after which they were sent a link to the *Driving to Health* trial website. Participants were instructed to use *Driving to Health* as much or as little as they liked, in any way they liked, for 4 weeks. Because we wanted to replicate as much as possible how apps are used in real life, participants were not required to login upon each visit to the site. This meant that participants in the study could potentially share the link with others. After 4 weeks, participants completed a second suite of paper-based questionnaires. This study was approved by the Human Research Ethics Committee at the University of Melbourne (ID: 1749740).

Participants

Taxi drivers working in metropolitan Melbourne, Australia, were recruited through advertisements at the Melbourne Airport Taxi Holding Yard and through the Facebook page of the Victorian Taxi Association. Drivers were eligible to participate in the study if they were aged between 21 and 70 years, had worked at least 4 driving shifts in the past month, and had an internet-enabled smartphone. Eligible drivers who expressed interest in participating were mailed out a study pack containing a plain language statement, consent form, baseline survey, and prepaid return envelope. Participants who returned both baseline and follow-up surveys were sent an Aus $150 gift card in recognition of their involvement in the study.

Sample Size

There are no formal sample size criteria for feasibility studies as they are not designed to test for significant differences [37]. We aimed to recruit between 35 and 40 participants to this study, which would allow us to perform before and after testing (using 2-tailed paired *t* tests) to estimate trends in the data.

Measures

Feasibility outcomes included recruitment, retention, and website use. Acceptability was determined by participants' willingness to recommend *Driving to Health* to others, their anticipated use over the next 12 months, and their overall rating of the website. Potential efficacy was measured by self-reported mental health awareness, self-help behaviors and help-seeking intentions, and symptoms of stress, anxiety, and depression over time.

Feasibility of Driving to Health

Recruitment and Retention

To determine the potential for *Driving to Health* to reach its target population, information on age, gender, education, relationship status, country of birth, year of settlement in Australia (if applicable), and main language spoken at home was obtained through the baseline questionnaire. Participants were also asked how many years they had worked as a taxi driver, the number of hours worked each week, and whether they worked night shift.

Use of the Website

Use of the website was examined using in-site analytic data. Google Analytics was used to measure the number of unique users, the duration of visits, and the number of pages viewed per session.

Acceptability

Acceptability of *Driving to Health* was measured at a 4-week follow-up using 3 items from Section E of the Mobile App Rating Scale—User Version (uMARS) [38]. Each question was answered using a 5-point rating scale. Participants were asked (1) if they would recommend the website to people who might benefit from it (rated from 1 [*I would not recommend this website to anyone*] to 5 [*I would recommend this website to everyone*]); (2) how often they think they would use the website in the next 12 months (rated from 1 [*1-2 times*] to 5 [*more than 50 times*]); and (3) their overall rating of the website (rated from 1 [*one of the worst apps I have ever used*] to 5 [*one of the best apps I have ever used*]).

Potential Efficacy

Perceived Impact of Driving to Health

Perceived impact of the website on awareness, attitudes, and behaviors was measured at the 4-week follow-up by 6 questions adapted from Section F of the uMARS [38]. Participants were asked if their use of *Driving to Health* had (1) increased their awareness of the importance of looking after their mental health; (2) increased their knowledge of mental health; (3) changed their attitudes to improving their mental health; (4) increased their intentions to look after their mental health; (5) encouraged them to seek help for their mental health; and (6) increased their behaviors for looking after their mental health. Each question was rated on a 5-point scale from 1 (*strongly agree*) to 5 (*strongly disagree*).

Help-Seeking Intentions

Intentions to seek help for mental health problems was measured using the General Help-Seeking Questionnaire (GHSQ) [39]. The GHSQ includes 3 categories of help: formal sources, informal sources, and self-help [39,40]. Formal sources of help include mental health professional (eg, psychologist, psychiatrist, social worker, and counselor), doctor/general practitioner (GP), religious leader (eg, Imam, Priest, Minister, and Rabbi), and phone helpline (eg, Lifeline). Informal sources of help include intimate partner (eg, wife/husband and girlfriend/boyfriend), friend, parent, family member/relative, and neighbor. Self-help options include internet support group and self-help group. Ratings for each item are made on a 7-point scale ranging from *extremely unlikely* (1) to *extremely likely* (7). Item scores within each of the 3 categories of help were used to calculate subscale scores. Studies on young people show that the GHSQ has reasonable reliability and validity [39].

Psychological Symptoms

Psychological distress was measured at baseline and at the 4-week follow-up using the short form of the Depression, Anxiety, and Stress Scale (DASS-21) [41]. The DASS-21 comprises 3 self-report subscales designed to measure symptoms of depression, anxiety, and tension/stress in the last week. Each of the 3 subscales includes 7 items and provides a valid measure of the dimensions of depression, anxiety, and stress [42]. Respondents use a 4-point scale to indicate how much each item applied to them with a range from 0 (*did not apply to me at all*) to 3 (*applied to me very much, or most of the time*). Scores for each item are summed to provide a subscale score. The DASS-21 has adequate construct validity and satisfactory to good reliability [42]. Ronk et al [43] reported that the minimal movement in scores required to indicate a clinically significant change (ie, a reliable and meaningful change) is 3.86 on the depression scale, 3.85 on the anxiety scale, and 4.90 on the stress scale.

Data Analysis

Analysis was performed using STATA version 13.1 [44]. Complete case analysis was conducted on participants who returned both baseline and follow-up surveys. Variables were described using counts, frequencies, means, standard deviations, and 95% confidence intervals. Mean changes in scores on the GHSQ and the DASS-21 at baseline and 1 month were estimated using paired *t* tests. We used an alpha level of .05 for statistical tests.

Results

Recruitment and Sample Characteristics

A total of 46 drivers met the eligibility criteria, provided consent, and completed a baseline survey. Of those, 42 (91.3%) drivers returned completed follow-up surveys (Figure 3) with no demographic differences between those who did and did not. The average age of participants was 38.2 years (SD 9.8; range 22-57 years), and all participants were male (Table 1). Over a third (35.7%) of the sample had a university degree and 42.9% had a certificate qualification. Nearly all participants (40/42, 95%) were immigrants, with 51.3% (20/39) having settled permanently in Australia in the last 10 years. Participants were most likely to have been born in India (23/42, 54.8%), Pakistan (6/42, 14.3%), and the Horn of Africa (ie, Eritrea, Ethiopia, and Somalia) (6/42, 14.2%,). A total of 14 languages were spoken at home, including Punjabi (18/42, 42.9%), Urdu (5/42, 11.9%), English (5/42, 11.9%), Amharic (2/42, 4.8%), Somali (2/42, 4.8%), and Telugu (2/42, 4.8%).

Figure 3. Flow of participants through the study.

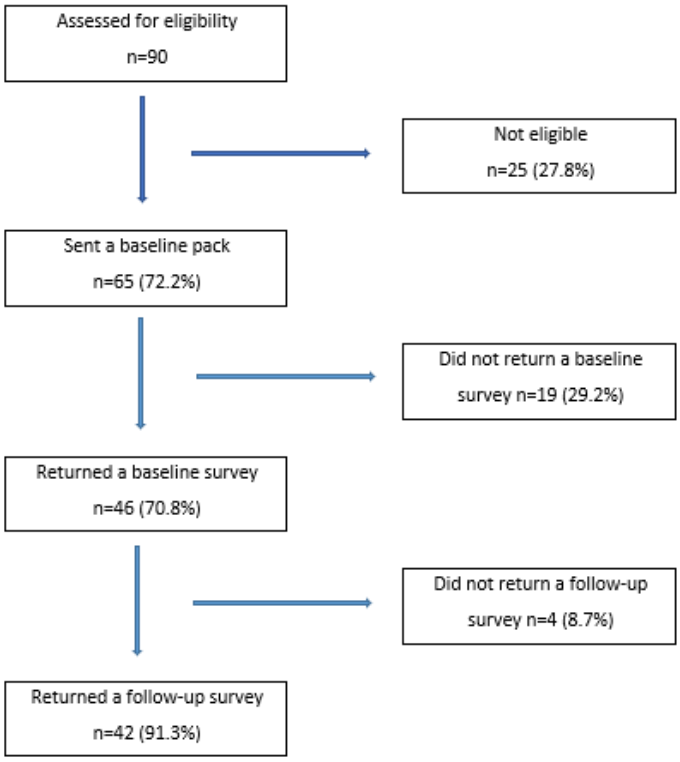


Table 1. Sample characteristics.

Characteristics	Value, n (%)
Male (n=42)	42 (100)
Age (n=40; years)	
20-29	9 (23)
30-49	24 (60)
50+	7 (18)
Education (n=42)	
Before year 10	2 (5)
Year 10 or equivalent	2 (5
Year 12 or equivalent	5 (12)
Certificate/diploma	18 (43)
Bachelor's degree	15 (36)
Marital status (n=42)	
Never married	8 (19)
Divorced	1 (2)
Separated	2 (5)
Married/de facto	31 (74)
Living arrangements (n=40)	
Alone	2 (5)
Spouse	29 (69)
Children	22 (52)
Parents	2 (5)
Unrelated flatmate	8 (19)
Other	3 (7)
Country of birth (n=42)	
Australia	2 (5)
Afghanistan	1 (2)
Eritrea	2 (5)
Ethiopia	2 (5)
India	23 (55)
Lebanon	2 (5)
Pakistan	6 (14)
Somalia	2 (5)
Latvia	1 (2)
Other	1 (2)
Time in Australia (n=41; years)	
≤5	5 (13)
6-10	15 (39)
≥11	19 (49)

Use

Analysis of Google Analytics for the study period showed that there were 89 unique users of *Driving to Health* (excluding members of the research team). Most users (85/89, 95.5%) accessed the website from Australia, with the remaining users accessing the website from Russia (2/89, 2.2%), India (1/89, 1.1%), and the United States (1/89, 1.1%). Overall, 91% of all

visits were from a smartphone, and 9% of visits were from a desktop. Of the 85 Australia-based users, 55.3% (47/85) used the website once and 44.7% (38/85) were returning users. The average duration of a visit was 2 min and 31 seconds for single visit users and 4 min and 8 seconds for returning users. Single visit users and returning users both viewed an average of 4.94 pages per visit.

Acceptability

A total of 24 % of participants (10/42) said that they would use the website more than 50 times in the next 12 months, and 40.5% (17/42) said that they would use it between 10 and 50 times (Table 2). Just over a quarter of the sample (11/42, 26.2%) said they would recommend *Driving to Health* to many people and 36% (15/42) said they would recommend it to everyone. More than two-thirds of participants (28/42, 67%) rated the website as above average.

Table 2. Acceptability of *Driving to Health*.

User rating of the app	Value, n (%)
Would you recommend this app to people who might benefit from it? (n=42)	
I would not recommend this app to anyone.	4 (10)
There are very few people I would recommend this app to	6 (14)
There are a few people I would recommend this app to	6 (14)
There are many people I would recommend this app to	11 (26)
I would recommend this app to everyone	15 (36)
How many times do you think you would use this app in the next 12 months? (n=42)	
None	2 (5)
1-2 times	5 (12)
3-10 times	8 (19)
10-50 times	17 (41)
More than 50 times	10 (24)
What is your overall (star) rating of the app? (n=42)	
One of the worst apps I have used	2 (5)
Below average	1 (2)
Average	11 (26)
Above average	21 (50)
One of the best apps I have used	7 (17)

Perceived Impact on Awareness, Behavior, and Intentions

Table 3 shows participants' perceptions of the impact of *Driving to Health* on their mental health awareness, attitudes, and behaviors. Overall, 95% (40/42) of participants *agreed* or *strongly agreed* that using *Driving to Health* increased their awareness of looking after their mental health, and 85.7% (36/42) agreed or strongly agreed that it increased their knowledge of mental health (Table 3). More than three-quarters 33/42, 78.6%) of the sample agreed or strongly agreed that using the website changed their attitudes to improving their mental health and increased their mental health behaviors, while 70.7% (29/41) agreed or strongly agreed that it increased their intentions to look after their mental health. The perceived impact of *Driving to Health* was lowest for seeking help, where 63.4% (26/41) said that it encouraged them to seek help for their mental health problems, and 9.7% (4/41) disagreed or strongly disagreed with this statement.

Table 3. Perceived impact of *Driving to Health*.

Perceived impact	Value, n[a] (%)
Increased awareness of importance of looking after my mental health (n=42)	
Agree/strongly agree	40 (95)
Neither agree nor disagree	1 (2)
Disagree/strongly disagree	1 (2)
Increased my knowledge of mental health (n=42)	
Agree/strongly agree	36 (86)
Neither agree nor disagree	5 (12)
Disagree/strongly disagree	1 (2)
Changed my attitudes to improving mental health (n=42)	
Agree/strongly agree	33 (78)
Neither agree nor disagree	7 (17)
Disagree/strongly disagree	2 (5)
Increased my intentions to look after my mental health (n=41)	
Agree/strongly agree	29 (71)
Neither agree nor disagree	10 (24)
Disagree/strongly disagree	2 (5)
Encouraged me to seek help for my mental health (n=41)	
Agree/strongly agree	26 (63)
Neither agree nor disagree	11 (27)
Disagree/strongly disagree	4 (10)
Increased my behaviors for looking after my mental health (n=42)	
Agree/strongly agree	32 (76)
Neither agree nor disagree	8 (19)
Disagree/strongly disagree	2 (5)

[a]Denominators vary because of missing data.

Help-Seeking Intentions

At baseline, participants reported that they would be most likely to seek help from their partner, a GP, their parent, or a mental health professional (Table 4). They were least likely to identify neighbors and telephone helplines as sources of potential support. Only 2 participants (4.87%) said that it was likely that they would not seek help from anyone. No significant changes in help-seeking intentions were reported at follow-up.

Psychological Symptoms

Scores increased on all 3 DASS-21 scales from baseline to follow-up, with paired *t* tests showing a statistically significant increase in anxiety symptoms (P=.02). However, as shown in Table 5, the magnitude of change did not meet the minimum movement required for reliable or meaningful change [43].

Table 4. General help-seeking questionnaire scores at baseline and follow-up.

Source of help	N[a]	Baseline, mean (SD)	Follow-up, mean (SD)	Difference	*P* value (*t* test; 2-sided)
Intimate partner	42	4.73 (2.23)	5.11 (1.99)	0.380	.33
Friend	41	3.97 (1.92)	4.36 (1.93)	0.390	.29
Parent	41	4.39 (2.32)	4.12 (2.29)	−0.268	.49
Relative	41	3.53 (2.19)	3.73 (1.91)	0.195	.58
Neighbor	42	2.00 (1.49)	2.30 (1.64)	0.309	.28
Mental health professional	42	4.28 (2.30)	4.19 (2.12)	−0.095	.81
Phone helpline	42	3.09 (2.09)	3.07 (2.06)	−0.023	.95
Doctor/general practitioner	42	4.71 (2.08)	4.88 (1.75)	0.166	.64
Religious leader	42	3.23 (2.10)	3.21 (2.05)	−0.023	.94
Internet support group	42	3.16 (2.11)	2.78 (1.85)	−0.308	.32
Self-help group	42	3.21 (1.98)	3.54 (1.91)	0.333	.36
Informal sources	39	18.53 (7.54)	20.17 (6.23)	1.64	.20
Formal sources	42	15.33 (7.16)	15.35 (6.17)	0.023	.98
Self-help	42	6.38 (3.66)	6.33 (3.06)	0.047	.94

[a]Denominators vary because of missing data.

Table 5. Depression, anxiety, and stress scale scores at baseline and follow-up.

Severity	n	Baseline			Follow-up			*t* test (*df*)	*P* value	Mean change	Minimal reliable change[a]
		%	Mean (SD)	95% CI	%	Mean (SD)	95% CI				
Depression	37	__[b]	6.15 (8.96)	3.17-9.15	—	7.08 (8.95)	4.09-10.06	1.22 (35)	.22	0.93	3.86
Normal	28	75.7			67.6						
Mild	5	13.5			13.5						
Moderate	2	5.4			13.5						
Severe	0	0			0						
Extremely severe	2	5.4			5.4						
Anxiety	41	—	5.75 (6.08)	3.83-7.67	—	7.80 (8.19)	5.21-10.39	2.45 (39)	.02	2.05	3.85
Normal	25	61.0			56.1						
Mild	9	22.0			12.2						
Moderate	2	4.9			9.8						
Severe	3	7.3			12.2						
Extremely severe	2	4.9			9.8						
Stress	34	—	6.88 (6.71)	4.53-9.22	—	8.58 (6.98)	6.14-11.02	1.79 (32)	.08	1.7	4.90
Normal	34	81.0			69.1						
Mild	2	4.8			11.9						
Moderate	3	7.1			4.8						
Severe	0	0			0						
Extremely severe	3	7.1			14.3						

[a]Change in scores required to indicate a reliable and meaningful change, as defined by Ronk et al [43].

[b]Not applicable.

Discussion

Principal Findings

Driving to Health is the world's first eHealth intervention designed for the taxi industry, which comprises a large population of mostly immigrant men. The high completion rate achieved in this study, combined with the diversity of participants recruited (participants born in 10 different countries speaking 14 different languages), provides strong support for the feasibility and acceptability of *Driving to Health* amongst its target population.

Almost two-thirds of participants strongly endorsed recommending the website to others. This finding was reflected by the fact that although only 46 drivers were sent the website link there were almost twice this number of unique users, suggesting that participants shared the link with others. Website analytics showed that just under half (45%) of all users were returning users, which is a retention rate similar to the average 1-month retention rate of 43% for mobile apps [45]. Because we did not require users to logon at each session, we were not able to track website use for individual study participants. Thus, average usage statistics may have been either diluted or exaggerated by the inclusion of users who were not part of the study. Self-reported intentions to use the website over the next 12 months showed a much higher level of engagement, with 41% of study participants saying they would use it between 10 and 50 times and 24% saying they would use it more than 50 times. Although this suggests that the average use statistics were diluted, rather than exaggerated, by the inclusion of nonstudy participants, it is also possible that the discrepancy between objective use and subject reports of intention to use the app is because of socially desirable responding. The average time spent using the website each session (4 min) was comparable with other eHealth interventions [46,47] and is roughly what we expected given the median duration of exercises included in the Healthy Activities section (5 min). This supports our decision to include short activities that can be completed in between jobs. It is worth noting, however, that the minimum *dose* of *Driving to Health* that could be considered effective is unclear. Although this study was not powered to investigate dose-response relationships, this is an avenue worthy of further exploration and may lead to recommendations for future users about how to get the most out of the site.

Results from the uMARS regarding the potential effectiveness of *Driving to Health* in increasing awareness, teaching self-help skills, and promoting help-seeking were very positive. Over 95% of participants agreed that using the site increased their awareness of mental health, and 86% agreed that it increased their knowledge of mental health. Over three-fourths agreed that *Driving to Health* improved their health behaviors, and 63% said it encouraged them to seek help for their mental health if they needed it. However, the GHSQ did not show an increase in intentions to seek help from either formal or informal sources.

Similarly, the self-reported acceptability and impact of the website were not reflected in self-reported psychological symptoms. In fact, there was a small increase in anxiety scores on the DASS-21 over the 4-week study period. We are unable to identify any obvious mechanism in the website that would contribute to this, and although we cannot verify it, it is possible that the slight increase in anxiety is attributable to some underreporting of symptoms at baseline and a subsequent correction in this at follow-up. Consistent with this explanation is the relatively low level of psychological symptoms at baseline combined with high rates of increased awareness and knowledge about mental health during the study period. Previous research has shown that increases in awareness and knowledge of mental health are associated with a reduction in stigmatizing attitudes and a subsequent increased willingness to disclose mental health symptoms [48].

Strengths and Limitations

That over 90% of the participating drivers completed a follow-up survey is a substantial strength of this study. This suggests that taxi drivers are interested in health interventions designed specifically for them, that the study methods were acceptable to this culturally and linguistically diverse population, and that a mobile phone platform is feasible for such interventions. Another strength of the study was measuring website use via objective data obtained through Google Analytics rather than relying on self-reported use, which previous studies have done. A weakness in our methodology was not requiring participants to login to the website. Although this approach enabled participants to access the site easily and to share the link with others, which provides an indication of acceptability, it meant we could not limit our usage analysis to study participants alone or identify whether users were unique (eg, study participants may have accessed the site from more than one device). It also meant that we could not link website use with DASS-21 scores and explore the relationship between the frequency of use and changes in psychological symptoms. In addition, the relatively low rates of baseline psychological symptoms may have resulted in a floor effect, where the potential for improvement was minimal, and may suggest either that drivers with the poorest mental health did not take part or that participants underreported their symptoms at baseline. This issue requires further investigation as both possibilities here pose different challenges to a future rollout of the *Driving to Health* app. It should also be noted that all the study measures were in English, whereas 95% of participants were from a non-English speaking background. It is unknown what influence this may have had on the results. Furthermore, the expression and understanding of psychological distress may be culturally bound, and our measures may not accurately capture the experience of the different cultural groups that comprise our sample. The 4-week time frame may also have been too short to produce meaningful changes in psychological symptoms. Finally, because we did not include a validated mental health literacy scale in the study, we cannot confirm our suspicion that the observed increase in psychological symptoms was because of an increase in mental health literacy.

Implications and Further Research

Hundreds of thousands of people work as taxi drivers across the world. They are a vulnerable workforce who have been neglected by occupational health interventions. This study shows that urban taxi drivers are receptive to mobile health

interventions designed specifically for them and are willing to participate in related research. Overall, the results suggest that a randomized controlled trial aimed at investigating the effectiveness of *Driving to Health* is feasible. However, the findings also indicate that several modifications to the study design are needed before progressing to a trial. In particular, the trial should include a validated measure of mental health literacy, require participants to login to the site so that we can track the relationship between individual use and outcomes, and use a different measure of psychological distress. The trial should also encompass a longer period. If found to be effective, *Driving to Health* could be scaled to other professional drivers, including delivery drivers and truck drivers. It could also be expanded to include physical health conditions and be integrated with peer or other industry support services to enhance its impact on mental health.

Conclusions

Taxi drivers' reports of the impact of *Driving to Health* indicate that it is a promising intervention, especially in terms of increasing mental health awareness and knowledge, which are precursors to seeking help for mental health problems [49,50]. We anticipate that ongoing refinement of the intervention and research into its efficacy will contribute to improvements in mental health behaviors and outcomes for a vulnerable occupational group.

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Conflicts of Interest

None declared.

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Abbreviations

DASS-21: Depression, Anxiety, and Stress scale
eHealth: electronic health
GHSQ: General Help-Seeking Questionnaire
GP: general practitioner
K10: 10-item Kessler Psychological Distress Scale
uMARS: user version of the Mobile App Rating Scale

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Review

Mobile Health Technology Interventions for Suicide Prevention: Systematic Review

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Abstract

Background: Digital interventions are proposed as one way by which effective treatments for self-harm and suicidal ideation may be improved and their scalability enhanced. Mobile devices offer a potentially powerful medium to deliver evidence-based interventions with greater specificity to the individual when the intervention is needed. The recent proliferation of publicly available mobile apps designed for suicide prevention underlines the need for robust evidence to promote safe practice.

Objective: This review aimed to examine the effectiveness of currently available mobile health (mHealth) technology tools in reducing suicide-specific outcomes.

Methods: The following databases were searched: Cochrane Central Register of Controlled Trials (The Cochrane Library), MEDLINE, EMBASE, PsycINFO, and relevant sources of gray literature. All published and unpublished randomized controlled trials (RCTs), pseudo-RCTs, and pre-post observational studies that evaluated the effectiveness of mHealth technology in suicide prevention delivered via mobile computing and communication technology were included. Studies were included if they measured at least one suicide outcome variable (ie, suicidal ideation, suicidal intent, nonsuicidal self-injurious behavior, and suicidal behavior). A total of 2 review authors independently extracted data and assessed study suitability, in accordance with the Cochrane Collaboration Risk of Bias Tool, on July 31, 2018. Owing to the heterogeneity of outcomes found across studies, results were not amenable for pooled synthesis, and a meta-analysis was not performed. A narrative synthesis of the available research is presented here.

Results: A total of 7 studies met criteria for inclusion . Four published articles that reported on the effectiveness of the following mobile phone apps were included: iBobbly, Virtual Hope Box, BlueIce, and Therapeutic Evaluative Conditioning. Results demonstrated some positive impacts for individuals at elevated risk of suicide or self-harm, including reductions in depression, psychological distress, and self-harm and increases in coping self-efficacy. None of the apps evaluated demonstrated the ability to significantly decrease suicidal ideation compared with a control condition. In addition, 3 unpublished and recently completed trials also met criteria for inclusion in the review.

Conclusions: Further research is needed to evaluate the efficacy of stand-alone mHealth technology–based interventions in suicide prevention. The small number of studies reported in this review tentatively indicate that such tools may have a positive impact on suicide-specific outcomes. Future mHealth intervention evaluations would benefit from addressing the following 3 main methodological limitations : (1) heterogeneity of outcomes: a lack of standardized measurement of suicide outcomes across studies; (2) ecological validity: the tendency to exclude potential participants because of the elevated suicide risk may reduce

generalizability within clinical settings; and (3) app regulation and definition: the lack of a standardized classification system for mHealth intervention type points to the need for better definition of the scope of such technologies to promote safe practice.

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KEYWORDS

mHealth; systematic review

Introduction

Background

Suicide Prevention

More than 800,000 people die by suicide every year globally, accounting for 1.4% of all deaths worldwide [1]. Suicide occurs throughout the lifespan and was the second leading cause of death among people aged 15 to 29 years globally in 2012. In addition, it is estimated that 25 suicide attempts (100-200 for youth) occur for every death by suicide [2], resulting in more than 400,000 emergency department visits annually in the United States [3]. Prior suicidal behavior increases the risk of subsequent death by suicide 10- to 60-fold [4-7]. Adolescents with depressive disorders and a history of suicidal behavior are a particularly high-risk group for repeated suicide attempts and suicide [8]. Prospective studies have attempted to predict which individuals will attempt or die by suicide [9], and a diverse range of risk factors that correlate with suicidal behavior has been proposed to support the identification of those at elevated risk, such as sleep disturbances [10], emotion regulation deficits [11], family history of suicide [12], and chronic pain and illness [13].

In a meta-analysis of studies that have attempted to longitudinally predict suicidal thoughts or behavior-related outcomes, Franklin et al [14] found that prediction was only slightly better than chance for all outcomes, and they highlighted several fundamental changes required in future research. They point toward the proliferation of mobile health (mHealth) technologies as a means by which to capture large datasets and to support the expansion of the research base from a focus on risk *factors* to risk *algorithms*. Furthermore, in an attempt to improve the accuracy of suicide estimates, Kristoufek et al [15] found that estimates drawing on Google search data are significantly better than estimates using previous suicide data alone.

In parallel, suicidology researchers have argued that Ecological Momentary Assessment (EMA)—high-frequency data collection in an individual's usual environment—provides the potential for the development of temporal, individualized prediction of risk states. Thompson et al [16] tested the ability of EMA to predict individual symptom change in suicidal ideation in a sample of 35 adults diagnosed with interepisode bipolar disorder. The results showed that EMA with functional linear models substantially increased the accuracy of prediction of study-emergent suicidal ideation. Advances in mHealth technologies provide potential opportunities to operationalize EMA research to support the sensitive and timely identification of those at risk of suicide.

Mobile Health and Suicide Prevention

mHealth is a component of electronic health (eHealth). The Global Observatory for eHealth defines mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices" [17]. According to the World Health Organization (WHO), "mHealth involves the use and capitalization on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and Bluetooth® technology" [18]. mHealth programs and interventions use mHealth technology for a range of functions from data collection tools for health care professionals and clinical decision support systems to supporting health behavior change and disease management by patients in the community.

Although effective face-to-face treatments for self-harm and suicidal ideation are available [19-21], access to effective psychotherapeutic options can be limited. Indeed, negative associations have been found between the availability of mental health services per capita and suicide rates in a number of countries [22]. Stigma and geographical isolation are 2 of the major barriers to help seeking for individuals at risk of suicide [23]. Recent advances in mHealth technology could address these barriers by directing individuals at risk of suicide, who would not otherwise seek help, to access appropriate evidence-based online programs or traditional mental health services [24]. The use of digital technology has been found to be beneficial in the delivery of Web-based suicide prevention interventions [25]. Furthermore, a survey in a psychiatric outpatient setting reported that 69% of respondents and 80% of those aged 45 years or younger indicated a desire to use a mobile app to track their mental health [26]. Public health services are being encouraged to harness digital technology to enhance and support psychological health [27,28]. Digital interventions, in general, have been proposed as one way by which the scalability of effective treatments for self-harm and suicidal ideation may be improved [29,30].

However, the regulation of such technologies and the identification of boundaries in terms of their clinical utility require further attention [31]. In the United States, the Food and Drug Administration (FDA) has announced a precertification program, where app makers are preapproved to release

FDA-approved health apps based on fulfilling certain quality control criteria. With more than 250,000 mHealth apps currently available, at least 10,000 of which target mental health conditions [32], the development of this technology is occurring at a faster rate than the evidence base needed to inform it. Mental health was the most common focus of disease-specific mobile apps in 2015, constituting 29% of all chronic condition management. Recent meta-analyses of apps aimed at the management of depression [33], anxiety disorders [34], and self-harm [30] report similar results, with a small evidence base derived from often heterogeneous pilot studies. With thousands of mental health apps readily available through Apple or Google marketplaces, finding a useful tool supported by robust evidence presents a considerable challenge to the individual at risk [35] and to clinicians wishing to use such technology as part of their work.

Despite the motivation to use mHealth technologies, there is a dearth of specific outcomes data on the efficacy of mHealth technology interventions on suicide outcomes. In 2014, Christensen et al [23] conducted a review of the literature on eHealth and suicide. Most eHealth interventions identified in their search were Web based as opposed to mobile based. The researchers concluded that there is some evidence to suggest that suicide interventions via the Web may be effective, but only if they target suicidal content specifically, as opposed to the associated symptoms of depression through cognitive behavioral therapy (CBT). Larsen et al [36] carried out a systematic assessment of mobile phone tools for suicide prevention, screening, and reviewing app content. The researchers concluded that many suicide prevention apps were available, some of which provided comprehensive evidence-based support. Apps with potentially harmful content were also identified.

As digital technology may be particularly attractive for young people, it is essential that mHealth technology and mobile phone apps, in particular, are subject to research evaluation [37] and co-designed with people who have lived experience [38]. Donker et al [39] found that mental health apps evaluated in randomized controlled trials (RCTs) were not publicly available, whereas those with no research evidence were publicly available. In addition, mobile apps that presented harmful content were also identified. Perry et al [40] conducted a systematic review of online and mobile psychosocial suicide prevention interventions for adolescents and young adults. The researchers searched 4 major psychological databases for interventions that explicitly targeted suicidality using a mobile, computer, or Web-based app for individuals aged between 12 and 25 years. However, only 1 study met the author's inclusion criteria. Witt et al [30] reviewed the effectiveness of online and mobile apps (digital interventions) for the self-management of suicidal ideation and self-harm. They identified 14 nonoverlapping studies, the majority of which described online as opposed to mHealth technologies and concluded that overall digital interventions were associated with reductions in suicidal ideation scores at postintervention. There was no treatment effect for self-harm or attempted suicide. Building on the work of Perry et al [40], this review used a broader search strategy to include unpublished studies and ongoing trials. Although Witt et al [30] examined digital interventions more broadly, this review focused on the research evidence examining mHealth technology specifically.

Why Is It Important to Do This Review?

The objective of this review was to examine the effectiveness of currently available mHealth technology tools in reducing suicide-specific outcomes in individuals taking part in a suicide prevention intervention delivered via mHealth technology.

Following the rise in the number of publicly available mHealth technology tools for suicide prevention, a review of the efficacy of this modality on suicide-specific outcomes is required. A review of the content and usability of available tools has been undertaken [36], and empirical data on their effectiveness in reducing suicide outcomes are warranted.

This review aimed to address the following research question: do suicide prevention mHealth technology tools effectively reduce suicide-specific outcomes?

Methods

Overview

The study procedure has been developed in line with the author's proposed protocol [41], the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement [42], and was registered with the International Prospective Register of Systematic Reviews database (systematic review number: CRD42017072899). In accordance with the PRISMA checklist recommendations, this review used the participants, interventions, comparisons, and outcome(s) (PICO) process for framing and reporting the review criteria; as such, the PICO and study design of the included studies were reported.

Eligibility Criteria

No restrictions were placed on diagnoses or any clinical or demographic characteristics of eligible samples. Studies using *active* or *inactive* control groups were eligible for inclusion. *Inactive* control groups were those in which participants received no intervention during the trial period (or were placed on a waiting list). *Active* control groups were those that used apps (not aimed at suicide outcomes), face-to-face interventions, or other forms of patient contact to control for the time/attention given to those in the intervention condition. Studies comparing mHealth-based interventions with antidepressants were eligible for inclusion.

Types of Studies

The types of studies included were all published and unpublished RCTs, pseudo-RCTs, and pre-post observational studies, which evaluated the effectiveness of mHealth technology in suicide prevention. Studies were included if the full report was accessible in English. Only studies that evaluated mobile tools relating specifically to suicide prevention or where suicidality is explicitly mentioned were included.

Types of Participants

Participants were individuals who took part in a suicide prevention intervention via mHealth technology. No restriction

was placed on the age or gender of participants included in the studies reviewed. mHealth technology represents a modality that is accessible across the lifespan. However, the age of participants included in each study was noted in this review, and, where this information was available, it was used to draw conclusions regarding the efficacy of this modality for specific age groups.

Types of Interventions

Included studies reported on a suicide prevention intervention delivered via mHealth technology, that is, interventions aimed to reduce suicide risk by employing mobile communication or mobile computing technology. The review included studies with psychological and nonpsychological interventions (eg, psychoeducation, diaries, mood monitors, and self-management programs). As defined by Slattery et al [43] in a protocol for a systematic review on eHealth interventions for chronic pain, psychological treatments are those that explicitly deliver a psychological component (eg, psychotherapy for suicidal thoughts). Studies were included regardless of treatment intensity or duration.

Outcomes

Primary Outcomes

Included studies comprised at least one suicide-specific outcome. This could include suicidal behavior, nonsuicidal self-injurious behavior, suicidal ideation, and suicidal intent.

Secondary Outcomes

Secondary outcomes were symptoms of depression or anxiety, as measured using administered or self-reported scales, where this information was available.

Search Strategy

All databases were searched from their start date. Studies were included if a full-text paper in English was made available, either through databases or through contact with the study authors. The following databases were searched: MEDLINE, EMBASE, PsycINFO, and Cochrane Central Register of Controlled Trials (The Cochrane Library). Although the same search strategy was used for each database, appropriate changes were made to accommodate the different interfaces. Details of the search strategy are provided in Textbox 1. Medical Subject Headings and text word terms were used.

Clinical trial registries were searched to identify completed and in-progress trials. This included ClinicalTrials.gov, the metaRegister of controlled trials, and the WHO International Clinical Trials Registry Platform. Grey literature was searched using the OpenGrey database, which included technical or research reports, doctoral dissertations, and conference papers from the previous 5 years.

The reference lists of relevant systematic reviews and of included studies were also searched to identify additional studies that may be relevant. A handsearch of the *Journal of Medical Internet Research* and a separate search in the PubMed database were also conducted to identify any additional relevant studies.

Textbox 1. Details of the search strategy.

- mobile* OR mobile phone* OR cell* phone* OR mobile health OR m-health OR mhealth OR mobile app* OR mobile technolog* OR text messag* OR smartphone* OR personal digital assist* OR patient monitoring device*
- suicid* OR suicid* gesture* OR suicid* behavio* OR suicid* idea* OR suicid* attempt* OR self?mutilat* OR self?harm* OR self?injur* OR suicid* intent* OR deliberate self?harm* OR deliberate self?injur*
- trials OR randomised controlled trials OR randomized controlled trials

The Review Team

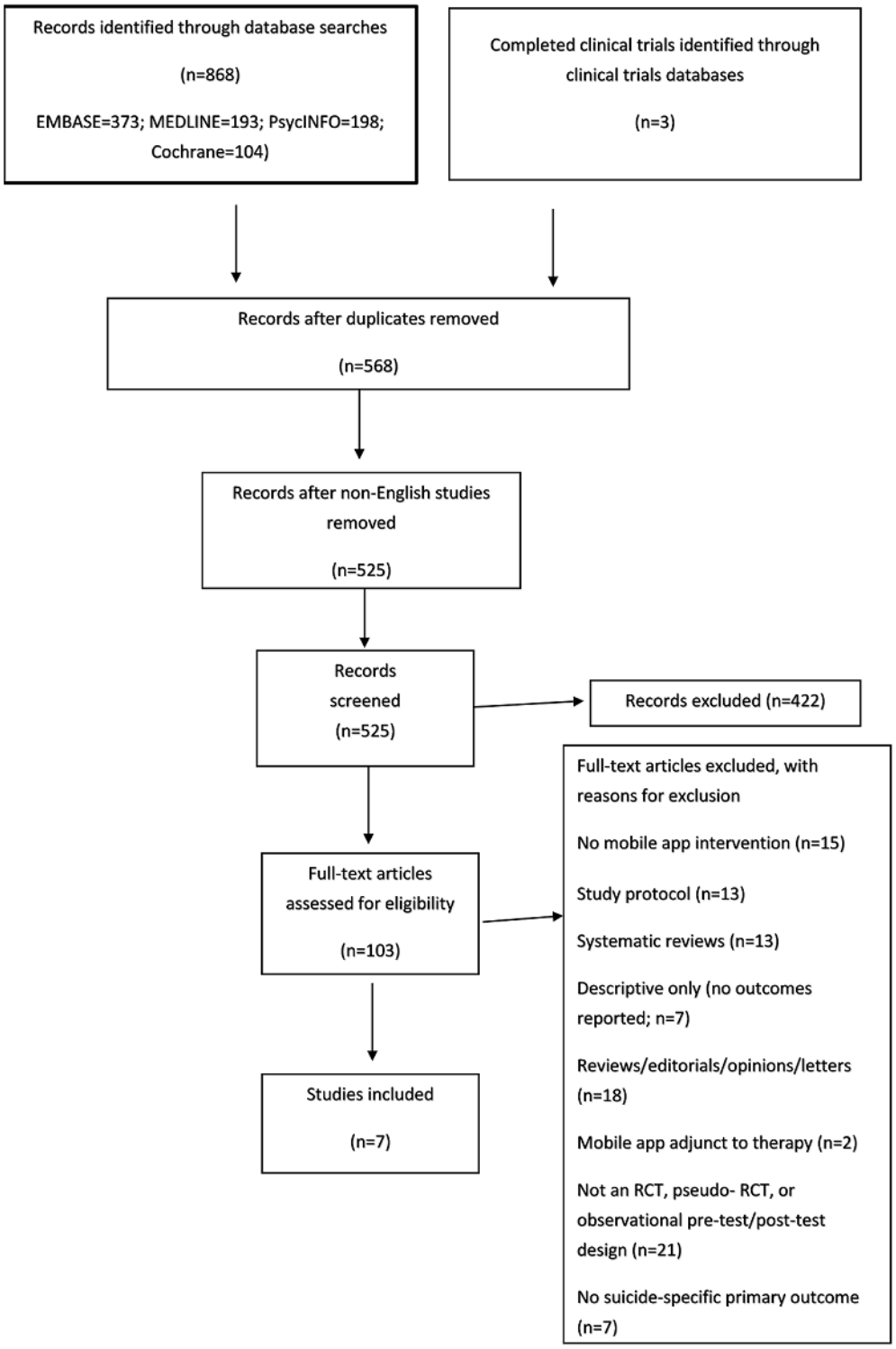
The review team managed and conducted the review and had experience in systematic review methods, information retrieval, and statistics. Furthermore, 2 independent investigators (KF and EH) judged article eligibility, with any disagreements resolved through discussion with a third reviewer (RM). In addition, 3 researchers were involved so that measures to minimize bias and error were implemented at all stages of the review.

In addition to the review team, a broader research group was consulted at various stages, including individuals (JD, JB, MO'S, and KY) with expertise in the areas of computer science, clinical psychology, and suicide prevention policy.

Selection of Studies

Studies that were identified by the search strategy were managed using EndNote X8 [44]. Members of the research team initially screened the titles and abstracts of publications for any duplicates of studies. They then screened for any studies that were not relevant to the review and exported them to a global exclusion folder. All remaining publications were retrieved for further scrutiny. Overall, 2 reviewers independently assessed the full-text articles of the remaining studies for inclusion. Papers that did not meet the inclusion criteria were systematically excluded via the exclusion categories, and the reason for exclusion was recorded. Disagreements between reviewers were discussed with a third reviewer until resolved. A PRISMA flowchart was created to graphically depict the inclusion and exclusion of studies (Figure 1).

Figure 1. Preferred Reporting Items for Systematic Review and Meta-Analysis flowchart.



Data Extraction and Management

A data extraction form was created before data extraction. Data were extracted independently by 2 reviewers and verified by another reviewer using a customized form. Where the necessary outcome data were unavailable, the study authors were contacted. The authors were not blind to the study author, institution, or journal. Data were extracted relevant to the following categories: (1) study population and design, (2) intervention, and (3) outcome. Tables were created to present the characteristics of the studies included, containing the following information, where available: participant characteristics, geographic location, assessment periods, assessment/screening measures, description of intervention and comparison interventions, primary and secondary outcomes, theoretical basis, therapeutic content, mode of delivery (mobile phone app, telephone, and text), suicide prevention strategies, behavior change techniques, control condition, intensity and frequency of use, and treatment engagement (retention and attrition).

Assessment of Risk of Bias in Included Studies

The reviewers independently assessed the risk of bias using the recommended Cochrane Collaboration's Risk of Bias Tool [45] to assess randomization procedures, bias, allocation, outcome assessor, reporting of findings, and losses to follow-up. Studies were classified as being of low, high, or an unclear risk of bias. The Risk of Bias in Nonrandomized Studies of Interventions was used to assess the risk of bias for controlled before/after designed studies.

Statistical Methods

The level of heterogeneity was taken into account when considering the suitability of the data for a meta-analysis. A small number of studies were identified with a large amount of heterogeneity present. The data were not amenable to synthesis, and a meta-analysis was not conducted. A full narrative review was undertaken using the *Narrative Synthesis in Systematic Reviews* tool [45].

The narrative synthesis involved the following elements:

- Developing a theory—the theoretical basis of the evaluated interventions was identified.
- Tabulation of data—extracted data from included studies included data on participants, interventions, outcome measures, country of origin, duration, delivery of the intervention, number of participants in each group, context in which intervention was delivered, results, and author comments.
- Textual descriptions summarizing each study were extracted to capture additional findings not identified during earlier stages of the synthesis.
- Vote counting as a descriptive tool—identified studies where the effect of the intervention was positive and statistically significant.

Results

Search Results

The PRISMA flowchart of the study selection process is presented in Figure 1. Electronic searches identified 868 publications. The clinical trials database search identified 3 further completed unpublished clinical trials. After excluding duplicates, 568 studies remained. After non-English studies were removed, 525 abstracts and titles were screened for suitability, with 422 records excluded. A total of 103 full-text articles were then assessed for eligibility via a full-text screening.

Any disagreements regarding study eligibility were resolved following consensus discussions between the 3 reviewers (KF, EH, and RM). The lead authors of the 3 unpublished studies were contacted for further information on program design, study design, data analysis, and methodology, as required. Overall, 4 published studies were included in this review (one of which described 3 RCTs), reporting on a total of 624 participants. A summary of the published studies included in this review is presented in Multimedia Appendix 1.

Study Characteristics

The studies were conducted in the United States [46], Australia [47] and the United Kingdom [48], with 1 paper reporting on 3 separate studies encompassing data from participants based in Canada, the United States, Australia, and Europe [49]. All included studies reported on samples with a current suicide risk or a history of self-harming and suicidal behaviors. The studies reported on veterans [46], indigenous youth in rural Australia [47], and individuals with a recent and severe history of self-injurious thoughts and behaviors recruited from Web forums focused on self-harm [48] and Child and Adolescent Mental Health Services (CAMHS) patients aged 12 to 17 years [47]. Participants in the Franklin study [48] were recruited from online forums (n=12) that focused on discussions of self-injury and related phenomena. Advertisements did not explicitly describe the study as a treatment study. The informed consent form made the treatment-related aspects of the study clear but did not provide details about Therapeutic Evaluative Conditioning (TEC) that would have allowed participants to discern whether or not they were in the active or control group.

A total of 4 studies met the criteria for inclusion in the review, including 2 RCTs [46,49], 1 pilot RCT [46], and 1 open-phase pre-post trial [47]. Although all studies were inclusive of participants with current or previous self-harm or suicidal ideation, some studies excluded participants who were *seriously contemplating or planning a suicide attempt* [47]. Of the 4 studies, 3 included a control group—only 1 provided a control version of the app [48], whereas the other 2 studies provided face-to-face meetings with study staff and safety checks with the same frequency as participants in the intervention condition [46,50].

In terms of therapeutic modalities, app content was informed by acceptance and commitment therapy (ACT) [46], dialectical behavior therapy [47], CBT [47,50], and TEC [48]. Suicide prevention–specific interventions included asking users to identify reasons for living [50], activities to help develop coping skills [46], emotional regulation strategies [46,47], providing emergency contact details [47,48], and developing an action plan [46]. The iBobbly mobile app [46], based on ACT, was the only of the 4 published studies that followed a module-based approach, whereby participants were asked to complete 3 ACT-based modules within a 6-week period. The Virtual Hope Box, BlueIce, and TEC mobile apps encouraged participants to use the app as often as they felt necessary. Participants in 3 of the 4 studies rated the mobile app with high acceptability [46,47] or high frequency of app use [50].

Suicide-specific outcomes were reported in each study. These included suicide ideation [46,50], self-injurious thoughts [48], and self-injurious behavior or self-harm [47,48]. Outcomes and their definitions differed across studies. A diverse range of measures was used to assess suicide-specific outcomes with no 2 studies using the same measure. Bush et al [50] used the Beck Scale for Suicide Ideation (BSS) [49] and the Columbia Suicide Severity Rating Scale (C-SSRS) [51]. Tighe et al [46] used the Depressive Symptom Inventory Suicidality Subscale [52] and the Patient Health Questionnaire (PHQ; item 9 of the PHQ-9 evaluates passive thoughts of death or self-injury within the last

2 weeks) [53]. Franklin [48] used the Self-Injurious Thoughts and Behaviors Interview [54], and Stallard et al [47] used self-reported changes in self-harming behavior.

In terms of efficacy, 2 studies described a statistically significant positive effect of the mobile app intervention on 1 or more suicide outcomes. Franklin's analyses of 3 studies reported that TEC produced moderate reductions for all self-injurious thoughts and behaviors except suicidal ideation. Reductions were reported for self-cutting episodes (32%-40%), suicide plans (21%-59%), and suicidal behaviors (33%-77%) [48]. TEC effects were not maintained at the 1-month posttreatment follow-up. Self-reported self-harm behavior reduced for 73% of participants in the intervention condition, who had used the BlueIce app over a 12-week period [47]. All of those who reported not self-harming in the 4 weeks before baseline assessment maintained their status and had not self-harmed over the course of the 12-week trial. Of the 26 participants who had self-harmed at baseline, 4 (15%, 4/26) had completely stopped, with a further 15/26 (58%) reporting less frequent acts of self-harm at follow-up. Tighe [47] reported that although pre- and postintervention changes were significant in the iBobbly arm ($t_{58.1}$=2.40; P=.02), the interaction of intervention arm by time (pre- vs postintervention) was not significant ($t_{57.8}$=1.05; P=.30). Estimated marginal means show that any difference between change in the 2 arms arose because of a slight but nonsignificant difference ($t_{59.0}$=0.84; P=.40) in mean baseline status between the 2 arms. Bush [50] measured the presence and intensity of suicidal ideation (BSS and C-SSRS); importance of reasons for living (Brief Reasons for Living Inventory); feelings of thwarted belongingness (Interpersonal Needs Questionnaire); and how unpredictable, uncontrollable, and overloaded individuals found their lives (Perceived Stress Scale). They found no statistically significant advantage of treatment augmented by the Virtual Hope Box app compared with the control condition for any of these outcomes.

All studies reported significant efficacy of the app interventions on secondary outcomes. Bush et al [50] found that Virtual Hope Box users reported a significantly greater ability to cope with unpleasant emotions and thoughts (Coping Self-Efficacy Scale) at 3 time points. Franklin et al [48] reported that the active group (mean −0.05, SD 0.27) showed a significantly smaller drop in positive affect toward self-related words compared with the control group (mean −0.17, SD 0.24; t_{49}=−1.77; P=.04; Cohen d=0.47). Diminished aversion toward the self was associated with less self-cutting (B=−2.49; SE=1.10; incidence rate ratio [IRR]=0.08; P=.02), nonsuicidal self-injury (B=−.77; SE=0.17; IRR=0.46; P=.001), suicidal ideation (B=−1.02; SE=0.20; IRR=0.36; P=.001), and suicide plans (B=−.92; SE=0.36; IRR=0.40; P=.01). Stallard [47] reported a statistically significant mean difference of 4.91 (t_{31}=2.11; P=.04; 95% CI 0.17-9.64) on postuse symptoms of depression (Mood and Feelings Questionnaire) and 13.53 on symptoms of anxiety (Revised Child Anxiety and Depression Scale; t_{30}=3.76; P=.001; 95% CI 6.17-20.90), which was evident across all anxiety subscales. Table 1 provides a summary of published results for each study.

Table 1. Summary of results of published studies included.

Study	Summary of results
Tighe et al, 2017 [46]	• Pre-post changes on the Depressive Symptom Inventory Suicidality Scale were significant in the iBobbly condition ($t_{58.1}$=2.40; P=.02), these differences were not significant when compared with the waitlist condition ($t_{57.8}$=1.05; P=.30). • Participants in the iBobbly group showed statistically significant reductions in the Patient Health Questionnaire-9 and Kessler 10-item questionnaire (K10) scores compared with waitlist. • No differences were observed between groups on impulsivity. • Waitlist participants improved after 6 weeks of app usage.
Bush et al, 2017 [50]	• VHB[a] users reported significantly greater ability to cope with unpleasant emotions and thoughts (Coping Self-Efficacy Scale) at 3 weeks (B=2.41; 95% CI 0.29-4.55) and 12 weeks (B=2.99; 95% CI 0.08-5.90) compared with the control group. • No significant advantage was found on other outcome measures for treatment augmented by the VHB.
Franklin et al, 2016 [48]	• TEC[b] produced moderate reductions for all SITBs[c] except suicide ideation when compared with the control app. • Consistent reductions were seen across studies for self-cutting episodes (32%-40%), suicide plans (21%-59%), and suicidal behaviors (33%-77%). • Of 3 studies, 2 showed that TEC impacted on its intended treatment targets, and that greater change in these targets was associated with greater SITB reductions. • TEC effects were not maintained at the 1-month posttreatment follow-up.
Stallard et al, 2018 [47]	• In all, 73% of those who have recently self-harmed reported reductions in self-harming after using BlueIce for 12 weeks. • Statistically significant mean difference of 4.91 (t_{31}=2.11; P=.04; 95% CI 0.17-9.64) on postuse symptoms of depression (Mood and Feelings Questionnaire) and 13.53 on symptoms of anxiety (Revised Child Anxiety and Depression Scale; t_{30}=33333.76; P=.001; 95% CI 6.17-20.90) evident across all anxiety subscales.

[a]VHB: Virtual Hope Box.

[b]TEC: Therapeutic Evaluative Conditioning.

[c]SITB: Self-Injurious Thoughts and Behaviour.

Risk of Bias in Included Studies

Risk of bias in the 4 published studies was evaluated using the Cochrane Collaboration Risk of Bias Tool [55]. Overall, 3 of the studies had high risk, and 1 had unclear risk, with biases most apparent for the domains of participant, clinical personnel, and outcome assessor blinding. Performance and detection bias, therefore, cannot be ruled out. Attrition bias was reported and was an important limitation for studies with small sample sizes [47,50]. Selection bias was apparent in 2 studies; in particular, Franklin et al [48] recruited participants online; therefore, their motivation and ability to engage may not be reflective of those recruited in the community. In the Stallard study [47], participants were identified by their CAMHS clinician for inclusion, and the study did not include a control group. Participants were also paid to complete the study [48]. Performance bias was evident in studies where allocation concealment was not described [50], and personnel were not blind to the intervention allocation [46], or where no method of blinding was reported in the study [48]. Sensitivity of outcome measures was poor in some studies because of a low number of items [46]. The amount of app usage was not specified in some studies, meaning that the level of engagement was not controlled for [48], and only 1 study controlled for the impact of a digital intervention by providing a control version of the app [48]. Table 2 provides a summary of risk of bias for each study.

Table 2. Risk of bias in the published studies included.

Study	Risk of bias
Bush et al, 2017 [50]	• Small sample size (attrition bias) • Authors did not report how the knowledge of allocated condition was blinded to participants and researchers during the study (performance and detection bias)
Tighe et al, 2017 [46]	• Owing to the changes in inclusion criteria after the commencement of the trial, one-fourth (26.2%) of the included participants did not meet the criterion for frequency of suicidal thoughts (attrition bias) • Participants, clinical personnel, and outcome assessors were not blind to treatment allocation • Data on usage were available for 65.6% of the included participants. Of these, 15% did not complete treatment • Small sample size • Sensitivity of measures was poor because of number of items (performance bias)
Franklin et al, 2016 [48]	• Neither participants nor clinical personnel were blind to treatment allocation (performance bias) • Participants were recruited online; therefore, motivation and ability to engage were potentially higher than recruitment through the community (selection bias) • Participants paid to complete study • Amount of app usage not specified—up to the user, level of engagement was not controlled for
Stallard et al, 2018 [47]	• Participants were identified by their Child and Adolescent Mental Health Services clinician. Participants themselves decided whether or not to take part (selection bias) • No control group present • No blinding reported. All participants in the study received an intervention as there was no control condition (performance and detection bias)

Unpublished Trials

In all, 3 completed but unpublished trials that met the criteria for inclusion are described in further detail in Multimedia Appendix 2 [56-58].

Discussion

Principal Findings

However, the evaluation studies included here indicate that mHealth tools show promise for individuals at elevated risk of suicide and self-harm and can be a useful adjunct to face-to-face therapy. This review confirms and updates the findings of Witt et al [30] who identified only 2 studies describing the efficacy of mobile apps, with the majority of digital intervention studies evaluating the effectiveness of online programs, and adds to the review conducted by Larsen et al [36], which identified that 24 apps for the prevention of suicidal behavior were available for download. This review identified 4 published and 3 unpublished studies evaluating the efficacy of mHealth technology in suicide prevention, indicating that the pace of development of such tools is not matched by evaluative research. Byambasuren et al [59] proposed a concept of *prescriptible* mHealth apps that are currently available, proven effective, and preferably stand-alone. The paucity of robust evidence evaluating the efficacy of mHealth interventions on suicide outcomes indicates that there is not yet sufficient research to support the prescribing of stand-alone mHealth tools for suicide prevention.

Overall, the evaluated mHealth technology interventions demonstrated some positive results for individuals at elevated risk of suicide or self-harm, including reductions in depression, psychological distress, and self-harm, and increases in coping self-efficacy. Mobile apps are one mechanism by which the scalability of effective interventions for suicide prevention can be improved [30]. The use of mobile apps has the capacity to increase accessibility to therapeutic interventions for at-risk individuals who may not otherwise seek help. Digital interventions have the potential to address major barriers to help-seeking behaviors, such as geographical location and stigma [23]. They also provide opportunities for evidence-based intervention to be accessed several times a day and at the time when it is most needed. Participants in 3 of the 4 published

studies were encouraged to use the mobile app as often as they felt necessary [46,48,49]. The findings revealed positive results for individuals who have decreased help-seeking behaviors [47] and who were at elevated risk of suicide and self-harm [46-49]. The utilization of mobile apps and other digital interventions is in line with the stepped-care treatment approach [30], which offers the least intensive and most accessible intervention, that has the best chance of delivering a positive outcome as the first line of treatment.

However, neither the iBobbly nor Virtual Hope Box or the TEC apps demonstrated the ability to significantly decrease suicidal ideation compared with a control condition. The studies included reported a positive impact on secondary outcomes, such as measures of depression and anxiety. This confirms parallel findings within face-to-face interventions. Insufficient evidence exists to suggest that CBT focusing on mental illness reduces suicidal cognitions and behaviors. CBT specifically focusing on suicidal cognitions and behaviors has been found to be effective [60]. Such interventions are likely to be most effective if they target the prominent risk factors that exist during acute suicidal crises [61]. The findings of this review may be reflective of the relatively small number of key suicide prevention strategies included in the apps described, with content focused instead on symptoms of depression and anxiety. Similarly, Larsen et al [36] found that although all apps evaluated contained at least 1 component that was broadly consistent with known evidence or best practice guidelines, there was limited concordance with high-quality, evidence-based practice.

In terms of clinical utility, suicide prevention mobile apps can be most beneficial for individuals at risk of suicide, particularly those with decreased help-seeking behaviors, when delivered as an adjunct to therapy, and when they deliver suicide-specific interventions. Future researchers could leverage the current and existing research findings by combining the delivery via mobile app of EMA with evidence-based psychological interventions. In-built EMA in suicide prevention apps has the potential to provide individualized time-stamped data spanning biological, social, and psychological variables, alongside behavioral measures of app usage and engagement to facilitate a greater understanding of suicide processes. The current evidence points to the need to focus on more dynamic intervention approaches, such as Just-In-Time Adaptive Interventions (JITAIs).

Limitations of the Studies Included

A significant limitation found across all studies pertained to the heterogeneity of the outcomes studied. This hampered the extent to which data could be compared and generalized. Diversity in nomenclature continues to challenge research in this area. Although in the United States, distinction is frequently made between nonsuicidal self-injury and suicidal behavior [62], for example, outside of the United States, these terms are yet to receive widespread acceptance [63]. The need for a standardized and shared labeling of suicidal ideation and behaviors has long been recognized. The International Association of Suicide Prevention Nomenclature Special Interest Group has formed a task force to generate an international standardized nomenclature on all terms within the area of suicidology, inclusive of death wishes, assisted suicide, and bereavement, which may render research more comparable around the world.

Similarly, no 2 studies used the same suicide outcome measure in this review. Studies used combinations of suicide-specific measures, single suicide-specific items, including measures assessing mental health more broadly, and self-report. Heterogeneity of outcomes evident across studies may be reflective of difficulties within research and clinical practice in identifying homogenous subgroups of self-harming patients [64]. It is imperative that to leverage previously completed work and maximize the available data, suicide prevention researchers work to develop and use standard practices in relation to suicide outcome measures.

A further methodological issue, which is likely to reduce ecological validity, is the practice of excluding individuals at increased risk of suicide from participation. Importing empirically supported treatments for depressed adolescents or suicidal adolescents may not be appropriate because the trials in which efficacy was established excluded suicidal teens [61]. Similarly, this review identified studies that excluded participants because of current suicide risk [47], a practice that may contribute to a sample bias and reduce generalizability of findings within clinical settings.

The findings highlight broader issues in relation to regulation and policy pertaining to mHealth technology. Some have argued that it is “now critical, even if paradoxical, to draw new boundaries in the seemingly boundless world of digital health” [31]. Indeed, the specific focus and purpose of the mHealth tools being evaluated in this review were not generally apparent without a full-text review and may underline a lack of standard categorization of tools to guide clinicians in their decision to use or recommend an app as part of their work. Torous and Hsin [31] argue that there is an urgent need to unite the potential of digital health with the fundamental ethics of clinical practice and to encourage innovation while protecting both the future of digital health and the trust it requires to engage patients and clinicians. They propose a practical taxonomy accessible to clinicians, comprising 3 categories of digital health use to illustrate these boundaries: (1) treatment and diagnosis, (2) care enhancement, and (3) resources. It is argued that adopting this rubric at the level of clinical judgment in direct patient care may facilitate empowerment of digital health technology by harnessing the utility of decision-guiding frameworks that clinicians already use in practice. Future research would also benefit from following the guidance of established standards of reporting on eHealth evaluations [65].

Strengths and Limitations of This Review

This review extends the reviews undertaken by Larsen et al [36] and Witt et al [30] by (1) not restricting the modalities reviewed to mobile phone apps and including other mHealth technology–delivered interventions and (2) evaluating efficacy using outcomes research to complement Larsen’s comprehensive assessment of content. However, the small number of studies identified hindered our ability to synthesize data and conduct a meta-analysis. There were not sufficient data to provide a comparison of mobile technology tools across outcome measures such as mobile phone apps, texting, and gaming, which could

help identify the most effective modes of delivery. This may be, in part, contributed to by the restrictive inclusion and exclusion criteria employed within this study. For example, 21 studies were excluded for not being an RCT, pseudo-RCT, or observational pre-/posttest design, and an additional 7 studies were excluded for not having a suicide-specific measure as a primary outcome. Therefore, had the inclusion criteria been less stringent, more studies would have been included within the review, which may have allowed for a meta-analysis to be completed. However, the current eligibility criteria were decided on for this review to capture the results of scientifically rigorous studies.

Risk of bias assessment indicated methodological issues across studies, which could be addressed in future research. The small sample sizes across studies and attrition during studies limited the generalization of findings. Blinding procedures were problematic across studies, and the small number of research-validated suicide prevention apps available makes comparisons with similar interventions difficult. These difficulties may signal a need for a shift in focus from traditional research methods investigating unidirectional cause-effect relationships to examining dynamic systems by applying machine learning approaches to big data.

Conclusions

The 4 completed and published studies included in this review evaluated the iBobbly, Virtual Hope Box, BlueIce, and TEC apps. Together, results evaluating the apps show some positive results for individuals at elevated risk of suicide or self-harm, including reductions in depression, psychological distress, and self-harm and increases in coping self-efficacy. Despite the continued growth in the development and availability of suicide prevention mHealth tools, there is currently limited evaluative research on the efficacy of such tools in reducing suicide-specific outcomes.

However, neither the use of iBobbly nor Virtual Hope Box or the TEC apps demonstrated the ability to significantly decrease suicidal ideation compared with a control condition. Further evaluation studies would benefit from addressing 3 main methodological issues, which arose across studies: (1) heterogeneity of outcomes, (2) exclusion of individuals at higher risk of suicide, and (3) performance biases arising because of blinding procedures. Although the evidence available indicates some progress, the pace of suicide prevention app development needs to be matched by a greater focus on empirically supported mHealth technology–based interventions. Future research endeavors would benefit from leveraging the current findings with existing EMA research to support the development and evaluation of dynamic interventions (such as JITAIs) delivered via mobile apps to provide effective intervention while simultaneously enhancing our understanding of suicide processes.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Published studies included in the review.
[DOCX File , 23 KB - mhealth_v8i1e12516_app1.docx]

Multimedia Appendix 2
Unpublished completed studies identified.
[DOCX File , 17 KB - mhealth_v8i1e12516_app2.docx]

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Abbreviations

ACT: acceptance and commitment therapy
BSS: Beck Scale for Suicide Ideation
C-SSRS: Columbia Suicide Severity Rating Scale
CAMHS: Child and Adolescent Mental Health Services
CBT: cognitive behavioral therapy
eHealth: electronic health
EMA: Ecological Momentary Assessment
FDA: Food and Drug Administration
JITAI: Just-In-Time Adaptive Intervention
mHealth: mobile health
PHQ: Patient Health Questionnaire
PICO: participants, interventions, comparisons, and outcome(s)
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
RCT: randomized controlled trial
TEC: Therapeutic Evaluative Conditioning
WHO: World Health Organization

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Original Paper

Effect of mHealth With Offline Antiobesity Treatment in a Community-Based Weight Management Program: Cross-Sectional Study

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Abstract

Background: Weight loss interventions using mobile phone apps have recently shown promising results.

Objective: This study aimed to analyze the short-term weight loss effect of a mobile coaching intervention when it is integrated with a local public health care center and a regional hospital's antiobesity clinic as a multidisciplinary model.

Methods: A total of 150 overweight or obese adults signed up to complete an 8-week antiobesity intervention program with human coaching through a mobile platform. Paired *t* tests and multiple linear regression analysis were used to identify the intervention factors related to weight change.

Results: Among the 150 participants enrolled in this study, 112 completed the 8-week weight loss intervention. Weight (baseline: mean 77.5 kg, SD 12.9; after intervention: mean 74.8 kg, SD 12.6; mean difference −2.73 kg), body mass index, waist circumference, fat mass (baseline: mean 28.3 kg, SD 6.6; after intervention: mean 25.7 kg, SD 6.3; mean difference −2.65 kg), and fat percentage all showed a statistically significant decrease, and metabolic equivalent of task (MET) showed a statistically significant increase after intervention. In multiple linear regression analysis, age (beta=.07; *P*=.06), △MET (beta=−.0009; *P*=.10), number of articles read (beta=−.01; *P*=.04), and frequency of weight records (beta=−.05; *P*=.10; R^2=0.4843) were identified as significant factors of weight change. Moreover, age (beta=.06; *P*=.03), sex (female; beta=1.16; *P*=.08), △MET (beta=−.0009; *P*<.001), and number of articles read (beta=−.02; *P*<.001; R^2=0.3728) were identified as significant variables of fat mass change.

Conclusions: The multidisciplinary approach, combining a mobile health (mHealth) care app by health care providers, was effective for short-term weight loss. Additional studies are needed to evaluate the efficacy of mHealth care apps in obesity treatment.

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KEYWORDS

obesity; mobile apps; mobile health; weight loss

Introduction

Background

Obesity is one of the most prominent problems in the global public health domain. Worldwide, in 2016, more than 1.9 billion adults were overweight, and 650 million were obese [1]. The global prevalence of obesity nearly tripled between 1975 and 2016 [1]. Obesity is well known to increase the risk of high blood pressure, dyslipidemia, type 2 diabetes, and cardiovascular diseases [2]. Exercise and dietary interventions are necessary to prevent and control obesity.

Dietary restriction and increased physical activity are known treatments for obesity. Self-weighing is also known to be associated with weight loss [3]. To deliver the best weight loss outcome using lifestyle modification and weight logging, multiple approaches using mobile technology have been applied, such as the use of telephone calls [4], text messaging [5,6], and mobile apps [7,8]. Some studies have shown that providing supplementary mobile intervention can enhance conventional offline weight loss intervention based on the clinical setting [9,10]. The limitation of prior studies related to the combination of mobile and offline interventions was that the mobile component mostly focused on the monitoring aspect. We wanted to enhance the mobile intervention by integrating human coaching to the monitoring aspect and also to enhance the offline intervention by integrating a local public health center, which recruits eligible participants, and a local hospital that evaluates and motivates these participants.

Objectives

As South Korea has a well-organized health care access, high-quality medical infrastructure, and high mobile phone penetration rate [11], it is a good environment to test our multidisciplinary model.

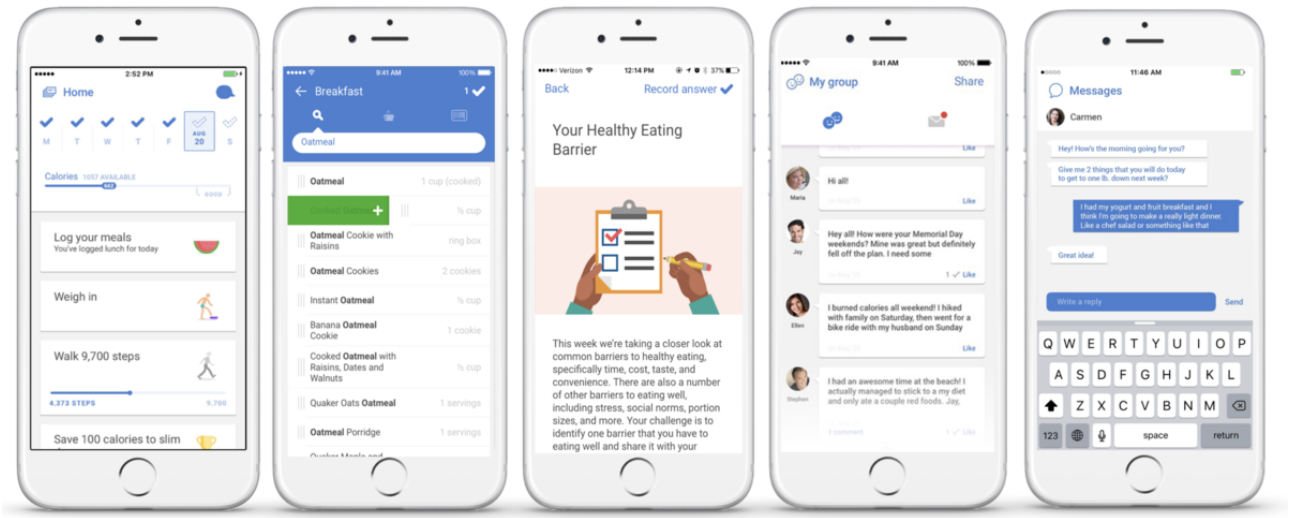
The purpose of this study was to analyze the short-term weight-loss effect of mobile coaching intervention when it is integrated with a local public health care center and a regional hospital's antiobesity clinic as a multidisciplinary model. For mobile coaching intervention, we used a commercially available mobile app to target a broader population.

Methods

Study Design

This was a single-arm study that assessed the impact of a mobile short-term weight loss intervention combined with a conventional offline intervention based on the local health care infrastructure. Participants were recruited by a local public health care center and sent to Myongji Hospital, a local hospital, for the initial offline intervention led by a physician. An 8-week mobile intervention using the Noom Coach (Noom Inc) was provided to the participants with the offline intervention after each participant underwent an orientation of the antiobesity program (Figure 1). Various measures were assessed after the 8-week weight loss intervention.

Figure 1. Features of the Noom Coach app.



Recruitment

Participants were recruited by Ilsan Dong-gu Public Health Center, a local public health center run by the government. A total of 150 participants were recruited from March 2017 to September 2017. We included participants who were overweight or obese, defined as a body mass index (BMI) greater than or equal to 23 kg/m^2 or waist circumference greater than or equal to 90 cm for men and greater than or equal to 80 cm for women per the World Health Organization criteria for Asian population [12]. Participants who showed no willingness to lose weight or did not have a mobile phone or could not visit both public health centers and hospitals were excluded. We also excluded pregnant women and subjects diagnosed as having cardiovascular or cerebrovascular disease within the recent 6 months. All the participants provided written informed consent. The Myongji Hospital Institutional Review Board (IRB) approved the study protocol (IRB no. 2018-03-012).

Antiobesity Program—Offline Intervention

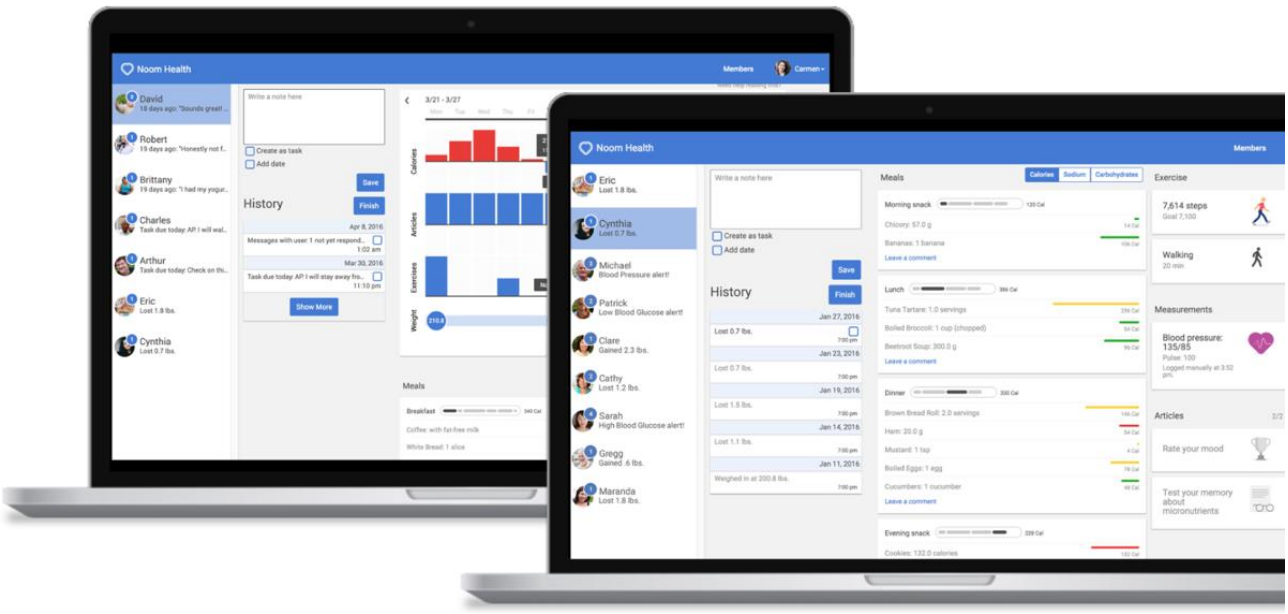
All participants visited the hospital's antiobesity clinic once a month during the 8-week study period. The offline weight loss

intervention consisted of an evaluation of the participants' initial obesity status followed by consultation for lifestyle modification with an obesity specialist. All the participants were recommended by physicians and dietitians to reduce 500 kcal from their daily dietary intake [13]. The participants were also asked to record their intakes using the mobile app. In addition, all the participants were encouraged to perform aerobic exercise for at least 5 hours per week [13]. During each monthly visit, the participants were re-evaluated by the health care providers, who provided feedback about their calorie intake, and were encouraged to increase or maintain a moderate exercise level.

Antiobesity Program—Mobile Intervention

Noom Coach is a commercialized mobile app launched in 2012 that provides various lifestyle-related logs and is available in Android and Apple app markets. The mobile intervention consisted of (1) food logging, (2) exercise logging, (3) weight logging, (4) in-app group activities, (5) in-app articles, and (6) messages from the coaches. Total counts using mobile app is the sum of diet records, exercise records, weight records, all in-app group records, number of messages, and number of articles read. The participants were encouraged to log their food intake and exercises on a daily basis and record their weight on a weekly basis. The participants were assigned to an in-app group where they can communicate with other participants, sharing their healthy behaviors. In-app articles were also provided for the participants to gain knowledge about healthy dietary intake and physical activities. In-app articles were written by physicians, nutritionists, and clinical psychologists. Individual coaches offered feedback to the participants based on their entries with praise, emotional support, encouragement, and validation. A Web-based dashboard was used to monitor the participants' data and provide individualized feedback (Figure 2). The coaches communicated with the participants via in-app messaging at least two times per week. The coaches and participants discussed their health-related struggles and set up realistic behavioral health goals on a weekly basis. The health goals were related to calorie restriction and increased aerobic physical activity. This process considered each participant's habits, preferences, and resources. For example, walking 5000 steps a day using an in-app pedometer, drinking 8 cups of water a day, and logging their food intake throughout the day were identified as missions for the participants to implement; the coaches followed up to see whether the participants had completed them. If they were successful, the coaches offered praise and set another goal. If they were unsuccessful, the coaches and participants discussed the barriers and set up another realistic goal.

Figure 2. Web-based dashboard.



The coaches received education from physicians, clinical nutritionists, and clinical psychologists before starting coaching services regarding the medical, nutritional, and behavioral components of obesity and weight loss. Among the 93 techniques of the Behavior Change Technique Taxonomy [14], 10 were used during the mobile intervention. Social reward and feedback on behavior were provided by the coaches. The in-app curriculum contained content related to habit formation, graded tasks, action planning, problem solving, and goal setting. Self-monitoring of behavior was applied by letting participants record their food intake and exercise. Social support was provided by the in-app groups.

Measurements

All measurements were taken according to a standard protocol at baseline and week 8. Adiposity indices, such as BMI, waist circumference, and body composition, were measured by registered nurses at both public health centers and the Myongji Hospital. Anthropometric measurements were performed with the subjects wearing light clothing without shoes. BMI was calculated by dividing weight by height squared (kg/m^2). Waist circumference was measured at the midpoint between the lower border of the rib cage and the iliac crest. Body composition, including whole-body muscle mass, fat mass, and fat percentage, was estimated using a bioelectrical impedance analysis device (InBody230; InBody). Blood pressure was measured in the right

arm after the participant was seated and allowed to rest for 15 min; two measurements were recorded. Metabolic equivalent of task (MET) was measured to track the exercise levels of the participants. MET was calculated using the MET formula using the exercise intensity and duration and physical activity data collected during the survey [15].

Statistical Analysis

The mean values and standard deviations of all variables before and after the weight reduction were calculated. The mean difference and 95% CI of all variables were also calculated. A paired *t* test and multiple linear regression analysis were used. Covariates with *P* values <.15 in the univariate analysis of their association with changes in weight and fat mass were further considered in the multiple linear regression model. The factors included in the final multiple regression model were selected based on statistical significance and clinical importance. For model 1, we used *total counts using a mobile app* during mobile intervention in the regression model. For model 2, we included all mobile health (mHealth) components in the regression model. We presented an effect estimate for the interquartile increase in each variable on weight, which was calculated by multiplying the regression coefficient by the interquartile range (75th–25th percentile) of each variable. The equation was applied for effective comparison of the effect estimates across various variables with different units and easy interpretation of weight change corresponding to a realistic increment of each risk factor [16]. We analyzed all data using the statistical program SAS 9.2 (SAS Institute, Cary, North Carolina). *P* values <.05 were considered significant.

Results

Demographic Data and Comparison of Participant's Characteristics Before and After the Intervention

Among the 150 participants, 112 completed the 8-week intervention (completion rate 74.7%). The mean age of the participants was 47.8 years (SD 10.2), and the proportion of females was 72.3% (82/112). The values of the variables before and after the 8-week intervention are presented in Table 1. Weight, BMI, waist circumference, fat mass, and fat percentage all showed a statistically significant decrease. MET showed a statistically significant increase, whereas muscle mass did not show any significant change.

Table 2 shows the mean total use frequency and each mHealth component during the 8-week antiobesity intervention.

Table 1. Clinical characteristics of the study subjects and comparison of change after intervention (N=112).

Variables	Baseline	After weight reduction	Mean difference	95% CI	*P* value[a]
Age (years), mean (SD)	47.8 (10.2)	—[b]	—	—	—
Female, n (%)	82 (72.3)	—	—	—	—
Weight (kg), mean (SD)	77.5 (12.9)	74.8 (12.6)	−2.73	−3.36 to −2.41	<.001
Height (cm), mean (SD)	163.6 (8.4)	—	—	—	—
BMI (kg/m^2), mean (SD)	28.8 (3.3)	27.8 (3.1)	−1.03	−1.27 to −0.91	<.001
Waist (cm), mean (SD)	94.2 (10.9)	90.5 (10.2)	−3.39	−4.62 to −2.76	<.001
Muscle mass, mean (SD)	27.0 (5.9)	27.2 (6.1)	0.19	−0.10 to 0.34	.21
Fat mass, mean (SD)	28.3 (6.6)	25.7 (6.3)	−2.65	−3.24 to −2.35	<.001
Fat percentage, mean (SD)	36.7 (6.0)	34.5 (6.6)	−2.22	−2.85 to −1.90	<.001
Systolic BP[c] (mm Hg), mean (SD)	126.5 (16.9)	125.0 (14.5)	−1.19	−4.05 to 0.27	.42
Diastolic BP (mm Hg), mean (SD)	79.1 (11.5)	77.7 (10.5)	−1.73	−3.71 to −0.72	.09
Metabolic equivalent (kcal/min/kg), mean (SD)	790.1 (841.2)	1365.1 (1507.4)	504.9	264.2 to 622.6	<.001

[a]Paired *t* test.

[b]No change from baseline value.

[c]BP: blood pressure.

Table 2. The mean counts of participants' mHealth components during 8 weeks of intervention.

mHealth components	Number of use per participants, mean (SD)
Total counts using a mobile app[a]	309.5 (254.6)
Frequency of diet records	105.2 (69.8)
Frequency of exercise records	21.0 (28.9)
Frequency of weight records	9.5 (13.2)
Number of articles read	86.5 (78.2)
Number of posting on in-app group	10.7 (19.1)
Number of replies to in-app group	7.3 (17.3)
Number of expressing a favor on in-app group	14.6 (41.4)
Number of coaching communications (in-app messages)	54.8 (57.0)

[a]Total counts using a mobile app is the sum of diet records, exercise records, weight records, all in-app group records, number of messages, and number of articles read.

Factors Associated With Weight Reduction

The variables associated with weight changes in the multiple linear regression analysis are displayed in Table 3. Age (beta=.06; *P*=.04), △MET (beta=−.0009; *P*<.001), and total counts using a mobile app (beta=−.005; *P*<.001; R^2=0.3936) significantly predicted short-term weight loss. Moreover, specific components of total counts using a mobile app were analyzed with multiple linear regression. Age (beta=.07; *P*=.06), △MET (beta=−.0009; *P*=.10), number of articles read (beta=−.01; *P*=.04), and frequency of weight records (beta=−.05; *P*=.10; R^2=0.4843) were identified as significant factors of weight change (Table 3). Moreover, we tried to identify variables associated with fat mass changes in the multiple linear regression analysis. As a result, age (beta=.05; *P*=.07), sex (female; beta=1.08; *P*=.10), △MET (beta=−.0009; *P*<.001), and total counts using a mobile app (beta=−.005; *P*<.001; R^2=0.3559) significantly related to fat mass change. In the analysis of specific components of the total counts using a mobile app, age (beta=.06; *P*=.03), sex (female; beta=1.16; *P*=.08), △MET (beta=−.0009; *P*<.001), and number of articles read (beta=−.02; *P*<.001; R^2=0.3728) were identified as significant variables. The results indicated that for every 1-year increase in age, there was a corresponding 0.07 kg increase in weight and 0.06 kg increase in fat mass. For every unit increase in MET, there was a 0.0009 kg decrease in weight and 0.00009 kg decrease in fat mass. Furthermore, for every one-time increase in the number of articles read, there was a 0.01 kg decrease in weight and a 0.02 kg decrease in fat mass, and for every one-time increase in weight record, there was a 0.05 kg decrease in weight in our study. In another explanation, the weight change per the interquartile range increase in age, △MET, and total counts using a mobile app were 0.75, −0.75, and −2.24 kg, respectively, and fat mass change per the interquartile range increase in age, △MET, and total counts using a mobile app were 0.63, −0.75, and −2.24 kg, respectively, in model 1. The fat mass change per the interquartile range increase in age, △MET, number of articles read, and frequency of weight record were 0.88, −0.75, −1.57, and −0.55 kg, respectively, and the fat mass change per the interquartile range increase in age, △MET, and total use frequency were 0.75, −0.75, and −3.14 kg, respectively, in model 2.

Table 3. Multiple linear regression analysis used to identify the factors provided by the antiobesity program with mHealth and clinical variables associated with weight change and fat mass change.

Variables	Weight change			Fat mass change		
	Beta coefficient	SE	*P* value	Beta coefficient	SE	*P* value
Model 1[a,b]						
Age	.06	0.03	.04	.05	0.03	.07
Sex	—[c]	—	—	1.08	0.65	.10
ΔMET[d]	−.0009	0.0003	<.001	−.0009	0.0003	<.001
Total counts using a mobile app[e]	−.005	0.001	<.001	−.005	0.001	<.001
Model 2[f,g]						
Age	.07	0.04	.06	.06	0.03	.03
Sex	—	—	—	1.16	0.64	.08
ΔMET	−.0009	0.0005	.10	−.0009	0.0003	<.001
Number of articles reads	−.01	0.006	.04	−.02	0.004	<.001
Number of weight records	−.05	0.03	.10	—	—	—

[a]Weight change R^2=0.3936.

[b]Fat mass change R^2=0.3559.

[c]Not applicable.

[d]MET: metabolic equivalent.

[e]Total counts using a mobile app is the sum of diet records, exercise records, weight records, all in-app group records, number of messages, and number of articles read.

[f]Weight change R^2=0.4843.

[g]Fat mass change R^2=0.3728.

Discussion

Principal Findings

This study examined the effectiveness of the obesity management program on the basis of the hospital setting with the mobile coaching program and revealed that younger age, increased number of articles read, and the amount of exercise were significant variables for short-term weight loss.

On the basis of the analysis, younger age showed a positive correlation with weight loss effect. The accessibility of the mobile platform might have been affected by age, which was reported in other studies on mobile platforms [17-19]. The number of articles read also showed a positive correlation with weight loss effect, implying that participants who read more articles had a better result. This was also reported in other studies that used mobile apps on weight loss [20,21], indicating that strategies to increase the reading adherence to the articles provided in mobile apps will be important for mobile weight loss interventions. Furthermore, increased physical activity measured using MET showed a positive correlation with weight loss effect. The correlation between increased physical activity and weight loss outcome has been reported in many studies [22-24]. In this study, we observed a similar outcome after the mobile weight loss intervention combined with local public health centers and local hospitals.

A significant association between self-monitoring and weight loss was reported in multiple studies [25-27], and adherence to self-monitoring increased with the receipt of feedback [26]. The traditional recording method using pens and notes is cumbersome [25], and the frequency of its use decreased with time [25]. For this reason, using a mobile phone app is an alternative method because anyone can use it, regardless of the time and location [28]. Several randomized trials reported that smartphone apps help participants monitor their weight and lead to behavioral changes through actionable and personalized feedback [29,30]. Moreover, several studies showed short-term use of mobile phone app could be effective in lifestyle modification of obese people and patients with kidney disease [31-33].

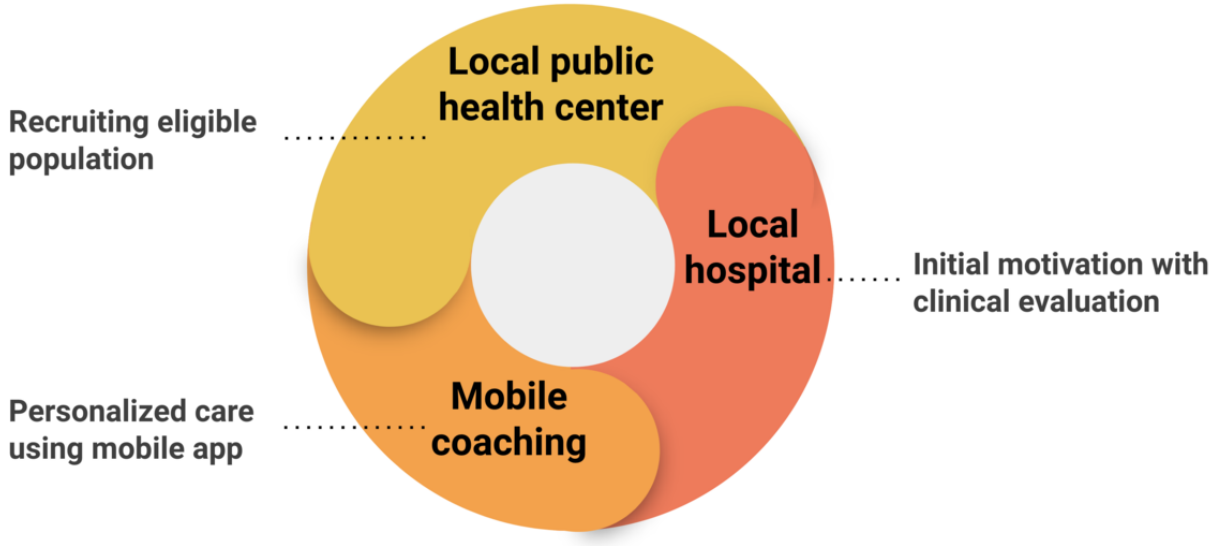
One of the key factors in the mobile intervention in this study was the use of human lifestyle coaches. Although a smartphone app is an effective method for recording and self-monitoring, the general retention rate is relatively low over time for many reasons (eg, boredom of repetitive tasks, naturally decreased motivation, or simply forgetting). A mobile phone app designed for accessibility and personalized features is most important [34]. The app in our study offers personalized feedback, timely alerts for actions within 24 hours, and professional counseling by a human being, which were helpful for increasing participant engagement in the program, implementing plans, and maintaining weight loss [35]. The ideal timing, frequency, and tone of message delivery have not been sufficiently examined in the literature; therefore, these factors can be evaluated in studies in the future. Moreover, mobile weight loss intervention

(combined with offline intervention) with added features to promote exercise will be strategically considered.

Multidisciplinary Approach

The major strategy of our intervention was using a multidisciplinary approach to weight loss (Figure 3). Overall, three types of synergistic effects were noted during the study period. First, a synergistic effect of public and private sectors was the unique component of our multidisciplinary intervention. The combination of public health centers and private hospitals was important during the initial engagement and risk assessment. Local public health centers recruited participants with obesity on the basis of the residents' risk data and referred them to the obesity clinics of private hospitals. Considering the difficulty encountered by private hospitals in recruiting an obese population without chronic diseases, the role of public health centers was important. Local hospitals played an important role in motivating the participants recruited by public health centers. The hospital clinic provided initial offline education along with the regular evaluation and face-to-face feedback. As there were limitations with respect to the evaluations performed and clinical expertise at the public health centers, private hospitals played an important role in providing high-quality assessment with in-depth intervention.

Figure 3. Public health, local hospital, and commercial mobile app framework.



Second, the combination of hospitals and mobile coaching provided continuous care within the participants' lifestyle on a daily basis. Mobile coaching supported the participants by providing them with specific daily tasks to meet the weight loss goals suggested by the hospital clinicians. The hospital clinic visits and mobile intervention supplemented their respective weaknesses. Offline encounters with and feedback from health care providers at the hospital clinic supplemented the low compliance and motivation problems of the mHealth care platform. The daily penetration of mobile coaching and easy logging supplemented the fragmented care in offline intervention.

Third, public health centers and mobile intervention showed a synergistic effect on the engagement of the users. The local public health centers promoted local resident leaderships to participate in in-app groups to better activate the mobile groups. As the group was always accessible through the mobile app, the dynamics between the participants were different from that among the participants of the offline group sessions at the local public health centers in terms of continuity.

Limitations

Our study has several limitations. First, this was a single-arm study designed to analyze effective intervention factors related to weight change. Therefore, a randomized control trial is required to analyze the effectiveness of the intervention compared with the control group. Second, the sample size was relatively small, and the intervention duration was short, so we could not measure the sustainability and long-term effect of our intervention. Third, our study has a potential reporting bias because the mobile data collected through the mobile app were self-reported data. Under- or overreporting was possible on the basis of the characteristics of each participant. This might be from some limitation of the calibration of the frequency and types of intervention.

Conclusions

The major outcome of this study shows that the multidisciplinary approach combining the public health sector and hospitals by health care providers with a mHealth care app had shown a short-term weight loss outcome. Further large, long-term studies are needed to evaluate the effectiveness and efficiency of the mobile health care app in an antiobesity program and to examine the possibility of a synergistic effect between mobile health care and the face-to-face approach for managing obesity.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
IRB: institutional review board
MET: metabolic equivalent
mHealth: mobile health

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Original Paper

Feasibility and Health Benefits of an Individualized Physical Activity Intervention in Women With Metastatic Breast Cancer: Intervention Study

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Abstract

Background: There is limited knowledge regarding the potential benefits of physical activity in patients with metastatic breast cancer.

Objective: The Advanced stage Breast cancer and Lifestyle Exercise (ABLE) Trial aimed to assess the feasibility of a physical activity intervention in women with metastatic breast cancer and to explore the effects of physical activity on functional, psychological, and clinical parameters.

Methods: The ABLE Trial was a single-arm, 6-month intervention study with a home-based, unsupervised, and personalized walking program using an activity tracker. At baseline and 6 months, we assessed anthropometrics, functional fitness, physical activity level, sedentary behavior, quality of life, fatigue, and tumor progression. Paired proportions were compared using the McNemar test and changes of parameters during the intervention were analyzed using the Wilcoxon signed-rank test, the Mann-Whitney test, and Spearman rank correlations.

Results: Overall, 49 participants (mean age 55 years; recruitment rate 94%) were enrolled and 96% adhered to the exercise prescription (attrition rate 2%). Statistically significant improvements in the 6-minute walking distance test (+7%, $P<.001$) and isometric quadriceps strength (+22%, $P<.001$), as well as decreases in body mass index (-2.5%, $P=.03$) and hip circumference

(-4.0%, *P*<.001) were observed at 6 months. Quality of life remained stable and a nonstatistically significant decrease (-16%, *P*=.07) in fatigue was observed.

Conclusions: The high recruitment and adherence rates suggest the willingness of patients with metastatic breast cancer to participate in a physical activity program. The beneficial outcomes regarding physical fitness and anthropometry of this unsupervised physical activity program may encourage these patients to maintain a physically active lifestyle. Future randomized controlled trials with larger sample sizes are warranted.

Trial Registration: ClinicalTrials.gov NCT03148886; https://clinicaltrials.gov/ct2/show/NCT03148886

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KEYWORDS

metastatic breast cancer; physical activity; activity trackers; feasibility; tumor progression

Introduction

Metastatic breast cancer remains an incurable disease, but treatments help maintain or improve quality of life and prolong overall survival through the control of symptoms [1-3]. Despite therapeutic advances, a decrease in quality of life in patients with metastatic breast cancer between 2005 and 2015 has been reported [4]. With metastatic disease, several domains of quality of life are affected from the time of diagnosis, with a decrease in physical, social, and role functioning and an increase in symptom burden, such as insomnia, fatigue, and pain, that deteriorate in advanced and palliative cancer [5].

In early-stage breast cancer, physical activity has been shown to reduce fatigue and side effects of treatments, increase quality of life, and limit physical deconditioning [6-8]. Thus far, there is limited knowledge regarding the potential benefits of physical activity in patients with metastatic breast cancer despite patients' needs and their desires to engage in exercise [9,10]. The new guidelines from the Macmillan Foundation for people with metastatic bone disease have highlighted the importance of remaining as physically active as possible and limiting sedentary behavior, despite the side effects of the disease and its treatment [11]. A review of physical activity in palliative cancer patients has shown that patients with metastatic cancer who walked 30 minutes or more per day reported a higher quality of life than those who walked less than 30 minutes per day [12]. However, the effect of physical activity in patients with metastatic breast cancer remains controversial, especially concerning quality of life [10], possibly because few physical intervention studies have focused on patients with metastatic breast cancer. Hence, there is a need for additional studies to determine the benefit of physical activity on patient-reported outcomes for this population.

Activity trackers are emerging as a means to motivate populations to increase their physical activity level to personal or recommended goals [13,14] as a result of the feedback received in real time (eg, steps) [13,15]. The benchmark performance of 10,000 steps per day for healthy populations has been associated with a reduced risk of cardiovascular disease, better psychological well-being, weight loss, and improved body composition [16]. However, for adults with health impairment such as disability and/or chronic illness, reducing sitting time, which is a recognized marker of sedentary behavior [17], and achieving 5000-7000 steps per day that correspond to a low active population, may be more appropriate targets than 10,000 steps per day [18].

The primary aim of the Advanced stage Breast cancer and Lifestyle Exercise (ABLE) single-arm Trial was to determine the feasibility of an unsupervised and personalized 6-month physical activity intervention, performed with activity trackers under real-life conditions, in patients with metastatic breast cancer. The secondary aims were to investigate changes in (1) physical activity, sedentary behavior, and physical fitness, (2) anthropometric measurements, (3) quality of life and fatigue, and (4) tumor progression, as well as their associations with the performed physical activity.

Methods

Study Design

The ABLE Trial was a single-arm intervention study in patients with metastatic breast cancer conducted at the Léon Bérard Comprehensive Cancer Centre, Lyon, France. The ABLE Trial protocol has been published previously [19]. The protocol was approved by the French Ethics Committee (Comité de Protection des Personnes Sud-Est IV). The study was reported to the National Commission for Data Protection and Liberties (CNIL; reference number: 1994192) and registered at ClinicalTrials.gov (trial number: NCT03148886).

Briefly, participants were identified during the weekly multidisciplinary board meeting for metastatic breast cancers. The study was proposed by medical oncologists to eligible patients being treated with chemotherapy at the day care unit. Patients treated with hormone therapy received an information letter signed by their oncologist and a study brochure via postal mail; a clinical research assistant contacted them by telephone one week later to know whether they agreed to be enrolled in the study. All patients provided written informed consent prior to their inclusion into the study.

Study Participants

Women were eligible to participate in the study if they were between 18 and 78 years of age, with de novo or secondary metastatic breast cancer that has been histologically confirmed. Subjects needed to be newly diagnosed patients (ie, within the last 3 months) in order to have comparable patients at inclusion. Patients were treated with chemotherapy, hormone therapy, targeted therapy, and/or radiation therapy. Additional eligibility criteria were as follows: having a medical clearance of no

contraindications to physical activity; having an Eastern Cooperative Oncology Group performance status of less than 2; being able to speak and understand French, to complete questionnaires, and to follow instructions in French; and having a valid health insurance affiliation. An active list of patients was extracted from the center's data to estimate the number of potential subjects and the age range for the inclusion criteria. These data were extracted from the numbers of patients treated at the center in 2015 for metastatic breast cancer with our inclusion criteria.

Patients with contraindications to physical activity (eg, uncontrolled hypertension or cardiac disease and unstable bone metastases) who were unable to be followed for medical, social, familial, geographical, or psychological reasons over the study period, or with deprivation of liberty by court or administrative decision, were deemed ineligible for the ABLE Trial.

Exercise Intervention

The intervention was a 6-month, home-based, unsupervised, personalized physical activity program based on international physical activity recommendations and was based on a goal of a number of steps to reach per day [19]. Participants were asked to wear a wrist activity tracker during the duration of the intervention (Nokia Go wristband, Nokia France). Based on their health status at baseline and the average number of steps registered during the first week, women received an individual goal of steps per day from a physical activity instructor. The goal was reviewed weekly and revised depending on the number of steps performed during the previous week, the participant's feelings, and her health status. The target number of steps was set within a maximum of 1000 steps above the average number of steps in the previous week. For participants who reached 10,000 steps per day, the target was to maintain their number of daily steps. For patients who found it difficult to reach the goal of daily step number, their goal could be lowered so that the new goal could be reached according to the patients' abilities and in accordance with the recent recommendations for the practice of physical activity in cancer patients [20]. To apply the intervention, we used two strategies. First, we adapted the number of steps to make it reasonably achievable because people need to experience the satisfaction of achieved goals in order to have the pleasure of mastery and to allow the participant to set goals and stay motivated. Second, there were times participants could have discussions with the physical activity professional to encourage evaluative feedback and encouragement, which contributes to social persuasion. Every week, all participants received the following from the physical activity instructor, either in person or by phone: individual feedback on their performance and personalized recommendations to increase or maintain their physical activity and reduce sedentary behavior.

Outcome Measures

The primary outcome is the feasibility of the intervention assessed with the proportion of participants achieving the international physical activity recommendations of 150 minutes per week of at least moderate-intensity physical activity [21], which was evaluated by the long form of the International Physical Activity Questionnaire (IPAQ) [22] during the last week of the study. Very little is known about this population and since we were not sure that participants would adhere to the activity tracker, an objective that could be measurable by questionnaire for all patients was chosen.

The adherence rate to the exercise program was calculated as the proportion of patients from the full study population who used the physical activity tracker throughout the duration of the study without interruption for more than one consecutive week. Secondary outcomes were the changes during the intervention in (1) the score of total physical activity and time spent in sedentary activities as assessed by the long-form IPAQ, and physical fitness assessed by the performance of the 6-minute walk test and the upper- and lower-limb strengths, (2) anthropometrics, (3) scores of quality of life and fatigue, and (4) both the progression rate and the overall survival—estimated by Kaplan-Meier analysis—to assess the disease evolution.

Data Collection

Overview

Parameters were assessed at baseline (T1) and at the end of the intervention at 6 months (T2). To assess survival, the vital status of the study participants was checked on June 2018 through the participants' electronic medical records after they had completed the intervention.

Demographic and Clinical Data

Demographics, including birth date, age at diagnosis, living situation, and employment status, were collected at baseline [19]. All clinical data were extracted from the participants' electronic medical records: hormone receptor status for both estrogen and progesterone receptors, tumor histology, personal history of breast cancer, sites of metastases, number of metastatic sites, and current treatment. The Response Evaluation Criteria In Solid Tumors (RECIST) V1.1 was used to assess tumor progression between diagnosis and the end of the physical activity intervention [23].

Physical Activity Level and Sedentary Behavior

Physical activity was evaluated by the long-form IPAQ score over the past week [22]. The long-form IPAQ is a validated self-administered physical activity questionnaire that has good reliability [22] and is comprised of 31 items grouped into four activity domains: work-related, transportation-related, domestic, and recreational physical activity [22]. The IPAQ provides scores—expressed in metabolic equivalent of task (MET)-minutes/week—separately for walking, moderate-intensity activity (ie, 3-6 METs), and vigorous-intensity activity (ie, >6 METs) within each of the work, transportation, and domestic chores, as well as the gardening and leisure-time domains. Sedentary activities were assessed using sitting time—in minutes/week—measured by the IPAQ questionnaire. The global IPAQ score was computed by summing the scores of each physical activity domain, then dividing into three categories of physical activity level used by the World Health Organization: low (<600 MET-minutes/week), moderate (≥600 and <3000 MET-minutes/week), and vigorous (≥3000 MET-minutes/week) physical activity [21]. To assess compliance with the 150 minutes/week physical activity

recommendations, we used the average intensity of 4.2 METs for moderate-intensity activities that these women were likely to perform (ie, computed as the mean of common moderate-intensity activities, including 3.8 METs for cleaning, 5.3 METs for hiking, 3.5 METs for walking for pleasure, and 4.3 METs for walking for exercise). Thus, participants reached the 150-minute physical activity recommendations if they achieved at least the threshold of 630 MET-minutes/week (ie, 150 minutes multiplied by 4.2 METs).

The number of steps per day measured by the wrist activity tracker was collected by regular transfer through the activity tracker mobile phone app (Nokia Health Mate) available on the participants' mobile phones or tablet PCs. For participants with no mobile phone, the number of steps was transferred when they came to the hospital for their weekly or biweekly consultation. Data were uploaded to the study phone and a screenshot was taken that was then sent to the participant by email. The physical activity instructor was able to use the activity tracker interface to monitor the number of daily steps and any change in the activity level in order to set the target number of daily steps and adapt physical activity recommendations.

Physical Fitness

During the 6-minute walk test, participants were asked to perform the maximum walking distance, in meters, during 6 minutes (ie, 6-minute walking distance [6MWD]) on a 30-meter-long flat corridor, while oxygen uptake consumption (computed as VO_{2peak}) and heart rate were recorded using a portable respiratory gas analyzer (MetaMax 3b, Cortex Biophysik).

The maximum upper-limb strength in kilograms and lower-limb strength in Newtons were measured using a hand dynamometer (Jamar Plus Digital Hand Dynamometer, Patterson Medical) and a back-leg dynamometer (DFS II Series Digital Force Gauges, Chatillon), respectively [24]. Two measures were performed on each hand and on the dominant leg and the best performances were registered.

Anthropometrics

Assessment of anthropometrics included measurements of standing height in centimeters, body weight in kilograms, and waist and hip circumferences in centimeters as well as the calculation of body mass index (BMI) in kg/m^2; metabolic risk, defined as waist circumference to height ratio of >0.5 [25]; risk of insulin resistance, defined as waist circumference of >80 cm; and cardiovascular risk, defined as waist circumference of >88 cm [26].

Participant-Reported Outcomes

Quality of life was assessed using the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30), a 30-item, self-administered questionnaire that evaluates a global quality-of-life domain, five functional domains (ie, physical, role, emotional, cognitive, and social), three symptom domains (ie, pain, fatigue, and nausea), and six single items (ie, dyspnea, insomnia, appetite loss, diarrhea, constipation, and financial impact) [27].

Fatigue was assessed by the global score of fatigue obtained from the EORTC QLQ-C30 and by the revised 22-item, self-report Piper Scale containing four subscales: behavioral and severity, affective, sensory, and cognitive and mood [27,28].

Social deprivation was assessed by the score of the Evaluation of Precarity and Inequalities in Health Examination Centers (EPICES) questionnaire based on 11 socioeconomic questions [29,30]. The score ranges from 0 (*the least deprived*) to 100 (*the most deprived*); social vulnerability is defined with a score of ≥30.17.

Statistical Analysis

Participants' characteristics were described using means and SDs or 95% CIs for quantitative data and were described with frequencies and percentages for qualitative data.

The recruitment rate was calculated as the proportion of participants who provided informed consent to participate in the ABLE Trial among eligible participants to whom the study was presented. The reasons for refusal were described.

For the primary outcome, paired proportions before and after the intervention were compared using the McNemar test. For secondary outcomes, changes of continuous parameters during the physical activity intervention were analyzed using nonparametric tests, since the distributions of physical activity data were highly skewed. The algorithm of the activity trackers detects when subjects do not wear it using an integrated triaxial accelerometer. Therefore, the analyses only included the days when the subjects wore their activity trackers. The evolution of the number of steps by days was analyzed with an unconditional growth model, a model with number of days as the only level 1 predictor and no substantive predictors at level 2. For the unconditional linear growth model, the level 1 model is as follows:

$$Step_{it}=\prod_{oi}+\prod_{1i}Time_{ij}+\varepsilon_{ij} \quad (1)$$

The level 2 model is as follows:

$$\prod_{oi}=\gamma_{00}+\varphi_{0i} \text{ and } \prod_{1i}=\gamma_{10}+\varphi_{1i} \quad (2)$$

In the level 2 model, the population-level estimates (ie, γ_{00} and γ_{10}) are referred to as the *fixed* effects. The individual deviations (ie, φ_{0i} and φ_{1i}), which can be thought of as the level 2 residuals, are referred to as the *random* effects. Overall survival was estimated using the Kaplan-Meier method. Median follow-up time was calculated using a reverse Kaplan-Meier estimate. Multivariate analyses were not possible given the limited sample size. Exploratory analyses on the relationship between variables were performed using Spearman rank correlations or Mann-Whitney tests when appropriate. The quality-of-life scores of the participants were compared with reference values for women with recurrent or metastatic breast cancer with a one-sample *t* test [31]. All *P* values under .05 were considered statistically significant. As the result of the exploratory setting of the analyses, no adjustments were performed in this feasibility study.

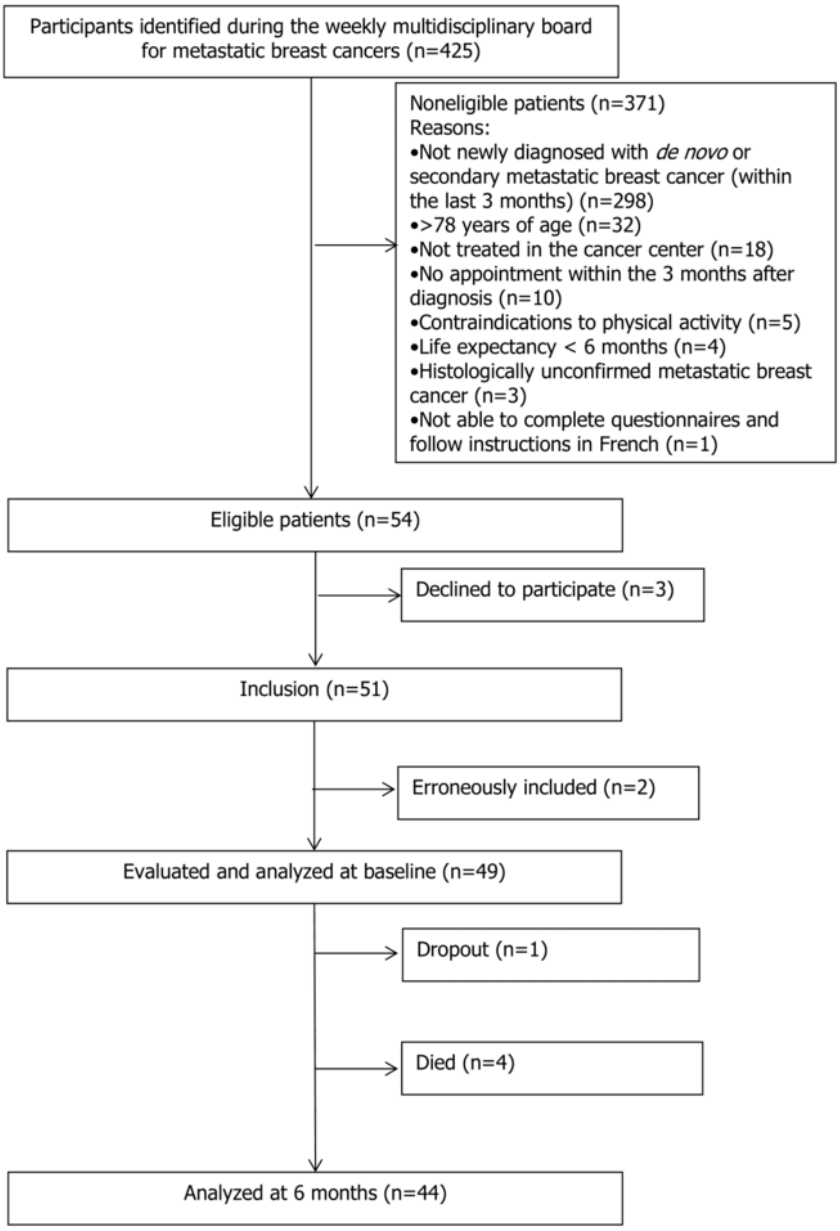
Data were analyzed using SAS software, version 9.4. (SAS Institute Inc).

Results

Recruitment and Follow-Up

Participants were recruited between October 27, 2016, and January 26, 2018. Among 425 patients screened, 54 (12.7%) were eligible (see Figure 1), then 3 declined to participate (acceptance rate of 94% [51/54], 95% CI 88.9-100.0). Another 2 participants were excluded because they were found not to have metastatic breast cancer. Overall, 49 women with metastatic breast cancer completed the baseline assessment, 1 participant dropped out after 3 months (attrition rate of 2% [1/49]), and 4 participants died from breast cancer before the end of intervention (see Figure 1). The participants were followed for their vital status over a total median time of 12.7 months (95% CI 11.0-14.2).

Figure 1. Flowchart of the Advanced stage Breast cancer and Lifestyle Exercise (ABLE) Trial.



Participants' Characteristics

At baseline, the mean age of the study participants was 55 years (SD 10). Most of them were not working (81%), had high education (ie, higher than or equal to high school, 67%), and were not considered socially vulnerable (67%) (see Table 1). A majority (71%) of participants presented with distant metastatic recurrence and 29% presented with de novo metastatic breast cancer. Among the women with distant metastatic recurrence, the mean time from de novo breast cancer diagnosis to metastatic recurrence was 94.3 months (SD 79.1). With respect to breast cancer subtypes, most women presented with positive hormone receptor status (71%), 26% had triple-negative breast cancer, and 2% overexpressed human epidermal growth factor receptor 2 (HER2). Most of the participants (67%) had bone metastases. The majority of participants (55%) were receiving hormone therapy and 45% received chemotherapy as first-line treatment.

Table 1. Demographics and baseline clinical characteristics of women with metastatic breast cancer in the ABLE[a] Trial, (N=49).

Characteristics	Mean (SD) or n (%)
Clinical	
Age at inclusion, mean (SD)	55 (10)
De novo metastatic breast cancer, n (%)	14 (29)
Secondary metastatic breast cancer, n (%)	35 (71)
Breast cancer histological subtypes, n (%)	
Hormone positive receptor	35 (71)
HER2+[b]	1 (2)
Triple negative	13 (27)
Number of metastatic localizations, mean (SD)	4.7 (3.1)
Locations of metastasis[c], n (%)	
Bones	33 (67)
Visceral	27 (55)
Brain	6 (12)
Treatment at inclusion[c], n (%)	
Chemotherapy	22 (45)
Hormone therapy	27 (55)
Targeted therapy	21 (43)
Demographics, n (%)	
Employment status	
Working	9 (18)
Sick leave	19 (39)
Retired	11 (22)
Unemployed	10 (20)
Education	
No diploma	5 (10)
Middle school	11 (22)
High school	9 (18)
1- to 2-year university degree	13 (27)
3- to 4-year university degree	6 (12)
≥5-year university degree	5 (10)
Social vulnerability score	
<30	33 (67)
≥30	16 (33)

[a]ABLE: Advanced stage Breast cancer and Lifestyle Exercise.

[b]HER2+: tested positive for human epidermal growth factor receptor 2 (HER2).

[c]The values do not add up to 49 (100%) because several responses could be reported by each participant.

At baseline, the average total physical activity level as measured by the IPAQ questionnaire was 2031 MET-minutes/week (SD 2213); 14 (29%) participants had achieved light physical activity level (<600 MET-minutes/week), 23 (47%) had achieved moderate physical activity level (≥600 and <3000 MET-minutes/week), and 12 (25%) had achieved vigorous physical activity level (≥3000 MET-minutes/week) (see Table 2). Participants walked an average of 451 meters during the 6MWD and 5593 steps per day, and 69% achieved the physical activity recommendations. The mean BMI was 26.1 kg/m² (SD 5.8). The global health score assessed with the EORTC QLQ-C30 was 63, and 61% of the patients declared fatigue at baseline.

Table 2. Change in anthropometric measures, physical fitness, and patient-reported outcomes in the ABLE[a] Trial.

Measure	Baseline (N=49), mean (SD) or n (%)	End of the study (N=44), mean (SD) or n (%)	*P* value
Physical activity level			
IPAQ[b]			
Total physical activity (MET[c]- minutes/week), mean (SD)	2031 (2213)	1940 (1762)	.66
Level of physical activity, n (%)			
Light physical activity (<600 MET-minutes/week)	14 (29)	10 (23)	.42
Moderate physical activity (≥600 and <3000 MET-minutes/week)	23 (47)	25 (57)	.42
Vigorous physical activity (>3000 MET-minutes/week)	12 (24)	9 (20)	.42
Type of physical activity, mean (SD)			
Work-related physical activity (MET-minutes/week)	182.3 (612.7)	410.2 (1147.0)	.43
Transportation-related physical activity (MET-minutes/week)	357.3 (631.1)	208.3 (234.5)	.32
Domestic physical activity (MET-minutes/week)	980.8 (1423.0)	471.6 (587.2)	.004
Recreational physical activity (MET-minutes/week)	543.7 (750.0)	850.8 (912.0)	.07
Moderate physical activity (MET-minutes/week)	1246.0 (1495.6)	980.2 (1430.8)	.10
Vigorous physical activity (MET-minutes/week)	22.5 (115.2)	16.4 (108.5)	>.99
Walking physical activity (MET-minutes/week)	795.6 (1073.5)	944.3 (1013.9)	.17
Sitting time (minutes/week)	2250.6 (1149.2)	1703.6 (853.3)	.004
Achieving recommendations (Yes), n (%)	34 (69)	34 (77)	.26
Physical fitness, mean (SD)			
6-minute walking test (6MWD) (m)[d]	451.6 (99.7)	482.6 (106.3)	<.001
VO_{2peak} (mL.min/kg)[e]	13.7 (4.4)	13.5 (6.0)	.71
Heart rate (beats/min)[f]	119.1 (18.6)	103.2 (19.3)	.11
Handgrip strength, left (kg)[g]	30.1 (35.3)	24.1 (4.4)	.25
Handgrip strength, right (kg)[g]	26.2 (6.1)	26.2 (4.3)	.17
Isometric quadriceps strength (N)[h]	194.2 (69.1)	236.4 (78.6)	<.001
Anthropometrics			
Weight (kg), mean (SD)	69.1 (15.7)	67.4 (15.4)	.03
Body mass index (BMI) (kg/m²)			
Mean (SD)	26.1 (5.8)	25.4 (5.8)	.03
Underweight (BMI <18.5 kg/m²), n (%)	3 (6)	3 (7)	N/A[i]
Normal weight (BMI <25 kg/m²), n (%)	20 (41)	21 (48)	N/A
Overweight (BMI=25-30 kg/m²), n (%)	16 (33)	12 (27)	N/A
Obese (BMI >30 kg/m²), n (%)	10 (20)	8 (18)	N/A
Waist circumference (cm), mean (SD)	91.4 (16.6)	90.4 (13.5)	.23
Hip circumference (cm)[j], mean (SD)	103.0 (11.3)	99.0 (11.8)	<.001
Metabolic risk, n (%)			.51
At risk of insulin resistance	5 (11)	6 (14)	N/A
At risk of cardiovascular disease	27 (57)	27 (61)	N/A
No risk	15 (32)	11 (25)	N/A
Patient-reported outcomes, EORTC QLQ-C30[k]			

Measure	Baseline (N=49), mean (SD) or n (%)	End of the study (N=44), mean (SD) or n (%)	*P* value
Global health, mean (SD)	62.7 (20.6)	63.5 (23.2)	.74
Function scales, mean (SD)			
Physical	76.3 (22.4)	82.0 (17.1)	.17
Role	67.4 (31.9)	74.0 (28.0)	.18
Emotional	67.8 (25.4)	70.7 (24.6)	.47
Cognitive	77.8 (25.1)	79.6 (20.9)	.77
Social	72.7 (31.6)	77.3 (30.1)	.96
Symptom scales, mean (SD)			
Fatigue	44.2 (27.4)	36.9 (27.6)	.08
Nausea and vomiting	10.1 (17.4)	6.44 (18.1)	.27
Pain	35.1 (31.6)	25.4 (26.3)	.29
Dyspnea	28.5 (30.7)	22.7 (26.7)	.70
Insomnia	40.3 (35.0)	28.8 (29.3)	.37
Appetite loss	20.8 (27.2)	9.9 (21.1)	.02
Constipation	26.4 (31.5)	19.4 (32.7)	.35
Diarrhea	15.6 (28.5)	23.5 (31.8)	.10
Financial difficulties	13.3 (24.7)	15.2 (25.4)	.48
Fatigue (Piper Scale), n (%)			
Yes	30 (61)	28 (61)	>.99
No	19 (39)	18 (39)	>.99

[a]ABLE: Advanced stage Breast cancer and Lifestyle Exercise.

[b]IPAQ: International Physical Activity Questionnaire.

[c]MET: metabolic equivalent of task.

[d]There are missing data for the 6MWD (n=1 at baseline).

[e]There are missing data for the oxygen uptake consumption (VO_{2peak}) (n=14 at baseline and n=7 at 6 months).

[f]There are missing data for heart rate (n=14 at baseline and n=7 at 6 months).

[g]There are missing data for handgrip strength, left (n=2 at baseline and n=1 at 6 months), and right (n=1 at 6 months).

[h]There are missing data for isometric quadriceps strength (n=1 at baseline and n=1 at 6 months).

[i]Not applicable.

[j]There are missing data for hip circumference (n=1 at baseline).

[k]There are missing data for the European Organization for Research and Treatment of Cancer 30-item Quality of Life Questionnaire (EORTC QLQ-C30) (n=1 at baseline).

There were no statistically significant differences between participants with de novo metastatic breast cancer (14/49, 29%) and participants with secondary metastatic breast cancer (35/49, 71%) in terms of isometric quadriceps strength, the 6MWD, average steps per day, and total IPAQ score, neither at baseline nor at 6 months (data not shown). Participants who received hormone therapy (27/49, 55%) had a higher average number of daily steps compared to participants receiving chemotherapy (22/49, 45%) (*P*=.01) at baseline (data not shown). No correlations were observed between treatment variables and 6MWD, the isometric quadriceps strength, and the total physical activity score at baseline.

Primary Objective of the Feasibility of the Physical Activity Intervention

For the primary end point, among the 44 participants evaluated at 6 months, 34 (77%, 95% CI 62.2-88.5) participants achieved the physical activity recommendations (≥630 MET-minutes/week). Of the 31 (70%) who met the recommendations at baseline, 29 met the recommendations at 6 months (*P*=.27) (see Table 2). With respect to the use of the physical activity tracker, 96% of patients wore the physical activity tracker during the 6 months of the study without interruption for more than one consecutive week.

Secondary Objectives

Changes in Physical Activity Level, Physical Activity Fitness, and Number of Steps per Day

At 6 months, the total physical activity level and the proportions of participants in low, moderate, and vigorous physical activity level categories remained stable (*P*=.66 and *P*=.42, respectively) (see Table 2). A statistically significant decrease was observed for sitting time (*P*<.01) and for the domestic physical activity score (*P*=.01).

A 7% increase in the 6MWD (*P*<.001) and a 22% increase in isometric quadriceps strength (*P*<.001) were observed between baseline and the end of the intervention at 6 months. However, the estimated average rate of change from the unconditional growth model was not significantly different from 0 (*P*=.75), indicating that no statistically significant change occurred in the number of daily steps per month throughout the study.

During the study, 54% of the study participants accumulated more than 5000 steps per day, which is the sedentary threshold. The VO_{2peak}, heart rate, and handgrip strength values did not change during the study (*P*=.71, *P*=.11, and *P*=.25, respectively) (see Table 2).

Changes in Anthropometrics Measurements and Markers of Metabolic Risk

A significant decrease in weight, BMI, and hip circumference was observed at 6 months (-2.5, *P*=.03; -2.5%, *P*=.03; and -4.0%, *P*<.001, respectively). No differences were observed for waist circumference, insulin-resistance risk, and cardiovascular risk (see Table 2).

Changes in Participant-Reported Outcomes

The quality-of-life scores remained stable for the total global health status and for all functional domains (see Table 2). A statistically significant decrease of 52% was observed for the appetite loss domain (*P*=.02), which means that after the end of the 6-month intervention, the patients significantly regained their appetites. The global health score of quality of life at baseline for the study participants (62.7, 95% CI 56.7-68.6) was not statistically significantly different from the reference score for participants with recurrent or metastatic breast cancer (*P*=.41) (data not shown).

Fatigue evaluated by the symptom scale of the EORTC QLQ-C30 questionnaire decreased by 16%, albeit in a nonstatistically significant manner (*P*=.07), while the fatigue score on the Piper Scale did not vary significantly (*P*>.99) between baseline and the end of the intervention (see Table2).

Tumor Progression and Survival

Among the 49 participants included in the analysis, 7 participants had metastatic progression during the study according to RECIST criteria.

A total of 4 participants died before the end of the intervention and 5 participants died during the subsequent follow-up until June 2018. The estimated median overall survival was not reached because more than half of participants were still living at the time of analysis. Overall survival rate at 12 months was 89.5% (95% CI 76.3-95.1).

Exploratory Analyses

Associations Between Physical Activity Fitness and Physical Activity Level

The variations in 6MWD, isometric quadriceps strength, handgrip strength, and VO_{2peak} were correlated neither with the variations of the IPAQ domain scores between baseline and 6 months, nor with the average number of steps per day.

Associations Between Physical Activity and Quality of Life

At baseline, the total IPAQ score was positively correlated with physical functioning (=.4, *P*=.01) and social function (=.3, *P*=.04) (see Table 3). The variation in the 6MWD during the study was positively correlated with the variation in the physical functioning domain (=.4, *P*=.01) and inversely correlated with the variation of dyspnea (=-.3, *P*=.04) (see Table 4). The variation in sitting time was inversely correlated with the variation in physical functioning (=-.6, *P*<.001), role functioning (=-.3, *P*=.03), and social functioning (=-.5, *P*<.001) and was positively correlated with the variation in fatigue (=.3, *P*=.05).

Table 3. Spearman correlations between physical activity and quality of life at baseline.

Baseline (T1)	Baseline (T1)				
	6MWD[a]	Isometric quadriceps strength	Average steps per day during the first month	Total IPAQ[b] score	Sitting time
Global health	.12	-.05	. 27	.21[c]	-.28[c]
Function scales					
Physical	.21	.03	.42[d]	.37[d]	-.40[d]
Social	.11	.07	.26	.30[d]	-.33[d]
Symptom scales					
Fatigue	-.20	-.04	-.49[d]	-.24[c]	.28[c]
Pain	-.20	.01	-.26	-.28[c]	.26[c]
Dyspnea	-.20	-.18	-.44[d]	-.20	.50[e]
Insomnia	-.08	.10	-.28[c]	-.15	.20
Appetite loss	.01	-.05	<.001	-.09	-.07

[a]6MWD: 6-minute walking distance.

[b]IPAQ: International Physical Activity Questionnaire.

[c]*P*=.10.

[d]*P*=.05.

[e]*P*<.001.

Table 4. Spearman correlations between physical activity and quality of life and differences between T2[a] and T1[b] in the ABLE[c] Trial.

Change between T2 and T1	Variation between T2 and T1				
	6MWD[d]	Isometric quadriceps strength	Average steps per day during the last month-first month	Total IPAQ[e] score	Sitting time
Global health	.13	.07	.27	.07	-.25
Function scales					
Physical	.39[f]	.11	.13	.13	-.55[g]
Social	.14	-.12	.09	.21	-.49[f]
Symptom scales					
Fatigue	.0	.08	-.41[h]	.08	.31[f]
Dyspnea	-.32[f]	.01	.54[f]	-.02	.24
Insomnia	.01	.43[f]	.26	-.08	.11
Appetite loss	-.10	.20	.17	-.19	-.02

[a]T2: end of the intervention at 6 months.

[b]T1: baseline.

[c]ABLE: Advanced stage Breast cancer and Lifestyle Exercise.

[d]6MWD: 6-minute walking distance.

[e]IPAQ: International Physical Activity Questionnaire.

[f]*P*=.05.

[g]*P*<.001.

[h]*P*=.10.

Discussion

Principal Findings

The ABLE Trial is the first European study to investigate a physical activity intervention for patients with metastatic breast cancer and to obtain preliminary data on anthropometrics, functional fitness, physical activity level, sedentary behavior, quality of life, fatigue, and tumor progression. One of the key findings is the high participation rate among women eligible for this trial (94%), stressing the willingness of the targeted population to participate in physical activity interventions. The low attrition and high adherence clearly demonstrated the feasibility of the proposed physical activity intervention in women with metastatic breast cancer. While a deterioration of the physical activity level and quality of life would have been expected due to treatment and disease [4,31,32], women maintained their physical activity levels and number of daily steps as well as their quality of life. Women further significantly increased their physical fitness and strength.

Overall, the ABLE Trial study population was relatively physically active, since 69% of the participants met the physical activity recommendations at baseline and 47% were considered moderately active. Although the heterogeneity of the physical activity-level assessments in five physical activity intervention studies makes direct comparisons difficult, the physical activity level of women in these studies was generally lower and below physical activity recommendations [33-37]. A randomized controlled study of 101 patients with metastatic breast cancer has highlighted the moderate level of physical activity of these participants (57.5 minutes per week for the exercise group and 79.2 minutes per week for the control group) [34]. The ABLE Trial participants' ages and clinical situations were similar to those of previous study participants who mainly had secondary metastatic breast cancer and mostly bone metastases [12,33,38,39]. The ABLE Trial participants had a slightly lower mean BMI (26.1 kg/m²) than women with metastatic breast cancer in four other studies that provided this information (ranging from 27.2 to 28 kg/m²) [33,37,40,41].

Recruitment, Attrition, and Adherence

The recruitment rate in the ABLE Trial (94%) was particularly high among eligible patients and was superior compared to the recruitment rate in 12 studies of patients with metastatic cancer ranging from 26% to 86% (average 49%) as well as three studies of patients with metastatic breast cancer (61%-65%) that provided this information [40,42,43]. The high recruitment rate in the ABLE Trial might be explained by the flexibility and simplicity of the intervention that was individualized to each participant as well as the regular weekly feedback provided to participants. In addition, the Centre Léon Bérard offers a physical activity program, and clinicians there are supportive of patients exercising during and after cancer treatments. The ABLE Trial also had very low attrition and excellent adherence. In contrast, Dittus et al reported a high attrition rate, ranging from 11% to 54% in 23 studies reporting this information [10]. Furthermore, three other studies of patients with metastatic breast cancer had lower adherence rates (63%-75%) compared to the ABLE Trial [34,41]. To increase adherence in home-based physical activity interventions, weekly calls and monthly home visits were performed as recommended by Headley et al [35]. Furthermore, previous research has shown that the majority of breast cancer survivors would like to use a physical activity mobile app and 90% would find a physical activity tracker useful to monitor and increase physical activity [44].

Physical Fitness

The observed statistically significant improvement in physical fitness in the ABLE Trial was consistent with the improvement in physical function reported in most other studies, though the outcome measures varied widely [10]. The exception was the study that Ligibel and colleagues performed in a home-based intervention in which no statistically significant improvements in aerobic capacity were found [34]. While the statistically significant decreases in weight and hip circumference observed in the ABLE Trial were significantly correlated with increased 6MWD, we cannot exclude that it might also be attributable to metastatic progression rather than to the benefits of the physical activity intervention [45,46]. The statistically significant improvement observed in isometric quadriceps strength in this study is consistent with the findings of the review by Dittus et al [10], where significant improvements of strength were reported in 11 out of 12 studies; this improvement was also consistent with the results of two cross-sectional studies of patients with metastatic breast cancer that found increased strength through physical activity interventions [37,40]. While women in the ABLE Trial maintained their level of physical activity and number of daily steps, their sitting time significantly decreased. This result is an important finding since greater total sedentary time has been shown to be significantly inversely associated with physical quality of life and associated with increased mortality in women with nonmetastatic breast cancer [47,48].

Quality of Life

Participants' quality of life at baseline in the ABLE Trial was similar to that of three other studies in women with metastatic breast cancer [34,37,40] and similar to the reference score for patients with recurrent or metastatic breast cancer [31]. The maintenance of overall quality of life in the ABLE Trial was consistent with a systematic review conducted in metastatic cancer showing that quality of life is maintained following physical activity interventions [10], while a decline is usually observed with disease progression and treatment in patients with metastatic breast cancer [4,31]. The ABLE Trial suggests that an increase in the physical activity capacity and a decrease in the sedentary behavior in this population may counteract the detrimental effect of the disease on quality of life [11].

Fatigue

Fatigue is one of the most common symptoms described by patients with metastatic breast cancer [49]. Fatigue at baseline was less frequent in the ABLE Trial (61%) than in other studies of metastatic cancer patients (92%), possibly due to the study population of the ABLE Trial, which was limited to patients with de novo or secondary metastatic breast cancer diagnosed within the last 3 months [19]. But the effects of physical activity on fatigue in patients with metastatic breast cancer remains

unclear [10]. While two studies have found a significant decrease in fatigue after a physical activity intervention [42,49], one has shown that fatigue increased over time despite a physical activity intervention—though, was less marked for the intervention group compared to the control group [35]—and a third trial was negative [34]. Maintaining the same level of fatigue, versus having it increase, through physical activity despite treatment and progression of the disease is an important clinical challenge.

Strengths and Limitations

The strengths of the ABLE Trial were the individualized intervention, the high recruitment rate, low attrition, and excellent adherence to the physical activity intervention. Activity trackers are innovative tools that can be easily used in everyday life to objectively measure patients' physical activity, such as distance travelled and number of steps.

The limitations of the ABLE Trial include the lack of a control group, which restricts assessments of the efficacy of the intervention; the small sample size, which reduces study power; the single-centered design and the select study population, which limit the study generalizability; the restriction to aerobic exercise training only; and the type of physical fitness tests used. The fitness assessments had some limitations in this study population since patients could not achieve maximal effort because of their painful bone metastases. Moreover, there is a discrepancy between the improvement in muscle function that is reflected in walking and quadriceps tests and the reported level of physical activity. Patients may also have been more confident in the postintervention tests because they knew the tests' protocol unlike at the time of inclusion. However, in any case it is still positive to have an improvement in muscle function that allows you to maintain a certain degree of autonomy. While the benefits of resistance exercise have been highlighted in various studies, the ABLE Trial did not include any resistance exercise training recommendations that could have further increased muscle mass [10,38]. A combined intervention with a flexible program based on steps recommendations and resistance exercises would ideally be investigated in a future randomized controlled trial. Concerning the physical activity questionnaire, it has been recognized in various scientific publications that physical activity questionnaires have several limitations and tend to under- or overestimate physical activity [50,51]. In addition, contrary to our initial hypothesis, the patients in the study already had a good level of physical activity at the time of inclusion, which did not allow us to show any improvement at the end of the study.

Conclusions

The ABLE Trial was the first study to propose a flexible, home-based, exercise intervention that used activity trackers in women with metastatic breast cancer. The improvements in physical fitness considered as clinically significant for the 6MWD and quadriceps extension strength may suggest that this 6-month physical activity intervention contributes to maintaining quality of life and physical fitness, despite the detrimental effect of treatments and disease progression. Maintaining functional capacity in these patients is all the more important to perform daily activities despite the physical deconditioning [10]. These preliminary results open new research possibilities to assess, through a randomized controlled trial, the effect of a flexible physical activity intervention based on steps recommendations, physical activity level, physical fitness, quality of life, fatigue, and tumor progression. Some cancer organizations are beginning to recognize that there is merit to encourage patients with metastatic breast cancer to be more active and to continue daily physical activity as much as possible [52]. Future research is needed to define the exact type, dose, and timing of physical activity interventions that are most beneficial to patients with metastatic disease to improve their quality and quantity of life.

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Conflicts of Interest

None declared.

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Abbreviations

6MWD: 6-minute walking distance
ABLE: Advanced stage Breast cancer and Lifestyle Exercise
BMI: body mass index
CNIL: National Commission for Data Protection and Liberties
EORTC: European Organization for Research and Treatment of Cancer
EPICES: Evaluation of Precarity and Inequalities in Health Examination Centers
HER2: human epidermal growth factor receptor 2
IPAQ: International Physical Activity Questionnaire
MET: metabolic equivalent of task
N/A: not applicable
QLQ-C30: 30-item Quality of Life Questionnaire
RECIST: Response Evaluation Criteria In Solid Tumors
T1: baseline
T2: end of the intervention at 6 months
VO_{2peak}: oxygen uptake consumption

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Original Paper

Engaging Users in the Behavior Change Process With Digitalized Motivational Interviewing and Gamification: Development and Feasibility Testing of the Precious App

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Abstract

Background: Most adults do not engage in sufficient physical activity to maintain good health. Smartphone apps are increasingly used to support physical activity but typically focus on tracking behaviors with no support for the complex process of behavior change. Tracking features do not engage all users, and apps could better reach their targets by engaging users in reflecting their reasons, capabilities, and opportunities to change. Motivational interviewing supports this active engagement in self-reflection and self-regulation by fostering psychological needs proposed by the self-determination theory (ie, autonomy, competence, and relatedness). However, it is unknown whether digitalized motivational interviewing in a smartphone app engages users in this process.

Objective: This study aimed to describe the theory- and evidence-based development of the Precious app and to examine how digitalized motivational interviewing using a smartphone app engages users in the behavior change process. Specifically, we aimed to determine if use of the Precious app elicits change talk in participants and how they perceive autonomy support in the app.

Methods: A multidisciplinary team built the Precious app to support engagement in the behavior change process. The Precious app targets reflective processes with motivational interviewing and spontaneous processes with gamified tools, and builds on the principles of self-determination theory and control theory by using 7 relational techniques and 12 behavior change techniques.

The feasibility of the app was tested among 12 adults, who were asked to interact with the prototype and think aloud. Semistructured interviews allowed participants to extend their statements. Participants' interactions with the app were video recorded, transcribed, and analyzed with deductive thematic analysis to identify the theoretical themes related to autonomy support and change talk.

Results: Participants valued the autonomy supportive features in the Precious app (eg, freedom to pursue personally relevant goals and receive tailored feedback). We identified the following five themes based on the theory-based theme autonomy support: valuing the chance to choose, concern about lack of autonomy, expecting controlling features, autonomous goals, and autonomy supportive feedback. The motivational interviewing features actively engaged participants in reflecting their outcome goals and reasons for activity, producing several types of change talk and very little sustain talk. The types of change talk identified were desire, need, reasons, ability, commitment, and taking steps toward change.

Conclusions: The Precious app takes a unique approach to engage users in the behavior change process by targeting both reflective and spontaneous processes. It allows motivational interviewing in a mobile form, supports psychological needs with relational techniques, and targets intrinsic motivation with gamified elements. The motivational interviewing approach shows promise, but the impact of its interactive features and tailored feedback needs to be studied over time. The Precious app is undergoing testing in a series of n-of-1 randomized controlled trials.

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KEYWORDS

health app; mHealth; human-computer interaction; prevention; service design; usability design; intrinsic motivation; reflective processes; spontaneous processes; engagement; self-determination theory; autonomous motivation; gamification; physical activity

Introduction

Background

Lifestyle-related diseases, such as cardiovascular diseases, type 2 diabetes, and cancers, lead to a decrease in quality of life and are the leading causes for years of life lost worldwide [1]. Stretched health care resources struggle with the complications that could, in many cases, be avoided with a physically active lifestyle [2,3]. There is a need for interventions that can effectively support people to achieve the amount of physical activity that is necessary for their health and well-being.

As a consequence, hundreds of thousands of smartphone health apps have emerged for tracking physical activity. With their interactive features, onboard sensors, and associated wearables, smartphones are a natural tool for tracking and self-monitoring activity [4,5]. Individuals tend to carry phones with them and keep them switched on continuously [6], use apps repeatedly for brief moments between other activities [6], and value this possibility for ubiquitous support [7].

Tracking physical activity is indeed a key element of many successful physical activity interventions. Self-regulatory behavior change techniques (BCTs) [8] related to control theory [9], such as self-monitoring, goal setting, action planning, feedback on behavior, and problem solving, have been consistently linked with positive changes in physical activity [10]. The more actively individuals enact these techniques, the more effective interventions are [11-14].

Smartphone apps have shown promise in reducing sedentary behaviors [15,16], but the evidence for increasing physical activity is modest [16-20]. One factor that explains this may be the importance of face-to-face contact for physical activity motivation [21]. For smartphone apps to achieve the same effectiveness as interventions delivered in person, apps should be engaging enough for users to keep returning to receive the necessary support. However, user commitment to smartphone apps is low: 22% of downloaded apps are opened only once [22], and users may spend less time with smartphone apps than computer-delivered interventions [6,23]. To engage users and build sustained motivation and commitment in the process of behavior change, apps need to offer more support than just tracking behaviors.

Engaging Users in the Behavior Change Process With an App

Engagement in digital interventions is conceptualized in different ways in different research traditions. Within behavioral literature, engagement often refers to the frequency or duration of time spent using a digital service [24-26]. This *summative* engagement, the quantitative metrics of usage time and frequency, is not enough for understanding neither the user experience in the moment-to-moment interaction with the app nor *how* apps support active involvement in the behavior change process and the intervention goals [27-29]. Some studies have found low frequency of usage being as effective as higher frequency [30], and increased usage time can even be a symptom of low usability instead of engaging content [30].

Within the usability and gaming literature, engagement is typically conceptualized as the subjective user experience with the service, including affect, interest, attention, and flow [26]. Studying user experience can provide information on how immersive an app is but does not typically explain cognitive engagement in the process of behavior change—a health app may be entertaining and have good usability but does not necessarily engage the user to reflect their behavior or make them take steps to approach their goals.

In this study, we have defined engagement as active involvement with the behavior change process that the app is aiming for. This includes all the steps the user takes toward behavior change, for instance, by reflecting reasons for change or engaging in planning and monitoring of the behavior in question. This concept of engagement with the behavior change process is close to *effective engagement*, which refers to the level of active

involvement that is necessary for the intervention to achieve intended outcomes [27,31].

It is recognized that the effectiveness of a digital service depends on the target behaviors (one-time action or lifestyle change), the BCTs used, and individuals using the service and their subjective user experience [26,31]. We have proposed that the effectiveness of a digital service also depends on the extent to which the individuals get cognitively involved in the process of behavior change: whether interaction with an app encourages users to think about their reasons, capabilities, and opportunities to change and whether the interaction increases their motivation and self-efficacy to change. To examine this concept of active cognitive engagement in the behavior change process, we used the approach widely used in face-to-face behavior change counseling (ie, motivational interviewing).

Motivational Interviewing

Motivational interviewing is a person-centered counseling method that provides practical techniques for improving intervention engagement and commitment to the behavior change process [32]. In addition to *content-focused* BCTs, practical tools for self-regulation, motivational interviewing offers tools for the interaction quality between the counselor and the client, suggesting several *relational* techniques and methods for fostering the alliance and engaging the client in the process [33,34]. Core elements of motivational interviewing include resolving ambivalence toward behavior change, eliciting reflection and *change talk*, individuals' self-expressed language in favor of change, and supporting client autonomy [32]. Motivational interviewing uses collaborative and nonauthoritarian interaction to work toward clients' goals [32].

Face-to-face motivational interviewing and telephone-delivered motivational interviewing have increased exercising and strength training and reduced sedentary time [35,36]. A systematic review of technology-delivered adaptations of motivational interviewing showed promise for a variety of health-related behaviors [37]. However, only two of the computer-based interventions targeted physical activity, and none of the interventions tested smartphone delivery [37].

Motivational Interviewing Increases Intervention Engagement

Motivational interviewing can lead to improved health outcomes through enhancing participant adherence and intervention engagement. It has improved engagement with various behavior change intervention components, including attendance to behavioral weight loss programs [38], and self-monitoring of food intake and blood glucose [35]. For instance, improved program attendance has led to more comprehensive self-monitoring diaries, which again have enhanced weight loss outcomes [39].

Despite the evidence for improving intervention engagement in face-to-face interventions, motivational interviewing–type motivational support is rarely present in health apps for smartphones. For instance, Pagoto et al [40] screened the hundred most popular apps for weight loss and found that none of them provided BCTs for low adherence and motivation.

One reason for the limited use of motivational interviewing may be its lack of having a coherent theoretical framework, which creates challenges for testing the specific mechanisms of action and linking studies to theoretical discussions in the field [41]. Thus, the self-determination theory has been suggested as the theoretical basis for the method, as it shares core principles with motivational interviewing [41].

Self-Determination Theory

Motivation research leaning on the self-determination theory [42] has established that the quality of motivation predicts individuals' physical activity levels [43,44]. Individuals with high autonomous motivation are more likely to engage in regular physical activity than those with externally controlled motivations, such as guilt and shame for not being active or pressure from others. Autonomous motivation consists of the following two elements: (1) motivational regulation that is based on the pleasure of the activity itself (ie, intrinsic motivation) and (2) motivational regulation that is guided by goals that are separate from the behavior but in line with the person's values and identity (ie, identified or integrated regulation). Promoting these different forms of autonomous motivation may require different intervention strategies. Individuals are also more likely to engage in active self-regulation when their motivation for physical activity is autonomous [45-47]. Self-determination theory–based interventions address autonomous motivation by aiming to satisfy the psychological needs of autonomy, competence, and relatedness [48].

Autonomy refers to the freedom to organize one's own experiences and behavior in accordance with one's integrated sense of self [42]. It can be supported by, for instance, offering choice and a meaningful rationale of the relevance of the behavior, by respecting and acknowledging individuals' viewpoints, and by avoiding controlling or guilt-inducing acts and language.

Experiences of *competence* can be offered through clear instructions and expectations, collaborative goal setting, and optimally challenging tasks, providing tailored strategies and feedback as well as guidance and skills training. Competence is closely related to Bandura's concept of self-efficacy [49], which describes an individual's perceptions of their own capabilities to perform a behavior.

Relatedness includes processes that create a meaningful connection, convey understanding, and engage participants with the process [48]. In addition to actual persons participating or supporting the behavior change, the connection can be experienced with individuals who would benefit from the change (eg, getting fitter to be a better team member or focusing on one's health to have more energy to spend with family). A digital intervention may also provide a sense of relatedness with the service, for instance, through experiencing the good intentions of the people providing the service. Relatedness to the intervention provider may be supported by taking the user's perspective with empathy, displaying appreciation or concern, involving the person, gathering knowledge about the person and paying careful attention to them, dedicating time and energy, and being available when needed [50].

Smartphones provide many opportunities for supporting these needs, for instance, by offering accurate and usage-based or sensor-based feedback or by adding fun and motivating challenges with gamified elements [51-53].

Gamification

An increasingly used approach for engaging users in the behavior change process is gamification, which refers to using elements from games, such as points, badges, visualizations, challenges, and surprises, in nongame contexts [54,55]. While motivational interviewing provides tools for motivational self-reflection and thus supports the active and conscious fulfillment of psychological needs, gamification can provide experiences of autonomy, competence, and relatedness by adding fun and excitement in the activities [52].

Evidence on gamification of behavior change interventions is sporadic because of varying multidisciplinary terminology and a lack of randomized controlled trials [56]. Some studies show promise in increasing user engagement [57,58], motivation [58,59], and physical activity [51,60,61]. Game mechanisms might also support the use of BCTs: apps with game elements have been found to use more BCTs than health apps in general [56]**.** Despite the promise, gamification is still used relatively rarely [56].

Game elements do not necessarily require users to reflect on their reasons for behavior, but they typically use intrinsic motivators, such as challenges and surprises, that may provide a spontaneous route to behavior change. For instance, users may engage in goal setting and self-monitoring of physical activity because of visualized goals and achievements instead of health targets. A successful example of this is an augmented reality game, Pokémon GO, which did not explicitly target physical activity but increased users' daily steps with the game mechanisms [51].

Theoretical Framework for Engaging App Users in the Behavior Change Process

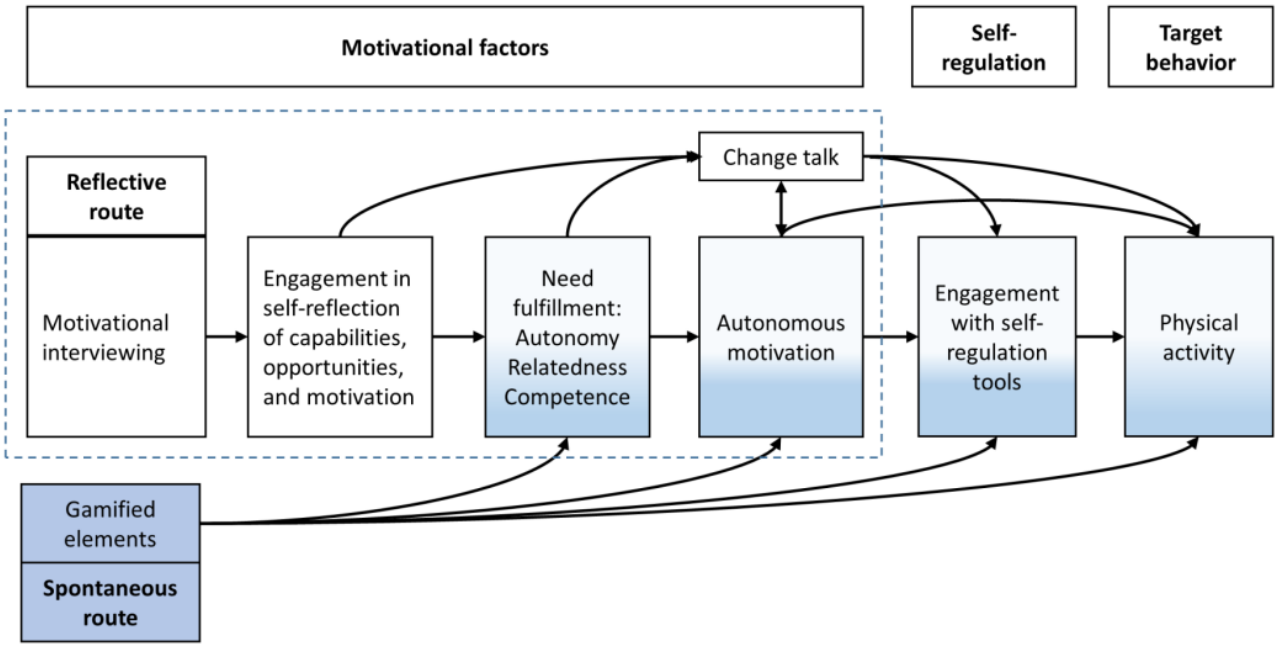
To draw together the range of theories, approaches, and evidence surrounding engagement with apps for behavior change, we propose the framework depicted in Figure 1. Gamification provides intrinsic pleasure with challenges and surprises. Together, these satisfy the self-determination theory's psychological needs and support autonomous motivation. This increased awareness of the pleasure and benefits of exercise engages users in self-regulation, such as goal setting, planning, and self-monitoring, leading to increased physical activity. The dotted line (Figure 1) shows the feasibility testing presented in this study.

We suggest that apps that support behavior change will be more effective if they engage users in the behavior change process. We characterize the behavior change process with the following three steps: (1) users are autonomously motivated to be physically active either by expecting intrinsic pleasure from the activity or by remembering that the activity supports their values, identity, or personally relevant goals [48]; (2) users enact self-regulation techniques, such as goal setting, planning, and self-monitoring [62]; and (3) users change their behavior (eg, walk to the supermarket instead of driving).

We suggest that users are more likely to actively engage in the behavior change process if the app addresses their basic psychological needs: supports their autonomy, creates a sense of relatedness, and provides them with experiences of competence and self-efficacy [42]. If these needs are met, users will have more motivation and other psychological resources to set challenging goals, make plans, and track their progress [45].

The psychological needs of autonomy, competence, and relatedness can be satisfied in two ways. *The reflective route* encourages users to actively consider their capabilities, opportunities, and the benefits of the behavior (eg, think what kind of physical activity they might enjoy or what they could achieve by being active) [63]. This self-reflection requires active cognitive engagement with the reflection tasks. Motivational interviewing is suggested as a method for engaging users in this motivational self-reflection because of its focus on building a successful working alliance and supporting engagement in behavior change [32]. Another pathway to engagement is through gamification. *The spontaneous route* does not require active self-reflection, as the game mechanisms can satisfy the psychological needs and engage the user in behavior change through intrinsic motivation [52]. This framework relying on reflective and spontaneous pathways draws from the studies by Hagger and Chatzisarantis and Strack and Deutsch [64,65].

Figure 1. A proposed method for engaging users in the behavior change process. Digitalized motivational interviewing techniques help users engage in motivational self-reflection; identify reasons, capabilities, and opportunities for physical activity; and produce change talk. Gamification provides intrinsic pleasure with challenges and surprises. Together, these satisfy the self-determination theory's psychological needs and support autonomous motivation. This increased awareness of the pleasure and benefits of exercise engages users in self-regulation, such as goal setting, planning, and self-monitoring, leading to increased physical activity. The dotted line shows the feasibility testing presented in this study.



Aims of This Study

This paper aimed to present the development and feasibility testing of the physical activity–related components of the Precious smartphone app. The Methods section describes how the theoretical framework was employed in the Precious app: how theory and evidence were used to inform the selection of app features and how motivational interviewing and self-regulation techniques were implemented within the app.

Furthermore, to add to the emerging literature moving beyond quantitative usage metrics and describing how digital delivery affects the user experience, engagement, and intervention uptake [27,29,66], we have presented a feasibility study that examines user interactions with the app. Specifically, this feasibility study sought to understand the extent to which app use engaged users in active self-reflection.

Our hypothesis was that active cognitive engagement with the app content is necessary for effective commitment to the behavior change process. We studied user engagement with the motivational interviewing components focusing on two research questions (RQ):

> *RQ1: How did the users discuss autonomy support in the Precious app? This question aimed to understand how users approach autonomy support in smartphone apps and if interacting with the Precious app fulfills the psychological need for autonomy.*
>
> *RQ2: What kind of change talk did the Precious app elicit in the users, if any? This question aimed to identify whether the motivational interviewing components met their target of engaging users in the behavior change process.*

Methods

Service Design

The *PREventive Care Infrastructure based On Ubiquitous Sensing* (PRECIOUS) project consisted of eight European multidisciplinary partners in social and behavioral sciences, health psychology and psychiatry, computer science including human-computer interaction, nutritional science, and sensor engineering who worked together to create a digital platform supporting physical activity, healthy nutrition, sleep hygiene, and stress management. The final design of the Precious app was created through collaborative writing of project deliverables and weekly design meetings with social and behavioral scientists, computer scientists, and usability and graphic designers. The consortium reviewed relevant theory and evidence on behavioral sciences, gamification [67], socioeconomic factors, and business models as requested by the European Community's Seventh Framework funding scheme [68] and created a system architecture for the overall service [69]. Each project partner identified the ethical and privacy principles related to their field of responsibility [70]. Full details on the project, including project publications, are reported [71].

The design of the physical activity arm of the Precious app started by drafting the theoretical framework (Figure 1), selecting the key service elements, and inventing ways to address the motivational and self-regulatory variables on a digital platform, through an iterative process of individual and collaborative design [72]. The systematic development of a motivational interviewing–based computer intervention by

Friederichs et al [73,74] served as an inspiration for the motivational tools in the Precious app. The text content and algorithm of the user-specific tailored suggestions were written collaboratively by JN and KK and implemented by TG [75].

The Precious App Development

The following sections describe the Precious app features and how these were drawn from behavioral theories. The aim of the Precious app is to increase users' daily physical activity by supporting their commitment to the behavior change process: increasing their motivation, self-reflection, self-regulation, and physical activity (Figure 1). We used several techniques to reach this aim.

The Precious app addresses the following two aspects of behavior change: (1) motivating individuals who may not yet see the need for health-enhancing physical activity and (2) providing self-regulation techniques to help translate motivation into physical activity [45]. The Precious app's tools for motivational self-reflection aim to increase autonomous motivation (eg, awareness of the personally meaningful outcomes of increasing daily physical activity). The self-reflection evoked by motivational interviewing and the personally relevant information on the effects of exercise from the biofeedback sensors aim to support active cognitive engagement with the behavior change process.

Increased motivation, such as joy of achieving challenges and salience of personally relevant outcomes, can help users to commit to the use of self-regulatory BCTs [45]. Goal setting, action planning, and self-monitoring will help users to initiate and sustain their activity. Altogether, the Precious app aims to remind users how their psychological needs can be met with physical activity. The functionalities of the Precious app are presented in detail in the following sections.

Relational Features

All texts in the Precious app aim to evoke relatedness with the app, drawing from the relational techniques of motivational interviewing and aiming to build an alliance with the user (Table 1, numbered with the taxonomy [33]). The motivational tools aim to create an encouraging environment open for exploration of options. They have been worded with the aim of acknowledging users' efforts and self-worth (T1.2) and emphasizing their autonomy (T3.16). The messages aim to normalize possible motivation deficits and failures in reaching behavioral targets (T3.22). The tools paraphrase users' selections and provide reflective feedback of the selections they had made previously (T1.3). All options are presented as acceptable and as a natural part of the behavior change process (T4.2). The app aims to transmit trust by assuming that users themselves know the options that are best for themselves (T4.5). All app content was written in empathetic and encouraging language, aiming to avoid any directive orders or judgmental feedback that could create guilt, shame, or feelings of being controlled, elements known to predict disengagement with activity [32,42]. These relational tools and self-reflection are hypothesized to satisfy the basic psychological needs of the self-determination theory and increase autonomous motivation [41]. Examples of the self-reflection tasks in each app are presented below.

Table 1 presents the ways motivational interviewing features target relational aspects and service engagement.

Table 1. Relational techniques from motivational interviewing implemented across the Precious app service (text in square brackets varies based on an individual's previously indicated preferences or previously made choices).

Technique[a]	Description	Examples of implementation in the Precious app	Targeted psychological needs to increase service engagement
T1.1: open-ended questions	Questions that cannot be answered with a limited response (ie, yes, no, or rarely)	"Imagine yourself being active and enjoying it. How is your life different?"	Open-ended questions aim to guide the user to think of reasons to increase physical activity and the positive changes that it may cause. Guiding users to imagine also supports their autonomy to choose the activities they enjoy
T1.2: affirmations	Acknowledging users' efforts and self-worth	• "Well done! First app completed!" • "Good job! You achieved your daily step goal."	Acknowledging efforts aims to support the users' competence and self-efficacy and create a sense of relatedness with the service. The users are hypothesized to return to the service, as they feel their efforts do not go unnoticed
T1.3: reflective statements	Paraphrasing users' choices (from multiple choice answers to reflective feedback)	"OK. So, in other words, physical activity is important to you because it could help you to achieve your [top outcome goal]."	Paraphrasing aims to support self-reflection and provide perspective on the selections the user has made. It supports autonomy by valuing user-made choices and targets relatedness by providing an experience of being heard
T3.16: emphasize autonomy	Freedom to choose outcome goals, behavioral goals, and activities and their timing	"Earlier, you said that being physically active would help you to [achieve your top outcome goal]. Well, there are many different ways to be active, and some which you would enjoy more than others. Swipe forward to ensure you will get recommendations you like."	This technique aims to support user autonomy and suggest activities that are intrinsically motivating
T3.22: normalizing	Acknowledging that it is not uncommon to find behavior change challenging	"Many people have difficulties recalling times when they enjoyed being active."	Normalizing is used to nurture the sense of relatedness through empathy and compassion, even if users indicate no intention to be active
T4.2: consider change options	Neutral and supporting language to consider all options and no guidance to specific choices	"The whole point is to support you with things that matter to you most. The more you interact with Precious, the more accurate these recommendations will become."	The neutral language used to support autonomy, competence, and relatedness, as users can feel that their choices are accepted and supported
T4.5: support change	Trusting users' ability to choose best options for them and remind them of their choices	"Based on your responses it seems that you think a change in your [chosen behavioral target] can help you to [achieve your top outcome goal]. That's good to know! Precious will now help you on the path to getting more of what you want."	Reminding users of their personally relevant goals may help them feel competent to execute their plans and autonomous to choose their goals and thus increase relatedness with the service

[a]Relational techniques from motivational interviewing as identified by Hardcastle et al [33].

Features Based on Self-Determination Theory

The Precious app's design draws from the qualitatively different motivational styles of self-determination theory [48]. To address intrinsic motivation by adding pleasurable elements to physical activity, the app was built to contain gamified challenges and visualizations. Other aspects of *autonomous motivation* were targeted with tasks that evoke users' personally important life goals and positive memories related to physical activity, aiming to remind them of factors that help them identify as an active person or that integrate physical activity as part of their lifestyle.

Cross-cutting features in all app components are the psychological needs of the self-determination theory: autonomy, competence, and relatedness. To address the need for *autonomy*, the basic structure of the app was chosen to consist of freely available tiles (Figure 2). Each tile hides a specific app feature or BCT. On the basis of user selections, the service recommends certain tiles on the top of the screen, but all tiles remain available for the user to explore. Users are offered freedom to choose the values that guide them and the ways to achieve their outcome goals and to adjust their behavioral goal each day. The tiled structure also adds flexibility for further use of the platform, as software developers can add new tiles with new features without modifying the original content.

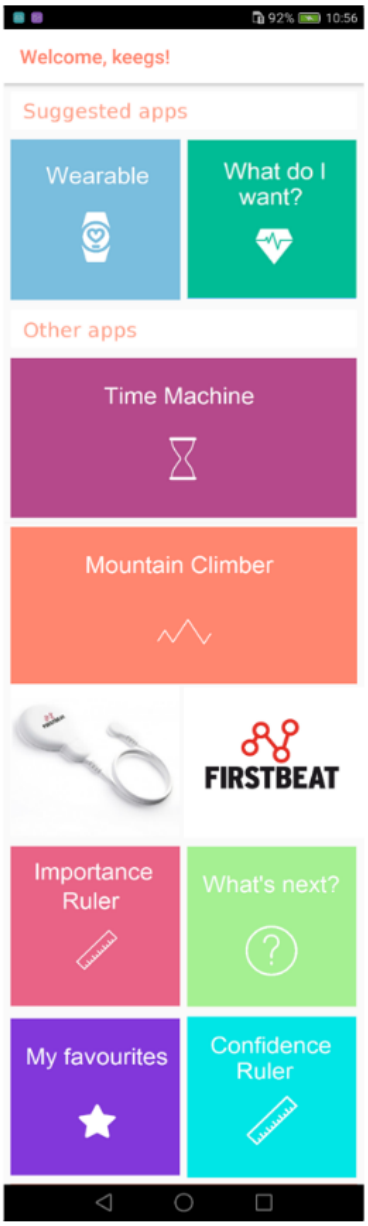
To offer experiences of *competence* and *self-efficacy*, the app notifies the user when approaching the daily step goal and celebrates achievements and service engagement with a notification. The self-regulation features in the Precious app are designed to increase competence by supporting individually tailored goals and comparing users' results with their previous results only (weekly average), not with other users' results. Instead of receiving a standard step goal, users are encouraged to set daily step goals that slightly exceed their current step average. Finally, users are encouraged to think about the good experiences they have had and might have with physical activity, hoping to remind them of times they have felt competent [75]. Competence is also addressed by aiming for an intuitive usability of the app functions, which has been associated with continued service use and higher experience of competence [76].

In addition to the relational techniques (Table 1), the need for *relatedness* is addressed with personalization. The main screen greets users with their name, and the motivational tools specify that recommendations the app provides will be based on their

selections. To increase the relevance of the recommendations, algorithms of the Precious app suggest motivational elements to those who do not express interest in tracking or physical activity and self-regulation techniques to those ready to act.

Users proceed through the motivational tools by swiping the screen as if turning a page in a book. The rules engine of the Precious app was designed to approach the user after recognizing a period of inactivity and to ask whether the user's previous choices still seem relevant or if they would want to reconsider their goals. This way the app is not imposing external requirements to the user but, with their permission, reminding them of their personally valued goals and activities [77].

Figure 2. Implementation of the Precious app home screen, with suggested apps at the top of the screen.



What Do I Want?

The first motivational tool of the Precious app is called *What do I want?* (Figure 3). It builds on the values exploration in motivational interviewing and starts by suggesting a list of outcome goals (BCT 1.3, Table 2) [78]. To address individuals with low motivation for physical activity, we do not impose exercise- or health-related goals but also offer options such as *feel connected with other people*, *face challenges*, and *relieve stress or tension*. These outcome goals set the context for further interactions with the Precious app. This tool aims to increase autonomous forms of motivation by increasing the salience of personally valued goals. This is done by encouraging the reflection of desirable and beneficial things in life that may be achieved with physical activity. This tool uses relational features T1.3, T3.16, T4.2, and T4.5 (Table 1).

Figure 3. Implementation of the What Do I Want? tool. Screen B shows implementation of outcome goal selection, focusing on the things the user wants out of life, and Screen C allows users to indicate which of these are most important to them at this moment. Screen D provides a simple reflection on the content of the user's chosen outcome goal and offers a menu of possible behavioral changes, which would be most likely to help them achieve the outcome goal set on Screen C. Screen E provides a summary of the user's interaction with this tool, highlighting their chosen outcome goal and behavioral target.

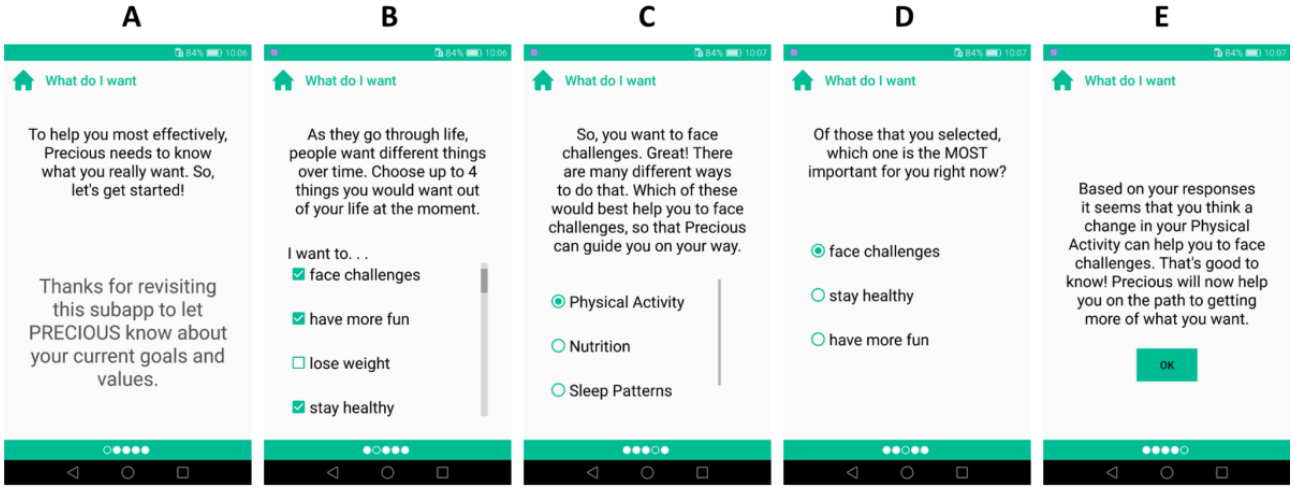


Table 2. Behavior change techniques in the Precious app.

Name of the feature	BCTs[a, b]	Description	Targeted behavior change mechanisms
Motivational components			
What do I want?	1.3 Outcome goal setting	The Precious app prompts users to reflect on their life goals and to choose their preferred outcome goal(s) from a list.	Selecting personally relevant outcome goals is hypothesized to support autonomy and nurture the relatedness with the service. Thinking about personally important reasons to be active may increase autonomous motivation for physical activity.
What do I want?	1.7 Review outcome goals	If a user's engagement or activity levels decrease, the Precious app asks them to consider selecting a new outcome goal in the *What do I want?* tool.	This technique aims to support user's relatedness with the service by empathetic concern of the user and by acknowledging that the current support offered may not be optimal. Providing new outcome goals to choose from targets user autonomy. Together these aim to increase motivation for physical activity.
Time machine	15.2 Mental rehearsal of successful performance	The Precious app asks users to visualize a future event in which they would enjoy physical activity and prompts users to reflect on the positive consequences of this experience.	Mental rehearsal provides full autonomy to choose the activity, the environment, and the company. This technique can thus address autonomy, competence, and relatedness and increase motivation to try out the activities in real life. The user may identify new or forgotten opportunities and capabilities for activity.
Time machine	15.3 Focus on past success	The Precious app asks users to reflect on a past event in which they enjoyed physical activity and prompts users to reflect on the positive consequences of this experience.	This imagination technique is targeting the psychological needs of autonomy, competence, and self-efficacy, reminding users of the moments they enjoyed being active and thus boosting their motivation. If users have good exercise memories with other people, this technique may also remind them of the sense of relatedness. The user may identify forgotten opportunities and capabilities for activity.
How to get there?	Additional BCT: linking behavioral goals with outcome goals	The Precious app reminds users that their behaviors (eg, football and gardening) can help them to achieve their outcome goals (eg, feeling connected to others and having fun)	This technique is expected to create a mental bond between users' valued goals and the tangible actions that help them achieve those goals. As both goals and behaviors are self-selected, this technique targets all three psychological needs of autonomy, competence, self-efficacy, and relatedness and may thus lead to increased motivation. The tool may help identify such opportunities to be active that serve a purpose
Smartphone notifications and biofeedback report	10.4 [Digital] Social reward	The Precious app delivers smartphone notifications with positive messages based on tracked service engagement or activity. Biofeedback reports include praise and encouragement for progress.	Supportive but accurate feedback aims to increase users' competence, self-efficacy, and relatedness with the service, which again should increase motivation to take care of their well-being
Self-regulation techniques			
Mountain climber	1.1 Behavioral goal setting	The Precious app allows users to set a daily step goal. To set a realistic goal, users see a suggestion of their past 7-day average as a starting point.	This self-regulation technique targets users' autonomy by letting them adjust their daily goals. Basing goal recommendations on each user's step average takes into account their capabilities and aims to increase competence and self-efficacy. Users can consider their opportunities to be active on the day while setting a goal.
Mountain climber	1.4 Action planning	The Precious app allows users to plan bouts of physical activity, including activity type, intensity, and time of day. Users then receive notifications when their planned activity is approaching.	Users' autonomy is supported as they can choose any physical activities and be supported in completing those. Making plans with the tool can remind users of their capabilities and opportunities for activity as they see the list of activities they like.

Name of the feature	BCTs[a, b]	Description	Targeted behavior change mechanisms
Mountain climber	1.5 Review behavior goal(s)	When opening the Mountain climber tool, users can review their previously set goals, the extent to which those were achieved, and adjust the goal for the current day.	Seeing their past behavior visualized as mountain panorama and achievements as flags on top of the mountains may help to celebrate successful goal achievement, increasing competence, self-efficacy, and awareness of capability. Users can change the daily goal anytime, which targets autonomy.
Smartphone notifications	1.6 Discrepancy between current behavior and goal	The Mountain climber tool shows in real time how many steps the user has taken and how far they are from their daily step goal. The user also receives messages on the percentage of steps that they have accomplished by afternoon.	Getting a reminder of goal progress may increase the sense of competence and self-efficacy in case users have already achieved their goal or they feel they can complete the remaining activity during the evening. Seeing the difference between their goal and current situation may create an intrinsically motivated challenge to achieve the goal.
Smartphone notifications	2.2 Feedback on behavior	The Precious app sends a notification about progress toward user's step goal and goal achievement.	Supportively worded messages about goal progress can increase relatedness to the service and sense of competence and self-efficacy if the goal seems achievable.
Activity bracelet	2.3 Self-monitoring of behavior	The Mountain climber app displays the number of steps a user has accumulated each day. This step total aggregates steps logged by the activity bracelet, the phone's onboard accelerometer, and manually logged activities. Users are asked to manually log other activities than walking, running, and cycling (which are automatically tracked). Action plans made with the tool can be marked completed with a single tap.	Aggregating activities from several sources can help users understand how all activity contributes to the daily total and that all occasions to be active count. This, in addition to visualization of their activity as a mountain panorama and achievements as flags on top of the mountains, may help to celebrate their efforts, increasing competence and self-efficacy. Seeing activities visualized as mountains to conquer may increase intrinsic motivation to use the tool.

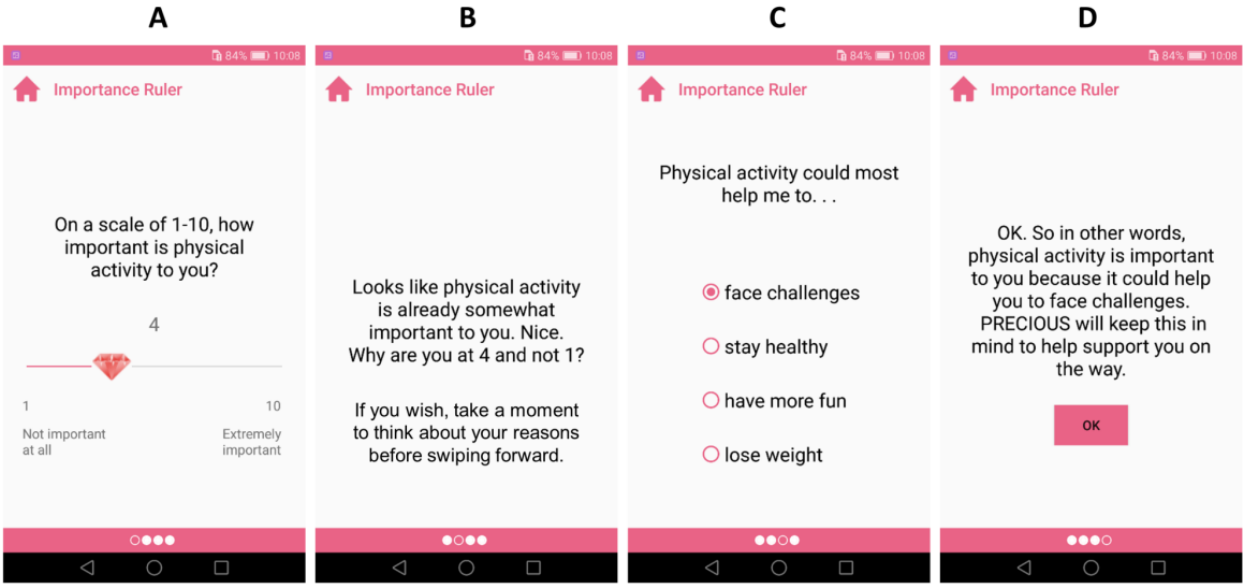
[a]BCT: behavior change technique.

[b]Behavior change technique numbering based on the study by Michie et al [8].

Importance Ruler

A technique taken directly from motivational interviewing, Importance ruler, first asks users how important they perceive physical activity on a scale of 1 to 10 (Figure 4) and then, depending on the answer, follows with an affirmation and asks why the user did not choose a lower number. The user is guided to think of reasons that would make physical activity matter to them. This reflection task is followed by a reminder of their previously chosen outcome goals. The purpose of this is to help the user to create a mental link between physical activity and their personally valued goals. Depending on user selections, this tool uses relational features T1.2, T1.3, T3.16, T3.22, T4.2, and T4.5 (Table 1).

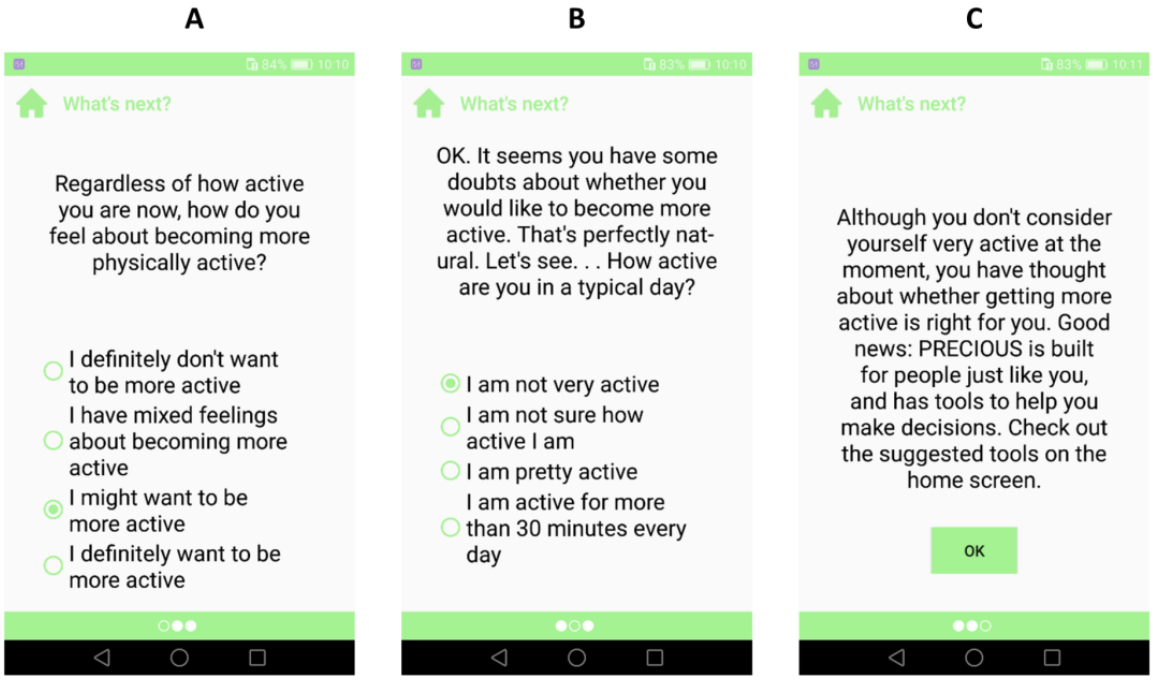
Figure 4. Implementation of the Importance ruler tool. Screen A shows the importance ruler itself. Screen B shows a follow-up question from the individual's initial response and a prompt to help users better introspect about why they chose a particular number on Screen A. Screen C shows a selection of possible positive outcomes of physical activity, populated from the choices made previously in the What Do I Want? tool. Screen D shows a reflection of the user's chosen responses on Screen C.



What's Next?

This tool aimed to assess users' motivation and activity status (stage of change [77]) to tailor the recommendations on the home screen (Figure 2) [75]. Indicating low motivation and intention for physical activity leads to features based on motivational interviewing and gamified challenges. If the user expresses intentions to start or maintain activity, the main screen will suggest goal setting, action planning, activity logging, and gamified challenges (Figure 5). Independent of user's selections, this tool aims to acknowledge users' efforts and self-worth by using empathetic language. This tool includes relational features T1.2, T1.3, T3.16, T3.22, T4.2, and T4.5 (Table 1).

Figure 5. What's Next tool. This tool assessed a user's stage of change for physical activity and directed users to either motivational or self-regulatory features based on their responses.

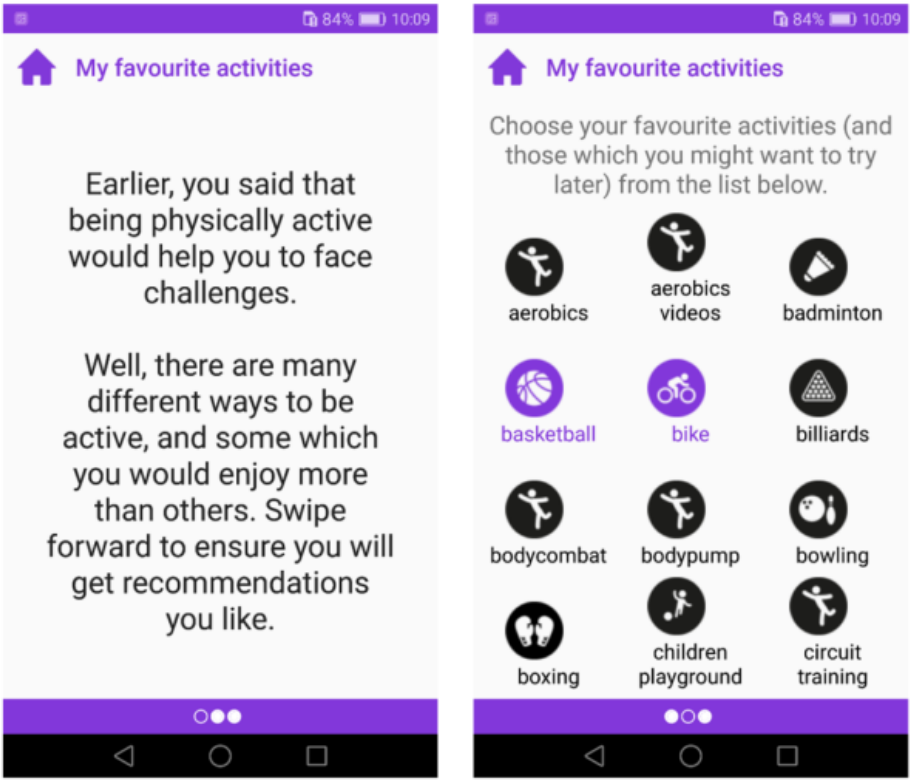


My Favorites

To acknowledge users' efforts and self-worth, users are asked to choose physical activities that they have enjoyed in the past and/or might like to try in the future (Figure 6). This offers them a freedom of choice, may evoke positive memories of exercising while going through the list of options, may present

opportunities for activities that the user was not thinking as physical activity (eg, gardening), and populates the database with options that may be used for later reminders, thus offering an experience of personalization. The chosen activities are also shown as the first suggestions in the self-regulation tool to improve the user experience. The *My favorites* tool was implemented with a simple tiled structure that shows all activities simultaneously and allows adding and removing them with one touch. The app was not finalized by the time of feasibility testing. The *My favorites* tool uses relational features T1.2, T3.16, T4.2, and T4.5 (Table 1).

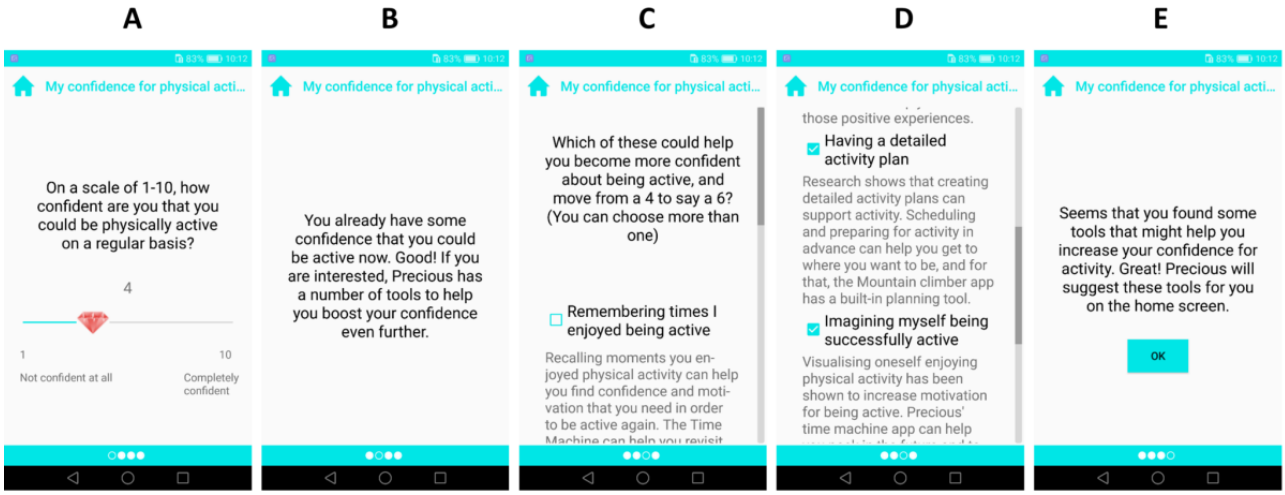
Figure 6. Implementation of the My Favorites tool, in which users choose the modes of PA that they might like to undertake. The prompt on Screen A recalls the outcome goal the user set in the What do I want? tool.



Confidence Ruler

The *Confidence ruler* tool implements a core technique of motivational interviewing and starts with the question "How confident are you that you could be physically active on a regular basis?" It then provides feedback on user choices and leads to asking which of the app's available tools could help the user to be more confident in their ability to be physically active. The answer options consist of all the tools that the Precious app has to offer and a rationale for their use (Figure 7). This tool aims to acknowledge users' efforts and self-worth (T1.2) and, depending on the user's selections, uses relational features T1.2, T1.3, T3.16, T3.22, T4.2, and T4.5 (Table 1).

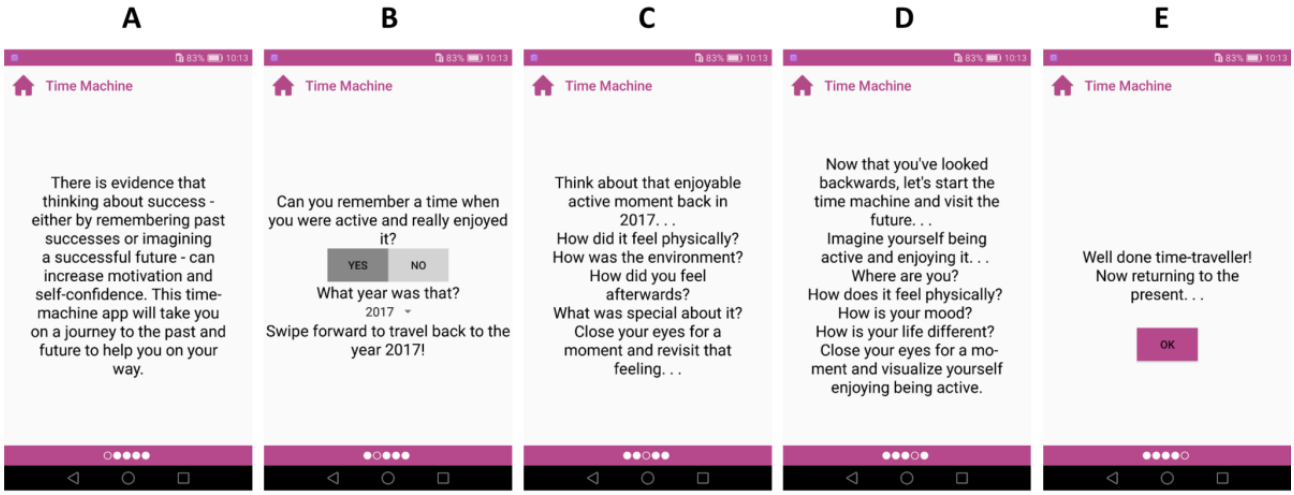
Figure 7. Implementation of the Confidence Ruler tool. Screen A shows the main question of this tool, which is followed up with a tailored reflection on Screen B. Screens C and D show a number of the tools available to users and the rationale for how each could help improve their confidence. Users were free to select as many or as few of these as they wished.



Time Machine

The *Time machine* tool aims to boost motivation, a sense of competence, and self-efficacy by evoking users' positive exercise memories and helping them to create vivid images of successfully engaging in physical activity and enjoying it (BCT15.2 and BCT15.3, Table 2). A mental rehearsal of a successful performance was found to be the most effective BCT in increasing intention to be physically active in a recent meta-analysis [21]. To create a gamified, *machine-like* experience, the app first asks whether a user has any positive experiences and then the year the user wants to be sent to. This is followed with detailed questions about their experience that aim to acknowledge users' efforts and self-worth (Figure 8). This tool uses relational features T1.2, T3.16, and T4.2 (Table 1).

Figure 8. Implementation of the Time Machine tool. Looking back exercises are shown on Screens B and C, and looking forward exercises are shown on Screen D.



How to Get There?

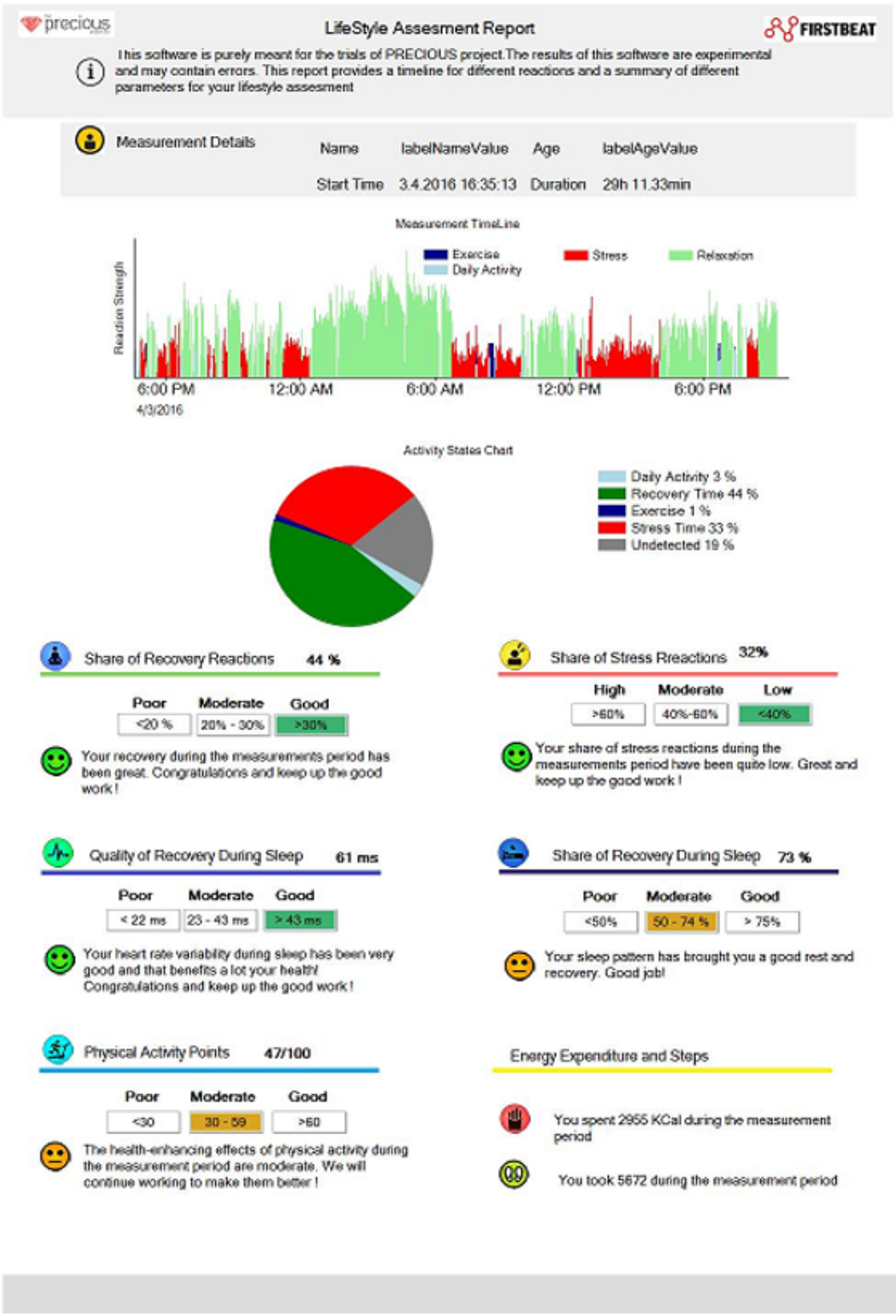
The aim of this tool is to strengthen the mental link between users' outcome goals and the specific actions that help them achieve it. This tool is suggested after completing the values exploration in *What do I want*? and selecting favorite physical activities in *My favorites*. The task is to select those activities that take the users closer to their outcome goal. For instance, if the user has chosen the outcome goal *feel socially connected*, the next step is to scroll through their favorite activities and choose the ones that allow them to connect socially (Multimedia Appendix 1). This feature helps the users to build a personal rationale for doing physical activity. This tool was not finalized by the feasibility testing.

Biofeedback

We integrated Firstbeat's (Firstbeat Technologies) heart rate variability sensor, Bodyguard 2, to the Precious app to offer the users the possibility to receive feedback on their physiological stress, recovery, and sleep quality (Figure 9) [79]. The feedback consists of graphs showing users' activity levels in colored bars and interpretations of these bars telling the user whether their levels of activity and recovery have been health enhancing. Encouraging messages congratulate the users or support them

to keep up their efforts. Users can access the reports in the Precious app behind a tile picturing the Firstbeat sensor after downloading the sensor data to the internet via a computer with a USB port. The aim of the biofeedback tool is to remind users that their behaviors have both immediate and long-term consequences on their well-being. Strengthening this mental link between their behavior and desired outcomes could strengthen their autonomous motivation. The feedback aims to acknowledge users' efforts and self-worth by congratulating them for physical activity, good sleep quality, and recovery. The biofeedback report uses relational features T1.2, T3.22, and T4.5 (Table 1).

Figure 9. Example view of Firstbeat heart rate variability report for Precious.



Gamified Elements

In addition to the gamified features of the Mountain Climber self-regulation tool, other components were also envisaged to help foster intrinsic motivation for using the Precious app [52]. These components were all built into working prototypes but only after the completion of feasibility tests that were undertaken with the app components described earlier.

The Journey

Swiping left in the main menu reveals the user their journey, a map of achievements. Completing the motivational tasks and activity challenges creates a badge on a background of changing landscapes. All actions accumulate points, with less points obtained from app use and more points, from sustained streaks in physical activity. Journey's main function is to increase the sense of competence and self-efficacy by showing visible cues of progress and listing all the actions taken on the way to an active life. The changing landscape may motivate users to complete actions to progress into new levels (Multimedia Appendix 2).

Conquer the City

A location-based activity game was designed to create entertaining challenges, tasks, and competition that would make walking intrinsically enjoyable. The aim of the game is to conquer areas on the map by walking around them and by collaborating and competing with other app users. This addresses the psychological needs of relatedness and adds an element of excitement and fun for those who enjoy competition [80,81]. Users could also challenge themselves, trying to conquer new areas or specific targets on the map (Figure 10).

Figure 10. Conquer the city, location-based activity game.

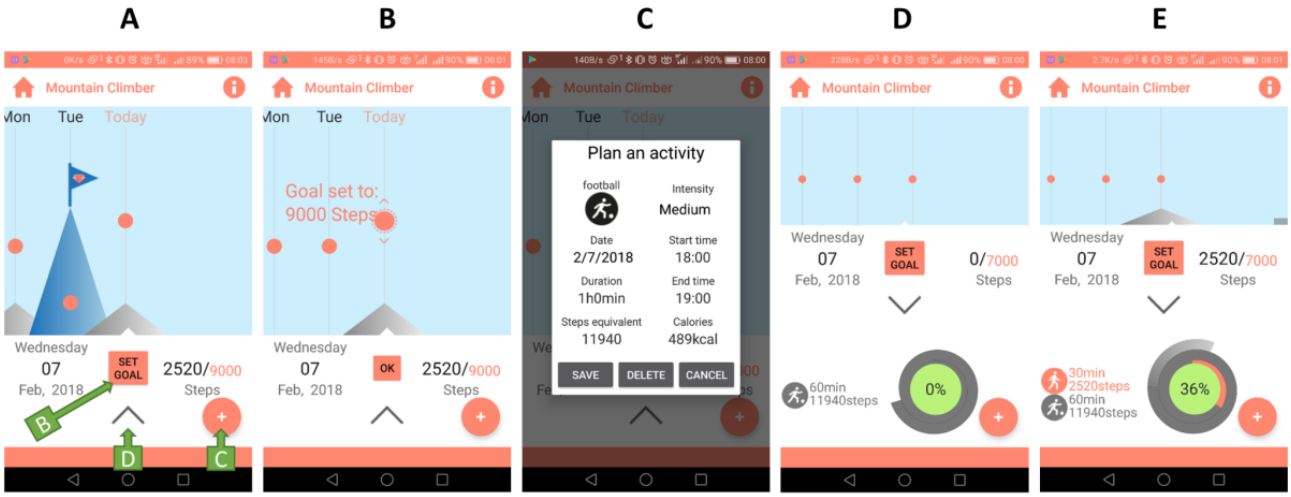
The Precious App Development: Self-Regulatory Tools

The purpose of the self-regulation tool is to give users a clear picture of their current activity level and how that compares with their target level (self-monitoring, BCT 2.3; discrepancy between current behavior and goal, BCT 1.6, Table 2 [8]) and guide them to set daily, realistic, and achievable activity goals (BCT 1.1). The planning tool was created for creating detailed activity plans (BCT 1.4) and logging of activities that were performed while not wearing an activity bracelet (BCT 2.3). To make these techniques intuitively usable, we created a graphical interface that aggregates all the activity the users have accumulated during the day, their daily goal achievement, and their progress over time.

Mountain Climber Self-Regulation Tool

These requirements lead to the development of *Mountain climber* (Figure 11), designed with game-like features, with the aim of increasing user engagement in self-regulation. These include the graphical presentation of the accumulated steps (mountain) and visual rewards for goal achievement (illustrations of mountain life) that appear randomly after successful goal achievement (by the time of the feasibility testing, only a flag on top of the mountain and a changing color were implemented). Mountain was considered a representation of daily achievement that would be easily understandable for every user and that would add symbolic meaning to the accumulating steps. Goal setting was done by scrolling a digital button on the screen and choosing a certain step goal for the day. The goal setting tool was set to display the mean of the past 7 days' steps when opening the Mountain climber. This was designed to educate users of their typical step amount to encourage reflection of how much activity could be embedded in the day ahead. Late afternoon, users receive feedback in a message providing the percentage of the daily step goal they have achieved to adapt their evening activities and accumulate the missing steps. Consecutive usage days create a panoramic view of user's physical activity, showing possible increases or decreases over time and reminding them of their achievements.

Figure 11. Implementation of the Mountain Climber self-regulatory tool. Screen A shows the main view, with blue mountain indicating an achieved goal. (Green tags on Screen A were not visible to users and are included here to indicate the destination screen after a tap action.) Screen B shows the step goal setting function. Screen C shows the action planning function. Action planning and logging are done by choosing an activity from a dropdown menu and setting the start and end time. The user can also adjust the intensity of the activity to either low, medium, or high, the default being medium. For ease of use, action planning is done in the same way as activity logging, with only the time being set in the future. The visual symbol of the planned activity appears in dim grey color, and the steps contribute to the daily total only after the user touches the button "I did it!". Screens D and E show a detailed daily view, with planned activities in grey and completed activities in orange, indicating how many percentages of the daily goal is reached with the activity.



Physical Activity Measurement

Within the Precious app, physical activity data are accumulated from three separate sources, which the app aggregates to a single step count for each day. Steps per day were chosen as the common metric for presenting physical activity data, as it is readily interpretable and allows for direct comparisons from day to day within an individual. To address the socioeconomic challenges related to the use of digital services [82], the Precious app was built as a stand-alone smartphone app, signifying that anyone with an affordable smartphone could use the service without accessories [83]. For increased physical activity data accuracy, the app can also be connected to external monitoring devices through Bluetooth. For pilot testing of the Precious app, the primary source of physical activity data was a wrist-worn activity bracelet (Xiaomi Mi Band 1S Pulse Bluetooth 4.0 IP67 Waterproof Smart Bracelet) [84]. Step counts from the activity bracelet were passed to the app via low-energy Bluetooth at regular 10-min intervals when a connection with the app could be established.

As users of the Precious app may not always wear their activity bracelet, and as some activities (eg, cycling and weightlifting) are not accurately recorded by wrist-worn accelerometers, users can also manually log their activities. The Mountain climber tool allows users to select a physical activity from a list and to specify the time and intensity of this activity. Knowing a user's height and weight, the Precious app converts the activity to steps using metabolic equivalent (MET) values and the following equation [85,86]:

Steps/minute for activity = (MET value of activity ×112.5)/3.5

As a final source of physical activity data, the Precious app used data collected from the phone's onboard accelerometer and the Google Play Services Fitness application programming interface (API). This allowed for identification of steps taken as well as minutes spent walking, running, cycling, traveling in a vehicle or being sedentary. This source of physical activity data was used in periods where the app was unable to communicate with the activity bracelet, and no physical activities had been manually entered.

When amalgamating data from various sources, users' manually entered activities were given the highest priority. Any step counts received from the Mi Band or onboard accelerometer that had timestamps that overlapped with the timestamps of manually entered activities were not added to an individual's total. Steps obtained from the Mi Band were given the second highest priority. Steps obtained from Google Play Services Fitness API were given the lowest priority and were only added to an individual's total in periods in which the Mi Band had not recorded any new step count activity. The aggregation of these three data sources was presented to users in real time, which offers users a comprehensive and realistic picture of how their steps accumulate during the day, how different activities contribute to the whole activity, and how their activity varies daily.

Feasibility Testing

Participants

The interviewers recruited a convenience sample of 12 adults living in two different Finnish regions, with diverse educational backgrounds (three without any university studies and one with a doctoral degree) and ages ranging from 25 to 63 years. Of 12 participants, 8 were women and 4 were men, both genders ranging from physically inactive to highly active. Participants had different levels of experience with smartphone apps, ranging from active sport app users to participants without a smartphone. With think-aloud studies, five participants are deemed sufficient for detecting most usability problems [87,88]. To assess the

feasibility of the digitalized motivational features, we recruited the maximum number of participants who could be interviewed within the project time limits, increasing the participant number to 12.

Overall, two participants (P6 and P7) agreed to participate only in a think-aloud study of the biofeedback report and were thus excluded from the current analyses (participant details are in Multimedia Appendix 3). The Precious app study received a favorable decision from the University of Helsinki Ethical Review Board in the Humanities and Social and Behavioural Sciences in January 2016. The project also addressed ethics and privacy in yearly reports to the European Commission. Participants were interviewed in person by a research group member (PhD researcher or intern) in June 2016 at a location that was convenient for them (office, home, or university lobby) and were rewarded with a movie ticket. Inclusion criteria were written informed consent, aged at least 18 years, sufficient language skills to use the English language app, and to conduct the interview in Finnish or English.

Procedure

After providing informed consent, participants were provided with a smartphone with the Precious app and a screen recording program, AZ Screen Recorder, and were asked to practice the think-aloud method with the smartphone's other preinstalled apps (eg, alarm clock and address book) until they were speaking continuously, describing everything they saw, thought, or did with the app [89]. Participants were then instructed to use the Precious app just as they would any other app they had just downloaded and to think aloud while doing so [89]. Participants were also requested to ask any questions that came to mind as they explored the app (eg, where they should tap or what does a certain button do), as such questions could help us better understand user experiences [89]. Participants could freely interact with the Precious app until all content had been explored (usually around 30 min, including the dietary features not presented in this study), and during this time, if a participant stopped thinking aloud or passed several features without commenting on them, the interviewer prompted them by asking what they were thinking. After the think-aloud study, participants were briefly interviewed about their physical activity levels and previous experiences with smartphone apps.

Measures

To assess participants' physical activity levels, we used a validated single-item question, "On a typical week, on how many days do you do a total of 30 minutes or more of physical activity, which was enough to raise your breathing rate. This may include sport, exercise, and brisk walking or cycling for recreation or to get to and from places but should not include housework or physical activity that may be part of your job" [90].

Think-aloud walkthrough interviews were followed by a semistructured interview with open-ended questions on participants' previous experience with mobile apps, general perceptions of the Precious app and its most/least useful features, suggestions for improvement and usage, possible features that could exclude potential users, and factors related to engagement with the service. These questions were mainly used for the technical usability analyses not presented in this study. Interviews and think-aloud walk-throughs as well as participants' on-screen interactions with the app were video recorded. Interview recordings were transcribed verbatim by a research assistant and a trainee. User actions such as tapping and swiping the screen were also transcribed, as the analysis of user engagement included all interactions with the app.

Analysis

Transcripts for each participant from think-aloud and semistructured interviews were analyzed with a deductive, theory-based thematic analysis, informed by Braun and Clarke's phases of thematic analysis [91], used previously to analyze think-aloud studies of smartphone use [92,93]. The method allows for the essential content of the interviews to be captured in themes that describe the data patterns in a summarized form [91]. First, we analyzed data from each participant individually to remain sensitive to their experience and to detect possible differing themes between participants. Second, themes were synthesized from each participant into a general set of themes. Discussions between three researchers (JN, KK, and AH) led to agreement on the primary themes.

The theory-driven RQs on change talk (motivational interviewing) and autonomy support (self-determination theory) were analyzed with a deductive approach, aiming to identify any passages that fit these theoretically defined constructs [91]. Change talk and sustain talk (counter-change talk) were coded following the guidelines of the CLEAR (Client Language EAsy Rating) coding system [94]. Following the CLEAR guidelines, any factual information of existing behavior was not coded as change talk (eg, "I walk to work every day"), and choices made at the ruler tasks were coded as change talk only if there were confirmatory comments [95]. The excerpts on change talk and autonomy support were analyzed with their semantic meaning, assuming a unidirectional relationship between meaning and experience and language [91]. After identifying all the change talk–related passages, these excerpts were then coded as specific subtypes of change talk (ie, theory-driven themes) [91]. Finally, to optimize the usefulness of the results for the reader, all data excerpts on change talk, marked with the theme they represented, were organized and summarized under the respective app functions. Presenting change talk under specific app functions allows the reader to evaluate the tools and techniques that can be reproduced elsewhere, as suggested by O'Halloran et al [36].

Results

Feasibility

The feasibility analysis on participants' engagement with the Precious app answered the following two RQs: (1) how participants discussed autonomy support during the think-aloud walkthrough and the end interview and (2) what kind of change talk did the Precious app elicit in the users during the walk-throughs.

Research Question 1: Perceived Autonomy Support During Interactions With the Precious App

We identified the following themes around the original, theory-based theme *autonomy support*: valuing the chance to choose, autonomy supportive feedback, expecting controlling features, concern about lack of autonomy, and autonomous goals.

Valuing the Chance to Choose

Consistent with the self-determination theory, participants valued autonomy supportive features, especially the chance to personalize the content and make selections:

> *It is good that this background information is added there so that it's not like the same for everyone. Absolutely, it's good to have it, so that you can influence it yourself.* [P8]

The chance to choose was especially relevant for the self-regulation features, as participants appreciated the possibility to adjust the daily step goal and consider the day ahead:

> *So, every day you can set the goal. But that sounds smart. Maybe a bit smarter than what I have in use, where there's for every day that...I think it has 10 000 the...Or you can't set a goal, they think that 10 000 is the recommendation...I think this is smarter that you can also...if, like, you know that this day will be...that maybe there's not so much walking, so...* [P4]

A participant with low levels of activity thought she would take advantage of the ability to set personal step goals to make sure she would achieve them:

> *I guess I'd probably put, if you could put, beforehand the goals, so, I'd probably put so… maybe even lower? So that they would be really, like, achievable and probably I would achieve them.* [P11]

The number of personalization options was generally found to be reasonable, and users found options that pleased them. However, overall, two participants felt that the list of 20 outcome goals had too many options to choose from:

> *I: What are you thinking?*
>
> *P9: Just that there's a lot of options again, there was four a moment ago and now there's like forty...already reading these, now that it's a busy situation...well at least, I'll tick some of these.*
>
> *P5: [chooses Feel more healthy] Yeah, there were too many. And again, you can choose so many different ones.*

When asked if the service would exclude any user groups, one participant saw the number of options as too high for elderly people:

> *Then if the idea was that this is for elderly people, then it might be a problem that there's so much of everything. This might be like a shock, or at least I remember when I've tried to teach my grand-parents Internet and computer use, and just when you open the screen and there's a lot of small icons, it's often very difficult. And when you need to click and...really self-evident stuff can become a threshold, but I don't know for how difficult population you are aiming this.* [P10]

Autonomy Supportive Feedback

In addition to freedom of choice and tailoring, participants wished to receive encouragement and praise and mentioned that the tone of interaction is important:

> *Although [another sport app] it's just an app, but it says something like "now you've missed your training session," it makes me feel somehow bad. So probably you should pay attention to that, how the feedback is.* [P4]

Expecting Controlling Features

The interviews revealed that participants were used to apps that prescribed specific goals or activities. They assumed that the app would tell them, for instance, how much activity they are expected to do:

> *P12: Here it's like 36 percent. 36% of what? Like...*
>
> *I: Yeah, that's not clear?*
>
> *P12:* [Taps 36% circle. Nothing happens]
>
> *P12: Probably like how much should I walk or something.*

These expectations were based on their previous experiences with apps that provided less autonomy support:

> *This is slightly different than what I've previously used of these health apps. Usually, very first question is height and weight and target weight. That's the most common. But well, this seems good...or like good so that it's not always necessarily the weight loss. That usually those apps have weight loss as default...* [P4]

Concern About Lack of Autonomy

In addition to expecting health apps to be controlling, participants also expressed concern about this *lack of autonomy*, for instance, that their early choices would tunnel them into unwanted recommendations later:

> *And then, choosing "stay healthy" brings to my mind immediately that now [Precious] will suggest to "take long walks" and "do yoga" and all these healthy activities, while I don't like that at all. So, it instantly brings to my mind those stereotypes that this kind of healthy activity includes. Which you might not want yourself- although I choose this "Stay healthy," I think however if I should have put some "Face challenges" so that I will get some fun to the activity.* [P9]
>
> *How is it programmed then [to provide suggestions]...Does it affect a lot if you choose the wrong one of the two* [goals]...[P8]

One participant experienced the question about his intention to be active as expectations set on him (*What's next* tool) as expectations set on him rather than being tailored:

This here thinks I'd need to change the level of physical activity, I personally thought about it more like...that it's just one central aspect...I didn't see I would somehow need to change it. [P10]

Autonomous Goals

Most users made selections that could be identified as autonomously motivated outcome goals, wanting to achieve health, well-being, fun, and challenges with physical activity instead of aiming for external goals. Several participants reflected about the importance of different types of goals:

P9: I am very stiff, I should probably put that ["feel more flexible"] but I don't really care about that I am stiff. [Chooses "Increase my stamina"]

I: So, you took into account that it asks what you want

P9: Yeah...Probably it would be good to be a bit more flexible...And I should lose some weight but that's not such a top thing for me...Would it be good to choose four?

I: Yeah, is it unclear whether you need to choose?

P9: No, it isn't, no you don't need to but...Well, there are that kind of options that I could choose from. [Chooses the option "Relieve stress or tension"]

P9: Health is the most important. [Chooses the options "Maintain my functional ability" and "Stay healthy"]

Research Question 2: Change Talk Elicited During Interactions With the Precious App

We examined whether and how app usage encourages self-reflection by observing the occurrence of change talk. Within the theoretical framework of motivational interviewing and the original theme of change talk, we identified the following themes: desire, need, reason, ability, commitment, taking steps toward change, sustain talk, and ambivalence. With this method, we aimed to analyze the feasibility of digitalized motivational interviewing features, and not users' views on behavior change. Thus, to support replication and further development of digitalized motivational interviewing, the need identified in a systematic review [37], examples of the themes are presented under specific tools.

What Do I Want? Tool

The *What do I want?* tool prompts users to select outcome goals that matter to them and to select behaviors that help them approach those goals. During think-aloud walk-throughs, all participants actively engaged in selecting options that were relevant to them and most of them expressed some form of change talk. The change talk produced was mainly of the *desire* and *reason* type [32], as, implicitly, these occurred each time a participant made a selection of the *things that they would want out of life*:

Hmm [reads options] maybe, maybe, maybe not, yeah quite nice. Well maybe, I want at least to be stronger. (Change talk—desire) [P2]

The list of outcome goals seemed to help some participants to find *reasons* for activity. A quote from participant 10 shows how he actively reflects what the options would mean in his life, first rejecting several options, but then finding suitable goals:

Do I want to "face challenges." Well I don't know what these challenges mean here so it is a bit...maybe it has something to do with sports then. Not in general, I don't have that feeling that I would like to face challenges..."More fun...," I am quite satisfied with my level of fun at the moment, and I don't feel that I would need to lose weight either, and staying healthy isn't...well, it is good, of course. Let's put that [selects "Stay healthy"]. "Functional abilities," that is also a good thing. [Selects "Maintain my functional ability"]. (Change talk—reason) [P10]

Participants also actively expressed *need* type of change talk, mainly when reflecting on which outcome goal options would be most relevant for them:

P9: [selects "Improve my general mood"] This is just what I need, to get out for a run or to be alone. - -

P9: Health is the most important. [Chooses the option "Maintain my functional ability" and "Stay healthy"] [chooses Physical activity as the behavioral strategy]. (Change talk—need, reason)

Although all participants engaged in the selection process and found four options that were suitable for them, not all of them actively voiced aloud the rationales behind their choices. Their *talk* consisted partly of the selections they made. We call this implicit change talk:

[Opens What do I want? tool] Hmm. So, I can put only one or then maximum four options here. [Selects "become more flexible" as an outcome goal] Okay, this is good. I become less...okay that's it. Hmm. (Implicit change talk—reason) [P12]

Presenting possible outcome goals as a list may not only be a positive resource for users. A couple of participants voiced sustain talk when arguing against a decision to choose certain outcome goals:

P9: I am very stiff, I should probably put that ["feel more flexible"] but I don't really care about being stiff. (sustain talk—reason not to change) [Chooses "Increase my stamina"] (Implicit change talk—desire)

I: So, you took into account that it asks what you want

P9: Yeah...Probably it would be good to be a bit more flexible...And I should lose some weight but that's not such a top thing for me...(need change talk and ambivalence)

Would it be good to choose four?

I: Yeah, is it unclear whether you need to choose?

P9: No, it isn't, no you don't need to but...Well, there are that kind of options that I could choose from. [Chooses the option "Relieve stress or tension"]

P9: Health is the most important. [Chooses the options "Maintain my functional ability" and "Stay healthy"]. (Change talk—need)

Participants reflected their actual *needs* in relation to their current life situation:

> *The program asks, which of these [outcome goals] is most important, but it's hard to give weight to one or the other.. On different moments, different things are important, but it asks what would be most important right now...Removing stress [selects "Relieve stress or tension"]. (Change talk—need).* [P3]

Sometimes participants did not express change talk spontaneously, but they appeared to have thought about the responses when asked:

> *P3: So, let's see what is in there...So the program wants to find out what I really want, and...now I'm thinking what it asked.*
>
> *I: So, what are you thinking?*
>
> *P3: So, sharing happy moments, adventures, being in the nature, doing successful things. (Change talk—desire).*

Importance Ruler Tool

All participants were happy to select a number describing their perception of the importance of physical activity, but as the app did not require text input, they swiped through the pages at a relatively fast pace. Only a few participants reflected aloud their choices spontaneously, but almost all provided reasons for the importance of physical activity when asked what they were thinking. We identified the themes desire, need, reason, and sustain talk from interactions with the importance ruler:

> *P1:* [moves the pointer from 7 to 4]
>
> *I: So, tell now, like, what you think or see?*
>
> *P1:* [moves the pointer from 4 to 7 and from 7 to 8]
>
> *P1: I think that [physical activity] is important*
>
> *I: Mm?*
>
> *P1: Do I need to think about something else? [swipes forward] I guess not. I've been thinking for a second.* [swipes forward]
>
> *P1: Because of course I wanted to be more active. [swipes to the next screen, sees the preselected option 'relieve stress or tension']. Yeah, that's alright. (Change talk, desire)*
>
> *P3: That it [physical activity] just keeps me active. It makes me feel healthy. So, in this question "physical activity would most help me to..." I would answer the button that was already selected, that it relieves stress and tension. (Change talk—need)*
>
> *P9: So, I would want to choose immediately all of them [four user's favorite outcome goals displayed], maybe least this "have fun"? Although it's [physical activity is] very important to me and it's fun for me.*
>
> *But still, I'd see that if you need to think of health, then all these three others. (Change talk—reason)*

Some participants chose the number by comparing themselves to their peers. Participant 9 had observed how the lack of activity has a different impact on her than on others:

> *Well...I don't know, I just find [physical activity] fun. It is important to me to stay in good shape so that I have energy to do things in life and so on. (change talk—need)Also, maybe I compare myself to other people. Like, how important [physical activity] is to me compared to my pals. They don't care if they can't go for a run every now and then or if they move, but I become a bag of nerves. It starts to feel like you get mad from everything (change talk—need) so, that kind of thoughts.* [P9]

Participant 8 saw himself as a less active person than his wife, which affected his selections and elicited some *sustain talk*:

> *When I think of my wife when she always says that she will feel bad if she can't go for a run, well, I am not at all like that. (sustain talk—reason not to change)* [P8]

Confidence Ruler Tool

The *Confidence ruler* tool asks about participants' confidence to be physically active and offers options to increase the confidence (Figure 7). It was tested by only two participants because of late implementation. Both reacted in a way corresponding to their physical activity status: the highly active participant was feeling confident and expressed *ability* to change:

> *[reading the question on the screen] How confident am I with physical activity...Well, let's say that I'm quite sure I could be regularly [active], let's put for instance 9. (Change talk—ability)* [P10]

An inactive participant expressed a *need* to increase activity:

> *I guess...I am not that active, so I feel like there's much to improve. (Change talk—need)* [P11]

While exploring the suggested BCTs in the *Confidence ruler*, participant 10 mentioned that a detailed plan might help him increase physical activity.

> *Ok, now this asks what would help me in this...Again, this suggests remembering...So, it's kind of asking me these, ok...I wonder if it has automatically chosen me that one or if I have accidentally touched it myself. Some accurate plan could maybe [help me to increase physical activity] [selects the option Having a detailed activity plan] (Change talk—ability).* [P10]

What's Next? Tool

The *What's next?* Tool assesses users' current levels of physical activity and intentions to be active to tailor further suggestions. The two participants testing the tool actively engaged, making the selections that were relevant for them. An inactive user expressed the *desire* to increase activity:

> *[reads the question "Regardless of how active you are now, how do you feel about becoming more physically active?"] Well I absolutely would want! [selects "I definitely want to be more active"]. (Change talk—desire)* [P11]

A physically active user did not see a need to increase his activity levels and, understandably, expressed sustain talk and ambivalence:

> *This here thinks I'd need to change the level of physical activity, I personally thought about it more like...that it's just one central aspect...I didn't see I would somehow need to change it. (Sustain talk—reason not to change)...Let's say that I have an ambivalent feeling, do I want to be more physically active. (Ambivalence)* [P10]

Time Machine Tool

> *The Time machine tool suggested imagination tasks of pleasurable physical activity in the past or in the future. It was tested by only two users, and no change talk was coded from their interviews.*

Mountain Climber Self-Regulation Tool

As opposed to the *needs*- and *reasons*-based change talk while using the motivational interviewing features, the change talk produced by the Mountain climber tool was *commitment* to the behavior change process and *taking steps toward change*. Participants used different Precious app tools in a random order, so this difference does not reflect the time spent using the app.

Participants saw the logging tool as a learning instrument and logging future activities as a commitment that might help them reach their goals. Participant 11 describes how she would learn about her activity levels while using the logging tool and could then increase her step goals:

> *Yes I believe I could even go and do [the planning], and I find it nice that I could add the goals for the next day, and then in the evening, add how I moved that day and then see whether it happened, and then add for the next day...then I would know if the goals were low but I moved much more, the steps just appear, just like that, then for the next day I could put a bit higher. (Change talk—taking steps toward change)* [P11]

Participant 12 realized that adding the activity in the Precious app makes it more likely that she will do the activity the next day:

> *P12:* [Selects an activity]
>
> *P12: If I already do it [the logging] now, then I have to go there tomorrow in the morning. That's actually quite good. (Change talk—commitment)*

Self-regulation features also received some criticism. Participant 9 expressed sustain change talk on self-regulation, as he thought he is not organized enough to do planning:

> *I: The meaning is that it could be used for planning, do you think it would work like that?*
>
> *P9: Ooh, not me at least, I'm so bad at planning anything in advance that I wouldn't...(Sustain talk—ability not to change) Maybe it could? Maybe it could be used as such. Certainly, if I were a bit more organized person. (Ambivalence)*

Discussion

Principal Findings

This study presented the development and feasibility testing of the Precious app, which aims to engage users in the behavior change process with relational techniques from motivational interviewing and gamified self-regulation. The feasibility study found that interaction with digitalized motivational interviewing features helped participants reflect their personally valuable goals, needs, desires, and reasons for physical activity. Autonomy supporting features were typically found to be important, although some participants criticized the number of available options and some expressed concerns about being profiled and possibly receiving the wrong types of suggestions. In this section, we will discuss the theoretical framework behind the Precious app and the results of the feasibility study on user engagement in behavior change.

Theory- and Evidence-Based Development of the Precious App

We developed the Precious app using a theoretical framework (Figure 1), which hypothesized that digitalized elements from motivational interviewing [32] and gamified elements [54] would help to satisfy the basic psychological needs of autonomy, competence, and relatedness, as suggested by the self-determination theory [41,52]. This novel method of combining reflective and spontaneous approaches with motivation and self-regulation has several strengths. This app addresses users with qualitatively different motivation for physical activity and offers support for both reflection of autonomously motivating goals and intrinsically motivating, spontaneous activities. Tailored suggestions provided to users are based on goals, activities, and motivational stages that users have indicated, offering different content to different individuals.

Digitalized motivational interviewing for physical activity has not been previously implemented for smartphones [37], although the need for motivational elements in health apps is recognized [40]. As acknowledged by participants, the Precious app differs from most available health apps, as it does not prescribe goals or behaviors. The choice of exercise as a behavioral strategy (instead of healthy diet, stress management, or sleep hygiene) is made only after a user has decided to aim for an outcome goal that can be achieved through physical activity (Figure 3). The relational features such as empathy, normalization, and affirmations may build a safe environment for change that would not be experienced with standard tracking features alone.

The Precious app's digitalized motivational interviewing features were implemented as seven question-based tools using seven relational techniques. These relational and motivational features were hypothesized to increase users' engagement in the behavior change process by increasing relatedness to the app and facilitating self-reflection and the use of self-regulatory BCTs [9], which could help individuals increase health-enhancing physical activity.

High intrinsic motivation is the best predictor of sustained physical activity [44], but not everyone finds physical activity enjoyable as such. Game-based elements can add intrinsically

motivating elements to the activity, such as exploring new areas with the *Conquer the city* feature or keeping daily steps up to create a panorama of high mountains with the *Mountain climber* tool.

Control theory–related self-regulatory BCTs were implemented as a *Mountain climber* tool that uses gamification principles to increase intrinsic motivation for BCT use. The self-regulatory BCTs included daily physical activity goal setting, reviewing behavioral goals, making action plans, self-monitoring, receiving feedback on behavior, perceiving the discrepancy between the current behavior and goal, and prompts to complete the daily step goal. These self-regulatory BCTs have been found to increase both physical activity [10] and motivation for physical activity [21], and the gamified visualizations may also appeal to users who would not find self-regulation techniques interesting as such.

Feasibility Testing

The feasibility analysis of participants' engagement with the Precious app addressed the following questions: (1) How did participants discuss autonomy support? and (2) what kind of change talk did the Precious app elicit in the users?

Research Question 1: How did participants discuss autonomy support?

In line with the self-determination theory, participants valued the autonomy supportive features, such as the tailoring of goals, behaviors, and activities, instead of an externally set behavioral target, as seen in previous Web-based interventions [92,96]. The amount of choice was generally perceived positively, although a couple of participants questioned the high number of options. Some also expressed concerns that their selections might limit their future options. To answer these concerns, we added tutorials emphasizing that all the app functionalities will stay available despite the personalized suggestions and that the suggestions are based on their selections only, which can be changed at any time.

As the Precious app was designed around a list of preselected answer options, it could not offer a complete freedom of choice to the users. A digital service needs to find a balance of the freedom given to the user and the amount of content that can be tailored to users' wishes. The more determined the answer options are, the more tailored suggestions can be offered to those specific choices. The more freedom the user has in indicating their preferences, the higher is the risk that the app content will not meet those wishes. It is also not known how accurately users want their ideas to be mirrored. Simply rephrasing users' preferences may not be optimally engaging: One study found an app more engaging when it included recommendations for people resembling the user, instead of recommendations based on personal history only [97]. One option would be an open platform that the users could use to create content for their own needs, creating their own goals, self-regulation techniques, and feedback systems. This type of tool would focus on offering information on possibilities and rationales of using specific techniques, as is done in the *What's next?* tool of the Precious app.

Research Question 2: What kind of change talk did the Precious app elicit in the users?

Participants engaged actively with the app during the think-aloud interviews, making selections and reflecting their choices in relation to their values and current life situation. They expressed a wide range of change talk: mainly *desire*, *reason*, and *need*, when using the motivational interviewing features, and *commitment* and *taking steps toward change*, when using the Mountain climber tool. Considering participants' varying levels of motivation and activity, it is promising that change talk was identified across the full sample. There were very few occasions of sustain talk and ambivalence. This may be a positive indicator about the ability of the Precious app to evoke positive cognitions about physical activity. The Precious app, however, has limited means for exploring possible negative elements related to increased physical activity or positive aspects of maintaining inactivity, which are often identified in face-to-face counseling [32]. One option for addressing sustain talk would be offering a problem-solving tool with strategies to overcome hurdles, as done by Friederichs et al [73,74].

Surprisingly, the *Time machine* tool for using mental rehearsal of past and future behavior did not elicit change talk during use. As the tool was tested by only two users, it is too early to conclude that this tool would not support other participants. On the basis of a fast pace with which participants advanced through all the Precious app features, more structured guidance (selecting options, typing answers, or listening to instructions) may work better on a smartphone platform than a list of open questions and imagination tasks.

Analyses of the think-aloud walk-throughs underlined how making selections while using the app is part of the discourse on change or a form of *implicit change talk*. The CLEAR coding system, used for recognizing change talk [94], suggests that when participants select numbers with tools such as the Importance and *Confidence rulers*, change talk should only be coded if the participant provides a verbal qualifier for the number. At the first stages of analysis, we aimed to extend this principle to all the interactions with the Precious app, analyzing only clear oral statements. Soon, we discovered that participants' selections were so embedded in the discourse that including interactions with the service was indispensable to get an accurate picture of the participants' thought processes.

The *implicit change talk* (ie, making selections that indicate exercise intentions) may differ from change talk that is elicited verbally in interactions with a coach or counselor. Miller and Rollnick [32] point out the difference of reactions when just thinking about questions silently, writing down the answers, or saying them to someone else. Although interacting with an app might not fully correspond to a face-to-face counseling, our results indicate that users can be encouraged to actively reflect options with a digital service. However, it should be noted that the think-aloud walkthrough procedures were undertaken in the presence of a researcher, which might have affected participants' reactions.

Offering a service with relational elements and tailored feedback may exceed the impact of simply writing down an answer, but it is possible that the relatedness experienced with the service

moderates this effect so that the more strongly the user feels an app is an active, responsive body in the interaction, the stronger the impact of the intervention is. The more autonomous and interactive digital services become, the more users may feel responsible for and committed to the actions negotiated with them. Getting users to select answers on their personal choices, values, and achievements may also increase their engagement with the app via activating users' representations of their identity and self-image. In gaming research, players have experienced digital games to be most intrinsically motivating when their gaming experiences have been congruent with their ideal selves [98].

Limitations

The think-aloud interviews only assessed a brief (30-60 min) use of the Precious app features. Participants did not have the chance to see how their physical activity accumulates over time or how the app's feedback messages depend on their goal progress. Thus, the interview only provided information on participants' initial reactions to the app's motivational and self-regulatory features. For this reason, despite studying perceived autonomy support, the interviews did not address the two other basic needs of the self-determination theory (ie, competence and relatedness), as we hypothesized these to increase through regular use of the app, with the rules engine providing encouragement and feedback on behavior. Similarly, the gamified elements can only be studied after extended use in the natural environment.

The features of the Precious app were still being developed through the feasibility interview phase, meaning that some features were available for the last interviewees only. *What's next?*, *Time machine*, and *Confidence ruler* were tested by only two participants because of late implementation. As is typical for pilot studies [27], the sample size is a potential limitation for generalizing the results to a wider population. Future studies could use larger samples of individuals of a certain age, activity level, or technology literacy to provide a broader representation of different types of users.

Future Directions

Interaction with technology needs further focus on the behavioral sciences. Despite the relational nature of motivational interviewing, studies offering digital motivational interviewing features rarely discuss how accurately it can be delivered with technology and how complexities related to digitalization of motivational interviewing might be addressed [37]. Current definitions of BCTs primarily relate to interactions between humans [8]. In future work, we need to define if digital services can be considered active participants in interactions. For instance, considering the technique *Review behavior goal(s) jointly with the person* [8], is the reviewing done *jointly* if it is suggested by a digital tool or a chatbot and is a digital service with relational elements able to provide *Social rewards*? [8]. These questions need addressing when artificial intelligence becomes increasingly widespread: at what point does an interactive, chatbot-type service start to be a companion in decision making?

The current implementation of the app is mostly text based. Several elements of gamification could be taken further, for instance, the Time machine tool offers a rich platform for visual elements that would enhance the user experience [80]. However, adding complex graphics does not automatically increase user engagement, and text-based elements have been found as effective in increasing physical activity as a digital avatar [99]. In addition, the level of service customization is currently tied to the user's time and patience to fill in self-evaluations. Evolving technologies offer increasing opportunities to automatically detect and tailor to user emotions [100], depression [101], stress [102], and even sarcasm [103]. Within the Precious app project, the use of social media posts for mood detection was examined but was not included in the current version [104]. These techniques offer promise, but more evidence is needed, whether gamified or chatbot-type interactive content engages users more in the behavior change process than text-based solutions.

Conclusions

This paper described the development and feasibility testing of the Precious app. We suggested that an app can support engagement in the behavior change process through two pathways: encouraging active reflection of users' motivations, capabilities, and opportunities for physical activity and providing gamified elements with challenges and fun. Both pathways can satisfy users' psychological needs of autonomy, competence, and relatedness, increase their autonomous motivation, and support their self-regulation.

The novelty of the Precious app is in providing relational support and addressing both reflective and spontaneous ways of motivating users. The Precious app aims to support an active cognitive engagement with the behavior change process using reflection tasks. The app builds relatedness with relational techniques from motivational interviewing and by supporting basic psychological needs described in the self-determination theory. Gamification elements include the self-regulation tool, which helps users to set goals, make plans, and monitor their progress with a mountain visualization. To collect and present physical activity data accurately, the app aggregates data from several sources: activity bracelets, smartphone sensors, and self-reports. The app consists of independent tools that can be switched on and off, enabling tailoring of personalized suggestions and testing specific intervention elements in a controlled way.

The feasibility interviews of the digitalized motivational interviewing features revealed that participants value personalization options, but the app also needs to clearly communicate how the information collected from users will be used for recommendations and tailoring and which choices users are able to change later. During the think-aloud interviews, motivational app features elicited change talk on needs, reasons, and desires to change, whereas self-regulatory features elicited commitment and taking steps toward change types of change talk. This active engagement in self-reflection can be perceived as a proxy for engagement in the first steps of the behavior change process. The fast pace with which users typically advanced through the app suggests that smartphone-based

interventions may benefit from interactive functions instead of open questions and imagination tasks.

Apps supporting behavior change need to engage users in the behavior change process. Feasibility tests with the Precious app suggest that this can be done by addressing users' psychological needs and by supporting active self-reflection. The impact of specific intervention elements on individuals' self-regulation and daily physical activity over time will be tested in a series of N-of-1 field studies [105].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
'How to get there?' tool for linking users' favorite activities and outcome goal.
[PNG File , 72 KB - mhealth_v8i1e12884_app1.png]

Multimedia Appendix 2
Journey view, map of gamified achievements.
[PNG File , 194 KB - mhealth_v8i1e12884_app2.png]

Multimedia Appendix 3
Table on participants' characteristics.
[DOCX File , 14 KB - mhealth_v8i1e12884_app3.docx]

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Abbreviations

API: application programming interface
BCT: behavior change technique
CLEAR: Client Language EAsy Rating
MET: metabolic equivalent
PRECIOUS: PREventive Care Infrastructure based On Ubiquitous Sensing
RQ: research question

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Original Paper

Digital HIV Care Navigation for Young People Living With HIV in San Francisco, California: Feasibility and Acceptability Study

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Abstract

Background: HIV continues to be a public health challenge adversely affecting youth and young adults, as they are the fastest-growing group of new HIV infections in the United States and the group with the poorest health outcomes among those living with HIV. HIV prevention science has turned to mobile health as a novel approach to reach and engage young people living with HIV (YPLWH) experiencing barriers to HIV care.

Objective: This study aimed to assess the feasibility and acceptability of a text message–based HIV care navigation intervention for YPLWH in San Francisco. Health eNavigation is a 6-month text message–based HIV care navigation where YPLWH are connected to their own HIV care navigator through text messaging to improve engagement in HIV primary care. Digital HIV care navigation included delivery of the following through SMS text messaging: (1) HIV care navigation, (2) health promotion and education, (3) motivational interviewing, and (4) social support.

Methods: We evaluated the feasibility and acceptability of a text message–based HIV care navigation intervention among YPLWH. We assessed feasibility using quantitative data for the overall sample (N=120) to describe participant text messaging activity during the intervention. Acceptability was assessed through semistructured, in-depth interviews with a subsample of 16 participants 12 months after enrollment. Interviews were audio-recorded, transcribed, and analyzed using grounded theory.

Results: Overall, the text message–based HIV care navigation intervention was feasible and acceptable. The majority of participants exhibited medium or high levels of engagement (50/120 [41.7%] and 26/120 [21.7%], respectively). Of the majority of participants who were newly diagnosed with HIV, 63% (24/38) had medium to high engagement. Similarly, among those who were not newly diagnosed, 63% (52/82) had medium to high engagement. The majority of participants found that the intervention added value to their lives and improved their engagement in HIV care, medication adherence, and viral suppression.

Conclusions: Text message–based HIV care navigation is a potentially powerful tool that may help bridge the gaps for linkage and retention and improve overall engagement in HIV care for many YPLWH. Our results indicate that participation in text message–based HIV care navigation is both feasible and acceptable across pervasive structural barriers that would otherwise hinder intervention engagement.

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KEYWORDS

HIV/AIDS; digital HIV care navigation; young people living with HIV; mHealth

Introduction

Background

HIV continues to be a public health challenge adversely affecting youth and young adults, as they are the fastest-growing group of new HIV infections in the United States. According to the Centers for Disease Control and Prevention (CDC), people aged 13 to 24 years accounted for 21% of all new HIV diagnoses in 2016, and approximately 81% of those cases were among young men who have sex with men (MSM) [1]. The CDC also states that 2351 transgender people were diagnosed with HIV in the United States from 2009 to 2014, almost all of whom were trans women [2]. In San Francisco, young people living with HIV (YPLWH) aged 13 to 24 years accounted for nearly 14% of the 223 new HIV cases in 2016, with young MSM and trans women accounting for majority of the cases [3]. Furthermore, young trans women are at equal or greater risk of HIV infection as young MSM, with one in five young trans women being infected with HIV before the age of 25 years [4-6].

YPLWH have poorer outcomes across the HIV care continuum. Specifically, only 63% of youth aged 13 to 24 years and 29% of young adults aged 25 to 34 years who are newly diagnosed with HIV achieve viral suppression 12 months after linkage to care in San Francisco [3]. Previous research has shown that structural barriers such as poverty, homelessness, mental health diagnoses, substance use, increased stigma, and the lack of access to personalized HIV care may explain poorer HIV care outcomes among YPLWH [7-12]. These findings emphasize the need for HIV care interventions among YPLWH, particularly among those with intersecting sexual and gender minority identities who disproportionately experience structural barriers to health [13,14]. It is imperative that interventions consider the structural inequities that YPLWH, particularly young MSM and trans women, face and utilize technology to disrupt the current standard of care that traditional HIV clinics provide.

HIV prevention science has turned to mobile health (mHealth) as a novel approach to reach and engage YPLWH experiencing barriers to HIV care. Various studies suggest that utilizing mHealth technologies such as text messaging is acceptable, feasible, and effective for improving outcomes along the HIV care continuum [15-21]. This study describes Health eNavigation (Health eNav), a text message–based HIV care navigation intervention, where YPLWH are connected to their own HIV care navigator through text messaging to improve engagement in HIV primary care. In this study, we assess the feasibility and acceptability of digital HIV care navigation as an mHealth intervention for YPLWH in San Francisco.

Overview of Health eNavigation

Health eNav is a 6-month text message–based HIV care navigation where YPLWH are connected to their own HIV care navigator through text messaging to improve engagement in HIV primary care. The intervention included delivery of the following: (1) HIV care navigation, (2) health promotion and education, (3) motivational interviewing, and (4) social support. *HIV care navigation* guides participants in knowing where, when, and how to access all health and related services and increases access to appropriate resources (eg, primary medical care, mental health care, housing, insurance, and benefits) [22]. *Health promotion and education* ensures optimal health literacy for all participants by providing information on the biology of HIV, disease management, communication with providers, risk reduction and healthy behavior, and antiretroviral therapy (ART) adherence. Health promotion content is tailored, personalized and specific to the needs of each participant, documented in their individual care plan, and updated on an ongoing basis. Health promotion and education are delivered to meet participants' education, developmental, language, gender, sexual, and cultural needs. *Motivational interviewing* is a technique and a style of counseling that can help resolve the ambivalence that prevents patients from realizing their personal goals. Motivational interviewing is directive and aims at eliciting self-motivational statements and behavioral change from the client in addition to creating client discrepancy to enhance motivation for positive change [23,24]. Motivational interviewing activates the capability for beneficial change that everyone possesses [25]. *Social support* is provided through establishing an open, nonjudgmental care relationship between participants and their HIV care navigator to address life events and topics most important to YPLWH that may not be solely focused on their HIV care. Active listening, joint problem-solving, and peer counseling were provided on an as-needed and ongoing basis during the 6-month intervention period.

Methods

Ethics Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Institutional Review Board at the University of California, San Francisco (IRB #16-19675).

Eligibility and Participant Recruitment

Eligible participants were youth and young adults, aged 18 to 34 years, diagnosed with HIV infection who identified as a man who has sex with men or a trans woman, and reported living in San Francisco. Eligible participants also met at least one of the following criteria: (1) newly diagnosed with HIV (people who have tested HIV positive for the first time within the last 12 months before enrollment), (2) not linked to HIV medical care (people who are aware of their HIV infection status but have never engaged in care or never had an HIV medical visit after being diagnosed with HIV), (3) out of care (people diagnosed with HIV more than 12 months before enrollment who had a gap in their HIV care that was >6 months within the last 24 months), and (4) not virally suppressed (people who have a viral load of ≤200 copies/mL at their last laboratory test). If participants did not have access to a mobile phone, they were provided with a mobile phone and 2 years of cellular service with unlimited text messaging.

Recruitment of participants occurred between January and December 2017. Nonprobability, convenience, and venue-based

sampling were used to recruit potential participants from San Francisco Department of Public Health clinics, AIDS service organizations, community-based organizations, and lesbian, gay, bisexual, transgender, and queer youth service providers. Recruiting materials (eg, flyers) and presentations to staff were used to advertise study recruitment. Staff referred potential participants to the study through phone and email communication and/or in-person meetings. Enrolled participants were also invited to refer peers from their social network. We screened 171 potential participants and 140 were eligible, of which 20 individuals were lost to follow-up following the screening, and 120 participants were enrolled into the study.

Study Procedures and Data Collection

Once screened, eligible participants were educated about the study and provided informed consent and completed administrative paperwork. Participants then met with their HIV care navigator in person and completed a short qualitative interview, a comprehensive care plan, and a computer-assisted self-interviewing (CASI) surveys. Participants and their HIV care navigator developed a comprehensive care plan together that identified at least three unmet needs and intentions for health-related behavior change. The comprehensive care plan identified specific responsibilities and follow-up actions for both the HIV care navigator and participants to work on jointly during the intervention period. This helped to tailor and personalize HIV care navigation to each participant. After 3 months, the HIV care navigator scheduled an in-person informal follow-up appointment to check-in and update comprehensive care plans and keep participants engaged and retained in the study activities.

During the 6-month intervention period, participants were able to communicate with their HIV care navigator via text messaging on an open schedule, and conversations spanned any topic that the participants wanted to discuss. The HIV care navigator sent weekly check-in messages to participants that included the following topics: general well-being, health education and health promotion, social support, and primary care appointment reminders. CASIs and electronic medical chart abstraction were administered in person every 6 months for 18 months. Data collection included a variety of socio-behavioral and HIV care continuum constructs, including information on substance use, mental health, engagement in HIV care, HIV stigma, and social media technology use. Each participant was eligible to receive US $590 in gift cards at baseline for completing all study-related activities over the duration of 18-month follow-up period.

Data Analysis

Demographics

At enrollment, participants were asked to provide their date of birth, and their age was calculated in real time. Participants were asked to self-identify their race and ethnicity. Gender identity was assessed with a 2-question measure, first asking participants to identify their sex assigned at birth and then their current gender identity. Housing status was measured by asking participants to identify which of the following best describes their current housing status: lives with family member, friend or partner who rents or owns a home, temporary or transitional housing, homeless or living in a shelter, or rent or own an apartment or house. Income was assessed by asking participants to self-report their income in the previous month from the following response categories: US $0 to US $250, US $251 to US $600, US $601 to US $1300, or US $1301 or more. Education was measured by self-report of the highest level of education participants received. Incarceration was measured dichotomously by asking if participants were incarcerated in the last 6 months (yes or no). Competing needs was measured dichotomously (yes or no) by asking participants the following two questions: “In the past 6 months, have you ever gone without HIV medications because you needed money for food, clothing, housing, or other basic needs?” and “In the past 6 months, have you ever gone without food, clothing, housing, or other basic needs because you needed the money for HIV medications?”. HIV diagnosis status was measured by asking participants if they were diagnosed with HIV in the last year (newly diagnosed) or if they were diagnosed with HIV more than 1 year ago (not newly diagnosed).

Intervention Feasibility

We assessed feasibility using quantitative data for the overall sample (N=120) to describe participant engagement with the intervention. We collected back-end data from a third-party text messaging platform. All text messages sent during the 6-month intervention period between an individual participant and their HIV care navigator were captured and maintained locally in a database and included the date, time, and body of each text message sent. We include quantitative feasibility data for the overall sample (N=120) and, in particular, for HIV diagnosis status to examine whether a text message–based HIV care navigation intervention would be feasible for either (or both) groups of people diagnosed with HIV within the last year and those who were not.

Intervention Acceptability

We assessed acceptability by conducting semistructured, in-depth interviews with a subsample of 16 participants 12 months after enrollment. Participants were purposively sampled to obtain diversity in levels of engagement, race or ethnicity, and gender identity. Participants were provided with US $75 in gift cards for their time. Interviews lasted 30 to 45 min and took place during a time that was most convenient for the participant. The interview guide was iterated to maximize coverage of participant experiences through theoretical sampling to reach theoretical saturation and to address the following research question, “What factors impacted acceptability of digital HIV care navigation for young people living with HIV?” [26]. The interview guide assessed the following constructs: overall acceptability, length, and individual and health-related impacts. Interviews were audio-recorded and transcribed verbatim. Transcriptions were randomly checked for quality and accuracy against original recordings. Qualitative interview data were coded and analyzed using grounded theory [26]. Two members of the research team independently coded qualitative data, line by line, and together organized codes into categories to identify specific factors that shaped the acceptability of digital HIV care navigation for YPLWH.

Results

Study Sample Demographic Characteristics

Table 1 shows that the majority of the participants identified as male (103/120, 85.8%), and about 14.2% (17/120) of the participants identified as trans women. The mean age of participants was 27 years, and the majority of participants completed high school/General Equivalency Diploma or some college and/or higher level of education (107/120, 89.2%). Overall, our sample was diverse, with nearly three-quarters of participants who identified as Hispanic or Latinx, black, and other or multiple race/ethnic identities (38/120, 31.7%; 22/120, 18.3%; and 28/120, 23.3%, respectively). More than two-thirds of the participants were diagnosed with HIV more than 1 year ago (82/120, 68.3%), and approximately one-third of the participants were diagnosed with HIV in the last year (38/120, 31.7%). Half of the participants reported being homelessness or living in temporary or transitional housing (60/120, 50.0%).

Feasibility

On the basis of the number of text messages sent between each participant and their digital HIV care navigator, we defined a low level of engagement as less than 50 or approximately 8 text messages a month during the 6-month intervention period, medium as 50 to 149 or approximately 9 to 24 text messages a month, and high as >150 or 25 or more text messages a month. The number of text messages per participant ranged from 1 to 467 over the intervention period. Overall, the majority of participants exhibited medium or high levels of engagement (50/120, 41.7% and 26/120, 21.7%, respectively). Of the majority of participants who were newly diagnosed with HIV, 63% (24/38) had medium to high engagement. Similarly, among those who were not newly diagnosed, 63% (52/82) had medium to high engagement.

Acceptability

Overall, 88% (14/16) of participants found that digital HIV care navigation was acceptable. In particular, participants expressed that digital HIV care navigation was motivating and working with their personal digital HIV care navigator was novel and integral to their lives. A participant (white, 25 years old) said:

> *It was nice to have that check-up. Even my case managers don't do that a lot of the time. It was just helpful, it's nice to have another resource available. It felt nice to receive the support through text message, it proved that community sense, it's like having a friend there that cares for your care, it felt good.*

The intervention bridged important gaps to support YPLWH in making and sustaining the changes necessary to engage in HIV care. A participant (white, 28 years old) said:

> *Now I take my meds every day and I see my doctor, and if I miss my doctor appointment, I immediately go in to reschedule it. When they say "Health eNav," it really helped you navigate your health and I really liked that. It has definitely been a positive experience. It really helped that [the digital HIV care navigator] was actually there, I was able to text and call [them], [they] were able to go with me to my appointments, and Health eNav got me to a point in my life where my health is my number one priority. I don't know where I would be without this.*

Most people (13/16, 81%) found the substantive content provided through digital HIV care navigation as the main reason for its acceptability. They felt encouraged by the interactions with their digital HIV care navigator. A participant (Hispanic/Latinx, 34 years old) said:

> *One of the times I went to the doctor and we [participant & digital navigator] were corresponding the entire time. I was in the waiting room and actually in the doctor's office texting the digital navigator and discussing the questions that I was going to ask the doctor and some of the information that I wanted to make sure to tell her. I needed the digital navigator to help me remember the questions that were important for me to ask which was good because I had always been told to write things down before. That was the first time I actually went to my doctor's appointment prepared.*

Intervention Length

According to the participants, most (11/16, 69%) felt that 6 months of digital HIV care navigation was a good amount of time for them to acquire new knowledge and information and engage with their HIV care. A participant (white, 24 years old) said:

> *I think six months is a good amount of time to actually get to know someone enough and to actually figure out their full medical care and figure out where they're at. You also get to see how the person's life has changed over that time and six months doesn't sound like a lot of time for someone who has all their stuff together but for someone like me who's still in the process of figuring out this and that, a lot of things can change in that time.*

Individual- and Health-Related Impacts

All (16/16, 100%) participants expressed that digital HIV care navigation impacted them in a positive way and improved their engagement in HIV care. A participant (white, 27 years old) said:

> *It helped me to remember that things are okay, the stigma is still there, but as long as you live healthy and do what you need to do, you're fine! I also gained information that I would have never though through digital HIV care navigation, like new meds that they're coming out with, the new tests that they're trying to do, and the things that they're trying to do to help us live longer and healthier lives. I would have never of done that sort of research by myself. This access was beneficial.*

Table 1. Sample characteristics, overall and by engagement level over the 6-month study period, Health eNavigation, 2017-2018 (N=120).

Construct	Overall[a]	Low: <50 texts[b]	Medium: 50-149 texts[b]	High: 150 texts or more[b]
Total, n (%)	120 (100.0)	44 (36.7)	50 (41.7)	26 (21.7)
Demographics				
Age, mean (SD)	27.75 (4.07)	27.05 (4.13)	28.38 (4.31)	27.73 (3.37)
Race or ethnicity, n (%)				
Black or African American	22 (18.3)	7 (31.8)	8 (36.4)	7 (31.8)
Hispanic or Latinx	38 (31.7)	18 (47.4)	12 (31.6)	8 (21.1)
Other[c] or multiple	28 (23.3)	9 (32.1)	11 (39.3)	8 (28.6)
White	32 (26.7)	10 (31.3)	19 (59.4)	3 (9.4)
Gender identity, n (%)				
Cisgender man	103 (85.8)	39 (37.9)	42 (40.8)	22 (21.4)
Trans woman	17 (14.2)	5 (29.4)	8 (47.1)	4 (23.5)
Socioeconomic factors				
Housing status, n (%)				
Lives with a family member, friend, or partner who rents or owns a home	21 (17.5)	6 (28.6)	7 (33.3)	8 (38.1)
Temporary or transitional housing[d]	43 (35.8)	16 (37.2)	22 (51.2)	5 (11.6)
Homeless or shelter	17 (14.2)	9 (52.9)	4 (23.5)	4 (23.5)
Rents or owns an apartment or house	39 (32.5)	13 (33.3)	17 (43.6)	9 (23.1)
Income in the previous month (US $), n (%)				
601-1300	30 (25.0)	11 (36.7)	12 (40.0)	7 (23.3)
251-600	30 (25.0)	13 (43.3)	12 (40.0)	5 (16.7)
0-250	30 (25.0)	11 (36.7)	13 (43.3)	6 (20.0)
≥1301	29 (24.2)	9 (31.0)	12 (41.4)	8 (27.6)
Education, n (%)				
High school or General Equivalency Diploma	39 (32.5)	17 (43.6)	15 (38.5)	7 (18.0)
Less than high school	13 (10.8)	5 (38.5)	6 (46.2)	2 (15.4)
Some college or more	68 (56.7)	22 (32.4)	29 (42.7)	17 (25.0)
Incarceration in the last 6 months, n (%)				
Yes	23 (19.2)	13 (56.5)	7 (30.4)	3 (13.0)
No	97 (80.8)	31 (32.0)	43 (44.3)	23 (23.7)
Competing needs, n (%)				
Went without HIV medications because needed money for basic needs (eg, food, housing, and clothing)	38 (31.7)	18 (47.4)	13 (34.2)	7 (18.4)
Went without basic needs (eg, food, housing, and clothing) to have money for HIV medications	32 (26.7)	18 (56.3)	10 (31.3)	4 (12.5)
HIV diagnosis status, n (%)				
Diagnosed in the last year	38 (31.7)	14 (36.8)	11 (29.0)	13 (34.2)
Diagnosed more than 1 year ago	82 (68.3)	30 (36.6)	39 (47.6)	13 (15.9)

[a]Percentages calculated out of the total number of participants in Health eNav (n=120), unless otherwise specified.

[b]Percentages row calculated out of the total number of participants in each demographic, structural barrier, or HIV diagnosis category.

[c]"Other" race or ethnicity included participants who identified as American Indian or Alaska Native (n=6) or Asian (n=7).

[d]"Temporary or transitional housing" included participants who lived in single-room occupancy hotels, motels, boarding houses, halfway houses, drug treatment centers, independent living units, domestic violence shelters, battered persons' shelters, or "safe houses."

Potential Challenges and Barriers

Three participants who felt that the length of the digital HIV care navigation was too short discussed how experiencing complex barriers to HIV care, which were primarily structural and temporal with regard to their HIV diagnosis status, detracted from their ability to focus on their participation in the intervention; as a result, they would have preferred to have a longer intervention period. A participant (black, 24 years old) said:

> *If it [the participant's enrollment in the intervention] were at a different time of me knowing my status, since it was so soon after I was diagnosed, I kind of didn't want to do or talk about anything related to HIV.*

For one participant, their active substance use prevented them from being able to prioritize their HIV care engagement and participation in the intervention. This participant (native American, 33 years old) said:

> *One thing that was impacting it [their participation in the intervention] was my [substance] use. 'Cause I would disappear on weeks and months at a time and no one would know where I was, then one day I would just show up. One time I was all the way in Bakersfield, but I made it back to San Francisco...I would disappear, it's just my little devil on my shoulder pulling me one way, the angel never wins.*

Discussion

Principal Findings

The Health eNav intervention for young MSM and trans women living with HIV was both feasible and acceptable. Participants unanimously agreed that participating in the intervention impacted them positively and improved their engagement in HIV care. Notably, this paper assessed the potential influence of structural factors and HIV diagnosis (within the last year or longer) as barriers to the intervention. These are vital components to examine, particularly among YPLWH and those with sexual and gender minority identities.

Although several mHealth interventions in the literature have demonstrated that text messages improve HIV outcomes, YPLWH are still experiencing poor outcomes when it comes to linkage and retention to HIV care as well as achieving viral suppression [19]. Much of the new research examining mHealth interventions for engagement in HIV care has solely focused on mHealth to support ART adherence; although these contributions are important, research is overlooking how to implement mHealth interventions within disadvantaged communities, such as young MSM or young trans women living with HIV [17], who disproportionately experience homelessness, incarceration, poverty, and other structural barriers that may hinder participation in HIV interventions [27,28].

Findings from Health eNav provide preliminary evidence of study feasibility across structural barriers previously shown to hinder intervention engagement [27-29]. Overall, a majority of participants (>50%) were classified as having medium or high levels in texting across gender identity, income, and education level. There were some barriers that persisted among this study sample. Notably, participants who were homeless or living in a shelter, those who were recently incarcerated, and those who went without basic needs to afford HIV medications were more likely to be low text engagers. These findings add evidence that basic needs and HIV care are in conflict for marginalized populations [30-32]. Still, almost half of those who were homeless, incarcerated, or experiencing competing needs managed to have medium and high levels of engagement in Health eNav. It could be that mHealth interventions such as Health eNav, which utilize a digital HIV care navigation system that provides personalized instrumental, social, and emotional support, have the capacity to reach across sociodemographic groups and effectively improve HIV care engagement; further research is needed to more definitively confirm this. Interestingly, most of the young MSM and trans women in Health eNav who found the intervention length to be too short explained that structural barriers (eg, homelessness and poverty) contributed to lower participation. Had the intervention stretched over a longer period, these participants felt that they could have taken the time needed to address these barriers and focus on the intervention.

Regardless of HIV diagnosis status (within the last year or earlier), participants in the study tended to be moderate or high engagers in the intervention. However, the acceptability responses of one participant noted that discussing HIV-related topics so soon after diagnosis was difficult. This same participant (black, 24 years old) went on to suggest the following:

> *It would have been better if I had the option for 3-6-9-12 months.*

Future digital HIV care navigation interventions should consider whether adaptable intervention exposure periods or stepped study designs would better meet the needs of YPLWH.

Limitations and Future Research

These findings should be interpreted with some limitations in mind. First, the study sample here represents young MSM and trans women living with HIV and who have a connection—albeit, possibly, a poor connection—with HIV care or community organizations. In addition, qualitative acceptability data were gathered for a small number of participants. Despite the subsequently limited generalizability of results, the Health eNav intervention enrolled a diverse segment of the target population (young MSM and trans women living with HIV) that represents a multitude of sociodemographic experiences. The study findings may also be subject to measurement bias, in that the categorizations of texting engagement may lose nuance in characterizing the true underlying pattern of intervention engagement. Future research on how to meaningfully characterize and analyze text messaging patterns and mHealth intervention–related big data is needed.

Conclusions

Regardless of the study limitations, digital HIV care navigation is a potentially powerful tool that may help bridge the gaps for linkage and retention and improve overall engagement in HIV care for many young MSM and young trans women living with

HIV. By utilizing digital technology, Health eNav capitalizes on the familiarity and accessibility of mobile devices and social media platforms to engage with hard-to-reach YPLWH who confront unique barriers to HIV care. Our results indicate that participation in digital HIV care navigation is both feasible and acceptable across pervasive structural barriers that would otherwise hinder intervention engagement.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral therapy
CASI: computer-assisted self-interviewing
CDC: Centers for Disease Control and Prevention
Health eNav: Health eNavigation
mHealth: mobile health
MSM: men who have sex with men
YPLWH: young people living with HIV

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Original Paper

A Mobile App for Longterm Monitoring of Narcolepsy Symptoms: Design, Development, and Evaluation

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Abstract

Background: Narcolepsy is a chronic sleep disorder with a broad variety of symptoms. Although narcolepsy is primarily characterized by excessive daytime sleepiness and cataplexy (loss of muscle control triggered by emotions), patients may suffer from hypnagogic hallucinations, sleep paralysis, and fragmented night sleep. However, the spectrum of narcolepsy also includes symptoms not related to sleep, such as cognitive or psychiatric problems. Symptoms vary greatly among patients and day-to-day variance can be considerable. Available narcolepsy questionnaires do not cover the whole symptom spectrum and may not capture symptom variability. Therefore, there is a clinical need for tools to monitor narcolepsy symptoms over time to evaluate their burden and the effect of treatment.

Objective: This study aimed to describe the design, development, implementation, and evaluation of the Narcolepsy Monitor, a companion app for long-term symptom monitoring in narcolepsy patients.

Methods: After several iterations during which content, interaction design, data management, and security were critically evaluated, a complete version of the app was built. The Narcolepsy Monitor allows patients to report a broad spectrum of experienced symptoms and rate their severity based on the level of burden that each symptom imposes. The app emphasizes the reporting of changes in relative severity of the symptoms. A total of 7 patients with narcolepsy were recruited and asked to use the app for 30 days. Evaluation was done by using in-depth interviews and user experience questionnaire.

Results: We designed and developed a final version of the Narcolepsy Monitor after which user evaluation took place. Patients used the app on an average of 45.3 (SD 19.2) days. The app was opened on 35% of those days. Daytime sleepiness was the most dynamic symptom, with a mean number of changes of 5.5 (SD 3.7) per month, in contrast to feelings of anxiety or panic, which was only moved 0.3 (SD 0.7) times per month. Mean symptom scores were highest for daytime sleepiness (1.8 [SD 1.0]), followed by lack of energy (1.6 [SD 1.4]) and often awake at night (1.5 [SD 1.0]). The personal in-depth interviews revealed 3 major themes: (1) reasons to use, (2) usability, and (3) features. Overall, patients appreciated the concept of ranking symptoms on subjective burden and found the app easy to use.

Conclusions: The Narcolepsy Monitor appears to be a helpful tool to gain more insight into the individual burden of narcolepsy symptoms over time and may serve as a patient-reported outcome measure for this debilitating disorder.

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KEYWORDS

outcome measure; hypersomnia; patient-related outcome measure; PROM; mHealth; symptom monitoring

Introduction

Background

Narcolepsy is a chronic neurological sleep disorder caused by a deficiency of the hypothalamic neurotransmitter, hypocretin [1,2]. Patients with narcolepsy experience a broad range of symptoms, the most common being excessive daytime sleepiness, manifested not only as attacks of falling asleep at inappropriate times but also as difficulties with concentration and memory [3-5]. Patients often experience attacks of muscle weakness triggered by emotions, called cataplexy [6]. These symptoms, together with hypnagogic hallucinations, sleep paralysis, and disturbed nocturnal sleep, are referred to as the classic pentad of narcolepsy [7]. However, the spectrum of narcolepsy symptoms is more extensive, including several symptoms that are not directly related to sleep. Increased weight and the presence of psychiatric symptoms (such as affective disorders, eating disorders, attention-deficit hyperactivity disorder, and schizophrenia) have been described in several studies [8-13]. Social functioning seems to be impaired in children with narcolepsy, and quality of life is negatively affected [14,15]. The severity of the symptoms varies greatly among patients and there also is significant day-to-day variance within patients. Differences in experienced severity are influenced by medication effect and medication tolerance as well as circumstances of daily living and individual variation in coping strategies. Both the broad symptom spectrum and symptom variability stress the need for individually tailored care in narcolepsy.

Narcolepsy affects approximately 1 in 2000 people but is often not correctly diagnosed. Delayed recognition is a well-described clinical problem and patients often receive a diagnosis several years after the onset of symptoms [16]. The core symptoms of excessive daytime sleepiness and cataplexy are essential in the diagnostic process, but quality of life of narcolepsy patients is not determined by these 2 symptoms alone. Maski et al [17] reported that patients stated their most troublesome symptoms were general fatigue and subjective cognitive complaints. Moreover, there are doubts about the meaning of the core symptoms in relation to the subjective severity of narcolepsy. For example, only a moderate correlation was found between the Epworth Sleepiness Scale and the results of the Multiple Sleep Latency Test, the current objective standard to assess sleepiness [18].

In a recent review by Kallweit et al [19], 7 narcolepsy questionnaires were evaluated. None of these questionnaires seem to fulfill the requirements to function as a tool to monitor the extensive spectrum of narcolepsy symptoms over a longer period. Digital solutions in health care (mobile health) may provide solutions in this area. With the development of an app designed to run on a mobile device, new possibilities emerge to record long-term subjective data. Digital data collection is perceived as less invasive and time consuming, which can have a positive effect on long-term adherence. Moreover, instead of the frequency of symptoms, which is used as a key marker of severity in all questionnaires, probing the *impact* of symptoms might help to understand the narcolepsy patient better and lead to more personalized treatment choices.

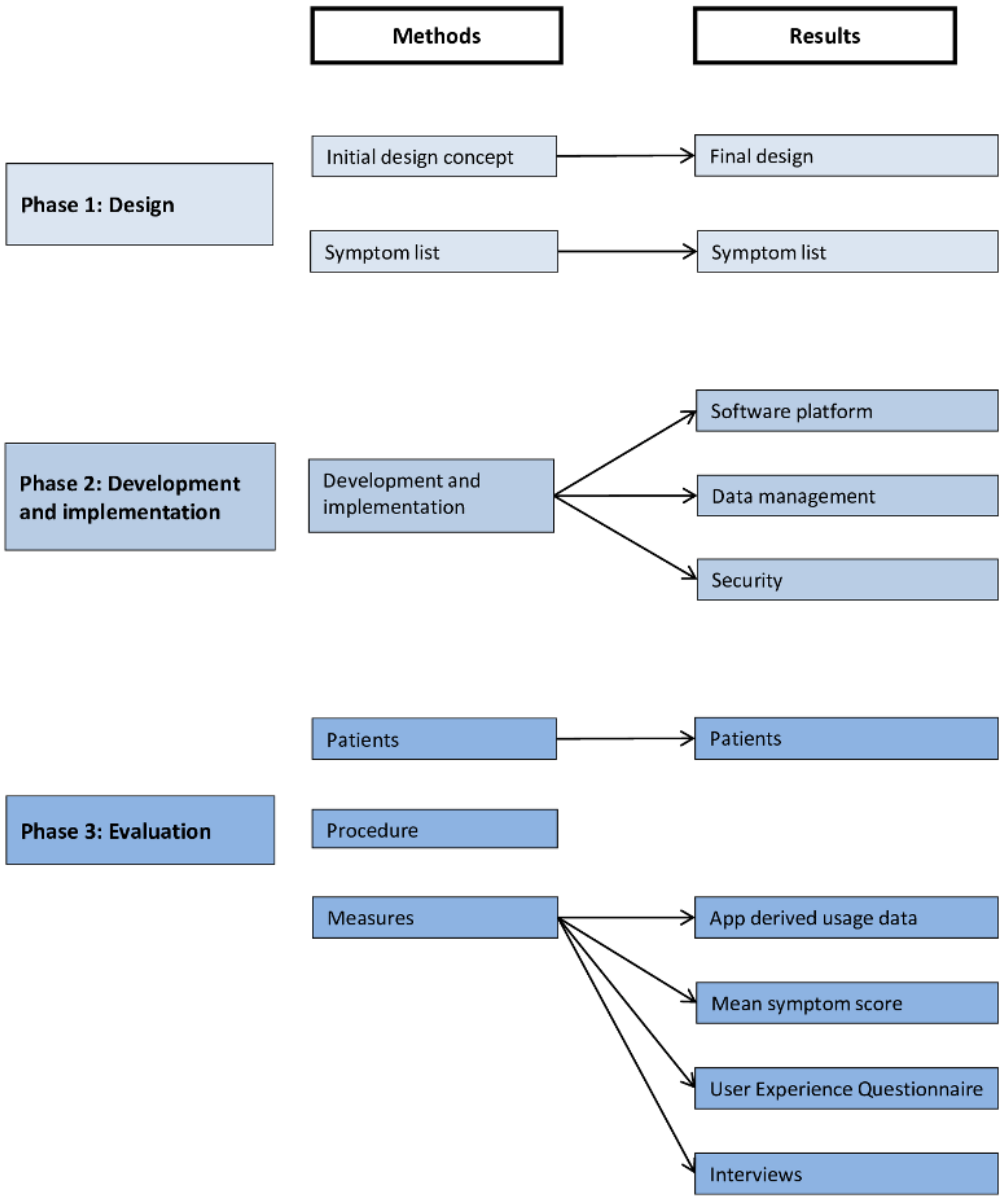
Objectives

Here, we describe the design, development, and evaluation of the Narcolepsy Monitor, a companion app for long-term symptom monitoring in narcolepsy patients. The purpose of the app is to allow patients to frequently self-report on the subjective burden of a variety of narcolepsy symptoms over time. During development, we aimed to make the app personalized, minimally invasive, and able to provide data meaningful for both patients and caregivers. We used a theory-driven and user-driven iterative approach, where user feedback supported content composition and ensured usability. We then evaluated the Narcolepsy Monitor with regard to usability and user experience feedback.

Methods

The development process of the Narcolepsy Monitor comprised 3 phases: (1) design, (2) development and implementation, and (3) evaluation (Figure 1).

Figure 1. The different phases of the development of the Narcolepsy Monitor.

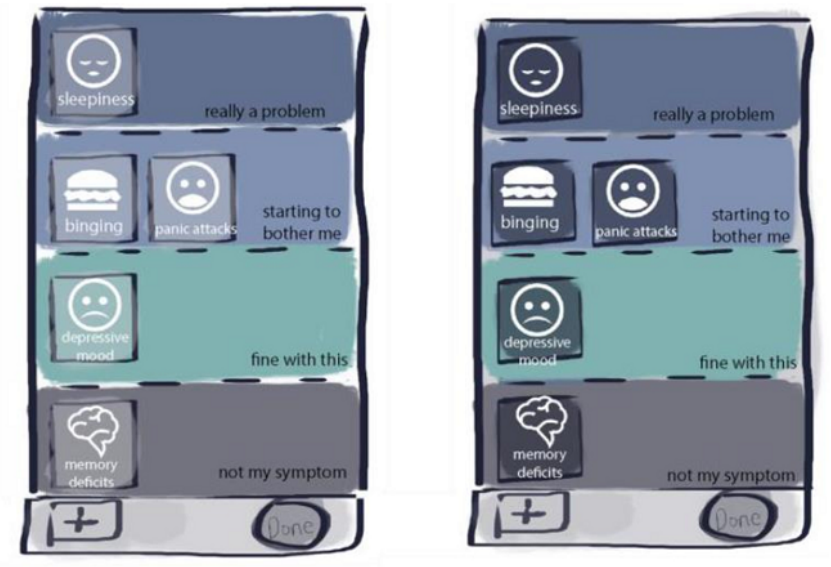


Phase 1: Design

Initial Design Concept

Under the supervision of the authors, a group of 5 students involved in the User System Interaction Program of the Eindhoven University of Technology (TU/e), started in 2016 with an exploration on the design statement, "Design a mobile app for narcolepsy patients that runs on their personal device, to self-monitor the subjective severity of narcolepsy symptoms." A total of 4 high-level requirements were formulated that would be informative for the design: (1) efficient and easy to use, (2) personalized, (3) highly visual, and (4) long-term commitment. After several iterations, the group reached consensus on the concept of a *ranking screen*, where all relevant symptoms would be visible in 1 overview (Figure 2). This concept was further refined taking all the requirements into account.

Figure 2. Concept for a symptom ranking screen.



Symptom List

The initial domains to be covered by the Narcolepsy Monitor were defined based on a literature review and expert opinion. When defining the symptom list, there was a specific intention to cover the large variation in complaints expressed by narcolepsy patients. Several preliminary versions of the symptom list were developed and reviewed by 3 physicians and 3 patients.

Phase 2: Development and Implementation

During the development of the Narcolepsy Monitor, special attention was given to data management and security aspects. The first version of the requirements with regard to data management, safety, and privacy was reviewed by the local medical ethics committee, which led to suggestions for further improvement. Consultation with a hospital information technology specialist led to a further augmentation of the security structure.

Phase 3: Evaluation

Patients

Patients were recruited from January 2017 till August 2017, from the outpatient clinics of Sleep Medicine Center Kempenhaeghe (Heeze, NL) and Sleep-Wake Center SEIN (Heemstede, NL). Patients were aged 18 years or above and included if they fulfilled the criteria of narcolepsy type 1 or 2 according to the standards of the International Classification of Sleep Disorders 3: Diagnostic and Coding Manual [20]. Patients were excluded if they were not able to read or speak Dutch or had severe cognitive impairments, comorbid medical diagnosis or psychiatric illness.

Study Procedure

Patients with a diagnosis of narcolepsy were informed by their treating physician about the study, both orally and in writing. After the patient agreed to participate in the study, written consent forms were signed. A manual on how to download and install the Narcolepsy Monitor was sent to the home address of the participants with the request to start using the app. Patients were asked to follow the instructions of the app for 30 days. Thereafter, the patients were asked to fill in the user experience questionnaire (UEQ; see User Experience Questionnaire section) [21]. In addition, patients were also invited for a personal in-depth interview through a secure consultation on the Web conducted by the first author. The medical ethics committee of the Maxima Medical Center in Veldhoven, NL (METC number: N16.084) approved this study.

Measures

Mean Symptom Score

Symptom severity was expressed as the mean score per symptom. Categories were given a numeric value (*not relevant*=0, *not really a problem*=1, *a little problem*=2, and *really a problem*=3). Although patients did not rate their symptoms on a daily basis, we assumed that the rating remained the same until a patient moved the icon to another category. As a result, for each day, a value was used in the calculations. The sum of these values was divided by the number of days the app was used in total to obtain an average score for the respective symptom (Table 1).

Table 1. Mean symptom scores and dynamics of the symptoms.

Symptoms in the app	Patients that chose this symptom, n	Severity score (N=7), mean (SD)	Number of changes, mean (SD)
Daytime sleepiness	7	1.8 (1.0)	5.6 (3.7)
Lack of energy	7	1.6 (1.4)	3.4 (2.4)
Often awake at night	7	1.5 (1.0)	3.6 (4.4)
Difficulty achieving things	6	1.1 (1.0)	2.2 (2.0)
Difficulty concentrating	7	1.1 (0.9)	3.1 (1.5)
Increase in weight	5	0.9 (1.1)	2.0 (2.4)
Difficulty with memory	4	0.8 (1.0)	1.0 (1.3)
Binge eating	5	0.7 (0.8)	1.9 (1.6)
Problems at work	4	0.6 (0.7)	1.6 (2.1)
Agitation	5	0.6 (0.8)	1.4 (1.3)
Cataplexy	5	0.6 (0.9)	2.3 (1.8)
Lifelike dreams	2	0.5 (0.9)	0.5 (1.2)
Problems with relationships	4	0.5 (0.8)	1.1 (2.0)
Sleep paralysis	2	0.4 (0.8)	0.4 (1.0)
Problems with libido	5	0.4 (0.7)	0.8 (0.9)
Sadness	2	0.3 (0.5)	0.7 (1.7)
Feelings of anxiety or panic	2	0.1 (0.2)	0.3 (0.7)
Problems at school	0	0.0 (0.0)	0.0 (0.0)

App-Derived Usage Data

The following variables were automatically retrieved from the app for analysis: (1) period during which the app was used, (2) number of days during which the app was opened, (3) number of different symptoms ranked, (4) total number of changes in all symptoms, and (5) number of changes per symptom (Table 2).

Table 2. App-derived usage data.

Usage data variables	Minimum	Maximum	Mean (SD)
Period for which app was used (days)	18	73	45.3 (19.2)
Percentage of days the app was opened	13.2	57.6	35 (16.3)
Number of symptoms ranked	9	16	11.7 (3.1)
Total number of changes made (per month)	14.2	48.3	31.6 (13.3)

User Experience Questionnaire

The UEQ is an easy-to-apply, reliable, and valid measure to assess user experience of interactive products [21]. The UEQ comprises both classical usability aspects (efficiency, perspicuity, and dependability) and user experience aspects (originality and stimulation). The scales of the UEQ can be grouped into pragmatic quality (perspicuity, efficiency, and dependability) and hedonic quality (stimulation and novelty). Pragmatic quality describes task-related quality aspects; hedonic quality describes the nontask-related quality aspects. Scale values above +1 indicate a positive impression of the users concerning this scale and values below −1 indicate a negative impression.

Interviews

Interviews varied in length, with a maximum of 66 min, and started with the open question: “How did you experience the use of the narcolepsy app?” This was followed by probing questions, further investigating the subjective experiences with the Narcolepsy Monitor. At the end, the interviewer checked the topic list to see if all subjects had been covered. Inclusion of patients stopped after reaching data saturation. All audio recordings were transcribed, and qualitative thematic analysis was applied. Recorded interviews were transcribed verbatim by a company specialized in transcribing for scientific purposes. The first author started reading the interviews several times to become acquainted with them. Afterward, the transcribed text was copied into Microsoft Excel, where each part of the text fragment was labeled with initial open codes after which several coding iterations were performed. Codes with similar content were grouped into themes. To support this process and enhance understanding of the results, 3 authors (LQ, SO, and SP) made mind maps, searching for themes and connection among themes.

Data Analysis

Data analysis was performed with SPSS, version 25, by using descriptive statistics. Data are shown as mean (SD) unless otherwise specified.

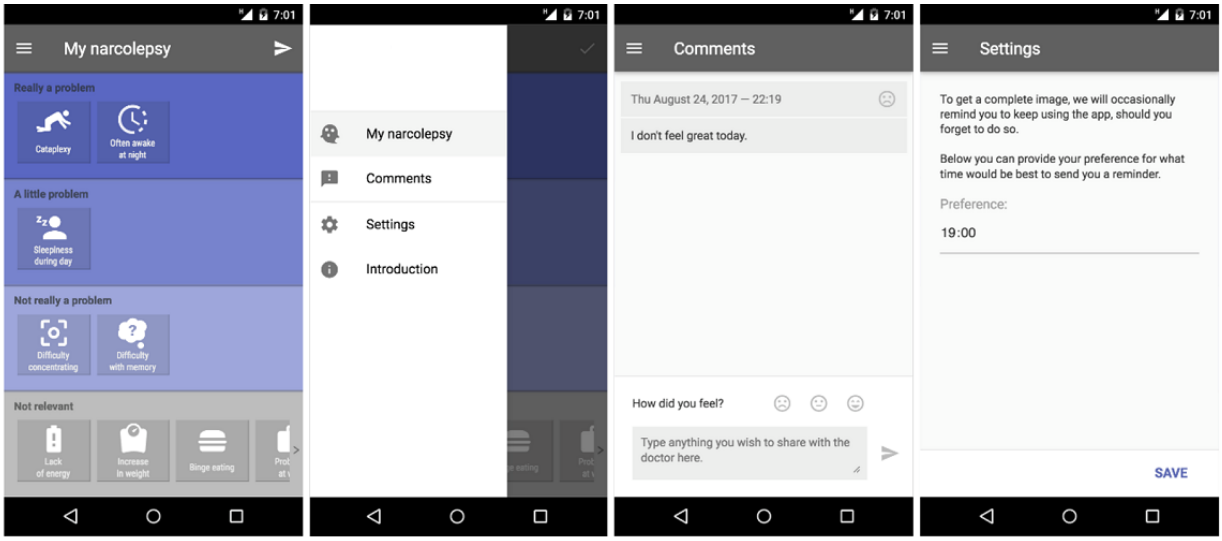
Results

Phase 1: Design

Final Design

We decided upon the core interaction concept in which a symptom ranking screen with all relevant symptoms is visible in 1 overview. Symptoms are represented as icons that can be dragged and dropped to zones of varying severity and changed if their severity changes. Importantly, severity is rated not by the *frequency* of a symptom but by the *burden* it poses to the individual. Patients can choose between *not really a problem*, *a little problem*, and *really a problem*. The advantage of this approach is that subjective symptom severity is indicated on a relative scale with other symptoms present in the same overview. This scaling also *normalizes* symptoms toward each other, removing differences in, for example, a pure frequency of occurrence. Figure 3 shows the version of the Narcolepsy Monitor that was evaluated here.

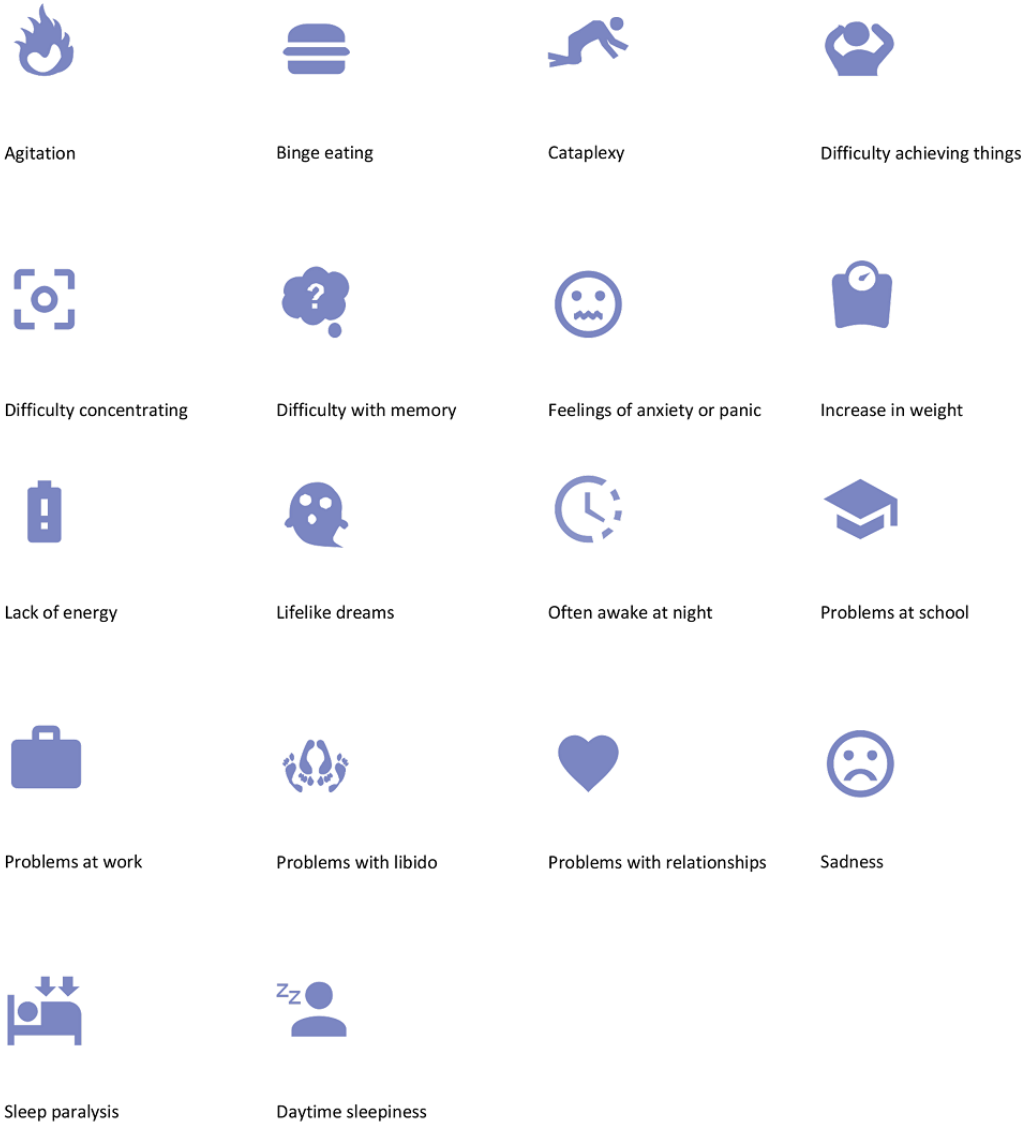
Figure 3. Final design of the Narcolepsy Monitor. The first panel shows the ranking environment in which patients list the narcolepsy symptom according to the subjectively experienced severity. The second panel shows the menu in which one can choose to navigate to the ranking screen, the comment section, personal settings and the introduction. In the third panel the possibility to add comments is shown. The last panel shows the possibility to adjust the time for the reminder to use the app.



Symptom List

The final set of 18 symptoms that can be ranked is shown in Figure 4, together with their iconic representation in the app. These symptoms include the classical pentad of narcolepsy, augmented with other symptoms that are often experienced. These are supplemented by symptoms more indirectly related to the condition, including psychiatric and cognitive aspects. Overall, 3 patients were asked to give feedback on the icons used to represent the narcolepsy symptoms. Furthermore, patients were asked if any symptoms were missing and if there were inappropriate symptoms on the list.

Figure 4. List of symptoms included in the Narcolepsy Monitor.

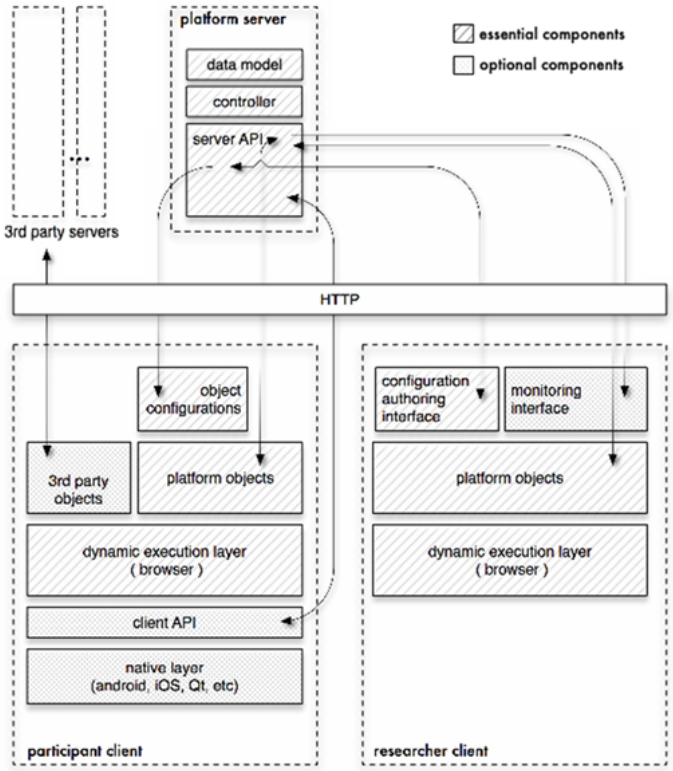


Phase 2: Development and Implementation

Software Platform

The Tempest platform, designed by N Batalas and P Markopoulos, was used as the basis on which the narcolepsy app was implemented. The Tempest platform is programmable, modular, and extendable, and through extensive use has been validated as fitting the needs of practitioners of a diverse range of fields [22-24]. It comprises a Web app (see Figure 5; this is referred to as *researcher client*) that allows the researcher to compose the interfaces and to arrange the manner in which they are to be displayed in terms of sequence and conditional logic, akin to simple imperative programming. A client app to study participants (referred to as *participant client* in Figure 5) renders HTML and JavaScript-based user interfaces. The client app can be distributed as either a pure Web app or an Android app, which then allows for more native mobile phone functionality such as setting alarms. Finally, it also comprises a Web server or database component that stores and communicates configuration and data between participant and researcher clients.

Figure 5. Tempest architecture.



Data Management

The server side of the Tempest framework is responsible for receiving the data of the participants and storing them in a central database. This server was managed by the TU/e.

Security

With regard to safety, a number of security measures were taken. This includes the security of the server, for example, by encrypting all communication channels and by implementing an update protocol for the operating system and the installed software package. As the most important security measure, personal information, such as the patients' names, contact information, diagnoses, and details regarding treatment, were not stored anywhere on the server or on the patient's device. All data that were logged through the system could only be linked to patients through a unique and randomly generated personal identification number and only the executive researcher (LQ) had access to a list that links this identification number to a patient.

Phase 3: Evaluation

Patients

Overall, 10 patients were included for this pilot study; 3 patients dropped out. As a result, a total of 7 patients (females) participated in the pilot study, with a mean age of 44 (SD 11.5) years.

App-Derived Usage Data

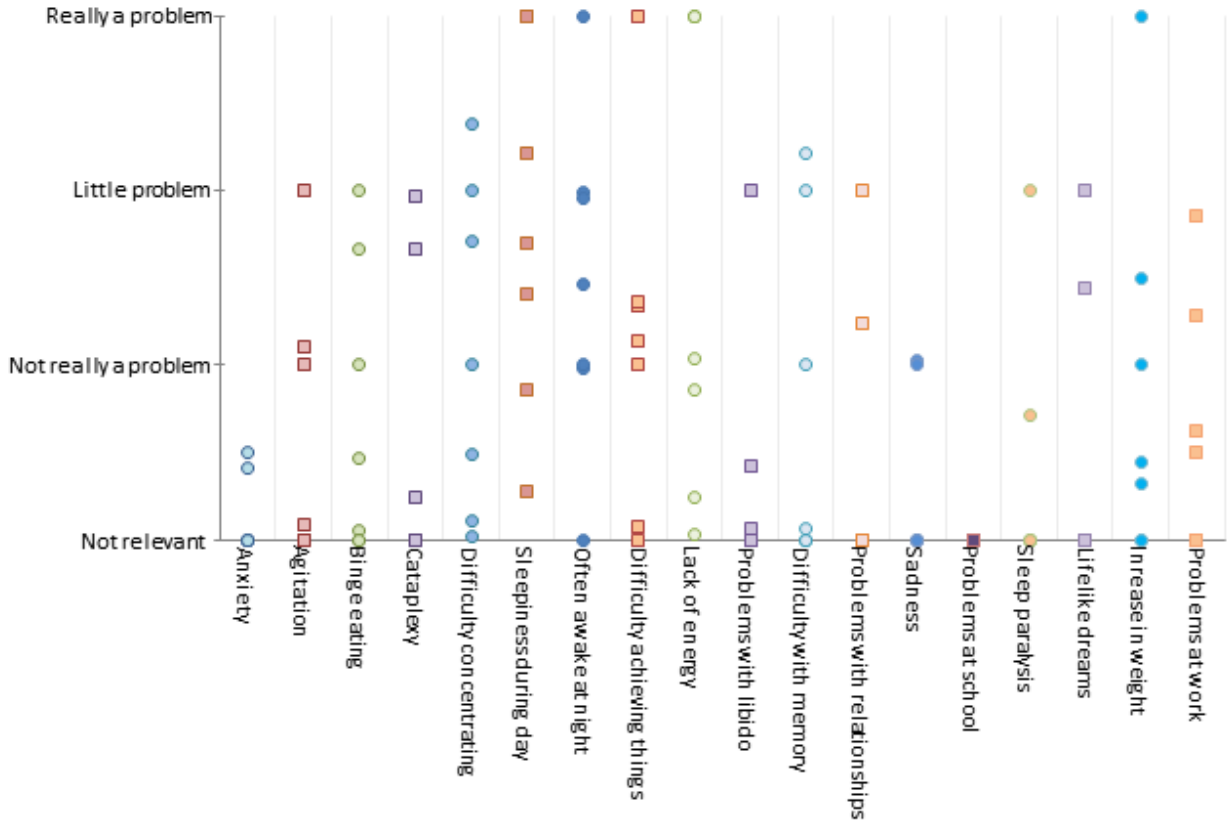
Table 2 shows data regarding the use of the Narcolepsy Monitor. Although patients were asked to use the app for 30 days, the range of period of use varied from 18 to 73 days. On an average, the app was opened on 35% of the days during the study period. Patients, on average, rated 11.7 symptoms out of the 18 options. Per month, patients on average made a total of 31.6 changes in the ranking of symptoms (a change was defined as a single change in 1 symptom), including the first use ranking of the symptoms.

Mean Symptom Scores

In Table 1, the mean score per symptom for all 7 patients combined is listed. The table also gives insight into the dynamics of the symptoms. Daytime sleepiness, lack of energy, and often awake at night were the 3 highest scored symptoms. As nobody attended school, the participants did not rank school problems. The symptoms rated as least bothering were problems with libido, sadness, and feelings of anxiety and panic. Cataplexy only had the 11th position in the ranking of the level of subjective severity, with a mean score of 0.5 (SD 0.9), despite being regarded as one of the most defining symptoms of narcolepsy. Lifelike dreams was 12th, with a mean score of 0.5 (SD 0.9), and sleep paralysis, with a mean score of 0.4 (SD 0.7), took the 14th position. Note that the latter 3 (cataplexy, lifelike dreams, and sleep paralysis) are part of the classic pentad of narcolepsy but nevertheless scored relatively low. Figure 6 illustrates the variance in mean score over patients per symptom.

The symptoms daytime sleepiness, difficulty concentrating, often awake at night, and lack of energy were used by all patients. The symptom daytime sleepiness varied the most (5.6 [SD 3.7]). This was followed by often awake at night (3.6 [SD 4.6]) and lack of energy (3.4 [SD 2.4]). The levels of severity of lifelike dreams, sleep paralysis, and feelings of anxiety or panic were changed the least (0.5 [SD 1.2], 0.4 [SD 1.0], and 0.3 [SD 0.7], respectively).

Figure 6. Mean score per patient per symptom. Patients provided input on all 18 symptoms. Bullet points may capture the input of more than 1 patient, especially on the "not relevant" and "really a problem" level.



User Experience Questionnaire

Perspicuity was rated very high (mean 2.1 [SD 0.3]), whereas novelty of the approach received the lowest rating (mean 0.3 [SD 0.8]). Pragmatic quality had a mean score of 1.4, followed by attractiveness with a score of 1.0 and hedonic quality with a score of 0.5.

Interviews

A total of 7 interviews took place after which inclusion stopped because of saturation of information. The average interview time was 36 min, varying between 15 min and 66 min. During the interviews, we identified 3 major themes: (1) reasons to use, (2) usability, and (3) features. Table 3 shows illustrative examples of patients' quotes matching these themes.

Table 3. Examples of quotes matching the themes.

Theme and subtheme	Quote
Reasons to use	
Personal value for patients	"Especially when one does not know what influences his or her complaints, the app could be a useful way to speed that process up." (patient 7415)
Type of setting	"I would be absolutely fine with using the app if my doctor would ask me to." (patient 7376)
Usability	
Ease of use	"It is simple to use, but not to simple. People should be able to understand it, just shifting around with the icons and then push the send button." (patient 7058)
Tutorial step	"The first time I started using the app, it was unclear to me that I had to make changes every day. So, after putting all my symptoms in the app, I started using the comments to give my input." (patient 7368)
Levels of subjective severity	"With three categories, there is little room to vary in complaints. Because regardless whether I have a good day or a bad day, my main complaint is still 'really a problem.'" (patient 7415)
Icons	"For me, the icons were clear and appropriate" (patient 5075)
Procedure for sending information	"The thing that is a bit odd to me, is that is seems like that when you do not make any changes in the ranking, you cannot send the information. If I feel the same, I should not have to make any changes and be able to send it anyway." (patient 7058)
Features	
Symptoms	"I suffer from headaches, which is more a consequence of a bad night or insufficient naps. It is not mentioned in the app, probably because it is to specific and not narcolepsy related, but for me it would be a valuable addition." (patient 6695)
Comments	"I did feel the urgency to explain fluctuations in my symptoms. Not only for my own learning, but also because I think it will add value for the doctor." (patient 7415)
Visualization	"The fact that I am not able to look back at the information that I have put in the app is not a very motivating factor." (patient 7058)
Personalizing	"...a sort of diary that follows your story and starts asking personalized questions." (patient 7415)

Theme 1: Reasons to Use

The first theme was *reasons to use* that incorporates 2 subthemes: type of setting and personal value for patients.

- Type of setting: Patients reported that the request of the treating physician would be enough to start and keep using the app. Participation in scientific research would be a good motivator as well. Patients rated the app as suitable for long-term use.
- Personal value for patients: Patients referred to the app as a helpful means to get a speedier insight about how narcolepsy affects an individual and, as a result, finding ways to deal with the condition. The level of personal value would be influenced by the disease phase and the day-to-day variance patients experienced. A possible motivator for patients would be to have insight about the course of their own symptoms in terms of a visualization of their recorded data.

Theme 2: Usability

The second important theme we identified was the usability of the app. This theme comprised 5 subthemes:

- Ease of use: Patients rated the Narcolepsy Monitor as being clear and user friendly and appreciated the layout of the app. All found that the use of the app was not time consuming. None of the patients experienced using the app as an emotional burden, although few participants saw some risk in being confronted with the disease on a frequent basis.
- Tutorial step: We chose an interactive way to support the user with pop-ups while performing simple tasks for the first time. However, the instructions were not sufficient for some patients, which led to some erroneous use of the app. Instead of ranking the symptoms, 1 patient used the comment section on a daily basis to elaborate on the symptoms.
- Levels of subjective severity: Patients had several remarks on the levels of severity. First, some patients had trouble with the terminology. The category not relevant and not really a problem were sometimes deemed too similar. A few patients proposed a category not existing to be used instead of not relevant. Second, the number of severity levels was perceived as too limited, insufficiently allowing to record nuances in complaints. Patients preferred more levels of severity to give additional insight into the dynamics of their symptoms.
- Icons: Patients were positive about the icons of the app, which they rated as pleasant and clear. In the bottom bar of the ranking screen, a horizontal menu is shown that features all symptoms marked as not relevant. As there are 18 symptoms, not all of them are visible at first glance and an action of the user is required to make all icons visible.

- Procedure for sending information: The procedure for sending input was not clear to all patients. Especially, it was not clear enough whether the entered information had been saved or not. Patients referred to the possibility of automatic behavior (one of the symptoms of narcolepsy), which is a state of reduced arousal during which semipurposeful actions can be performed without someone realizing it. Therefore, patients would be more prone to forget their actions and would depend more on active feedback. For this reason, a send button was built in the app. As patients were under the assumption that pushing the send button was necessary, they felt compelled to always make changes to save the data. It was not clear enough that the send button activates automatically when something in the ranking was changed.

Theme 3: Features

In terms of the content of the Narcolepsy Monitor, 4 aspects were deemed important:

- Symptoms: First, patients appreciated the extended list of symptoms. Some patients suggested to add the option of an additional symptom, a category other symptom namely: …, which would be very personal. Some patients were not sure if they had to register symptoms that they assumed as not narcolepsy related, such as headaches.
- Comments: Patients experienced the possibility of adding comments as positive. Adding extra information makes it easier to track certain patterns in symptoms with regard to potential influencing factors.
- Visualization: The fact that a personal visualization of entered data was lacking was mentioned as a limitation by all 7 patients. Not receiving any feedback might conflict with the goal to use the app over a longer period. Patients wanted to have insights about when the app was opened and obtain an overview of symptoms scores, medication use, and comments over a longer period.
- Personalizing: In response to possible improvements, patients mentioned the idea of making the Narcolepsy Monitor more personal with the possibility of receiving more personalized feedback. For example, screening the comments for specific topics and probing the user with questions regarding this topic. Another suggestion was to include a signaling function, in case the severity of narcolepsy symptoms worsened.

Discussion

Clinical Findings

Narcolepsy is a debilitating chronic sleep disorder with a broad symptom spectrum of highly variable severity. To aid in the follow-up and treatment of narcolepsy patients, the Narcolepsy Monitor was developed as a new way to monitor the severity of narcolepsy symptoms over a longer period. The results show that the Narcolepsy Monitor not only has potential as a follow-up tool for individual patients but may also be used in a research setting to gain more insight into the overall clinical picture of narcolepsy and the influence of individual symptoms on everyday life.

The ranking of symptoms based on the level of subjective severity confirms the notion of a broad symptom spectrum in narcolepsy exceeding the classical pentad of symptoms. Patients rated daytime sleepiness as the most interfering symptom; however, cataplexy, lifelike dreams (hypnagogic hallucinations), and sleep paralysis only reached the 11th, 12th, and 14th position, respectively. A recent review by Raggi et al shows that narcolepsy has an extensive impact on the health-related quality of life (HRQoL) [25]. Excessive daytime sleepiness is argued to be the symptom most affecting the HRQoL, even more than the other symptoms of the narcolepsy pentad. Excessive daytime sleepiness, however, could be viewed as a multidimensional complaint. Rather than falling asleep at inappropriate times during the day, difficulty achieving things (fourth position), lack of energy (second position), and difficulty concentrating (fifth position) can also be viewed as part of this excessive daytime sleepiness. Maski et al [17] hypothesized that subjective cognitive impairments, such as mental fog and difficulty thinking, remembering, concentrating, or paying attention, are among the most significant symptoms affecting daily life.

Narcolepsy questionnaires often primarily address the core symptoms of the disease (excessive daytime sleepiness and cataplexy) [26-29]. Recently, the Narcolepsy Severity Scale (NSS) was developed to evaluate the severity and consequences of the symptoms [30]. This 15-item questionnaire not only includes sleepiness and cataplexy but also includes hallucinations, sleep paralysis, and disturbed night time sleep. It seems to be a reliable and valid clinical tool for the quantification of narcolepsy symptoms. However, as we argue that a broader spectrum of symptoms might cause disease burden, the NSS might not be comprehensive enough to truly understand the patient with narcolepsy. Thus, despite the existence of a number of screening, diagnostic, and treatment monitoring tools, there seems to be a paucity of measures that reflect the subjective severity and the broad spectrum of narcolepsy symptoms.

Besides the experienced disease burden, the Narcolepsy Monitor also gives insight into the stability of symptoms (Table 2). Very little is known about the development of symptoms over a longer period, and patient reports might be influenced by a recall bias [31]. Day-to-day variance can not only be caused by multiple factors such as environmental changes, medication, and stress but possibly also by functional changes in the brain over time [32]. In our study, daytime sleepiness, lack of energy, and difficulty concentrating seem to be the most variable complaints, stressing the importance of a long-term monitoring tool.

Usability

Analysis of the in-depth interviews confirmed that the patients appreciate the concept of ranking their symptoms. They experienced the use of the Narcolepsy Monitor as minimally invasive. On the other hand, the app should be improved in several aspects. Patients argued that the 3 levels did not provide enough opportunity to reflect the nuances in the change of symptoms. The 3 levels of subjective severity might also enhance the risk of a central tendency bias in which patients avoid the endpoints of a response scale and prefer responses

closer to the midpoint. To keep patients motivated to use the tool over a longer period, a personal visualization of recorded data is required.

Potential of the Narcolepsy Monitor

With the described improvements, the Narcolepsy Monitor can be used in clinical settings to monitor subjective symptom severity of narcolepsy patients and give input to clinical treatment decisions. In trails on pharmacological or nonpharmacological interventions, the app could be used as an outcome parameter. Another potential of the Narcolepsy Monitor is the further exploration as a patient-reported outcome measure (PROM). There is a growing need to gather insight into the patient perspective of a disease. Current questionnaires do not fulfill the requirements of such *patient perspective–centered* measurement. Another approach could be to make the Narcolepsy Monitor available worldwide for narcolepsy patients. This would enable the collection of large datasets to further explore, refine, and understand the narcolepsy symptom landscape.

The app was designed and built for narcolepsy patients. Narcolepsy can be seen as a *model* disease as it has a broad variety of symptoms with large differences among patients and variations over time. The concept of ranking symptoms to measure personal burden seems well suited for various kinds of disorders. Hence, by translating the app to other diseases, the principle could be more generally regarded as a *symptom monitoring tool*.

This study has some limitations. Patients were asked by their physician to participate. It is possible that the included patients are more positive toward innovations compared with those who did not choose to participate. An issue concerning the layout might have caused a bias in the results. As not all 18 symptoms were visible at first sight, patients had to actively *swipe* to see them all. This may have positively biased the ranking of the symptoms that were initially visible.

Conclusions

This paper outlines the development and evaluation process of the Narcolepsy Monitor. Results from the pilot study suggest that this app can be used to obtain insight into the subjective severity and dynamics of narcolepsy symptoms and has interesting potential for long-term data collection and as a PROM.

Acknowledgments

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Conflicts of Interest

This study was partly supported by an unrestricted research grant from Union Chimique Belge (UCB) Pharma. UCB was not involved in any way in the design and execution of the work. GJL is a member of the international advisory board on narcolepsy UCB, Jazz Pharmaceuticals and UCB Pharma and does consultancy for Jazz Pharmaceuticals. The authors have indicated no financial conflicts of interest.

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Abbreviations

HRQoL: health-related quality of life
NSS: Narcolepsy Severity Scale
PROM: patient-reported outcome measure
TU/e: Technical University Eindhoven
UCB: Union Chimique Belge
UEQ: User Experience Questionnaire

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Original Paper

Considerations for Improved Mobile Health Evaluation: Retrospective Qualitative Investigation

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Abstract

Background: Mobile phone use and, consequently, mobile health (mHealth) interventions have seen an exponential increase in the last decade. There is an excess of 318,000 health-related apps available free of cost for consumers to download. However, many of these interventions are not evaluated and are lacking appropriate regulations. Randomized controlled trials are often considered the gold standard study design in determining the effectiveness of interventions, but recent literature has identified limitations in the methodology when used to evaluate mHealth.

Objective: The objective of this study was to investigate the system developers' experiences of evaluating mHealth interventions in the context of a developing country.

Methods: We employed a qualitative exploratory approach, conducting semistructured interviews with multidisciplinary members of an mHealth project consortium. A conventional content analysis approach was used to allow codes and themes to be identified directly from the data.

Results: The findings from this study identified the system developers' perceptions of mHealth evaluation, providing an insight into the requirements of an effective mHealth evaluation. This study identified social and technical factors which should be taken into account when evaluating an mHealth intervention.

Conclusions: Contextual issues represented one of the most recurrent challenges of mHealth evaluation in the context of a developing country, highlighting the importance of a mixed method evaluation. There is a myriad of social, technical, and regulatory variables, which may impact the effectiveness of an mHealth intervention. Failure to account for these variables in an evaluation may limit the ability of the intervention to achieve long-term implementation and scale.

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KEYWORDS

telemedicine; mHealth; research design; developing countries

Introduction

Background

Mobile health (mHealth) is the use of mobile technologies to improve health care and public health [1]. The driving forces for mHealth are the clinician's need for providing care at any time, in any place, and the rapid advancement of new and emerging mobile technologies [2]. The developing world has the fastest growing mobile phone subscriber market in the world [3], producing millions of potential points of care [4]. As a result, the use of mHealth interventions has increased [5]. However, there is little existing quality control, regulatory oversight, or understanding of the clinical utility or clinical impact of many of these apps. Research is needed to assess when, where, and for whom mHealth is beneficial [6]. Rigorous evaluation of these platforms is essential for estimating their impact, along with the potential risks and benefits for end users, consumers, and the health care system as a whole [7].

The Evaluation of Mobile Health

The current evidence for the efficacy of mHealth interventions is sparse [3,6,8-11], which may be because of a lack of high-quality, rigorous evaluations [12], with many mHealth projects explored only at the pilot phase [13]. In addition, there is limited information on the resources that should be invested in evaluation, and mHealth developers are citing the need for greater support and guidance when evaluating their projects [12]. Currently, there is little consensus on the methodological standards for evaluating mHealth interventions [4,14,15], but calls for more rigor in evaluation have led to an increase in the number of mHealth randomized controlled trials (RCTs) conducted in developed and developing countries [8,16,17].

RCTs are typically considered to be the *gold standard* study design for determining the effectiveness of clinical interventions [18] and are commonly used for mHealth evaluations [19]. However, there are increasing suggestions that RCTs may be impractical for mHealth evaluation [20,21]. mHealth interventions are inherently challenging to evaluate because of the fast moving and evolving technologies resulting in many platforms becoming obsolete even over the course of a single clinical trial; the high level of financial, human, and time resources needed to conduct rigorous evaluations; the complexity of many mHealth interventions, with regard to outcome measures of the intervention itself; the involvement of a multidisciplinary team; and the complex sociotechnical aspects on which the success of mHealth depends [10,19,22]. These factors make it difficult to adhere stringently to the standards and practicality of conducting RCTs for mHealth and using them to inform practice and policy decisions. The lack of a unified or standardized approach to mHealth evaluation is a major weakness and threatens the credibility of mHealth [9] as a premature scale-up of an mHealth initiative could harm the entire field [10,23].

Objective of the Study

The aim of this qualitative study was to explore mHealth evaluation, identifying the factors contributing to an effective evaluation. We used the context of an ongoing mHealth project to explore the perspective of system developers directly involved in designing and evaluating an mHealth solution.

Methods

Overview

A qualitative approach was employed to facilitate deeper exploration of the factors that were instrumental in deciding how to evaluate the mHealth solution [24]. This study gathered data from a multidisciplinary sample of system developers (combining technical, clinical, managerial, and operational personnel) working on a single mHealth-based trial, incorporating those responsible for building the mHealth system, including software developers, health care professionals, and researchers [25]. This study was conducted as part of the first author's master's degree research.

Study Setting—Randomized Controlled Trial for a Mobile Health Intervention in a Developing Country (The Supporting Low-Cost Intervention for Disease Control Project)

The Supporting Low-cost Intervention For disEase control (Supporting LIFE) project was a European Commission–funded project aimed at addressing child mortality rates in the under-5 population in Malawi, Africa [26]. As malaria and infantile diarrhea are the 2 main causes of mortality in this area, an mHealth project was designed to provide low-cost, effective, and targeted intervention in remote and resource-poor settings to overcome inadequate health care infrastructures. The project included a multinational group of experts, institutions, and nongovernmental organizations in the United Kingdom, Ireland, Sweden, United States, Malawi, and Switzerland. The project supported health surveillance assistants (Malawian term for community health workers) at the point of patient care to aid the community health service delivery to children under 5 years. It utilized mobile technology, existing application programming interfaces, and a clinical decision support system to support the limited health care infrastructure. The mHealth intervention was an Android-based smartphone app developed by the project consortium for use by health surveillance assistants in rural communities. The services provided by the health surveillance assistants followed the integrated Community Case Management of the Ministry of Health, adopted from the World Health Organization and the United Nations Children's Fund guidelines. The app replicated the validated paper-based integrated Community Case Management guidelines from the Ministry of Health, with decision aid and logic checks to be used by health surveillance assistants in routine practice in Malawi. The mobile app was evaluated in a pragmatic, stepped-wedge cluster RCT between October 2016 and February 2017. The trial recruited 102 health surveillance assistants and 6995 patients.

Participants and Recruitment

Recruitment for this investigation took place within the context of the Supporting LIFE project being conducted in Malawi [26]. Participants were selected using positional and reputational methods, techniques that have been developed to identify key participants for research [27]. Positional methods involved identifying persons who occupy key roles in a system [27]. In

the case of an RCT, these individuals include the principal investigator and the project coordinator. Reputational methods involve identifying individuals believed to have the power to *move and shake* the system [27]. In the case of an RCT, these individuals include the project manager and the trial manager. Participants comprised a multidisciplinary group of system developers, encompassing all aspects of clinical trial and mHealth experience across a spectrum of clinical, technical, managerial, and operational disciplines. This cohort of participants was identified as being able to provide rich insights into the diverse aspects of an mHealth evaluation. A total of 15 system developers were identified from the project consortium. Table 1 outlines the project role and background of the participants in each category.

For inclusion in this study, participants were required to be currently or previously involved in an mHealth evaluation, aged 18 years or above, and fluent in spoken English. Participants were contacted by email in December 2017 to invite them to partake in the study. No individuals declined participation.

Table 1. System developers' project roles and backgrounds.

System developers' category	Participant identifier	Project role	Participant background
Clinical (n=4)	C1, C2, C3, and C4	• Advisory committee • Ethical application • Clinical partner • Data monitoring committee	• Primary care and family medicine • Infectious diseases
Technical (n=5)	T1, T2, T3, T4, and T5	• Surveillance • Testing • Engineering lead • Team leader • App update	• Information systems • Decision support systems • System architecture design • Disease surveillance • Software development
Managerial (n=2)	M1 and M2	• Lead investigator • Principal investigator	• Health information systems • Global health and electronic health • Computer science
Operational (n=4)	O1, O2, O3, and O4	• Scientific activity monitoring • Project support • Investigator • Trial manager	• Electronic health • Global health • Mental health • Noncommunicable diseases

Data Collection and Analysis

An interview guide was developed for the purpose of this study, and semistructured interviews were used to collect data from the participants in Malawi in January 2017. All potential participants were contacted before the interview to request their permission to participate in the study. All participants were provided with information sheets outlining the purpose of the research and consent forms, which they signed and returned by hand or by email before the interview. A conventional content analysis approach was used to analyze the transcripts [28,29]. All interviews and data analysis were conducted by 1 researcher (first author). A total of 9 private face-to-face interviews were conducted on the ground during a week-long field trip to Malawi in January 2017. Furthermore, 1 face-to-face and 5 Skype interviews were conducted with participants who were not available in Malawi. All interviews were audiorecorded and transcripts were returned to the participants on request.

The 15 interviews were transcribed verbatim. Before beginning coding, the interview audio was played alongside the transcript to allow for refamiliarization with the data and identification of any transcription errors. Line-by-line open coding was carried out by hand for 3 manuscripts. Accumulated codes were entered into NVivo 11 software (QSR) to allow for the organization and management of codes. Several codes were renamed or merged at this stage. Hand coding continued with each transcript and subsequent entry of codes into NVivo 11. Following the completion of open coding, 167 codes were identified. A visual mapping exercise was conducted to identify similar and duplicate codes and to group codes into categories. After the merging of similar codes and the removal of redundant codes, 4 major themes were abstracted from the categories [24]. A sample of the coding process is presented in Multimedia Appendix 1.

Ethical Considerations

Ethical approval for this study was granted from the Social Research Ethics Committee at University College Cork. All data were anonymized at source, and participants are represented by their role in the study. The reporting of this study adheres to the consolidated criteria for reporting qualitative research guidelines [30] (see Multimedia Appendix 2).

Results

Summary of Results

In-depth interviews were conducted with 4 clinical, 4 operational, 5 technical, and 2 managerial team members of the Supporting LIFE project. Participants collectively contributed 425 min of interview time. Participants were predominantly males (n=11), with a mean age of 42 years (range 27-66 years). Most participants held a PhD (n=9), and over half of the participants (n=8) had prior experience with at least one mHealth evaluation. A total of 4 major themes emerged during the

discussions of mHealth evaluation: (1) developing world context, (2) end users' experience, (3) challenges to mHealth evaluation, and (4) mHealth regulation. Table 2 presents an illustration of the number of references to each theme by each project role category.

For clinical participants, the predominant focus was on mHealth challenges, followed by the regulatory issues in mHealth. Operational participants focused on mHealth challenges, the developing country context, and end users, with very little focus on mHealth regulation. Both technical and managerial participants were predominantly concerned with both end users and mHealth challenges.

Table 2. Number of theme references by project role category.

System developers' category	Context	End users	mHealth challenges	Regulation
Clinical	27	25	63	34
Operational	15	13	16	1
Technical	13	56	45	18
Managerial	7	23	27	18

The Developing World Context

The developing world context incorporated 3 subthemes: (1) infrastructural limitations, (2) perceptions of mobile phones, and (3) end users' technological ability. All participants (n=15) discussed the impact of context on the evaluation of mHealth and the particular challenges of a developing country context:

> *Contexts are vastly different from one country, and sometimes even one area in a country to another.* [C1]

Infrastructural Limitations

A predominant focus was on the infrastructural limitations mentioned by most participants (n=11). One example was the issue of inadequate health record data; in Malawi, there are missing and incomplete birth and death registries as well as severely inadequate health records. Participants spoke of these issues being "out of our control" (O3) and having to "go with practicalities" (O2). Decisions were "heavily dependent on the infrastructure" (C3) to facilitate them:

> *Telecommunications was a big factor for us, the lack of network connectivity.* [T5]

Perceptions of Mobile Phones

A number of participants (n=5) discussed concerns regarding potential negative impacts of end users in varying contexts, namely, the health surveillance assistants. Potential "unhappiness" (C2 and C3) concerning the random allocation of smartphones could influence trial design changes, introduce biases, and jeopardize the success of the trial. It was suggested that this may be a problem in developing countries as "not everyone has a mobile device" (T5), and these devices are often perceived as being "valuable" and "exciting" (C2):

> *People without the device in the control group may get unhappy and withdraw.* [C2]
>
> *These interventions carry a lot of prestige, and they're automatically seen as better and more reliable, and patients view health workers with these gadgets differently.* [C3]

End Users' Technological Ability

Furthermore, the differences between the abilities of the technology developers and the end users were highlighted as a potential challenge as the gap is likely to be more pronounced in developing countries. Technology developers are "tech-savvy" (T2 and C1) and have a deep understanding of the characteristics of technology, but the end user, particularly a user in a low- or middle-income country, may have had very limited exposure to technology and may struggle with carrying out simple commands:

> *We're developing technologies in a different context, we can't expect that they're just going to run the same way they would here... we need to get on the ground and talk to people, and really understand the cultural barriers and the cultural opportunities associated with using these technologies.* [M2]

The End User's Experience

The end user's experience incorporated 2 subthemes: (1) understanding the end user and (2) the need for qualitative data. A deep understanding of the end users of the mHealth intervention was highlighted as key by all participants (n=15). Several participants (n=7) emphasized the importance of the end users' involvement throughout the development and evaluation of the intervention:

> *You do want to know what user perceptions of the device are because uptake and successful long-term adoption is dependent on acceptability of the end users themselves.* [C3]
>
> *If the stakeholders aren't happy with it, it's never going to take off.* [C3]

Understanding the End User

Over half of the participants (n=8) discussed the importance of understanding the user experience of the mHealth intervention. Aspects of user experience included the user's understanding and knowledge of the intervention (n=4) and the user's interaction with the intervention (n=4). It was suggested that if the end users are not aware of the contribution they are making by using the mHealth tool, their decision to adopt the mHealth intervention in the long term could be adversely affected:

> *Do they [the Health Surveillance Assistants] fully appreciate the affordances of being able to contribute to that dataset… and the potential or advantages and derived value for public health and policy?* [M2]

Furthermore, several participants (n=6) discussed the importance of producing an mHealth intervention that does not place a burden on the end user. An mHealth intervention that fails in this area is more likely to fail in the long-term implementation:

> *[We should be designing] a technology that does its job, does it really well but in a really inconspicuous way so that the person can get on with doing all of the other really important things that they do.* [M2]
>
> *How comfortable or convenient is it for the person to use?* [T2]

The Need for Qualitative Data

The benefits of qualitative data were frequently mentioned by almost all participants (n=14), in terms of contributing to a deep understanding of the end users' experience, suggesting its immense importance in mHealth evaluation. The rich understanding of the end users required for successful mHealth adoption cannot be achieved without the collection and analysis of qualitative data:

> *If we'd have not measured these qualitative elements, we would have missed many important benefits.* [C2]
>
> *We took the decision that in order to really understand the challenges around using and adopting the technology that we needed to use interview, focus group type techniques to actually explore the rich data around that.* [M2]
>
> *The interface with the community… going deep into where they are in their natural environment... you get very important information.* [O1]

Challenges to Mobile Health Evaluation

The challenges of mHealth evaluation incorporated 3 subthemes: (1) mHealth complexity, (2) external influences, and (3) multidisciplinary involvement. The challenges of mHealth evaluation were discussed by all participants (n=15).

Mobile Health Complexity

The complexity of mHealth interventions was frequently mentioned by several participants (n=6), with particular focus on identifying a primary outcome measure for this mHealth study. It was also highlighted how this problem is compounded by the vast spectrum of mHealth apps and their varying complexity:

> *mHealth interventions are not black and white, there are so many aspects that you need to measure… how do you synthesise that into one trial because you have a limited number of outcomes because you can measure enough but you get to the point where it's just making it really complicated, there are so many different outcomes that we're measuring and I think that is a challenge.* [C3]
>
> *The RCT is the gold standard and if you get an RCT that is showing you a good positive result then you know, thumbs up, everyone is happy about that, but if it shows a negative result, you know, that sort of kills your project in a sense so it could have sort of, an unintended negative consequence in that it writes off your intervention as being useless when actually it might not be useless, it might actually be quite useful, it's just you just didn't measure the right outcome measure.* [C1]
>
> *For mHealth, I think there are so many other variables that it makes it much more difficult.* [M2]

External Influences

Almost all participants (n=13) discussed the external influencers of the evaluation design. For example, high-level stakeholders such as the Ministry of Health influence the type of evaluation used. These key decision makers often control the ongoing financial support for the interventions and their long-term implementation. Other participants spoke of the importance of having government-level stakeholders involved to ensure financial and political support after the initial research funding comes to an end:

> *I think by putting the RCT as a prerequisite up front it might help you to secure research funding.* [T5]
>
> *Malawi's Ministry of Health are actively encouraging as many rigorous trials on mHealth technologies as possible, but they also want to gain an understanding of why they are potentially beneficial... I think that contributed to our decision to include a qualitative component.* [C3]
>
> *In terms of protocols and monitoring and the ethical side of things, it's something we know how to do and I think research institutions in general are relatively comfortable with the idea of a RCT.* [M2]
>
> *It's important because it is an international project… for the credibility of the whole research and the institutions.* [T2]

Furthermore, participants mentioned other influences as the outcome measures (n=5) and the availability of resources (n=4):

> *It depends on what you are measuring, so if you're measuring just truly clinical outcomes, I suppose it doesn't necessarily capture the technical issues.* [C3]
>
> *This trial specifically is a stepped-wedge approach and that was changed a few months before we actually implemented the study… it was resource constrained.* [O3]

Multidisciplinary Involvement

Participants from all 4 role categories (n=7) spoke about the challenges involved with the evaluation of an mHealth intervention, which requires the involvement of a multidisciplinary group of individuals, often from different institutions in different countries. Although all project members spoke English, overcoming disciplinary differences to find a *common language* among the members of an mHealth project proved challenging:

> *One of the key barriers to evaluating mHealth interventions is you have all these people coming together from different disciplines and none of them speak the same language.* [C3]

Although challenging, participants acknowledged the benefits of the diverse skill set. One-third of the participants (n=5) identified the general lack of evaluation in the field as a limitation in the guidance for conducting future mHealth evaluations. Most participants (n=12) identified the need for an alternative evaluation.

Mobile Health Regulation

The mHealth regulations incorporated 2 subthemes: (1) lack of standards and (2) development of a hierarchy of risk. Two-thirds of the participants (n=10) discussed the regulatory issues in mHealth.

Lack of Standards

The most commonly raised issue was the lack of minimum standards (n=8) in the present mHealth evaluations globally. Several issues with setting a minimum standard were identified. First, the sheer volume of mHealth apps currently available is too great to suggest that RCTs should be conducted for each; hundreds of thousands of apps "are not going to have trials done" (C2). Second, the difficulty of deciding which type of evaluation should be conducted was emphasized. It was suggested that the type of evaluation should depend on the type of mHealth being evaluated, such as an app providing information or testing or diagnosis, and perhaps that aspect should inform the standards for mHealth evaluation:

> *When they start moving away from consumer health devices, to more medical devices needing some regulatory approval or evidence or proof for a country to adopt them or pay for them... what is that bar?* [C2]

> *When you read the guidelines, they're a bit ambiguous and I think that it would really help my perception of when a RCT should be used.* [T5]

In addition, participants questioned the level of evidence required and whether an RCT was truly needed. The absence of standards for mHealth evaluations are potentially impacted by the lack of a clear definition of what exactly constitutes an mHealth intervention:

> *I think you've got to weigh up the benefits of going to the rigour of an RCT and the necessary requirements... versus whether [the intervention] could be evaluated by something simpler such as a before and after.* [C4]

> *Whether you call them mHealth or not depends on the definition.* [C2]

Development of a Hierarchy of Risk

Tying in closely with minimum standards is the development of a hierarchy of risk. This would allow for the classification of mHealth interventions based on their level of risk. mHealth is a broad term encompassing varying types of intervention, with differing levels of risk associated with each type. Several participants (n=6) spoke of the risk or level of anticipated harm and how it would contribute to defining standards and regulations and also how it could determine the type of evaluation design required for a particular mHealth intervention. A particular challenge across this theme was highlighted by several participants (C2, M1, and T2): "Who is going to take responsibility for it?" Questions were asked as to whether it should be an industry or governmental problem, if app stores should take the responsibility, or if there should be national and international policies in place.

Discussion

Principal Findings

This study aimed to explore the system developers' experiences of mHealth evaluation to identify factors contributing to an effective evaluation. This study was conducted within the context of an ongoing cluster randomized clinical trial of an mHealth intervention being conducted in Malawi. Participants identified the impact of the developing country context. These include deficiencies in the existing health data systems; poor infrastructure such as roads, buildings, and telecommunications affecting data transfer and storage; and differing perceptions of mobile phone value, particularly smartphones, among study participants, impacting their involvement in the study. Emphasis was placed on the need to gain a comprehensive understanding of the end user's experience of the intervention, and the importance of qualitative data collection and analysis was frequently mentioned. To ensure that the mHealth intervention being designed and developed is usable and useful, we need rich data to understand the end user's needs, experiences, and attitudes toward the intervention and its potential deployment. This would promote the adoption of mHealth intervention and is a positive step toward enhancing the possibility of implementation in the future [31].

Several challenges were highlighted that potentially impact on the type of evaluation chosen for mHealth interventions. These included the complex nature of mHealth interventions; selecting appropriate outcome measures; the influence of funders, regulatory agencies, and multidisciplinary project teams; and an overall lack of evaluation across the field of mHealth, which limits the guidance available to project teams. Participants further identified regulatory issues in the field of mHealth, namely, the lack of minimum standards to guide evaluation. Participants discussed the benefits of devising a hierarchy of risk to inform mHealth evaluation.

Comparison With the Literature

Technology and the people who use it are interdependent, each affecting the other [32]. The successful adoption of mHealth depends on the ability of the end user to operate the device and understand the technology. In a developing world context in particular, it is likely that the design-actuality gap [33] is large, so it is imperative that a comprehensive understanding of the social factors influencing mHealth is sought. The social aspects of mHealth include the social, cultural, religious, and behavioral interactions of the end user [10]. The importance of the end user's involvement in the mHealth project from the outset was highlighted. Qualitative data collection and analysis is essential

to derive rich insights from the end users. Utilizing qualitative data allows for the determination of social and contextual issues, desired effects, and usage factors [34,35]. The findings outline the aspects of the end user's involvement that are critical to the long-term success of an mHealth intervention. The significance of the inclusion of qualitative evaluation is clear; this was highlighted in the Supporting LIFE project where a qualitative approach was embedded within the RCT, but this raises questions about current evaluations that fail to account for the unique characteristics of the mHealth apps they are evaluating [19].

The lack of regulation in the area of mHealth as outlined by Boudreaux et al [14] is supported by these findings. The potential damage to the credibility of the field of mHealth was highlighted by several participants who admitted the ease with which an unregulated, untested app could be released for public use. This finding has ramifications for mHealth as an area of study, and action must be taken to protect the patients and consumers of these apps, researchers, funders, and the reputation of mHealth. However, this study uncovered a challenge to the development of standards, which is compounded by the complexity of mHealth and the differing levels of risk involved within the diverse spectrum of available mHealth interventions. These complications may stem from the definition of mHealth, which encapsulates many technologies from sophisticated mobile medical devices for specific diseases and treatments to free apps for public use. The broad nature of the definition creates ambiguity when attempting to define standards by which mHealth interventions should be measured. This study emphasizes a number of challenges to the evaluation of mHealth, in support of the existing literature [6,7,19,22,36], highlighting an opportunity for the development of new methods for evaluating mHealth, which are able to adequately evaluate the complexities of mHealth interventions.

Implications

To the best of our knowledge, this is one of the first studies to conduct an in-depth exploration of mHealth evaluation in the context of an ongoing clinical trial, and it contributes an urgently needed evidence base on the unique challenges of mHealth evaluation. Qualitative data can uncover important differences in the study populations, such as why a technology may work in one area but not in another, uncovering cultural, age, and education-related issues which quantitative data would fail to identify, and this is a major weakness in the use of an RCT alone for mHealth evaluation. In addition, the technical aspects identified are particularly important in the developing country context as mobile phone usage is vastly different, both in terms of the quality of the device and user ability. The findings from this study could contribute to the development of a more suitable, highly rigorous, cost-effective, and timely evaluation technique for mHealth. In the absence of clear consensus on mHealth evaluation, an appropriate next step may be the development of a decision support tool to enable mHealth project teams to identify the optimum study design or designs to select for evaluation using objective criteria, which could include quantitative, qualitative, or mixed method designs of various types.

mHealth incorporates a variety of interventions, with varying levels of risk associated with each. Therefore, a one-size-fits-all evaluation approach is unlikely to be suitable for mHealth, despite the external influence of funders and institutions. An mHealth intervention can be assessed from multiple perspectives, depending on the goals of the stakeholder. However, there should, at best, be a minimum standard of evaluation depending on the type of mHealth intervention. All mHealth interventions should pass a minimum standardized certification as to their quality, but mHealth interventions which aim to have a quantifiable impact on health should be further subject to a rigorous evaluation. One potential solution to the regulatory problems highlighted in this study is the development of a hierarchy of risk. If an intervention has a low risk of anticipated harm, such as an app giving clinical information, then a less rigorous evaluation design would be suitable, as opposed to an app that is more complex, requiring data from multiple sources, such as a brand-new decision support tool. Classifying mHealth as low-, medium-, and high-risk interventions would be based on factors such as the novelty of the intervention and the level at which it intervenes (and thereby potential risk) with human health and well-being. For example, interventions that provide descriptive information could be categorized as low risk; medium-risk interventions could include calorie and exercise tracking; and high-risk interventions could include diagnostic and treatment-centric interventions, which provide a prescriptive element.

White et al [21] outline that a successful mHealth evaluation should examine user feedback and outcome measures as well as the robustness of the technology, intervention principles, engagement strategies, and user interaction. Several alternative evaluation techniques to the RCT have been proposed, for example, continuous evaluation of evolving behavioral intervention technologies (CEEBIT) [37], the multiphase optimization strategy (MOST) [38], the sequential multiple assignment randomized trial (SMART) [39], and the microrandomized trial [40]. The next steps are required to determine the minimum level of evaluation and regulation required at each risk level. Using a hierarchy of risk as a guideline, mHealth project teams could justify their evaluation technique based on the evaluation requirement, perhaps avoiding situations where the evaluation technique is used to justify the funding. This will be particularly important as mHealth is adopted in developing countries where resources are scarce. On a larger scale, identifying an entity to take responsibility for the regulation and minimum standards of mHealth as a whole is extremely challenging, given the large reach of the mHealth field and the involvement of multidisciplinary research teams, ministries of health, app stores, and private industry.

Limitations

This study has a number of limitations. First, the sample size of this study is small as it included only 15 participants. However, determining an adequate sample size in qualitative research is ultimately a matter of judgment in evaluating the quality of the information collected [41]. Participants in this study were selected using positional and reputational methods [27] to identify the key actors in an mHealth evaluation, but all participants from this study were part of the same mHealth

project and may not be representative of other mHealth projects, which may be conducted in different contexts. Future research should explore mHealth evaluations in different contexts to identify challenges and considerations for successful evaluation. The field study methodology pursued in this study allowed the research to be conducted in the natural setting of an ongoing mHealth evaluation in a developing country, producing a rich, detailed insight of the evaluation process. Finally, all interviews and data analysis were conducted by 1 researcher. This is a weakness as qualitative data analysis is subjective and open to interpretation, but this has been mitigated by using analyst triangulation [42], whereby several of the study participants reviewed, discussed, and refined the findings of this study. Furthermore, a sample of the inductive, open coding approach has been provided in Multimedia Appendix 1.

Conclusions

Contextual issues represented one of the most important challenges to evaluating an mHealth intervention in a developing country context and highlighted qualitative evaluation as imperative to ensure that the sociotechnical needs of end users are considered. The failure of mHealth interventions to address social and technical problems could have a profoundly damaging effect on the chances of long-term implementation and must be identified early on. Although RCTs have several important limitations in the mHealth context, the use of this rigorous evaluation methodology is the best approach in the absence of appropriate alternatives. However, it should be acknowledged that new evaluation methodologies are emerging, such as the CEEBIT, MOST, and SMART methodologies, which may be more suited to the complexities of mHealth, and project teams should be open to exploring these alternatives. There is an opportunity to design alternative approaches to mHealth evaluation, incorporating the hierarchy of risk, which challenge the one-size-fits-all approach and provide greater guidance and flexibility in evaluating different mHealth interventions in different contexts.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Sample of coding process.
[DOCX File , 14 KB - mhealth_v8i1e12424_app1.docx]

Multimedia Appendix 2
Consolidated criteria for reporting qualitative research checklist.
[DOCX File , 14 KB - mhealth_v8i1e12424_app2.docx]

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Abbreviations

CEEBIT: continuous evaluation of evolving behavioral intervention technologies
mHealth: mobile health
MOST: multiphase optimization strategy
RCT: randomized controlled trial
SMART: sequential multiple assignment randomized trial
Supporting LIFE: Supporting Low-cost Intervention For disEase control

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Original Paper

Use of Evidence-Based Best Practices and Behavior Change Techniques in Breast Cancer Apps: Systematic Analysis

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Abstract

Background: Theoretically designed mobile health (mHealth) breast cancer interventions are essential for achieving positive behavior change. In the case of breast cancer, they can improve the health outcomes of millions of women by increasing prevention and care efforts. However, little is known about the theoretical underpinnings of breast cancer apps available to the general public.

Objective: Given that theories may strengthen mHealth interventions, this study aimed to identify breast cancer apps designed to support behavior change, to assess the extent to which they address content along the cancer care continuum and contain behavior change techniques, and to assess the degree to which star rating is related to theory-based design.

Methods: Using a criteria-based screening process, we searched 2 major app stores for breast cancer apps designed to promote behavior change. Apps were coded for content along the cancer care continuum and analyzed for behavior change techniques. The Mann-Whitney *U* test was used to examine the relationship between star ratings and the use of behavior change techniques in apps with star ratings compared to those without ratings.

Results: The search resulted in a total of 302 apps, of which 133 were identified as containing breast cancer content. Only 9.9% (30/302) of apps supported behavior change and were further analyzed. These apps were disproportionally focused on behaviors to enhance early detection, whereas only a few apps supported care management, treatment, and posttreatment behaviors. Regarding theories, 63% (19/30) of apps customized content to users, 70% (21/30) established a health-behavior link, and 80% (24/30) provided behavior change instructions. Of the 30 apps, 15 (50%) prompted intention formation whereas less than half of the apps included goal setting (9/30, 30%) and goal reviewing (7/30, 23%). Most apps did not provide information on peer behavior (7/30, 23%) or allow for social comparison (6/30, 20%). None of the apps mobilized social norms. Only half of the apps (15/30, 50%) were user rated. The results of the Mann-Whitney *U* test showed that apps with star ratings contained significantly more behavior change techniques (median 6.00) than apps without ratings. The analysis of behavior change techniques used in apps revealed their shortcomings in the use of goal setting and social influence features.

Conclusions: Our findings indicate that commercially available breast cancer apps have not yet fully realized their potential to promote behavior change, with only a minority of apps focusing on behavior change, and even fewer including theoretical design to support behavior change along the cancer care continuum. These shortcomings are likely limiting the effectiveness of apps and their ability to improve public health. More attention needs to be paid to the involvement of professionals in app development and adherence to theories and best practices in app design to support individuals along the cancer care continuum.

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KEYWORDS

mHealth; breast cancer; mobile apps; health behavior; health apps

Introduction

Background

Globally, more than 1 million women are diagnosed with breast cancer every year, making it the most common cancer type among women [1]. With an estimated 410,000 individuals dying from the disease annually, breast cancer constitutes the leading cause of death from cancer among women across the globe [1,2]. Breast cancer morbidity and mortality can be reduced through the promotion of exercise, healthy diet, and limited alcohol intake and adequate access to screening services, treatment, and care management. However, many women lack information and support for behavior change along the cancer care continuum [2-4]. The cancer care continuum provides a framework to evaluate care plans, priorities, progress, and research gaps, as it refers to the various stages of cancer etiology, prevention, early detection, diagnosis, treatment, survivorship, and end-of-life care [5]. For example, advances in screening and treatment help increase the number of breast cancer survivors. In the United States alone, 3.5 million women are breast cancer survivors [6]. They have specific social, psychoemotional, health care, diet, and exercise needs that are different from the general public, and interventions should target these specific needs [7].

Mobile phone apps are promising platforms to extend current health care efforts and to reduce health disparities. Mobile phone ownership is growing rapidly across countries, and health and medical apps are becoming increasingly popular [8]. A national survey on the use of health apps among mobile phone owners in the United States showed that more than half of all mobile phone users have downloaded health-related apps and, of those, two-thirds felt that health apps improved their health [9].

The use of mobile communication technologies for health purposes (mobile health, mHealth) shows great promise in supporting health-related behavior change [10]. Apps have been used in a variety of health contexts with a wide spectrum of functions, ranging from supporting weight loss and physical exercises to the management of chronic diseases [11]. Research on the effectiveness of mHealth interventions strongly supports the integration of behavior change theories into app content and design, and guidelines have been developed and validated to measure the degree to which apps use theoretically based design, such as the taxonomy of behavior change techniques [10,12]. A systematic review of mHealth interventions showed that apps that were based on theoretical constructs significantly increased behavior change efforts [10]. Of the studies included in the review, the majority of interventions used action and feedback cues and social support as theoretical constructs, whereas the most prominent theories included the social cognitive and self-determination theories. Other studies reported success in pain assessment and management through mobile apps by using diaries and direct provider feedback [11].

In the context of breast cancer, apps have the potential to support healthy behaviors along the cancer care continuum, and studies have explored the potential of apps in the prevention, treatment, and management of breast cancer. The following sections provide an overview of how apps have been used to support behavior change and disease management on the cancer care continuum, from prevention and risk to diagnosis, treatment, survivorship, and end-of-life care.

Prevention, Risk Assessment, and Screening

mHealth interventions targeting cancer preventive behaviors have shown some success in encouraging preventive behaviors through the integration of behavioral constructs in intervention design, such as text message reminders, tailored feedback, and narratives [13]. Primary preventive behaviors include being physically active, maintaining a healthy weight, reducing the use of tobacco, limiting alcohol intake, and eating a healthy diet. Apps have been used to promote these behaviors by providing information about risk reduction strategies and by offering tracking features to monitor dietary intake and physical exercise [14].

Furthermore, breast cancer screenings can help detect the disease early on, thus increasing treatment options and chances of survival [15]. Mammograms are the only screening method that has shown to increase longevity [15-17]. Certain women who have a family history of breast or ovarian cancer or are of Ashkenazi Jewish heritage are further advised to undergo genetic testing for BRCA1 or BRCA2 mutations and may benefit from regular and enhanced screenings at an earlier age [15]. Apps have been used to assist in the promotion of regular screening for breast cancer and have shown to increase knowledge of breast cancer screening guidelines as well as screening attendance [18,19]. However, there is a considerable body of evidence indicating that increasing knowledge alone has limited to no effectiveness in changing health behavior [20-22].

Diagnosis, Management, and End-of-Life Care or Survivorship

Apps can provide targeted and personalized information to patients with breast cancer after diagnosis and during and after treatment. Diagnosis-related information includes cancer stage, tumor type, and prognosis. For patients and survivors, mHealth interventions have been used to facilitate disease management, support patient-provider communication, increase patients' quality of life, and enhance self-care strategies [23,24]. For example, Uhm et al [25] had success in increasing physical activity in breast cancer patients through the use of an app coupled with a pedometer. An mHealth-supported behavioral counseling intervention resulted in positive physiological changes, including weight loss and increased vegetable and fruit intake [26]. In a qualitative assessment of an app supporting patients with breast cancer during treatment, patients reported that they found audio recordings of conversations and personalized information useful [27].

Previous Research on Breast Cancer Apps

Although studies have explored the integration of theoretical constructs in breast cancer interventions, little is known about theoretical underpinnings of breast cancer apps available to the general public. Despite the importance of the issue and the availability of the taxonomy that has been used effectively in other contexts [12,28,29], past analyses of cancer apps, in general, have focused primarily on the examination of content and functionalities of apps, without considering the importance of health behavior change techniques in app design. An analysis of the content of cancer apps found that the goal of cancer apps was mainly to raise awareness and to provide information, forfeiting opportunities to promote behavior change [18]. Only 1 study explored the integration of behavior change techniques into cancer-related apps, reporting missed opportunities to take advantage of interactive and user-centered features that may support behavior change, such as personalization, review of goals, and feedback [29]. However, the study examined apps for cancer survivors only, defined as individuals "diagnosed with cancer from the time of diagnosis through the balance of life" [29]; thus, this prior study did not take into account cancer apps developed for prevention purposes. Furthermore, data collection took place in 2013, representing an early stage in the development and dissemination of cancer apps. Since 2013, the number of health apps downloaded from major app stores has more than doubled, stressing the need for further evaluation [30].

Only 3 previous studies analyzed breast cancer apps specifically, examining the prevalence of gamification elements [31], the degree of medical professional involvement [32], and adherence to health literacy and interactivity strategies [33]. Findings across these studies suggest a lack of involvement of health experts in app design and content as well as limited adherence to theory- and evidence-based constructs [31-33]. However, 2 of the studies analyzed apps based on their description on the app store [31,32], which may not accurately reflect the content provided in the apps. Moreover, although theoretical guidance is paramount and a recommended best practice [10,12], none of these studies examined the use of behavior change theories and constructs in app content and design across the cancer care continuum.

In view of the difficulties facing consumers in identifying quality apps, consumer ratings might be a helpful tool. The 2 measures currently employed by the major app stores that indicate the quality of apps are peer star ratings and written reviews from users [34]. However, previous studies identified major flaws in these rating systems, as only a minority of apps received written reviews or star ratings, and written reviews were found to be unstructured, subjective, and short [31,32]. This lack of standardized measures in app stores' rating systems makes it difficult for users to find apps that are of high quality in terms of content and design [31,32].

Nevertheless, star ratings and written peer reviews are the only 2 measures available to users that indicate the quality of apps, and it would thus be beneficial to examine whether users' ratings accurately reflect the quality of apps. Our past study identified a relationship between star ratings and adherence to literate design, with higher star ratings being positively correlated with higher health literacy scores [33]. Similarly, apps that integrated evidence- and theory-based constructs were found to receive higher ratings [34]. Although app users are probably unaware of these constructs, these findings may suggest that they intuitively prefer evidence- and theory-based app design. It is possible that the integration of evidence- and theory-based constructs makes apps more effective, which increases user satisfaction, and, in turn, leads to higher ratings. Identifying whether the integration of behavior change techniques into app design is related to star ratings could provide additional insight into the accuracy of star ratings to measure app quality. We thus hypothesized that breast cancer apps that incorporate behavior change techniques would receive higher star ratings.

Study Aims

Breast cancer has specific prevention, treatment, and care management and survivorship information, behavior, and support needs, and therefore, studies should explore the availability, content, and quality of cancer-specific apps. Given that apps have shown success in supporting healthy behaviors along the cancer care continuum, the goal of this study was to focus on commercial breast cancer apps that target behavior change. In contrast to a previous study of breast cancer apps' content and health literacy standards that we conducted in 2016 [33], this study sought to focus primarily on the use of behavior change techniques integrated into app design supporting both preventive and postdiagnosis behavior change. Specifically, we sought to answer the following research questions (RQs):

> *RQ1: How many breast cancer apps are available on the iOS and Android app stores that focus on behavior change across the cancer care continuum?*
>
> *RQ2: To what extent do breast cancer apps that seek to support behavior change include content along the cancer care continuum?*
>
> *RQ3: To what degree are breast cancer apps theory based?*

Given that star ratings are one of the only publicly available measures to indicate the quality of apps and previous studies have found positive correlations between evidence- and theory-based constructs and star ratings, we constructed the following hypothesis:

> *H1: Star ratings of the quality of apps will be positively associated with the degree to which apps incorporate behavior change techniques.*

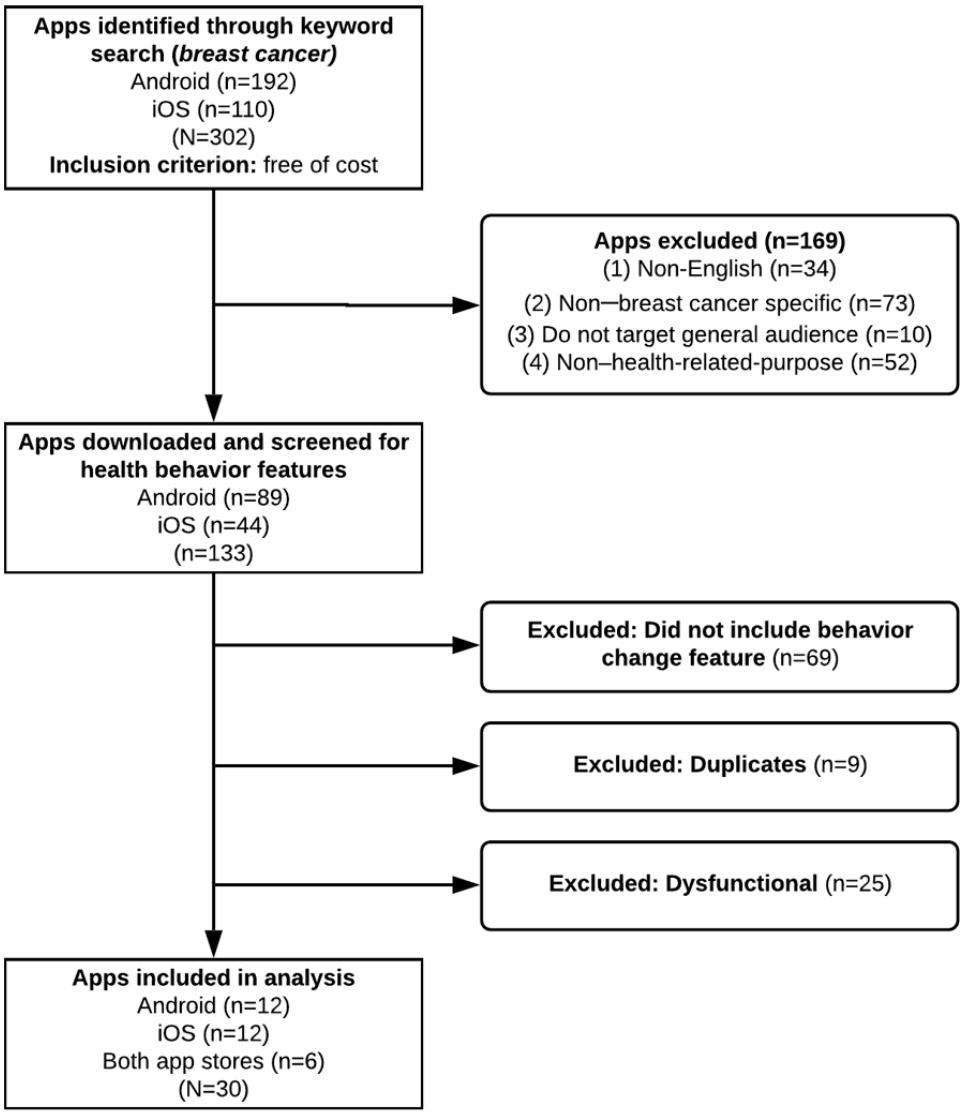
Methods

Sampling

The screening process and content analysis of breast cancer apps followed procedures outlined in previous content analyses of health apps [28,33]. In February 2018, the iOS App Store and the Android Play Store were screened for relevant apps using tablet devices. Only apps that were free of cost were included in the analysis, as previous studies suggest that users are reluctant to pay for apps and prefer apps that are free of cost [29,33]. The search term, *breast cancer*, was typed into the search bars in both app stores, and data on all free apps were

transferred to a spreadsheet. A total of 302 free apps were identified in both app stores (192 for Android and 110 for iOS). Apps were included in the further analysis if they were (1) in English, (2) specific to breast cancer, (3) for the general public (as opposed to health professionals), and (4) developed for health promotion or prevention purposes (as opposed to providing screen savers or conference information). A total of 133 apps (89 Android and 44 for iOS) met the inclusion criteria and were downloaded onto tablet devices. The primary focus of this study was on the analysis of behavior change apps, and consequently, apps were screened for features or functions that aimed at supporting behavior change. Features or functions defined as supporting behavior change were reminders, scheduling options, interactive questionnaires, and similar features that clearly aimed at supporting certain behaviors, as opposed to only providing information. Several apps were duplicates (n=9) or did not open or crashed (n=25) and were excluded, leading to a final sample size of 30 breast cancer apps containing features that clearly aimed at supporting behavior change. See Figure 1 for the screening process and exclusion and inclusion of apps.

Figure 1. Screening process for sample selection.



Coding Process

The coding scheme used in this study was adapted from the previous analysis conducted in 2016 and included coding items related to the purpose of the app and evidence-based best practices along the cancer care continuum [33]. Assessment of behavior change theories followed a coding scheme based on Abraham and Michie's [12] taxonomy of behavior change techniques and adapted to the coding of behavior change techniques in cancer apps [29].

A total of 2 graduate students were trained in three 2-hour-long sessions to ensure consistency in conceptualizations of coding items. A sample of 10 apps was coded to test for intercoder reliability. Intercoder reliability was calculated using Krippendorff alpha (see Table 1). Alphas for 26 variables were between .79 and 1, indicating excellent intercoder reliability. Alphas for the remaining 6 variables were not calculated because there was no data variance. Disagreements were discussed until consensus was reached.

Table 1. Krippendorff alpha values and percentage of agreement for each item.

Items	Krippendorff alpha	Percentage of agreement
Content		
Primary prevention	1	100
Genetic risk	1	100
Genetic screening	1	100
Mammography	1	100
Clinical breast examination	1	100
Self-breast examination	1	100
Symptoms	1	100
Stage	1	100
Type of tumor	1	100
Prognosis	1	100
Treatment options	1	100
Side effects	1	100
Care management	1	100
Prevention pills	1	100
Survivorship	Undefined[a]	100
End-of-life care/hospice	Undefined[a]	100
Biological process	1	100
Clinical trials	1	100
Research referenced	1	100
Behavior change techniques		
Customization	1	100
Health-behavior link	1	100
Behavior/consequences	.79	90
Intention formation	1	100
Goal setting	1	100
Review of goals	Undefined[a]	100
Instructions	Undefined[a]	100
Materials/education	1	100
Self-monitoring	Undefined[a]	100
Persuasion	1	100
Peer behavior	1	100
Social comparison	1	100
Mobilize social norms	Undefined[a]	100

[a]Krippendorff alpha is undefined when there is no expected disagreement between coders. This happens when all coders code a particular variable the same for every case, leading to division by zero in the calculation of alpha.

Coding Scheme

A coding scheme was developed, which included information on app characteristics and user rating, the content of apps along the cancer care continuum, and the integration of behavior change techniques. The following sections provide an overview of how these categories were conceptualized and coded.

App Characteristics

General characteristics of each app were recorded, including the name of the app, developer, age rating, user star rating, and app category.

Primary Prevention

To assess apps' content on prediagnosis behaviors, apps were analyzed for content related to preventive behaviors, such as being physically active and keeping a healthy weight.

Genetics

Apps were further coded for content related to (1) genetic risk and (2) genetic screening guidelines for individuals who may have an increased risk for developing breast cancer.

Early Detection

Information on early detection of breast cancer was coded for the following items: (1) mammography, (2) clinical breast examination, (3) self-breast examination, and (4) symptoms.

Diagnosis

Apps were coded for information on diagnosis of breast cancer, including content regarding (1) cancer stage, (2) tumor type, and (3) prognosis.

Breast Cancer Management and Therapeutics

Breast cancer apps were further analyzed for content related to breast cancer care and management following a breast cancer diagnosis, including the following items: (1) treatment options, (2) side effects, (3) care management and medication, and (4) prevention pills (eg, tamoxifen for individuals with increased risk).

Survivorship and End-of-Life Care

To assess whether apps provided information postdiagnosis and treatment, we coded for content related to survivorship and end-of-life care or hospice.

Research and Science

Apps were also coded for (1) containing biological information, such as explaining the biological process of developing breast cancer; (2) providing information on clinical trials; and (3) providing references for further biological and research-based information.

Behavior Change Techniques

The integration of behavior change techniques was assessed using a coding scheme previously developed to code behavior change techniques in cancer survivorship apps [29]. This coding scheme was based on Abraham and Michie's [12] taxonomy of behavior change techniques but adapted to the analysis of apps developed for cancer survivors. Behavior change techniques included in the coding scheme were associated with several behavior change theories, including the Elaboration Likelihood Model [35], the social cognitive theory [36], the control theory [37], operant conditioning [38], the information-motivation-behavioral skills model [39], and the theory of planned behavior [40]. Further included were items related to tailored health communication and social support [41,42]. The final coding scheme included the following categories: (1) customization (ie, personalization or tailoring), (2) information/behavior relationship (ie, health-behavior link, behavior and consequences), (3) intention (ie, intention formation, goal setting, and review of goals), (4) facilitation (ie, instructions and information/education), (5) self-efficacy (ie, self-monitoring of goals and persuasion), and (6) social influence (information on peer behavior, comparison, and mobilizing social norms). These 6 categories contained a total of 13 specific behavior change techniques, which were summed to create a *behavior change technique score* with a possible range of 0 to 13, which was used for the statistical analysis to test H1.

Statistical Analysis

SPSS version 25 (IBM Corp) was used to examine the relationship between the occurrence of behavior change techniques in apps and star ratings. Significance was determined at an alpha level of .05.

Results

Availability and Characteristics of Breast Cancer Apps Supporting Behavior Change

The first RQ sought to identify the availability of breast cancer apps that focused on supporting behavior change. The search resulted in a total of 302 free apps, of which 133 were identified as including breast cancer content. Only 30 apps met the inclusion criteria for supporting behavior change and were further analyzed. Multimedia Appendix 1 lists all 30 apps that were included in the final sample and provides characteristics and the behavior change technique score for each app.

Of the 30 apps analyzed, 12 (40%) were available on iOS only, 12 (40%) were available on Android only, and the others were available on both platforms (6/30, 20%). Most apps were rated either for everyone (12/30, 40%) or for users aged 12 years and older (10/30, 33%). There were also 3 apps rated for users aged 4 years and older, 3 (10%) rated for users aged 17 years and older, and 2 (6%) that did not have age ratings. The majority of the apps were categorized under either *medical* (13/30, 43%) or *health and fitness* (12/30, 40%).

Apps' Content Along the Cancer Care Continuum

The second RQ focused on the information presented in apps along the cancer care continuum. Table 2 provides a breakdown of the frequency of items coded in each stage of the cancer care continuum, ranging from primary prevention to survivorship or end-of-life care.

Table 2. Frequency of breast cancer app items (N=30).

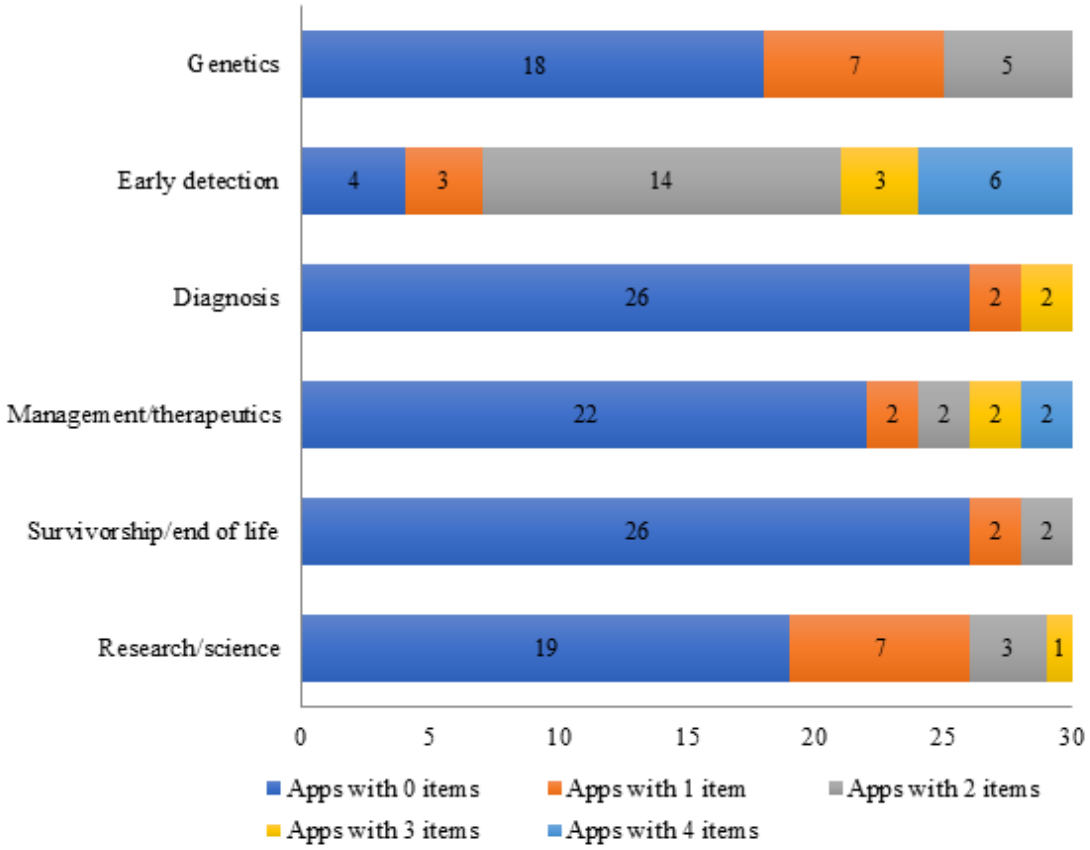
Category and items	Value, n (%)	Behavior change technique score, mean (SD)
Primary prevention	13 (43)	5.31 (2.93)
Genetics		
Risk	12 (40)	5.67 (2.46)
Screening	5 (16)	6.40 (2.70)
Early detection		
Mammography	12 (40)	5.25 (2.45)
Clinical breast examination	10 (33)	5.10 (2.28)
Self-breast examination	21 (70)	5.04 (2.58)
Symptoms	21 (70)	5.38 (2.52)
Diagnosis		
Stage	3 (10)	8.00 (1.73)
Type of tumor	2 (6)	7.50 (2.12)
Prognosis	3 (10)	7.33 (1.53)
Management/therapeutics		
Treatment options	7 (23)	6.71 (2.50)
Side effects	4 (13)	6.25 (2.50)
Care management	6 (20)	6.33 (2.50)
Prevention pills	3 (10)	8.33 (1.15)
End-of-life care/hospice		
Survivorship	4 (13)	8.25 (0.96)
End-of-life care/hospice	0 (0)	N/A[a]
Research/science		
Biological process	4 (13)	7.00 (3.46)
Clinical trials	3 (10)	7.00 (1.00)
Research referenced	9 (30)	6.00 (2.94)

[a]N/A: not applicable.

With regard to prediagnosis behaviors and information, fewer than half of all apps addressed primary prevention (13/30, 43%), dealt with genetic risk (12/30, 40%), or provided recommendations for screening for genetic risk (5/30, 16%). Most apps offered guidance about self-breast examinations (21/30, 70%) and the symptoms of breast cancer (21/30, 70%). Fewer than half of the apps included information about mammography (12/30, 40%) or clinical breast examinations (10/30, 33%). With regard to diagnosis, 3 (10%) apps included information on cancer stage or prognosis, and 2 (6%) apps addressed the type of tumor. Similarly, content related to breast cancer management and therapeutics was discussed in less than one-fourth of all apps. More specifically, treatment options were discussed in 7 (23%) apps, care management in 6 (20%) apps, side effects in 4 (13%) apps, and prevention pills in 3 (10%) apps. Only 4 (13%) apps addressed survivorship, and there was no app that included information about end-of-life care.

Figure 2 shows the comprehensiveness in which apps addressed each stage in the cancer care continuum by reporting on the number of relevant items they addressed. As explained earlier, each stage of the cancer care continuum was coded with several items, with the exception of primary prevention (refer to Table 2 for a breakdown of items coded in each stage of the cancer care continuum). For example, content related to genetics was coded with 2 items, namely (1) genetic risk and (2) genetic screening. Specifically, 18 (60%) apps did not address either 1 of the 2 items related to genetics, 7 (23%) apps addressed 1 item, and 5 (16%) apps addressed both of the items. Early detection received the most detailed attention. In addition, 3 (10%) apps contained 1 item related to early detection, 14 (46%) apps contained 2 items from this cancer stage, 3 (10%) apps contained 3 items, and 6 (20%) apps contained all 4 items. Only 4 (13%) apps did not address any of the items.

Figure 2. Comprehensiveness of apps' (N=30) content on each cancer care continuum stage.



Diagnosis-related items, which included cancer stage, tumor type, and prognosis, were absent from most apps (26/30, 86%). Moreover, 2 (6%) apps addressed all 3 items, and 2 (6%) apps discussed only 1 of the 3 items. Similarly, the majority of apps did not discuss items related to breast cancer management (22/30, 73%), with only 8 (26%) apps including at least one item. Information related to survivorship and end-of-life care was also largely absent in apps (26/30, 86%), with 2 (6%) apps addressing 1 item and 2 (6%) apps addressing both items.

In addition to content related to each stage of the cancer care continuum, apps were also examined for the provision of scientific information, including the biological process of developing breast cancer, clinical trials, and citations. The majority of apps (19/30, 63%) included none of the 3 items, and 11 (36%) apps addressed at least one of the items.

Use of Behavior Change Techniques in App Design

The third RQ focused on apps' integration of behavior change techniques. As shown in Table 3, the most common element was related to facilitation. Most apps (24/30, 80%) provided instructions, although only 10 (33%) apps provided educational information on a specific health behavior. Most apps also contributed to knowledge and awareness by addressing the health-behavior link (21/30, 70%) and behavior and consequences (18/30, 60%). Nearly two-thirds of the apps allowed users to customize their experience through personalization and/or tailoring (19/30, 63%). Half of the apps (15/30, 50%) sought to prompt users to form intentions. No other behavior change technique appeared in more than one-third of the apps.

The possible range of the behavior change technique score was 0 to 13, although the actual range was 0 to 9 (mean 10 [SD 2.48]). Owing to the small sample, the assumptions of most parametric tests were not met, so such tests were not conducted. However, a behavior change technique score was calculated for each of the items (see Multimedia Appendix 1 for the behavior change technique score for each app). These numbers simply show the average number of behavior change techniques in apps with certain types of content. For example, the 3 apps dealing with chemoprevention pills had the highest average number of behavior change techniques (mean 8.33 [SD 1.15]), followed by the 4 apps addressing survivorship (mean 8.25 [SD 0.96]). The apps with the lowest average behavior change technique score were the 21 apps that dealt with breast self-examinations (mean 5.04 [SD 2.58]).

Table 3. Frequency of behavior change techniques (N=30).

Category and behavior change technique	Value, n (%)
Customization	
Tailoring/personalization	19 (63)
Information/behavior relationship	
Health-behavior link	21 (70)
Behavior and consequences	18 (60)
Intention	
Prompt intention formation	15 (50)
Prompt goal setting	9 (30)
Review of goals	7 (23)
Facilitation	
Provides instructions	24 (80)
Provides materials/education	10 (33)
Self-efficacy	
Self-monitoring of goals	9 (30)
Persuasion	8 (26)
Social influence	
Information on peer behavior	7 (23)
Social comparison (peer active)	6 (20)
Mobilize social norms	0 (0)

Relationship Between App Ratings and Prevalence of Behavior Change Techniques

We hypothesized that star ratings of apps and the integration of behavior change techniques would be positively associated. However, the small dataset made it impossible to directly test this hypothesis. Only half of the apps in our sample (n=15) had star ratings. The data were not normally distributed, and 2 apps accounted for a majority (n=593) of the total number of star ratings for all 15 apps (N=875). The median number of ratings per app was 20. The average star rating for these 15 breast cancer apps was quite high—4.3 on a 5-point scale (SD 0.67). No app that was rated earned an average lower than 3 stars.

Given the small number of available apps, it was not surprising that the Spearman rho test was not statistically significant. We decided to compare the number of behavior change techniques in apps that received star ratings and apps that received no star ratings. We theorized that star ratings are evidence that users are, at least somewhat, engaging with an app, and more behavior change techniques might make apps more engaging. As the data were not normally distributed, we used the Mann-Whitney *U* test to compare the 15 apps with user ratings against the 15 apps without user ratings. Apps with star ratings contained significantly more behavior change techniques (median 6.00) than apps without any star ratings (median 4.00; U=161.50; z=2.07; P=.04; r=0.38).

Discussion

Principal Findings

The goal of this study was to assess breast cancer apps currently available to users on the Android Play Store and iOS App Store for their inclusion of content along the cancer care continuum and their integration of behavior change techniques. Consistent with previous research, this study revealed significant shortcomings in apps' adherence to evidence-based best practices and use of behavior change techniques [29,32].

The screening process of the Android and iOS app stores identified 133 breast cancer apps available to users, of which less than one-fourth had the clear goal of promoting healthy behaviors or facilitating behavior change through specific features or functions. This finding is consistent with previous findings [31,32] and reveals that most breast cancer app developers continue to focus on educational and informational purposes only. Although apps are important platforms for the dissemination of breast health information and resources, research suggests that providing information in itself is insufficient to promote behavioral changes [20]. These findings are particularly disappointing, given the advantage of mHealth in providing customized and interactive features that may enhance accessibility to health information and support behavior change.

Another concern relates to the prevalence of apps supporting breast self-examinations, which is a screening modality not recommended by leading health care organizations in the United

States [15]. Research suggests that breast self-examinations are largely ineffective at reducing mortality rates and may lead to adverse health outcomes because of increased invasive diagnostic procedures [43]. Perhaps not surprisingly, the 21 apps focusing primarily on enhancing breast self-examinations were also the apps with the lowest average behavior change technique score, indicating that design of the apps developed for primary prevention purposes likely lacks involvement of health professionals and behavioral scientists. These findings indicate the persistence of the trend identified in previous analyses of breast cancer apps criticizing a lack of theory and evidence-based concepts in app development [32,33]. Given the potential influence of apps on preventive behaviors, it is essential to ensure that app content follows guidelines that are evidence based and not likely to cause unnecessary harm to individuals. It is also noteworthy that although almost half of the apps provided information on genetic risk, only one-sixth included information on screening or testing for genetic risk. Individuals who have an increased risk of developing breast cancer are recommended to get screened more regularly and at an earlier age and providing at-risk women with these screening guidelines may increase their attendance of medical checkups and screenings [15].

In contrast to the number of apps promoting preventive behaviors, only a few apps focused on postdiagnosis behaviors, such as treatment and care management, survivorship, or end-of-life care. These findings are consistent with results from our earlier analysis in 2016 [33] but deviate from other content analyses of breast cancer apps. For example, a content analysis conducted in 2016 reported that few apps addressed prevention and early detection, whereas more apps focused on disease and treatment information and disease management [31]. Apps in the study were classified based on the app store description, which could explain the different findings. This analysis and the analysis done in 2016 [33] revealed major discrepancies between the description of apps on the app store and their actual content. Hence, our findings underline the importance of downloading and analyzing apps, which is a rigorous and time-intensive approach to analysis compared with relying on apps' content descriptions on the app stores.

Given the potential of apps to increase healthy behaviors in breast cancer patients, the less number of apps targeting postdiagnosis behaviors reveals missed opportunities to support care management and treatment decisions [33]. In particular, with only 3 apps providing information on survivorship and no app focusing on end-of-life care, our findings emphasize the pressing need for apps providing information and support for posttreatment health promotion and medical management. For the growing number of breast cancer survivors, who experience specific care management support and needs, these findings are particularly disappointing [6].

Our findings further lend support to the need for increased attention to the integration of behavior change techniques into app content and design. Research strongly supports the use of behavior change theories in mHealth interventions; however, adherence to behavior change techniques varied widely across apps. Apps demonstrated strong results in the presentation of a health-behavior link, the discussion of consequences of health behaviors, and the provision of clear instructions to facilitate behavior change. Furthermore, customization options offered by the majority of apps are promising. Apps allowed users to customize content in different ways, including through the collection of personal data, tailoring of content to specific diagnoses, or personal settings of reminder and scheduling functions. Our finding that most apps take advantage of interactive features to increase user engagement shows that apps have started to move away from a rather linear to a more user-centered presentation of content.

Although apps took advantage of the technical capabilities of the mobile devices to adapt content to users, they did not do so to increase self-efficacy in users or to encourage goal setting behaviors. This was particularly surprising considering the high number of features used in apps that sought to enhance these behavioral constructs. Examples of these features found in breast cancer apps included scheduling and reminder functions of mammogram appointments or medical checkups, journals to track changes in the breast, and diaries to record conversations with physicians or to note distress. Goal setting and self-monitoring have shown to effectively enhance behavioral changes, but the majority of apps fell short on introducing goal setting instructions that are actionable, providing an aggregated report of achieved goals, or prompting users to monitor their goals. Offering features without providing clear instructions and feedback may decrease the effectiveness of these functions to support behavior change. Similar results have been reported in earlier studies that identified the low scores of human-computer interaction components, such as control, tracking, and feedback systems [18,29]. Our findings, therefore, point at a disappointing lack of progress in the design of theoretically based cancer-related apps and in the integration of best practices.

Similarly, apps did not take advantage of social networking options to strengthen users' social support system. Only 7 apps provided stories or experiences of other breast cancer patients or survivors, and only 6 apps allowed users to share their own story or to connect with others. None of the apps sought to mobilize social norms by exposing users to opinions from known or popular individuals. Apps are increasingly used as a communication and educational tool, and the sparse opportunities offered in breast cancer apps for individuals to connect with others undergoing similar experiences largely limit their potential to provide additional support. The lack of social media options and social influence has also been reported in analyses of cancer survivorship apps [29] and general cancer apps [18]. Given that social ties can increase patients' well-being and the potential of apps to connect people across spatial boundaries, these findings are particularly disappointing.

Finally, our analysis highlights the need for safeguards and measures to increase the quality of available apps as has been identified in many previous analyses of health-related apps, including breast cancer apps [31,32]. Less than one-third of the apps reviewed in this study included references, whereas the majority of apps did not indicate their sources of information. This is concerning because references can help users evaluate the quality of information provided in apps.

In both the Android and iOS app stores, it is difficult for users to accurately assess the quality of health apps. The user rating system may serve as an indicator for app quality, but it does not necessarily reflect the reliability of information. As only half of all apps had user ratings, many apps do not provide users with any feedback regarding the quality of apps as assessed by users. The limitations of the data did not allow us to accurately test whether star ratings were correlated to the incorporations of behavior change techniques in app design. However, we did find that rated apps included more behavior change techniques than apps that were not rated. This finding is consistent with our previous study that reported a correlation between user rating and literate design [33]. Future research should continue to examine this relationship and whether apps that incorporate more behavior change techniques are more engaging for users. Moreover, as limitations in app stores' rating systems impede identification of reliable and credible apps, there is a need to improve rating systems available to users.

Strengths and Limitations of This Study

This is the first study focusing on the degree to which breast cancer apps that aim at initiating and supporting behavior change use constructs and features based on behavior change theories across the cancer care continuum. Although previous studies examined the overall content of breast cancer apps, including their adherence to health literacy principles [33], use of gamification elements [31], and purpose of breast cancer apps [31,32], this study is the first to primarily focus on apps that target behavior change.

There are also certain limitations to this study. First, this review only included free and commercially available breast cancer apps. It could be possible that apps developed by health care professionals or health care organizations are recommended to patients that are based on behavior change theories, but those were not included in this analysis. Second, we only focused on apps that were specifically created for breast cancer; as a result, we may have missed apps that included breast cancer information in general cancer apps. Third, this analysis reviewed apps in English only, and we may have missed apps developed for specific cultural groups. Finally, we used a shortened version of the taxonomy of behavior change techniques as a coding scheme. Other frameworks are available that could further guide the analysis of behavioral constructs in app design, for example, from a motivational or goal-oriented perspective [44]. Similarly, we did not include app-level data that would indicate actual app usage, which could provide insight into how users use breast cancer apps.

Conclusions

Mobile apps have the potential to reduce health disparities and to overcome barriers of limited access to health care services and resources by providing evidence- and theory-based interventions to individuals. In view of the global breast cancer burden, mHealth interventions can serve as promising platforms to enhance preventive and postdiagnosis behavior change. However, our analysis shows that current breast cancer apps are disproportionally focused on behaviors to enhance primary prevention and early detection, most of which are not evidence based, whereas only few apps support care management, treatment, and posttreatment behaviors. Moreover, the analysis of behavior change techniques used in apps revealed significant shortcomings in apps' use of goal setting and social influence features, which may decrease effectiveness in improving the overall health and well-being of individuals. More attention needs to be paid to the involvement of health professionals and behavioral and communication scientists in app development and adherence to theories in the design of mHealth apps to provide individuals with the support they need along the cancer care continuum.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
List of breast cancer apps in final content analysis ranked by behavior change technique score (N=30).
[PDF File (Adobe PDF File), 84 KB - mhealth_v8i1e14082_app1.pdf]

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Abbreviations

mHealth: mobile health
RQ: research question

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Original Paper

Mobile Health Projects in a High-Complexity Reference Hospital: Case Study

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Abstract

Background: The widespread adoption of mobile and wearable devices and apps makes it essential to assess their possible impact on the management of health and diseases. Health care providers (HCPs) find themselves faced with a new situation in their setting with the proliferation of mobile health (mHealth) intervention tests. Few studies have addressed the development of mHealth and the methodologies to manage these apps in a tertiary hospital.

Objective: The aim of this study was to evaluate the mHealth projects implemented in the Hospital Clínic of Barcelona to increase awareness of the context in which they are used and to develop policies for the development of good practice in mHealth innovation.

Methods: A prospective, descriptive cross-sectional study was conducted in a highly specialized university hospital with 850 beds for adults and a reference population of 520,000 inhabitants. A specific questionnaire was developed based on the Mobile Health 5 Dimensions European (MOHE 5D-EU) theoretical model to find mHealth projects. Apps, telemedicine, and wearable devices were included in the systematic search. For that purpose, a vertical (top-down) email-based *snowball* process was conducted. Data were collected from February to December 2018 by conducting personal interviews with HCPs using a structured questionnaire.

Results: During the study period, 45 interviews were conducted; 35 mHealth initiatives were found, with 25 targeted to patients and 10 to health professionals. Most mHealth initiatives (34/35, 97%) were related to the software field (apps and telemedicine initiatives), and one was related to wearable devices. Among the projects, 68% (24/35) were classified as medical devices or developments at the edge (developments susceptible to limitations depending on the *intended* use). In relation to data protection, 27 initiatives managing personal data (27/35, 77%) considered data protection legislation. Only 9% (3/35) of the initiatives had foreseen the use of interconnectivity standards. Most of the initiatives were funded by grants (14/35, 40%), sponsorships (5/35, 14%), or the hospital itself (5/35, 14%). In terms of clinical management, most projects were developed in the field of research, followed by professional tools, clinical information, and therapeutic education. Only 6 projects were involved with health care; all were led by either the industry or small and medium enterprises.

Conclusions: This study helped create the design of a map of the mHealth projects conducted in our hospital that showed the stages of development of the different ongoing projects. This will allow monitoring of mHealth projects and construction of tools

to reinforce areas with detected deficiencies. Our theoretical approach using a modified MOHE 5D-EU model was found to be useful for analyzing the characteristics of mHealth projects.

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KEYWORDS

mobile health; observational study

Introduction

Background

There are more than 5 billion mobile phone lines in the world [1,2]. Since the launch of the Google Play and iTunes platforms in 2008, the number of apps for mobile phones has continuously grown, exceeding 2.1 million for the Android platform and 1.8 million for the Apple platform in 2019 [3].

It has been estimated that there are about 325,000 apps [4] classified in the categories of health and medicine. Of these, 65% are dedicated to well-being (exercise, healthy lifestyle, control of stress, dieting, and nutrition). Those dedicated to specific diseases constitute 9% of the total, followed by those related to pregnancy (7%) and apps focused on treatment adherence or alarms to take medication (6%).

The widespread usage of mobile devices, apps, and wearable devices makes it essential to assess their possible impact on the management of health and diseases and to determine how health care providers (HCPs) manage their implementation. The mobile health (mHealth) care survey by Spok [5] (with more than 300 health care professionals, of which 44% were clinicians) found that more than half of the hospitals reported having mobile strategies in place (mostly telemedicine). The National Institute for Health and Care Excellence developed a document that describes an *evidence standards framework* for digital health technologies for English National Health Service providers in 2018 [6]. The World Health Organization also developed a guideline with recommendations for digital interventions aimed at *the health system strengthening* [7].

Technology providers and their organizations often monitor the market through studies such as the *Mobile Strategies in Healthcare report* by Spok, the report by the IQVIA Institute (formerly the Intercontinental Medical Statistics Health Institute), or the *Use, Evidence and Remaining Barriers to Mainstream Acceptance Patient Adoption of mHealth* [8], or they take a very simple approach such as Healthcare Information and Management Systems Society, with the classification of hospitals according to the *Electronic Medical Record Adoption Model* adoption scale [9].

HCPs are progressively integrating management and monitoring of the development of new mHealth interventions into ethics committee procedures. There are only a few studies that address the development of apps in a tertiary hospital [10].

To facilitate the management of knowledge related to mHealth, an observatory was created at the Hospital Clínic of Barcelona (HCB). The mHealth observatory has a technical committee comprising representatives from the different departments of the linked hospital, including information systems management, medical informatics, legal department, innovation, technology transfer, bioengineering, and patient experience. A coordinator directs a community of practice to ensure proper knowledge management within the organization. The functions of the observatory are to generate usable knowledge, facilitate the use of this knowledge, and manage the changes incurred [11].

The mHealth observatory has three subobjectives: first, the marshaling function, which refers to the collection of relevant datasets from various sources; second, the analysis and synthesis function regarding the transformation of data into usable knowledge and the integration of information to generate comprehensive understanding; and finally, the sharing function, which is related to facilitating the exchange of information to support decision making.

The first step is to be aware of the actual situation of the hospital and its environment. Therefore, the main objective of this study was to describe and map the mHealth projects implemented in a high-complexity reference hospital.

Objective

The aim of this study was to identify and to describe the level of development of mHealth projects in the HCB and, thus, contribute to the improvement of mHealth policies in this health care center.

Methods

Study Design and Setting

A cross-sectional study was conducted in the HCB, a highly specialized hospital with 850 beds for adults and a reference population of 520,000 inhabitants.

An interdisciplinary team of researchers comprising two nurse educators, a specialist in patient experience, two specialists in public health, a general practitioner, two experts in medical technology, and a psychiatrist were commissioned to map the mHealth projects at the HCB.

In addition to focusing on obtaining concrete clinical or quality-of-life–related outcomes, the following indicators were also considered to determine the level of maturity of the projects:

- Assessment by the development team on whether the project results were medical devices (MDs) or not [12]
- Use of data and protection of the data [13] and the possible connection with health providers and electronic medical records [14-16]
- Development of viability or business plan to ensure the survival and scalability of the project [17]
- Patient participation

Methodology

To complete the cartography of mHealth projects, a work plan was agreed upon by the research team. This included reaching a consensus as to the basic definitions of the research subject, choosing the theoretical approximation model, constructing an ad hoc questionnaire, and, finally, conducting the fieldwork.

A standard description of mHealth was adopted by the researchers: "mHealth are tools and strategies to improve health through the use of mobile technologies."

The inclusion criteria were as follows: projects involving the participation of HCPs from the hospital and projects involving apps (autonomous software initiatives), telemedicine projects including the use of mobile devices, and projects with wearable devices (such as bracelet pedometers and glucose meters).

The exclusion criteria were as follows: ideas or projects with protocols that were inadequate to apply for competitive funding and projects developed without HCP participation.

The questionnaire was developed to collect contextual data and characterize the initiatives. It had 8 sections to characterize the ongoing initiatives and their level of development. Overall, 3 sections were related to affiliation, the use of mHealth in the setting of the interviewee, and a semistructured interview. The remaining 5 sections were related to the description of the project according to the Mobile Health 5 Dimensions European (MOHE 5D-EU) model, a theoretical reference model [11]. The questionnaire was developed considering five dimensions [18]: legal, technological, sustainability, patient participation, and clinical management:

1. The legal dimension had three sections. One section was related to whether or not the apps or the wearable devices were in fact MDs according to European and Spanish regulations. This dimension answers the questions "What is it?" The second section answers the question "Who is the owner?" (Who owns the software or the device related to intellectual property?). The last section was related to concerns about data protection. The definition of MD was as follows: a device is considered an MD if (1) it is a computer program (not an informational document only), (2) it performs some action on data (not just stored) to facilitate the interpretative tasks of the health personnel, (3) it benefits individual patients (no population aggregation and generic diagnostics according to literature), and (4) this is done for the purpose of care, provided in the definition of MD [12].
2. The technological dimension was related to interoperability, use of connection technology standards, and data management and data protection.
3. Sustainability was evaluated by the Research2Guidance models [17]. To classify the development phase, five categories were defined: project, when a project document of requirements was already available; in development, when a project was under construction; prototype, when the development of the project was complete but had not yet been tested with patients; pilot, when the test was conducted with patients; and working, when the project was already in use in the workplace.
4. A two-question approach was implemented in the patient dimension in relation to whether patients had been considered during project development. Project coordinators would be asked to confirm patient participation.
5. Finally, four categories were defined in the dimension of clinical management: one for HCPs and three for patients (research, assistance, and information or patient education).

To identify mHealth initiatives, a vertical (top-down) email-based *snowball* process was conducted. Once the coordinators of the initiatives were identified, they were asked to attend an interview conducted by a researcher using the related questionnaire.

The data were collected by personal interviews with HCPs over a 6-month period in 2018.

The research team classified the projects by medical specialty and the theoretical strategy followed and incorporated the projects in a surveillance system using five-dimensional characterization.

The app type classification used by the Mobile App Rating Scale (developed by the Queensland University of Technology and the Young and Well Cooperative Research Centre) [19] was chosen to label the type of apps for patients to identify the use of the underlying theoretical strategies of the projects for patients. The following aspects were used in different projects: evaluation; feedback, information/education, and monitoring/follow-up; goal setting; counseling/guidelines/skills training; cognitive behavioral therapy (CBT)–behavioral (positive events); CBT–cognitive (thought challenging); acceptance and commitment therapy; mindfulness/meditation, relaxation, and gratitude; strengths; and others.

In addition, the Fogg triad [20] was used to classify professional apps as a tool, mediator, or social actor.

Statistical Analysis

The analysis of power and statistical significance used in studies that test a hypothesis do not apply in descriptive studies such as this. Therefore, the responses of the questionnaires were summarized using descriptive statistical techniques such as mean for continuous data, median for stratified data, and percentage as needed. The answers were also examined graphically, with percentiles to identify outliers.

Ethical Aspects

Data collection is one of the functions of the mHealth observatory. The observatory was implemented by the administration of the hospital as part of an innovation strategy. No data were collected from patients. All the participant projects are linked to an HCP of the hospital.

Results

During the 6-month study period, 45 mHealth projects were identified; 35 met the inclusion criteria, of which 25 were targeted to patients and 10 were related to HCPs. A total of 34 projects were in the software field (apps and telemedicine initiatives), and only 1 was in the wearable devices field (a fall detector).

With regard to mHealth projects, 8 projects were related to infectious diseases, mainly drug dose calculators; 7 were related to mental health; 2 projects each were related to central services neonatology, cardiology, nephrology, pneumology, anesthesia, and emergency care; and 1 project each was conducted in pharmacy, endocrinology, oncology, rheumatology, gastroenterology, and obstetrics (Table 1).

With reference to theoretical background/strategies, only 8 of the 14 possible categories of apps classification were used to categorize patient apps, and only 2 of 3 Fogg categories were used for professional apps. The results obtained are shown in Table 2.

The results of the questionnaire conducted during the interviews were codified in a calculation sheet, and the results were presented in the five dimensions of the MOHE 5D-EU model (Table 3).

Table 1. Summary of mobile health initiatives found according to the medical specialty.

Focus of the mobile health initiatives	Projects, n
Infectious diseases	8
Mental health	7
Central services	2
Neonatology	2
Cardiology	2
Pneumology	2
Nephrology	2
Anesthesia	2
Emergency	2
Pharmacy	1
Diabetes	1
Oncology	1
Rheumatology	1
Gastroenterology	1
Obstetrics	1

Table 2. Theoretical background and strategies (total number of mobile health initiatives=35).

Mobile health initiatives, Characteristics	Values, n (%)[a]
Patients (n=25)	
Feedback	16 (64)
Monitoring/tracking	15 (60)
Information/education	13 (52)
Advice/tips/skill training	11 (44)
Assessment	5 (20)
Goal setting	2 (8)
CBT[b]–behavioral positive events	1 (4)
CBT–cognitive thought challenging	1 (4)
Professionals (n=10)	
Tool—increases capability	9 (90)
Medium—provides experience	2 (20)

[a]Note that one app can have more than one characteristic.

[b]CBT: cognitive behavioral therapy.

Table 3. Legal, technological, sustainability, and patient participation aspects adapted from the Mobile Health 5 Dimensions European model.

Dimension, Detail	Patients, n	Professionals, n	Total, n (%)
Legal			
What is it?			
Medical device	8	5	13 (37)
Edge	10	1	11 (31)
Nonmedical device	6	2	8 (23)
Telemedicine	2	1	3 (9)
Who is the owner?			
Hospital	3	2	5 (14)
Hospital+public/nonprofit	7	1	8 (23)
Hospital+private	2	6	8 (23)
Hospital+public/nonprofit+private	6	1	7 (20)
No hospital	7	0	7 (20)
Technological			
Willingness to connect with the hospital system			
Yes	11	2	13 (37)
No	14	8	22 (63)
Uses interoperability standards			
Yes	3	0	3 (9)
No	13	7	20 (57)
Telemedicine	2	1	3 (9)
Don’t know or no opinion	7	2	9 (26)
Sustainability and phase			
Paid by the user			
Pay per download	0	2	2 (6)
In-app purchase	3	0	3 (9)
License	0	2	2 (6)
Crowdfunding	1	1	2 (6)
Linked to a medical device	2	0	2 (6)
Paid by a third party			
Grants	12	2	14 (40)
Sponsorships and donations	4	1	5 (14)
Institutions	4	0	4 (11)
Software as Service	2	0	2 (6)
Paid by the hospital			
Hospital Clínic	3	2	5 (14)
Phase			
Project	4	1	5 (14)
Development	0	2	2 (6)
Prototype	5	1	6 (176)
Pilot	7	1	8 (23)
Working	8	5	13 (37)
Discarded	1	0	1 (3)

Dimension, Detail	Patients, n	Professionals, n	Total, n (%)
Patients			
Focus of projects			
Professional	N/A[a]	10	10 (29)
Patients	25	N/A	25 (71)
Patient participation in projects			
Continued	14	N/A	14 (56)
Punctual	6	N/A	6 (24)
They have not participated	5	N/A	5 (20)
Clinical management			
Area			
Information and patient education	6	0	6 (17)
Health care	7	0	7 (20)
Research	12	0	12 (34)
Professionals	0	10	10 (29)

[a]Not applicable.

Legal Dimension

In this dimension, the characteristics of the projects were evaluated. In addition to the 3 basic categories, *apps*, *telemedicine*, and *wearable devices*, it was necessary to determine whether developments could be classified as MD or not, considering that the malfunction of such a device may affect people's health. The results were as follows: 13 developments were classified as *MDs*, 11 were at the *edge* (developments susceptible to limitations depending on the *intended use*), 8 projects were classified as *non-MDs* (eg, *Clinic Maps*), and 3 were classified as *telemedicine* (Table 3 under *Legal*).

The ownership of the development in response to the question of "Who's the owner?" was also analyzed in terms of responsibility, profits, and use of the brand. Of the total, 8 initiatives were found to be public (including 5 from the hospital) and 27 were from private entities.

With regard to data protection and considering that the whole sample comprised apps that do not collect sensitive data, a notable 77% (27/35) of the total developments (all sensitive cases) had foreseen data protection, thereby indicating a high level of awareness toward this topic.

Technological Dimension

In the technological dimension, it was important to determine whether the use of connection standards was foreseen (interoperability) as this would allow data sharing from the apps to the hospital information systems, which would contribute to knowledge building. Similarly, it was determined whether the connection between apps and the hospital information systems was planned.

Only 9% (3/35) of the initiatives had foreseen the use of connection standards, and 26% (9/35) were not aware of these standards. With regard to the projection to connect with the hospital information systems, a little over one-third (13/35, 37%) of the project coordinators aimed for full integration (Table 3, under *Technological*).

Economic Management Dimension (Sustainability and Phase)

The section on economic management included the business model or the prognosis of sustainability and the phase of the development cycle in which the projects were located in the cycle (Table 3 under *Sustainability and phase*).

The research team added two categories to the project financing model (crowd funding and hospital funding). The results were largely dominated by scholarships, grants, and sponsorships, which places the developments at low levels of business. Note that a project could have more than one funding source.

The lack of a business plan beyond the scholarships was of note. Having such a plan would facilitate the pathway to the market. Sponsorship and hospital funding were also determined to be the usual sources of funding.

Overall, 5 categories were described to classify the development phase: project, in development, prototype, pilot, and working.

The projects were found to be spread across all phases of the development cycle, with most projects in the working phase (n=14), followed by those in the *pilot* phase (n=8).

Patient Dimension

In relation to the dimension of patient participation, 20 projects responded positively to the question about the involvement of patients. Considering that 10 projects were aimed at HCPs and 2 projects at information about the operation of the hospital, the percentage obtained was very satisfactory. Overall, 80% (20/25) of patient participation was on an ongoing basis. On the basis of the information collected, it was not clear whether patient participation had taken place from the beginning or not.

Clinical Management Dimension

The dimension of clinical management provided interesting insights into the models of project creation. This section was divided into four categories *information and patient education*, *health care*, *research*, and *professional*, and projects were able to move from one category to another over time. An app was considered *professional* when the patient did not interact directly with the app.

Most projects were in the category of research (n=12) and were usually initiated by clinicians to solve problems associated with patient care. Tools aimed at helping achieve diagnoses predominated in the category of *professional* (n=10). In the *information and patient education* category (n=6), various initiatives by small entities were found. In addition, the industry also had an important role in health care initiatives within the field of industry products (n=7), with apps related to enabling the follow-up of patients with a product marketed by their company.

Discussion

Principal Findings

The results of this study show that it is possible to generate usable knowledge related to the collection of relevant datasets. Analysis and synthesis functions were also achieved, transforming data into practical knowledge and integrating the information to generate a comprehensive understanding. In addition, the application of the MOHE-5D-EU contextual model with the five dimensions used in this study, using an adapted questionnaire, proved to be useful in characterizing mHealth projects.

In the projects reviewed, a fairly established accomplishment of data protection rules and patients' participation was found (although not always in a structured way).

Knowledge related to the development of new projects should be potentiated to help determine whether or not an initiative is to be used as an *MD* and to evaluate sustainability, the importance of the use of technological standards to facilitate connectivity, and in relation to the exploitation of data, among other aspects.

To know if a development will be an MD is important, especially considering that 68.5% of the projects found are likely to be MDs and that the new, more restrictive European regulations will be effective from May 2020 [12]. Although it should be noted that the developments led by hospital professionals are mostly in the research quadrant, where the MD commercialization regulations are not yet applicable, they will be mandatory as soon as the development enters the market. Moreover, making proposals solely in the domain of research, without considering sustainability and, therefore, its release to the market, punishes the consolidation of projects.

Unawareness of interoperability standards and their great importance for the exchange of health information and the construction of knowledge significantly reduced the contribution that mHealth can provide. It does not allow HCPs access to systematic collection of data, leaving the data fractionated in different platforms and of no benefit to electronic medical records.

One strength of this study was that it provided an overall vision of mHealth in our institution. By categorizing the results, the research team was able to develop a map of the projects and observe their weaknesses and strengths, which subsequently allowed the team to develop a toolkit to help new initiatives and those which are ongoing.

One limitation of the study was the introduction of aspects of different disciplines (eg, legal, information technology, and human behavior). It is more complex to analyze an interdisciplinary setting.

Funding of highly personalized initiatives through grants makes it difficult to detect all the initiatives undertaken. In these cases, the Ethics Committee of Investigation is the gatekeeper.

In addition, it was difficult to establish comparisons with previous studies as the studies available usually focus on the content of an initiative and on achieving a concrete, clinical and/or quality-of-life outcome [10,19,21,22] rather than context viability.

The mHealth observatory proposed the development of a series of guidelines and tools to facilitate the adequate development and implementation of useful, advantageous, and sustainable mHealth projects.[22]

Studies designed to link mHealth to the diagnosis and improvement of patients' experiences would be of interest to define the scenarios that patients face.

Conclusions

A map of the mHealth projects available in the HCB was created within a complex scenario involving different approaches and many different professionals, with many of the projects being developed without sufficient multidisciplinary knowledge.

From now on, we will be able to monitor the development of mHealth projects within the hospital and build tools that assist the reinforcement of the detected deficiencies.

Finally, according to the results obtained, our theoretical approximation model, which was an adaptation of the MOHE 5D-EU model, was found to be useful for analyzing the characteristics of mHealth initiatives and detecting their strengths and weaknesses.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
HCB: Hospital Clínic of Barcelona
HCP: health care provider
MD: medical device
mHealth: mobile health
MOHE 5D-EU: Mobile Health 5 Dimensions European

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Original Paper

The Florida Mobile Health Adherence Project for People Living With HIV (FL-mAPP): Longitudinal Assessment of Feasibility, Acceptability, and Clinical Outcomes

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Abstract

Background: For people living with HIV (PLWH), antiretroviral therapy (ART) adherence is crucial to attain better health outcomes. Although research has leveraged consumer health information technologies to enhance ART adherence, no study has evaluated feasibility and clinical outcomes associated with the usage of a commercially available, regularly updated mobile health (mHealth) app for improving ART adherence among PLWH.

Objective: This study aimed to assess the feasibility, acceptability, and clinical outcomes of Care4Today, an existing, free, biprogrammatic mHealth app for improving ART adherence among PLWH.

Methods: The Florida mHealth Application Adherence Project (FL-mAPP) was a 90-day longitudinal pilot study conducted in 3 public HIV clinics in Florida, United States. After obtaining informed consent, 132 participants completed a survey and then were given the option to try an existing mHealth app to help with ART adherence. Of these, 33.3% (44/132) declined, 31.1% (41/132) agreed but never used the app, and 35.6% (47/132) used the app. All were asked to complete follow-up surveys at 30 days and 90 days after enrollment. Usage data were used to assess feasibility. Clinical outcomes of self-reported ART adherence and chart-obtained HIV viral load and CD4+ T-cell counts were compared among those who used the platform (users) versus those who did not (nonusers). Participants and HIV care providers also provided responses to open-ended questions about what they liked and did not like about the app; comments were analyzed using thematic analysis.

Results: Of 132 participants, 47 (35.6%) and 85 (64.4%) were categorized as users and nonusers, respectively. Among users, a Kaplan-Meier plot showed that 25 persons (53%) continued using the app after the 90-day follow-up. At 30-day follow-up, 13 (81.3%) of those who used the mHealth app reported ≥95% ART adherence, compared with 17 (58.6%) nonusers (P=.12). Overall, 39 (82%) users liked or somewhat liked using the platform. Participants' favorite features were medication reminders, ability to create custom reminders, and adherence reports.

Conclusions: This longitudinal study found that a commercially available medication adherence mHealth app was a feasible and acceptable intervention to improve ART adherence among PLWH and engaged in clinical care across 3 public HIV clinics in the state of Florida. Overall, participants liked the Care4Today app and thought the medication reminders were their favorite

feature. Generally, self-reports of ART adherence were better among users than nonusers, both at 30- and 90-day follow-ups. Further clinical research needs to address user fatigue for improving app usage.

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KEYWORDS

mHealth; HIV; ART adherence; feasibility; acceptability

Introduction

Background

For people living with HIV (PLWH), antiretroviral therapy (ART) adherence is crucial to attain both viral load suppression and optimal health outcomes. Although up to 85% of PLWH in the United States report >95% ART adherence [1], concerns remain about the dynamic nature of and potential decline in adherence over time [2-10]. Although research has leveraged consumer health information technologies to enhance ART adherence, such as SMS [11-25] and mobile health (mHealth) apps [26-31], no study has evaluated the longitudinal feasibility and acceptability of an existing, commercially available, free, and regularly updated mHealth app for improving ART adherence among PLWH [32].

Although 3 meta-analyses [33-35] found SMS reminders to be efficacious for improving ART adherence across diverse populations, the effects were modest and declined over time [34]. Given most studies were descriptive, evidence for mHealth apps that improve HIV medication adherence is limited [36,37]. For example, previous research showed mobile apps to improve ART adherence are feasible and acceptable [28,38], and reminders seem to be effective in helping initiate a medication adherence routine. Data-guided counseling may help PLWH to identify strategies to overcome adherence barriers [39]. However, mHealth interventions seem to have a limited scope during the efficacy trial phase, failing to incorporate functions identified as useful by PLWH [40]. In addition, the traditional research approach of developing and testing homegrown mHealth apps may no longer be practical, given the rapid pace of innovation in mHealth technologies and the budgetary requirements of maintaining, debugging, updating, and upgrading a mobile app [41,42].

Care4Today Mobile Health Manager (Johnson & Johnson) is a commercially available mHealth app designed to improve medication adherence and has been described in detail elsewhere [43]. The app is biprogrammatic (ie, designed for both smartphones [iPhone or Android] and SMS interfaces). Previously, we reported that among PLWH recruited from public HIV clinics in Florida, United States, over 70% of participants were interested in using an app to monitor their medication adherence. We found that perceived need and availability of someone at the clinic to assist with the app were strongly associated with willingness to try it [43]. These findings informed the implementation of the study we report here.

Objectives

The objective of this study was to assess the feasibility and acceptability of Care4Today among PLWH. More specifically, we sought to evaluate (1) app usage pattern; (2) changes in self-reported ART adherence, HIV viral load, and CD4+ T-cell count among PLWH who used the app compared with those who did not; and (3) preferences and suggestions for app features for PLWH. As a secondary goal, we sought to assess the interest of HIV providers and clinical staff in receiving app-generated adherence data.

Methods

Design, Participants, and Setting

The Florida mHealth Application Adherence Project (FL-mAPP) was a 90-day feasibility and acceptability longitudinal pilot study of a commercially available mHealth app for treatment adherence among PLWH, conducted from 2015 to 2016. As previously described, participants were recruited from public HIV clinics (2 urban and 1 rural) affiliated with the Florida Department of Health [43]. Eligibility criteria included (1) having an HIV positive laboratory result and having been prescribed ART, (2) documented viral load or scheduled viral load test within 4 weeks before or after enrollment, (3) 18 years of age or older, (4) capable of reading and speaking English, (5) owner of a smartphone or feature phone, and (6) able and willing to incur the cost of receiving and sending SMS messages. Potential participants were excluded if they were visually impaired or if they shared their phone with another person.

After providing informed consent, participants completed a survey questionnaire. They were then able to choose by trying the app in 2 forms: (1) SMS reminders only (for flip phone owners) or (2) full app (for smartphone owners). Clinic personnel assisted participants as needed with downloading the app, creating their account, and configuring the app or SMS reminders. All participants were asked to complete 2 follow-up surveys at 30 and 90 days after enrollment. Participants who chose to try the app or SMS reminders were asked if we could submit a dashboard-generated adherence report to be reviewed by their provider as part of ongoing clinical care. All of these participants accepted the request.

Participants received gift cards totaling US $30 over the course of the study in compensation for their time completing the surveys regardless of the decision to use the app. Follow-up clinical measures included 30- and 90-day self-reported ART adherence, HIV viral load, and CD4+ T-cell count.

Data and Measures

Surveys were conducted at baseline, interim (day 30), and endpoint (day 90). Baseline paper surveys were completed in person at the clinics, and follow-ups were conducted either in person or over the phone by research staff, as described previously [43]. The baseline survey assessed demographic characteristics, self-reported ART adherence, and mobile phone

and mHealth app use. Interim and endpoint surveys assessed self-reported ART adherence only.

Demographic Variables

Participants reported their age in years (categorized in 4 groups [ie, 18-29, 30-35, 37-39, 43-49, and 50 and older]), gender assigned at birth, race and ethnicity (categorized as Hispanic; white, non-Hispanic; black, non-Hispanic; and other, non-Hispanic), highest education level attained (less than high school, high school graduate or general education diploma, and more than high school), and marital status (single/never married, divorced/widowed/separated, and married/living with a long-time partner).

Feasibility

We assessed usage of the app at 30 and 90 days after enrollment among those who used the SMS or app at least once. For each participant, continued use was defined as number of days elapsed from enrollment until the last time the participant reported either a taken or a missed dose via the app or SMS. For analysis, persons who declined to try the app and those who agreed to try but never actually used it were categorized together as *nonusers*, and those who used the app at least once were defined as *users*.

Clinical Outcomes: Antiretroviral Therapy Adherence, HIV Viral Load, and CD4+ T-Cell Count

We measured self-reported ART adherence using a previously developed item that was validated for PLWH [44]. Participants were asked, *Over the last 30 days, how many days did you forget or miss your HIV medications, even partially?* We categorized participants' ≥95% adherence if they reported missing doses on less than 2 days in the previous month. We also attempted to define ART adherence according to the responses from the app, but if participants did not report on a specific day, it was not possible to tell if they were nonadherent or just forgot to enter information into the system.

We collected HIV viral load and CD4+ T-cell count at 2 distinct intervals: (1) baseline viral load and CD4+ T-cell count at enrollment day or the 30 days preceding enrollment and (2) the next available medical record laboratory results after enrollment. We used a plasma level cut-off point of less than 40 copies/ml of HIV-1 RNA to define optimal viral suppression.

Acceptability

At study day 30, participants who chose to try the app answered open-ended questions that assessed acceptability [45]. Items included the following: *How did you like using the Care4Today system? What stopped you from using the system more? Which features did you like the most? What did you not like about Care4Today? How can the system be improved?*

Provider Survey

Participant providers were invited to participate in the study by receiving printed copies of app-generated adherence reports at day 30, 60, and 90. After day 90 of the study, consenting providers completed brief surveys regarding their interest in receiving the app-generated adherence data. Items included the following: *How interested would you be in continuing to receive information on patients' self-reported adherence with this dashboard?How often would you like to see these type of data about your patients?* and *How interested would you be in learning how to access the dashboard online to look at adherence reports of your patients who are using the "Care4Today" app?*

Data Analyses

For quantitative data, proportions and chi-square tests compared baseline demographic characteristics, ART adherence, and clinical variables between users versus nonusers [43], both at baseline and follow-up. A Kaplan-Meier plot curve described the proportion of persons who continued to use the app over time. To measure ART adherence, we compared ≥95% versus <95% ART adherence at follow-up among users and nonusers with poor adherence at baseline (n=57). Then, chi-square tests were used to determine the difference in adherence between those who used the mHealth platform and those who did not, at days 30 and 90 after enrollment.

For responses to open-ended questions, we used an inductive thematic analysis [46] to unveil barriers and facilitators of app use. Participant answers were organized in 2 separate spreadsheets. In total, 2 of the authors (RLC and CGEV) created initial codes and labeled the data using these codes. Next, the codes were categorized into themes and interpreted. Throughout the process, discrepancies were resolved among the qualitative research team.

Ethics and Consent Process

All participants were provided with written informed consent, and Health Insurance Portability and Accountability Act required health authorization to use personal health information for research. The institutional review boards of the Florida Department of Health, the University of South Florida, and the University of Florida reviewed and approved all procedures and data management processes.

Results

Participant Characteristics and Mobile Health Platform Feasibility

As previously reported by this study group [43], of the total 132 participants at baseline, 47 (47/132, 35.6%) agreed to use the app and used it at least once (*users*). *Nonusers* (85/132, 64.4%) comprised 44 participants (44/132, 33.3%) who declined to try the app and 41 (41/132, 31.1%) who agreed to try the app but did not use it. Of 47 *Users*, 37 (78%) who chose to use the full smartphone app and 10 (21%) who chose SMS. We conducted an analysis to compare these 2 groups and found no significant differences other than smartphone ownership, which was significantly more frequent among those who chose to use the full app. At baseline and follow-up, no significant differences were found in ART adherence, HIV viral load, or CD4+ T-cell count between users and nonusers (Table 1). Among users, more than 50% continued to use the app for 90 days or more, with 6% (3/47) using the app for less than 30 days, 19% (9/47) between 30 and 59 days, 21% (10/47) between 60 and 89 days, and 53% (25/47) for over 90 days (Figure 1).

From baseline, 81% (38/47) of app users and 64% (54/85) of nonusers completed 90-day follow-up surveys. Table 2 shows the proportion of persons who reported >95% adherence at 30- and 90-day follow-up among participants that reported <95% ART adherence at baseline. At enrollment, 57/132 persons (44.5%) reported <95% ART adherence. At 30-day follow-up, we found a nonsignificant difference (*P*=.12) between ≥95% adherence reported by app users (81%, 13/16) compared with just over half of nonusers (58%, 17/29). Similarly, at 90-day follow-up, 7/15 users (46%) reported ≥95% ART adherence compared with 9/22 nonusers (40%), although this difference was not significant.

Table 1. Baseline and follow-up of antiretroviral adherence and clinical parameters of Care4Today users and nonusers, Florida Mobile Health Application Adherence Project study, 2015 to 2016 (N=132).

Characteristics	Total (N=132)[a], n (%)	Users (n=47), n (%)	Nonusers (n=85), n (%)	*P* value[b]
Antiretroviral therapy adherence ≥95%				
Baseline	71 (55.5)	26 (57.8)	45 (54.2)	0.7
30-day follow-up	85 (79.4)	35 (85.4)	50 (75.8)	0.23
90-day follow-up	65 (70.7)	25 (65.8)	40 (74.1)	0.39
HIV RNA ≤200 copies/mL				
Baseline	91 (71.0)	37 (78.7)	54 (66.7)	0.15
90-day follow-up	97 (88.2)	60 (85.7)	37 (92.5)	0.37
CD4 count >500 cells/μL				
Baseline	69 (54.3)	25 (54.4)	44 (54.3)	0.99
90-day follow-up	61 (56.0)	23 (59.0)	38 (54.3)	0.64
Mean CD4 count (cells/μL), mean (SD)				
Baseline	575 (311)	560 (329)	583 (280)	0.68
90-day follow-up	629 (346)	635 (352)	626 (345)	0.88

[a]Some variables might not total 132 owing to missing data.

[b]*P* value derived using chi-square analysis comparing proportions in each category.

Figure 1. Proportion of persons who continued to use the app to input antiretroviral therapy adherence information after enrollment (N=47).

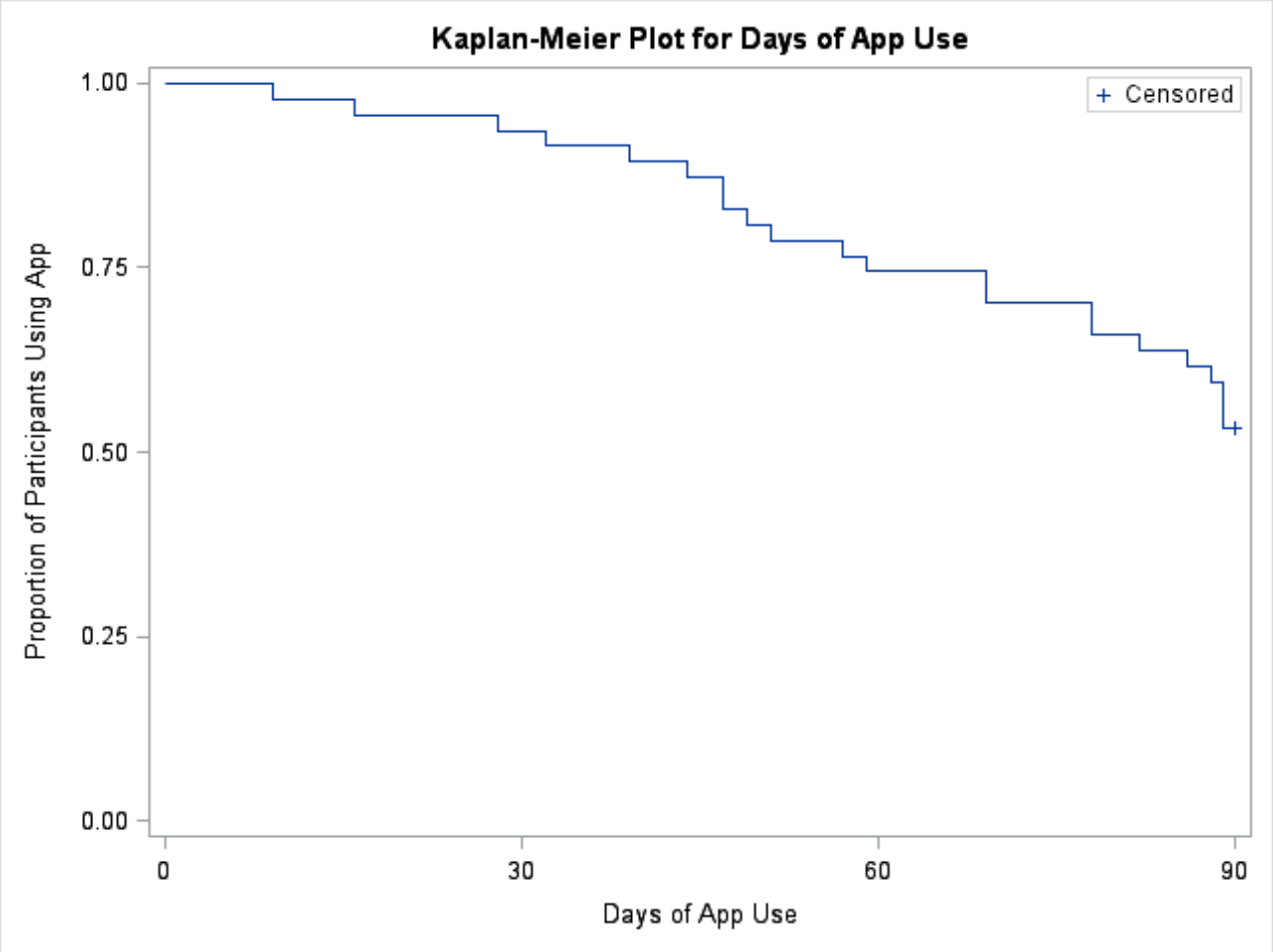

Table 2. Self-reported antiretroviral adherence and clinical parameters at 30- and 90-day follow-up among participants with <95% adherence at baseline (N=57).

Parameter	Users (n=19)[a]	Nonusers (n=38)[b]	*P* value[c]
Self-reported antiretroviral therapy adherence, n (%)			
30-day follow-up			.12
≥95%	13 (81)	17 (58)	
90-day follow-up			.73
≥95%	7 (46)	9 (40)	
HIV viral load , n (%)			
Baseline			.30
<40 copies/mL	12 (63)	17 (48)	
Follow-up			.74
<40 copies/mL	12 (75)	20 (69)	
CD4+ T-cell count , n (%)			
Baseline			.13
0-200 cells/mL^3	5 (26)	2 (5)	
201-500 cells/mL^3	6 (31)	14 (40)	
>500 cells/mL^3	8 (42)	19 (54)	
Follow-up			.36
0-200 cells/mL^3	4 (26)	3 (10)	
201-500 cells/mL^3	5 (33)	10 (34)	
>500 cells/mL^3	6 (40)	16 (55)	

[a]Some variables might not be total 19 owing to missing data.

[b]Some variables might not be total 38 owing to missing data.

[c]*P* value derived using chi-square analysis comparing proportions in each category.

Acceptability

Overall, at 30-day follow-up, there were 47 users who used the app at least once, of whom 39/47 (82%) liked or somewhat liked using the app, 1/47 (2%) did not like it, and 7/47 (15%) did not respond the question. Favorite features were medication reminders (n=25), ability to create custom reminders (n=5), adherence reports (n=5), and multiple features (n=4). Open-ended questions identified app features and technical issues that participants found challenging. The qualitative findings are available in Multimedia Appendix 1. Users reported that these issues kept them from using the app and could be improved for future use. Among these, lack of consistency in receiving reminders, characteristics of these reminders (eg, frequency, sound type, and duration), and inability to use all the features when not connected to the internet were main complaints and barriers to use. In terms of the features, users wanted more flexibility to report their medication taking, both if medication was taken a little early or a little late. Suggestions for improvement focused on enhancing the reminders in frequency, recurrence, or volume. Nevertheless, 36/47 users (80%) reported that they intended to keep using the Care4Today app.

Provider Survey

A total of 10 clinicians completed the survey: 5 nurse practioners and 5 physicians. The average age was 47.8 years (SD 15.6) with the majority being female (80%, 8/10) and white non-Hispanic (70%, 7/10). Of the 10 providers, 6 had over 10 years of experience working with PLWH, 1 had 6 to 10 years, and 3 had 5 years or less. Although 90% (9/10) of providers were either very or somewhat interested in reviewing adherence reports through the app, 80% (8/10) wanted to see these reports either monthly or quarterly (as opposed to daily or weekly). Finally, 5 providers (3 nurse practitioners and 2 physicians) had low to no interest in logging in to the provider interface to access the reports.

Discussion

Principal Findings

This longitudinal study found that a commercially available medication adherence mHealth app was a feasible and acceptable intervention to improve ART adherence among PLWH engaged in clinical care across 3 public HIV clinics in the state of Florida. To our knowledge, this is the first feasibility pilot study that used a free, commercially available mHealth app to improve medication adherence among PLWH. Overall,

participants liked the Care4Today app and favored the medication reminders feature. Generally, self-reports of ART adherence were better among users than nonusers, both at 30- and 90-day follow-ups, although the difference between groups was not statistically significant. Given the main goal of this study was to assess acceptability and feasibility of the intervention, we did not intend to demonstrate statistical significance of our findings. Rather, we sought to identify trends and factors that might inform a larger efficacy study. Importantly, although our findings do not support larger implementation of commercially available medication adherence apps for PLWH at this time, we did identify promising results in clinical outcomes that are commonly accepted proxies for efficacy (ie, self-reported ART adherence).

Among participants who had less than optimal ART adherence at baseline, over half of them started and kept using the intervention for the entire duration of the study. Although the drop-in usage between 30- and 90-day follow-ups might seem considerable when compared with previous research [30,47], some clarifications might help to interpret these findings. On one hand, study participants were not financially compensated to use the platform, and all usage was completely voluntary. On the other hand, almost half of the platform users already reported an ART adherence of ≥95% at baseline; therefore, some participants might have found the intervention less critical for their compliance than others. It would be appropriate to have future research on commercially available adherence apps looking more specifically at usage behavior of a larger group of persons with less than optimal ART adherence at the start of the study.

Of our participants with less than optimal ART adherence at baseline, the proportion of persons who reported good ART adherence at follow-up was higher among app users than nonusers. Although this difference was not statistically significant, this finding suggests that use of the app did improve medication taking, and this could be assessed with a larger clinical trial. Although self-reported ART adherence has been consistently associated with improved clinical outcomes, including viral suppression [48,49], most self-report measures are a proxy of true adherence and present some limitations. To address this limitation, we used a carefully validated measure of self-report ART adherence that is both simple and convenient for PLWH [44].

Participants' feedback focused on suggestions to improve features and technical aspects of the app. Among these, suggestions about personalized and customized reminder characteristics were paramount. Moreover, users wanted an app that would work even if they were off a wireless internet connection. These recommendations speak about the user's desire of more independence when using mHealth apps. However, these requests need to be balanced with the need to keep apps efficient and fun to use. Potentially, these objectives can be met with commercially available apps that are developed and maintained by dedicated personnel in charge of updating and enhancing app databases and features. On the contrary, providers' feedback showed clinicians see value in accessing self-reported adherence data from their patients during clinical visits. This seems to fit well with the clinical workflow; visits provide the opportunity to address adherence inconsistencies that may be reported through the mHealth app reports. However, in order for providers to retrieve these data on their own, mHealth apps should be able to easily communicate with information systems already being used by health professionals. Clinicians had less interest in viewing these reports on a daily or weekly basis. One potential way to link these reports into a workflow could be to establish a critical number of missing doses that would trigger an increased frequency of medication reminders, or suggestions for tele-consultations with clinical staff in advance of the next visit to address adherence inconsistencies promptly.

Limitations and Summary

Our work has several limitations. This study was conducted at 3 HIV clinics affiliated to the Florida Health Department. Thus, our findings cannot be generalized to sites that operate with different procedures for patient engagement and follow-up. However, our work is of interest given that these clinics draw from a distinct socioeconomic group of diverse backgrounds. Almost two-thirds of study participants were categorized as app nonusers, either because they declined to try the app at all, had problems downloading and using the app, or did not use it after downloading. As reported previously [43], interest in using the app was associated both with perceived benefits and with perceptions that someone at the clinic would assist them on how to use it. Although a detailed description of our study participants (both users and nonusers) is available elsewhere [43], we did not collect information on nonparticipants, who may have not participated because the study was not available in Spanish, they did not have the correct type of phone, or may have been concerned about costs for SMS services. Given the sample size of both app *users* and *nonusers*, we were limited in our ability to conduct subgroup analyses at this time. These would be valuable to further contextualize the app's utility in subpopulations of PLWH, and future research on commercially available medication adherence apps should consider assessing these differences. We noticed that almost 50% of participants had user fatigue throughout this 90-day pilot study. Active updates and app maintenance and a more robust contingency system (such as gamification) might help to sustain novelty and address this concern. ART adherence data relied on self-report. Future research should include not only a larger sample and experimental design, but also an objective measure of medication adherence.

In summary, Care4Today Mobile Health Manager, a commercially available, biprogrammatic medication adherence app that operates with both iOS and Android operating systems, as well as SMS, was found feasible and acceptable for improving ART adherence among PLWH during a 3-month longitudinal study. Further clinical research needs to address user fatigue to improve platform usage.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of responses to open-ended questions regarding the acceptability of the mobile health platform, Florida Mobile Health Adherence Project for People Living With HIV Study, 2016.
[DOCX File , 14 KB - mhealth_v8i1e14557_app1.docx]

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Abbreviations

ART: antiretroviral therapy
FL-mAPP: Florida mHealth Application Adherence Project
mHealth: mobile health
PLWH: people living with HIV

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Original Paper

Usability and Utility of a Mobile App to Improve Medication Adherence Among Ambulatory Care Patients in Malaysia: Qualitative Study

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Abstract

Background: To date, several medication adherence apps have been developed. However, the existing apps have been developed without involving relevant stakeholders and were not subjected to mobile health app guidelines. In addition, the usability and utility of these apps have not been tested with end users.

Objective: This study aimed to describe the usability and utility testing of a newly developed medication adherence app—Med Assist—among ambulatory care patients in Malaysia.

Methods: The Med Assist app was developed based on the Theory of Planned Behavior and the Nielson usability model. Beta testing was conducted from March to May 2016 at a primary care clinic in Kuala Lumpur. Ambulatory care patients who scored ≥40% on the electronic health literacy scale, were aged ≥21 years, and were taking two or more long-term medications were recruited. Two rounds of in-depth interviews were conducted with each participant. The first interview, which was conducted upon participant recruitment, was to assess the usability of Med Assist. Participants were asked to download Med Assist on their phone and perform two tasks (register themselves on Med Assist and enter at least one medication). Participants were encouraged to "concurrently think aloud" when using Med Assist, while nonverbal cues were observed and recorded. The participants were then invited for a second interview (conducted ≥7 days after the first interview) to assess the utility of Med Assist after using the app for 1 week. This was done using "retrospective probing" based on a topic guide developed for utilities that could improve medication adherence.

Results: Usability and utility testing was performed for the Med Assist app (version P4). A total of 13 participants were recruited (6 men, 7 women) for beta testing. Three themes emerged from the usability testing, while three themes emerged from the utility testing. From the usability testing, participants found Med Assist easy to use and user friendly, as they were able to complete the tasks given to them. However, the details required when adding a new medication were found to be confusing despite displaying information in a hierarchical order. Participants who were caregivers as well as patients found the multiple-user support and pill buddy utility useful. This suggests that Med Assist may improve the medication adherence of patients on multiple long-term medications.

Conclusions: The usability and utility testing of Med Assist with end users made the app more patient centered in ambulatory care. From the usability testing, the overall design and layout of Med Assist were simple and user friendly enough for participants to navigate through the app and add a new medication. From the participants' perspectives, Med Assist was a useful and reliable tool with the potential to improve medication adherence. In addition, utilities such as multiple user support and a medication refill reminder encouraged improved medication management.

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KEYWORDS

medication adherence app; usability testing; utility testing

Introduction

Background

Medication adherence is defined as the "extent to which a person's behaviour-taking medication, following diet, and/or executing lifestyle changes corresponds with agreed recommendations from a healthcare provider" [1]. Unintentional nonadherence to medications is an important issue that needs to be addressed among ambulatory care patients, as they are responsible for the procurement and correct administration of their own medication(s) [2]. Nonadherence to medications not only affects patient clinical health outcome, but also patient safety, health care costs, and health care service utilization [1]. In the United States, 50%-71% of ambulatory care patients have two or more chronic diseases, which increases their risk of medication administration errors [3] such as taking unauthorized medications, taking an extra dose or the wrong dose, taking medications at the wrong time or frequency, or omitting a dose [4,5]. The prevalence of nonadherence to long-term medications in developed countries ranged from 50% to 70% [1,3], while in developing countries, the rate of nonadherence ranged from 40% to 80% [1,6,7]. Studies in Malaysia reported that 47%-53% of patients were nonadherent [8,9]. Most errors that occur in ambulatory care setting are preventable [10], and medication administration–related errors represent the largest component of preventable medication errors [11]. However, little is known about the extent of medication administration–related errors in the ambulatory care setting, as most studies were conducted in an inpatient setting [1,12,13].

Several interventions have been developed to improve medication adherence and reduce medication administration–related errors [14,15]. However, these interventions have varying success rates. These interventions usually involve a health care professional (doctor, pharmacist, or nurse) in preparing the patient's pillbox, providing patient counselling and education [16,17], simplifying the medication regime [18], involving the patient in shared decision making [19], or improving patient-provider communication [14,15].

In recent years, mobile health (mHealth)—defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [20]—has provided a new platform that could improve a patient's medication adherence [21] (defined as "the extent to which a person's behaviour- taking medication, following a diet, and/or executing lifestyle changes corresponds with the agreed recommendations from a health care provider") [1]. Mobile apps have the potential to improve medication adherence and management of medications [22,23] through an active reminder system [24].

To date, several smartphone medication adherence apps have been developed [25]. However, existing apps were developed without involving relevant stakeholders (such as health care professionals or patients) [24,26] and were not subjected to mobile health app guidelines [23,27]. This may have resulted in some apps being "sub-standard" [27-29]. Some existing apps are also commercial in nature, requiring a subscription fee; are available only in one operating software platform; or can only be used in countries where it was developed [25]. Usability is defined as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [30]. Utility is defined as the functionality of the app and how useful it is to users [31]. To the best of our knowledge, no study has assessed the usability and utility of a medication adherence app once it has been developed.

Objectives

This study aimed to assess the usability and utility of a newly developed medication adherence app—*Med Assist*—among real end users.

Methods

Study Design

A qualitative methodology was utilized to obtain an in-depth understanding of end users' experiences when using *Med Assist* from the usability and utility aspects.

Beta Testing in the Development Phase

The development phase consisted of two parts: alpha and beta testing. Alpha testing involved testing the design of *Med Assist* using a conceptual framework (Figure 1), which combined the Theory of Planned Behavior and the Nielson usability model and a utility model. To the best of our knowledge, existing frameworks on the design of mobile apps solely focused on the usability of the app. Most medication adherence apps did not incorporate health behavior theories [32]. We decided to develop our own framework, as we wanted to incorporate both the usability and utility of *Med Assist*. Additionally, our framework also included factors that could affect medication adherence. The design of Med Assist was also based on the utilities requested by the steering committee (Table 1).

Figure 1. The conceptual framework for the design and development of Med Assist based on the Theory of Planned Behavior and the Nielson Usability Model.

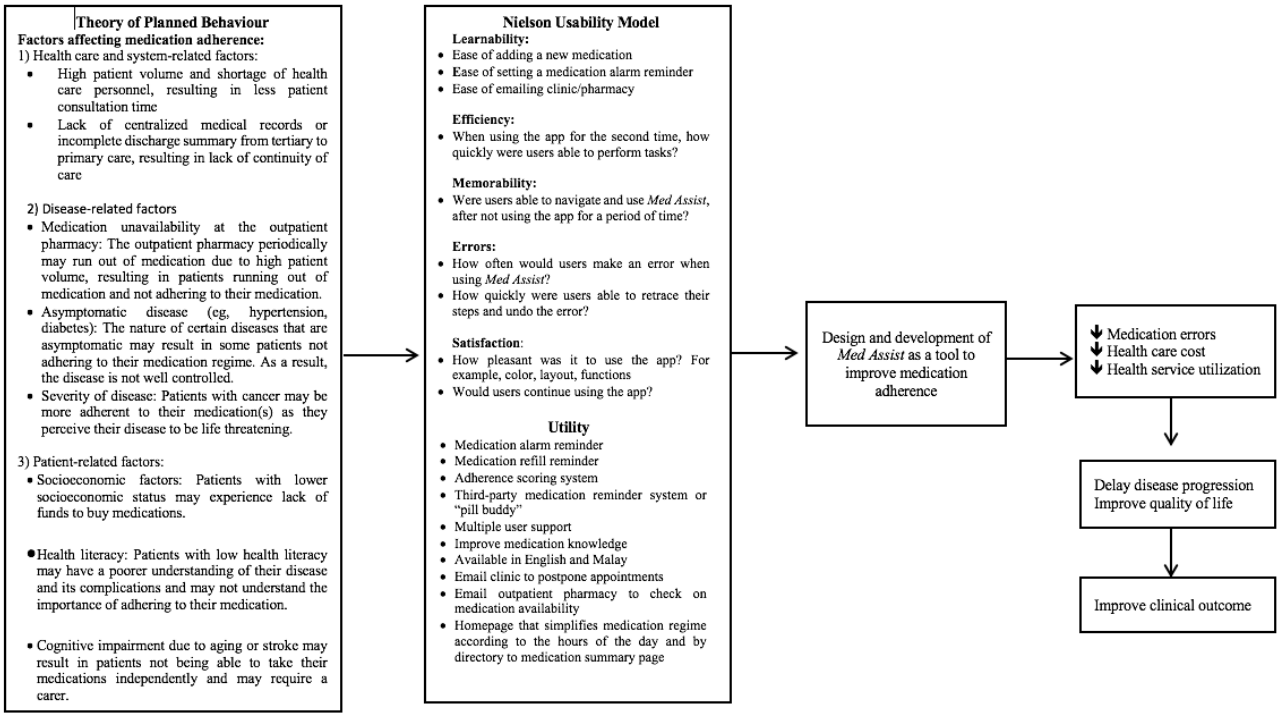


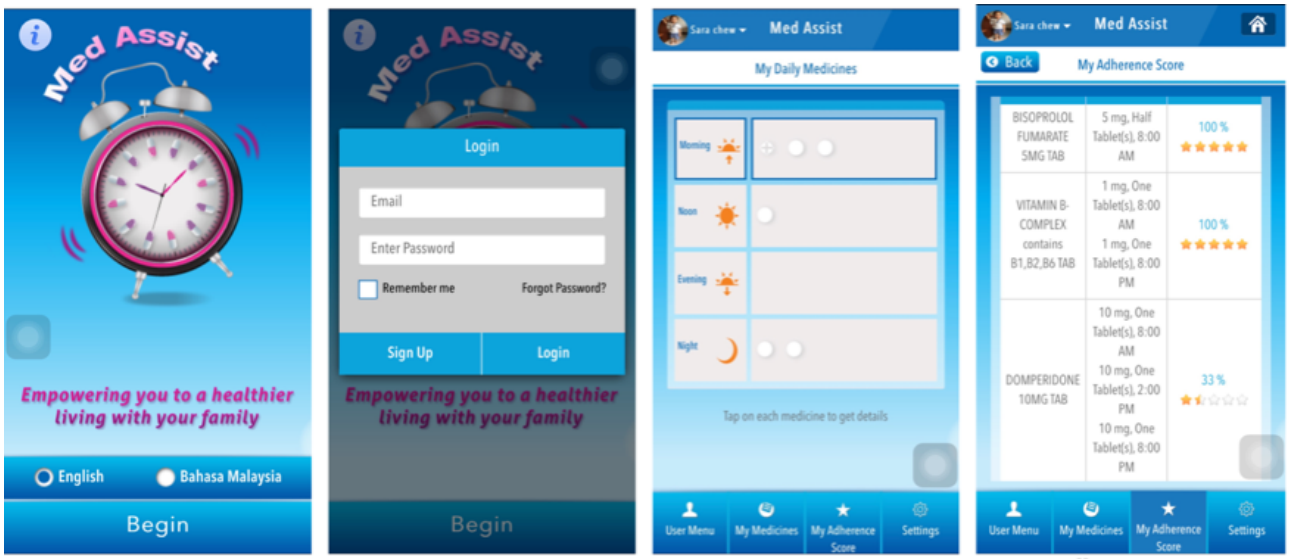
Table 1. Summary of the preferred features and utilities of Med Assist.

Utility	Description
Specific medication reminder	Users will be able to set specific medication reminders with a personalized tone
Specific medication refill reminders	Users can set specific medication refill reminders, which prompt users to procure a prescription refill before running out of medications.
Complex medication regime	Ability to aid patients in managing complex medication regime.
Adherence scoring system	Users are able to calculate their adherence to medications. A 100% adherence to medications is displayed as five stars.
Multiple user support	Users can enter another individual's list of medications in addition to their own.
Third party reminder or "pill buddy"	This function allows a family member to receive text message notification stating that the user has missed three consecutive medication reminders.
Contact clinic or pharmacy by email	Users can contact the clinic receptionist via email to postpone an appointment or the outpatient pharmacy to check on medication availability. This maximizes appointment schedules and allocates last-minute vacant slots to other patients.
Available in dual language	*Med Assist* is available in English and Malay to reach out to a wider group of users in Malaysia.

Setting and Study Period

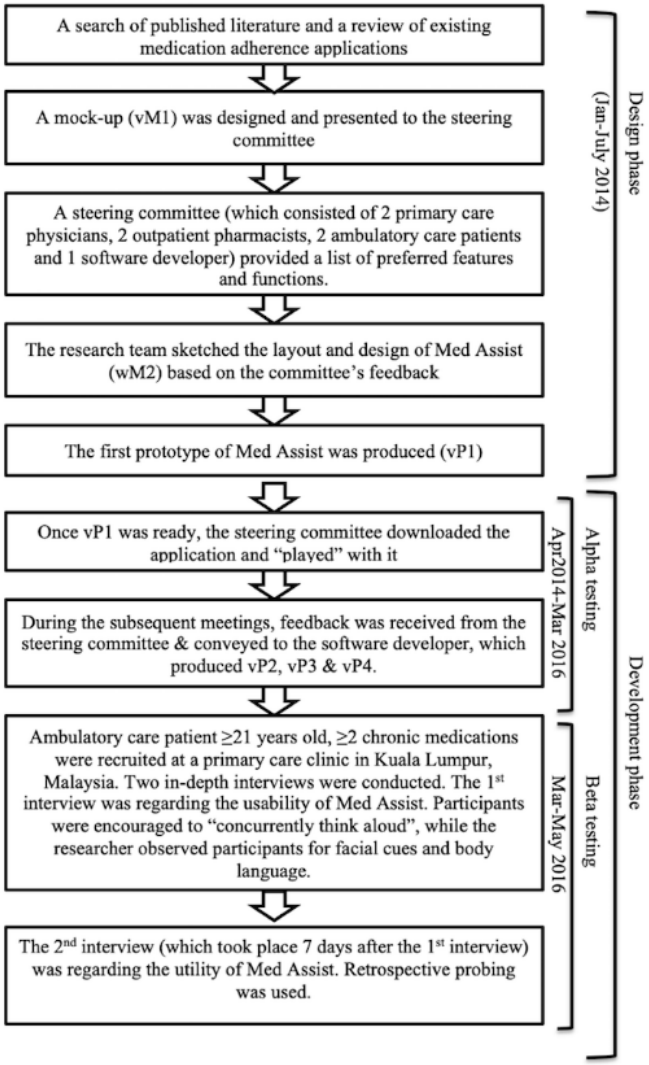
Med Assist vP4 (Figure 2) was the version used for beta testing. Beta testing was conducted from March to May 2016 (Figure 3). The first round of in-depth interviews was conducted at a primary care clinic in Kuala Lumpur, while the second round of in-depth interviews was conducted at a location convenient to the participants (eg, at their homes, a café nearby). In-depth interviews were conducted so that we could explore the views of participants regarding the usability and utility of Med Assist when using it for the first time. We asked participants to "concurrently think aloud," so that their impressions and difficulties encountered could be recorded on the tape recorder. We also supplemented this interview process by observing the participant and documenting these observations as field notes. This allowed us to understand if they encountered any difficulties and whether they liked or disliked the utility. In-depth interviews allowed us to focus on the individual, assist the individual in using Med Assist, and create an environment where the individual would be able to express his/her views without being influenced by others.

Figure 2. The start, registration, homepage, and adherence score of Med Assist (vP4).



A: Start page B: Registration page C: Homepage D: Adherence score

Figure 3. Flowchart of Med Assist design and development.



Participants

We included participants who had an electronic health literacy score of ≥40%, who understood English or Malay, and were taking two or more prescribed medications for their chronic condition. We excluded participants aged <21 years or who had mental disabilities. Purposive sampling was used to recruit older (≥65 years of age) and younger (<65 years of age) participants, as we wanted the experiences of older participants who may have more comorbidities, but may not be comfortable in using mobile apps, as well as younger participants who may have lesser comorbidities (than older persons) but may be more comfortable with using mobile apps. The purpose of recruiting participants based on age was to obtain a wider perspective when using *Med Assist*.

Research Instruments

Topic Guide

A topic guide based on the Nielson usability model [33] and utility model was used to guide the in-depth interviews. This ensured that participants were asked for their experiences in terms of all aspects of user interface and user experience.

During the first interview, the usability of *Med Assist* was explored using the topic guide based on the Nielson usability model. This model was used, as it explored five components of usability: learnability (ease of navigating and using the app for the first time), efficiency (ease and speed of users navigating and using the apps for the second time), memorability (how much users remember regarding the use of the app after not using it for some time), errors (how often users would make an error using the app and how quickly they were able to retrace their steps and undo the error), and satisfaction (how pleasant the app was and if users continue would using it).

During the second interview, the utility of *Med Assist* was explored using a topic guide based on the utilities of *Med Assist* that would improve medication adherence and management, as decided by the steering committee during the design phase of *Med Assist*.

Med Assist Handbook

A *Med Assist* user manual (ie, a step-by-step guide on how to use *Med Assist*) was developed by the researcher and given to participants upon recruitment. This was to help participants explore *Med Assist* in their own time.

E-Health Literacy Scale

The electronic health literacy scale (eHEALS) was used to assess participants' literacy skill in using their smart devices to find health-related information on the internet [34]. eHEALS, which consists of eight items, with a 4-point Likert scale, has been validated in Malaysia [34]. Participants who scored a higher eHEALS score indicated that they had higher literacy skills in using the internet as a resource to obtain more information.

Ethics Approval

Ethics approval was obtained from the University of Malaya Medical Ethics Committee prior to the study (MECID no. 20143-12).

Data Collection Process

A researcher approached participants who were "using" their smartphone while waiting to see their doctor. Participants were asked several "screening questions" such as "how often do you use your smartphone?" "what do you use your smartphone for?" "do you use any smartphone applications?" and "if yes, what applications do you use?" These questions were asked, so that the researcher could identify participants who used their smartphone as more than just a telecommunication device. For those who agreed to participate, written informed consent was obtained. Participants were then asked to fill in the demographic form and the eHEALS.

Each participant was interviewed twice. During the first interview, participants were encouraged to "concurrently think aloud" [35]. This method was employed so that the "first impression" of using *Med Assist* would be captured [35]. This enabled the researcher to capture any possible navigation issues that may arise from the end users' perspective. The researcher took detailed notes and observed for nonverbal cues during each interview. Facial expressions and body language that were portrayed subconsciously by the participants were noted down by the researcher. Participants were encouraged to voice their first impressions and opinions about the app [36].

Participants were "probed retrospectively" during the second interview [35]. This was done by prompting participants with questions regarding the utilities of *Med Assist*. The researcher took detailed notes and observed for nonverbal cues. All interviews were audio recorded.

Participants were recruited until data saturation occurred. Data saturation was defined as "no new themes or codes emerging from interviews." This was established when the next three participants recruited provided perspectives that were previously highlighted by other participants [37].

Data Analysis

All interviews were transcribed verbatim. One researcher (SC) immersed herself in the data. An interpretive-descriptive approach was used to identify the themes that emerged from the data. This approach was used to obtain a deeper understanding of the usability and utility of *Med Assist* from the participants' perspectives and experience of using the app. The researcher (SC) reflected on the data and began constructing an interpretive account of what the codes signified from the participants' perspective and its application into clinical practice [38]. Four transcripts were first coded using the interpretive-descriptive approach that was based on the Nielson usability model and the utility model. This was done independently from the research team. SC also referred to the field notes for reflections, facial cues, and body language observed during the interviews. The research team then met to discuss the coding of the transcripts. Any coding discrepancies were resolved through discussion until a consensus was reached. Coding of the transcripts was performed using NVIVO v10 (QSL International Pty Ltd, Melbourne, Australia). Nodes were organized under larger categories, and the research team discussed the themes that emerged from the categories.

Results

Participants

A total of 13 participants (6 men, 7 women) were recruited (Table 2) for the first interview. Only 12 participants were interviewed consecutively (which occurred 2 weeks later), as one declined participation.

Usability Testing

Three themes emerged from usability testing. They were challenges encountered when adding a new medication, with regard to patients' understanding of their complex medication regime, and on the medication summary page.

Challenges Encountered When Adding a New Medication

Several subthemes emerged under this theme: confusion by terms used when adding medications into *Med Assist*, unfamiliarity with entering the generic name of the medication, and patients' understanding of their complex medication regime.

Table 2. Demographic characteristics of participants recruited for beta testing.

ID[a]	Gender	Age (years)	Ethnicity	Level of education	Number of medication(s)	Patient/carer	iPhone/android user	eHEALS[b] score (%)
P1	Male	66	Chinese	Secondary	3	Patient/carer	iPhone	84.4
P2	Female	29	Eurasian	Secondary	_[c]	Carer	Android	75.0
P3	Female	43	Chinese	Tertiary	4	Patient	Android	59.4
P4	Female	55	Indian	Secondary	2	Patient	Android	75.0
P5	Female	72	Malay	Tertiary	2	Patient	Android	75.0
P6	Male	56	Indian	Tertiary	3	Patient	iPhone	90.6
P7	Male	72	Malay	Secondary	4	Patient	Android	68.7
P8	Male	62	Chinese	Tertiary	6	Patient	Android	75.0
P9	Female	42	Malay	Tertiary	3	Patient	Android	46.9
P10	Female	64	Malay	Secondary	2	Patient/carer	Android	78.0
P11	Female	57	Indian	Tertiary	2	Patient	Android	50.0
P12	Female	27	Malay	Tertiary	4	Patient	Android	56.0
P13	Male	44	Malay	Tertiary	5	Patient	Android	75.0

[a]ID: identification.

[b]eHEALS: electronic health literacy scale.

[c]Not available.

Confusion by the Terms Used in Med Assist

Two terms—"timing" and "variable dosing"—confused most participants. In *Med Assist*, "timing" referred to the frequency with which users were required to take their medications (ie, daily or twice a day) rather than the time (ie, 7 AM) that they had to take their medications. Some participants understood what the term implied upon tapping on it.

> *Hmm..(Participant was initially confused by the term, but able to figure it out on her own) (taps on "timing) okay…once a day.. (participant thinks aloud)...* [47 years old/female/android user/P3]

> *How do I specify the frequency to take my medication? What does "timing" mean? What do I put here? (taps on timing) Oh I see!* [72 years old/male/iOS user/P7]

"Variable dosing" is a feature in *Med Assist* that allowed users to enter medications that are prescribed at different doses in one day; for example, 1700 mg metformin mane (taken in the morning) and 850 mg metformin nocte (taken at night). All participants were confused by this term, as most participants did not have medications with variable dosing. However, one participant who was prescribed 1700 mg metformin mane and 850 mg metformin nocte had no problems in entering metformin into *Med Assist* once the function of "variable dose" option was explained to him.

> *Okay...variable dose how...[taps on variable dose, switching it on]...850...take two tablets...no, strength is 850, strength supplied is 850 and strength to take is 850. I'm taking two tablets what...[after researcher helps him]...timing...twice a day, okay good...* [56 years old/male/android user/P6]

Unfamiliarity With the Generic Name of the Medication

When entering medication details into the app, most participants knew their medication by the brand name, but not by its generic name. *Med Assist* requires users to enter the generic name of the medication, as the pharmacy label only contains the generic name. Using generic names reduces the risk of confusion among patients, as different pharmacies may stock different brands of the same medication.

> *I'm not too sure what is the name of my medication. I know it by its brand name. I do know what the medication is for so having the indication automatically linked to the medication name is good to have.* [72 years old/female/android user/P5]
>
> *This part, I am not sure of the name of my medication, for example my cholesterol tablet, simvas or something.* [47 years old/female/android user/P3]

Patients' Understanding of Their Complex Medication Regime

One participant was prescribed 75 µg levothyroxine daily but was supplied with 50 µg and 25 µg tablets. The participant was aware that she was supplied with two different strengths but was unaware that she had to enter the medication (levothyroxine) twice into *Med Assist*, treating 50 µg and 25 µg levothyroxine as two separate medications.

> *For strength prescribed it is 75 µg but I am given 50 µg and 25 µg by the pharmacy. Okay so for strength to take I should enter 75 µg because that is what I am taking, but the app won't let me enter 75 µg. Why is that?* [54 years old/female/android user/P4]

Most participants understood their medication regime and the reason for taking their medication.

> *Yes I do know my medication regime better after using Med Assist. I have previously been relying on my wife who takes care of my medication supply and gives me my tablets in the morning.* [44 years old/male/android user/P13]

Medication Summary Page

Once all the details of the medication were entered, a summary page appears. The medication summary page could be accessed from the home page by tapping on the medication icon. All participants found this feature useful, as a list of all the medications that they had to take was summarized onto one page.

> *Oh having a medication summary page makes sense. This is very useful, makes the information simplified and more organized. It's nice to have this feature.* [64 years old/female/android user/P10]

Utility Testing

Two themes emerged from the utility testing of *Med Assist*. They were utilities that could improve medication adherence and the management of medication(s).

Utilities That Could Improve Medication Adherence

Three subthemes emerged: a medication alarm reminder system, an adherence scoring system, and the pill buddy option.

A Medication Alarm Reminder System

All participants found the medication alarm reminder useful, including the customizable alarm tone. One participant expressed concern that if the device was not with the user when the alarm rang, the alarm reminder would not have reminded the user to adhere to his/her medication regime. However, a snooze option was available on the medication reminder, which would remind users to take their medication at a later time. Another participant was unsure what time he/she could fix the reminder, as he/she did not have a fixed daily schedule.

> *Oh yes this was helpful. It prompted me to remind my mum to take her medications.* [34 years old/female/android user/P2]
>
> *Because I know… being ladies you tend to leave your handbag in the bedroom and you're wandering around in the house and all that so I … the times that I actually took my phone with me, it does ring, it does ring that (short) tone beep. So if I were busy doing something else, I would have just missed it and of course it wouldn't serve its purpose.* [47 years old/female/android user/P3]
>
> *Oh dear, the problem with setting the reminder is that I don't have set times. It would have to depend on what time I wake up in the morning and go to bed in the evening, which varies day to day.* [62 years old/male/android user/P8]

A Medication Adherence Scoring System

Of the 13 participants, 7 were not aware that *Med Assist* could calculate their adherence score when they reported that they had taken their medication. However, one participant/caregiver who was adherent to her medications was shocked when her adherence score was zero. She then realized that *Med Assist* calculated her adherence score as 0, because she did not acknowledge that she had taken her medication by tapping on the medication reminder.

> *I'm sorry what was that? Oh! I wasn't aware of that. So this would show what medications I have missed and when? And I am rated based on my adherence?* [66 years old/male/iOS user/P1]
>
> *Huh? I didn't take my medicine? But...if I didn't take my medicine, my husband also didn't take the medicine? [This participant used the multiple user support feature] (After explanation) Oh that means each time I must tap on 'take medicine.' I didn't know...*" [64 years old/female/android user/P10]

The Pill Buddy System

The pill buddy system allowed family members of a user to check that they had taken their medications remotely. Family members added as a "pill buddy" in the app will be sent a text message when the user missed taking their medication three times consecutively. Users who were caregivers found this feature useful, as they were able to "monitor" family members remotely.

> *Oh this is good. It allows me to keep an eye on my mum even when I am not with her.* [34 years old/female/android user/P2]
>
> *Oh I didn't really explore that. I used the app for personal use only.* [47 years old/female/android user/P3]

Utilities to Improve the Management of Medications

Only one subtheme emerged: multiple user support system.

Multiple User Support

Participants who were not only patients but also caregivers were pleased to be able to enter medication details of the person under their care in the same app.

> *Oh I used this function to enter a separate profile for my mum's medications. And it was amazing. It had all the tablet icons on the homepage and its own alarm reminder.* [34 years old/female/android user/P2]

Discussion

Principal Findings

From this study, three themes emerged from the usability testing of *Med Assist*, while another two themes emerged from the utility testing of *Med Assist*. *Med Assist* was designed and developed using the waterfall lifecycle software model. This model comprised five phases: users' requirements, design, development of the software (*Med Assist* app), testing of the software app, and its release. The requirement phase was based on utilities that could improve medication adherence. This led to the design and development of *Med Assist* until the steering committee was satisfied with the prototype. The final prototype (version P4) was used for the beta testing of *Med Assist*. This paper focuses on the usability and utility (beta) testing of *Med Assist* where ambulatory care patients were recruited to use the app and provide feedback. *Med Assist* was designed for both iOS and android operating software systems. *Med Assist* was developed to be compatible with the technology (hardware and software) available in smart devices at the time of this study.

The steps to add a medication were simplified and displayed in a hierarchical order to prevent cognitive overload [39]. However, some participants struggled when adding a new medication due to the complexity of this task. Data input into a small device is challenging, as it requires the user to navigate through the app on a small screen [40]. In addition, the information displayed in a smaller screen device is crucial and needs to be in a hierarchical order [41]. This will ensure that users are able to process information without being overloaded or losing navigational direction when using the app [39,41]. Despite the challenges encountered by patients, the process of adding a new medication "manually" benefited patients with regard to their medication knowledge. Participants had to "learn" the generic name of their medications, administration frequency, and the purpose of their medication. In Malaysia, mandatory generic substitution is practiced by all public hospitals. Hospital outpatient pharmacies are required to only dispense generic medications regardless of the brand prescribed. At the time of this study, there were no published studies that reported the findings on medication data entry in an adherence app. Further research needs to be performed to fill this gap, as complex data entry can deter users from using the app [42].

The terms used in a medication adherence app should be self-explanatory. Although health care providers were involved in the design of *Med Assist*, the terms used in *Med Assist* confused participants. The term "timing" confused participants, as they thought that they had to enter the time that they took their medications. "Variable dosing" was added to offer flexibility to patients who were prescribed medications with variable dosing (eg, metformin). Individuals with lower literacy may require assistance when encountering such complex terms. This may lead to incorrect medication data entry, which compromises patient safety, leading to medication error and increased health care service utilization such as hospitalization and costs. One solution to improve the usability of *Med Assist* would be to have a "question mark icon" over the term, so that users could tap on the icon, which would then provide a brief explanation. The simplicity of the icon needs to be recognizable at a glance [43] and improve the user's experience [40].

To our knowledge, no other study has reported the experiences of participants when using a medication adherence app. Participants also reported that the medication summary page, which was accessible through tapping on the medication icon on the homepage of *Med Assist* was useful, as it provided a concise overview of their medication details. This would further enhance the usability of *Med Assist*, as it would be more patient centered and more likely to be adopted.

Several studies have shown that behavioral change is achievable through active reminders, which reinforces the benefits of medication adherence apps [24,44]. A review in 2016 found that only 56% of medication adherence apps accommodate flexible scheduling for medication reminders [29]. Medication reminders with flexible scheduling (where users may opt for alternate days or weekly medication reminders) allows for personalization of the app to suit their individual needs. Participants also reported that they had a better understanding of the medication regime frequency and the indication of the medication, which appeared on the alarm reminder, thereby improving their medication knowledge. Improved patient knowledge is known to improve medication adherence and patient clinical health outcome [45]. However, areas involving strategies to improve patients' medication knowledge requires further research [45,46]. Another useful utility was the multiple user support. Participants who were caregivers found this utility useful, as they were able to keep a separate profile and individualized a patient's medication regime on the profile without affecting their own medication regime.

A review on mHealth apps found that most apps were based on a one-way reminder system (which sent reminders to users to take their medications) [32]. *Med Assist* offers a "snooze option," which allowed users who were unable to take their medications at that point of time to take their medications later (ie, a two-way alarm reminder system). *Med Assist* required users to acknowledge the reminder that, theoretically, would make users more conscious of their adherence to their medications [32]. The medication alarm reminder actively prompted participants to take their medications correctly and on time. However, users who were aware of the adherence scoring system missed acknowledgement on the medication reminder. This resulted in their low adherence scores.

The adherence score serves as a gamification process (a process where the user is rewarded upon achieving the goal of the app) [47], which engaged users. Participants who knew about this feature were pleased that they were able to keep track of their adherence to their medication regime. A study on the design of

an mHealth app for type 1 diabetes found that engaging users through a gamification process improved patient mediation adherence behavior [48].

In the Asian community, it is common for working adults to look after their elderly parents [49]. For younger individuals who still live with their elderly parents, the multiple user support function was a utility that enabled a separate profile to be created in addition to the patient's own profile. Many working adults migrate to bigger cities to seek employment. Therefore, being present physically to ensure that their parents take their medications becomes difficult [50]. The pill buddy system allowed individuals to remotely check on their elderly parents' medication adherence behavior. Although external monitoring utilities such as multiple user support and pill buddy system enable a third party to be more involved in patient care, a review in 2018 found that such functions were underutilized [46]. Future research could assess the external monitoring utilities, as they have the potential of improving patient medication adherence and its impact on patient clinical outcome.

Strengths and Limitations

This study used a two-phase in-depth interview for the data collection process, which allowed us to explore patients' and caregivers' experience and perspectives in using the app for the first time and its utility after a period of using the app. To the best of our knowledge, no other medication adherence apps have conducted a similar study [46]. The usability and utility testing of *Med Assist* allowed us to understand the needs of ambulatory care patients and caregivers better and tailor *Med Assist* to suit their needs. This ensured that *Med Assist* would be a more patient-centered app and more likely to be used [31]. In addition, the wide demographic range of participants of this study provided experiences of both young and old users.

The generalizability of this study is limited by the use of a local hospital medication database. Although this simplified the entry of new medications into *Med Assist* (as a drop-down menu would appear and link to the indication of the medication), it limited the use of *Med Assist* to the local health care setting. There were several utilities of *Med Assist* that were not explored due to the short period between the two-phased in-depth interviews, such as medication refill reminders and the option to email health care professionals (ie, doctor, pharmacist). Future studies should have a longer time frame between the usability and utility testing to fully explore end users' perspectives and experiences when using a medication adherence app. All participants recruited were from Kuala Lumpur (ie, a major city in Malaysia). A wider participant recruitment process should be carried out to explore the experiences and perspectives of rural end users. Due to time constraints, we were unable to incorporate the perspectives of the users in beta testing to modify *Med Assist* and retest *Med Assist* before progressing to the release phase.

Conclusions

Our study found that the overall design and layout of *Med Assist* was simple and user friendly enough for participants to navigate and complete certain tasks. However, the process of adding a new medication was confusing for some participants and may require assistance features; The flexible medication alarm reminder and pill buddy system encouraged a positive change in patients' medication adherence behavior. In addition, participants reported that the multiple user support and medication refill reminder encouraged better medication management. Our study suggests that *Med Assist* could aid ambulatory patients who are on long-term medications to improve medication adherence through active reminders.

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Conflicts of Interest

None declared.

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Abbreviations

eHEALS: electronic health literacy scale
mHealth: mobile health

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Original Paper

Effect of 5-Minute Movies Shown via a Mobile Phone App on Risk Factors and Mortality After Stroke in a Low- to Middle-Income Country: Randomized Controlled Trial for the Stroke Caregiver Dyad Education Intervention (Movies4Stroke)

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Abstract

Background: Pakistan is the sixth most populous nation in the world and has an estimated 4 million stroke survivors. Most survivors are taken care of by community-based caregivers, and there are no inpatient rehabilitation facilities.

Objective: The objective of this study was to evaluate the effectiveness and safety of locally designed 5-min movies rolled out in order of relevance that are thematically delivered in a 3-month program to deliver poststroke education to stroke survivor and caregiver dyads returning to the community.

Methods: This study was a randomized controlled, outcome assessor–blinded, parallel group, single-center superiority trial in which participants (stroke survivor-caregiver dyads) with first-ever stroke (both ischemic and hemorrhagic) incidence were randomized within 48 hours of their stroke into either the video-based education intervention group or the control group. The video-based education intervention group had health education delivered through short videos that were shown to the participants and their caregivers at the time of admission, before discharge, and the first and third months of follow-up after discharge. The control group had standardized care including predischarge education and counseling according to defined protocols. All participants enrolled in the video education intervention and control groups were followed for 12 months after discharge for outcome assessment in the outpatient stroke clinics. The primary outcome measures were the proportion of participants achieving control of blood pressure, blood sugar, and blood cholesterol in the video intervention versus the control group. Several predefined secondary outcomes were included in this study, of which we report the mortality and functional disability in this paper. Analysis was by performed using the intention-to-treat principle.

Results: A total of 310 stroke survivors and their caregiver dyads (participant dyads) were recruited over a duration of 6 months. In total, 155 participant dyads were randomized into the intervention and control groups, each. The primary outcome of control of three major risk factors revealed that at 12 months, there was a greater percentage of participants with a systolic B*P*<125 mm Hg (18/54, 33% vs 11/52, 21%; *P*=.16), diastolic B*P*<85 mm Hg (44/54, 81% vs 37/52, 71%; *P*=.21), HbA_{1c} level<7% (36/55, 65% vs 30/40, 75%; *P*=.32), and low-density lipoprotein level<100 mg/dL (36/51, 70% vs 30/45, 67%; *P*=.68) in the intervention

group than in the control group. The secondary outcome reported is the mortality among the stroke survivors because the number of stroke-related complications was higher in the control group than in the intervention group (13/155, 8.4% vs 2/155, 1.3%), and this difference was statistically significant (P<.001).

Conclusions: The Movies4Stroke trial failed to achieve its primary specified outcome. However, secondary outcomes that directly related to survival skills of stroke survivors demonstrated the effectiveness of the video-based intervention on improving stroke-related mortality and survival without disability.

Trial Registration: ClinicalTrials.gov NCT02202330; https://www.clinicaltrials.gov/ct2/show/NCT02202330

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KEYWORDS

stroke; mobile health; noncommunicable diseases; adherence

Introduction

Background

Stroke is the second leading cause of death globally and the principal cause of acquired disability in adults. About two-thirds of this burden is endured by the developing world [1].

Noncommunicable diseases (NCDs) are the biggest contributors to the rising incidence of stroke. Around 90.5% of the global stroke burden is attributable to modifiable risk factors, including 74.2% attributed to behavioral factors (smoking, poor diet, and low physical activity). In addition, hypertension, type 2 diabetes mellitus, and coronary artery disease are important modifiable risk factors for stroke [2]. Pakistan also has a disproportionate burden of stroke and NCD risk factors. At present, around 1 in 4 adult Pakistanis has hypertension or diabetes, heart disease, or a stroke equivalent, with most being unaware of their risks [3]. A local study investigated the prevalence of stroke in Pakistan among adult Pashtun population and reported a prevalence of 4.8%, which is equal to 4 million persons affected in a country with a population of 180 million [3].

Studies that describe the outcomes of stroke survivors in this setting report that at a median of 5.5 months after discharge, 12.3% of the patients had died, mostly from recurrent vascular events or stroke complications. Poor functional outcome, defined as Modified Rankin Scale (mRS) score>2, was seen in 51% of the study participants, and cognitive outcomes were poor in 42% of the survivors [4].

In a country of a population of 180 million, roughly only 23 centers exist to provide physical medicine or help with rehabilitation; most have not adopted a multidisciplinary approach toward patients, and none have inpatient services [5]. Currently, there are no organized home care survival programs involving primary caretakers for stroke survivors in Pakistan.

Despite these challenges, there is potential to leverage mobile technology to improve stroke outcomes. Pakistan has widespread mobile connectivity, with a cellular density of 77% [6]. These infrastructure enablers create distinct opportunities for mobile health (mHealth). Our rationale was to leverage information technology (IT)–based mHealth to provide a solution and knowledge and direct skills to the survivor and caregiver where the provision of chronic care is rudimentary.

Objective

In this study, we aimed to evaluate the effectiveness and safety of locally designed 5-min movies rolled out in order of relevance that are thematically delivered in a 3-month program to deliver poststroke education to stroke survivor and caregiver dyads returning to the community. We hypothesized that the absence of trained personnel in the health community could be mitigated by actually providing high-quality repetitive training using audio visual aids that served as a checklist for competency and survival skills to the stroke survivor and caregiver dyad [7,8].

Methods

Study Design

A randomized controlled, outcome assessor–blinded, parallel group, single-center superiority trial was conducted to assess the efficacy of mobile phone video–based IT intervention for controlling 3 major risk factors–blood pressure [BP], blood glucose, and cholesterol—among adult stroke survivors. Important secondary outcomes included postdischarge mortality attributable to stroke and measures of functional disability. Our detailed protocol has been published separately [9].

Study Site

This trial was conducted in the Stroke unit, Neurology Ward, Aga Khan University Hospital (AKUH), Karachi, Pakistan. AKUH is an internationally recognized tertiary care institution, certified by Joint Commission International Accreditation, and caters to the needs of a large multiethnic urban population of 18 million people. Stroke care follows international protocols, with defined order sets and standardized pathways.

Participants

The sample population comprised adults (aged>18 years) admitted to AKUH with first-ever acute stroke and having a designated caregiver, meeting the eligibility criteria, and giving informed consent.

The criteria used while recruiting participants and caregivers at the initial phase of the selection process are listed below.

Eligibility Criteria

The eligibility criteria have been presented in Textboxes 1 and 2.

Textbox 1. Inclusion criteria.

- Adult men and women aged ≥18 years of age
- Residents of Karachi and planning to live in Karachi till the follow-up period
- Able to understand Urdu (language of the videos) and the national language
- Admitted with first-ever stroke (ischemic or hemorrhagic)
- Modified Rankin Scale score≤4 (mild to moderate disability)
- Having at least one vascular risk factor that requires medical intervention
- Consenting to participate in the study and for follow-up visits, both stroke survivor and caregiver
- Have a designated caregiver at home who is responsible for appointments, follow-up, and overall care and are mobile phone literate, for example, wife, daughters, daughter-in-law, and husband
- Stroke was medically stable, and participant was likely to return to the community after the in-hospital stay (thus actively treated strokes such as decompressive surgeries, carotid endarterectomy, in-hospital sepsis, and ventilator complications that essentially preclude return to the community settings were not offered in this chronic care support study).

Textbox 2. Exclusion criteria.

- Serious aphasia, visual hemineglect, short-term memory loss in the stroke survivor precluding understanding, visualization, or retention of the video material.
- Serious aphasia, visual hemineglect, short-term memory loss, dementia in the caregiver precluding understanding, visualization, or retention of the video material.
- Iatrogenic stroke, that is, stroke due to nonatherosclerotic vascular disease and rare causes, for example, carotid dissections, gunshot to neck, and coronary artery bypass surgery
- Stroke survivor/caregiver dyad continued poststroke care in a nursing-assisted, professional, or hospital setting and does not return to the community after discharge
- Serious concurrent medical illnesses such as cancer, renal failure, acute liver disease in past 6 months (that precludes use of statins), and chronic liver disease, which that exclude the use of stroke preventive medications or require nonstandardized therapy
- Any use of off-label, nonguideline medications, because of the stroke survivors' unique comorbidities, that interferes with medication compliance to antihypertensive, statins, antiplatelet, and antidiabetic agents

Randomization Process

Stroke survivors and their caregivers (dyad) were assigned to either the intervention or the usual care (control) groups in a parallel manner in a ratio of 1:1. Block randomization technique with a fixed block size of 10 was used. A computer-generated randomization list was used to randomize participants into the intervention or control group. The randomization center was performed in a secure computer in the clinical trials unit (CTU), and the randomization list was generated by CTU staff not involved in recruitment, outcome ascertainment, or any aspect of the study.

Allocation Concealment

The randomization list was centralized and thus not predictable. No one from the research team had any access to randomization list, randomization envelopes, and block size or code. Envelopes were sealed and opaque, and it was impossible to view the sequence even if held against bright sunlight. Randomization list and opaque envelopes containing the randomization sequence were always kept inside the premises of CTU under lock and key.

Identification and Enrollment of the Study Participants

Informed consent was obtained from eligible participants who volunteered to be a part of this study after they were provided a thorough explanation regarding the nature of the study and the scheduled follow-up visits. A detailed face-to-face interview of stroke survivors and their caregivers was conducted to gather data on sociodemographic and medical history. A baseline clinical and functional assessment was performed, after which they were randomly assigned into the intervention or control group by a trained research officer who was not blinded to the assignment of the intervention. Details regarding the proper functioning of mobile app and its installation were taught to the participants in the intervention group. A memory card containing Movies4Stroke app was installed in the participant's Android phone along with the delivery of the first set of 5-min videos. Videos were shown at the time of enrollment into the study, at discharge, and at the first and third month after discharge from the hospital. The app was designed to provide access to the videos in a scheduled manner. To maintain contact and follow-up, a Stroke Helpline number was provided to participants in both the groups. The helpline number was active 24/7, and the person operating at the helpline number was trained to receive calls with the most frequently anticipated questions and to answer them accordingly. The operator had access to a stroke specialist at all times for support. If the participant was allocated to the usual care group, he/she was informed about the details regarding discharge, follow-up

appointments at the clinic, and access to free lab vouchers at the 6th and 12th months.

Sampling Technique

A purposive sample was selected from adult stroke survivors admitted into the Stroke unit, Neurology Ward, AKUH, Karachi, after the assessment of the eligibility criteria and obtaining informed consent.

Technical Part of the Intervention

The Movies4Stroke app was developed by biomedical and software engineers of Aga Khan Development Network Electronic Health (eHealth) Resource Center in collaboration with stroke specialists, rehabilitation and swallowing experts, and epidemiologists. The intervention was first pilot tested on study team members' Android cell phones. Any discrepancies and bugs were removed from the app. The intervention was then launched on tablets, specially purchased for showing movies to the stroke survivors and their caregivers in clinical ward settings. Memory chips were also purchased, so that the Movies4Stroke app could be transferred into the participants' cell phones.

Participants in the intervention group were sent weekly messages twice as a reminder to watch the movies at home. These messages were sent through a Web-based, programmed, open-access software entitled *Frontline* by a trained IT professional.

Intervention Group

In addition to the usual care, the intervention group at the time of admission received the introductory teaching session with installation of the app and the first set of 5-min videos on various stroke-related topics as described below. In the first session, different skills such as swallowing exercises, different rehabilitation exercises, and nasogastric tube feeding were taught to the caregivers. The second session was delivered at the time of discharge, which included videos on emergency preparedness, such as cardiopulmonary resuscitation, seizures, heart attack, and hypoglycemia, while simultaneously discussing and answering any queries the participants had after watching each set of videos. The third session was delivered at the first month of follow-up after discharge and included videos on frequently used medications by stroke survivors, such as anticoagulants, antihypertensive, and lipid-lowering drugs. The fourth session was delivered at the third-month of follow-up after discharge and included videos on secondary stroke prevention (recurrent attack)—exercise, physical activity, recognition of depression, diet modification, and accurate measurement of BP and blood sugar levels (Figure 1).

Figure 1. Movies4Stroke collage. CPR: cardiopulmonary resuscitation.

Control Group

Participants in the control group received the standard of care that is provided to stroke patients at AKUH. Stroke survivors were given instructions before discharge regarding diet, the need for rehabilitation, possible complications, and medication use; information booklets were also handed out. A multidisciplinary team comprising a neurophysician, stroke nurse, dietitian, and physiotherapist imparted the information. Verbal instructions were given to stroke survivors and their caregivers. On the day of discharge, or 24 hours before discharge, a discharge coordinator provided the researchers details about the skills learned and ensured that the medical, social, and rehabilitation requirements were in place before going out of the hospital. All the study participants were provided follow-up appointments at the clinic. A detailed written discharge summary was handed over to the caregiver, detailing all aspects of care, including follow-up visit, medications, lab investigations, and serious alerts. The control group compliance to this standard of care was ensured, as all staff follow the abovementioned discharge protocol and document education. There is designated staff education and a safe discharge coordinator dedicated for all admissions at this center. The center at which this study was performed is an internationally accredited center, and performance and documentation of these quality of care standards are a part of the standard of care protocol. This standard of care was followed for all participants in the control group because of these regulations that are in place to maintain accreditation and auditable quality of care. The control group did not receive the additional visual teaching of the video-based intervention. This standard of care was followed for all participants including those who received the video-based intervention.

Compliance During the Administration of the Intervention

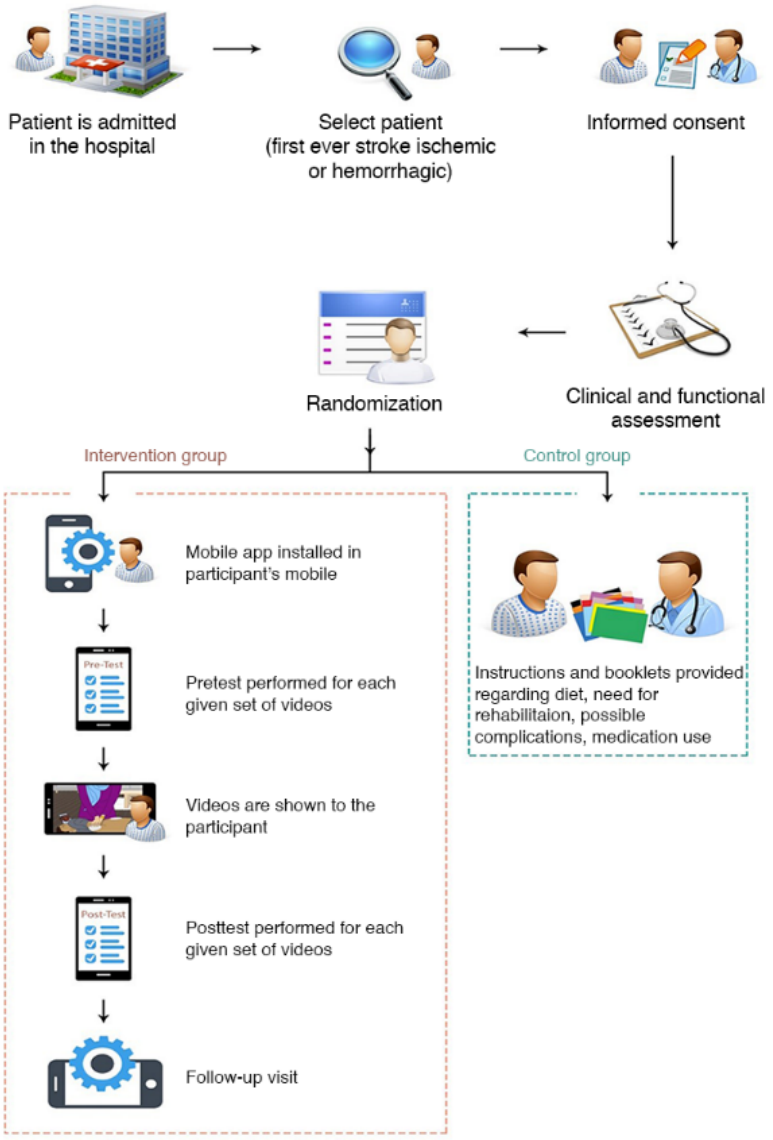
A study officer who was not blinded to the intervention group took several measures to ensure compliance of the participants to the videos as mentioned in the protocol [9]. There were trained research officers to ensure compliance of the intervention group participants at each video delivery; moreover, constant SMS reminders were sent to the study participants in the intervention group (as a measure of reinforcement) to watch these thematic movies in a relaxed home environment, and they were also reminded about their scheduled follow-up visits.

Follow-Up

Follow-up visit for each stroke survivor-caregiver dyad was organized at 1, 3, 6, 9, and 12 months after discharge in the neurology clinic for outcome ascertainment. Stroke survivors and their caregivers were given a handout with instructions and basic information about their subsequent follow-up visit. Caregivers were also explained verbally about the importance of their follow-up visit. They were asked to contact the study team through the Stroke Helpline for any queries regarding their health.

The follow-up rates were maximized by sending SMS reminders to all the study participants about their respective follow-up visits at least a day before their scheduled follow-up visit through our Stroke Helpline number and by also allowing an approximate 14-day grace period to the stroke survivor and caregiver who were unable to report as per their scheduled follow-up visit. Those participants who did not appear for their scheduled follow-up visit were contacted through phone or approached through indirect means, such as contacting them when they came to the AKUH for any other clinic or physiotherapy visit or lab investigations. Details of stroke survivors' visit to the AKUH, other than the neurology clinic, was obtained through telecommunication with the caregiver or tracking the stroke survivor through the synchronized electronic medical record system of the AKUH (Figure 2).

Figure 2. Study flow (enrollment to follow-up).



Participants' Timeline

After recruiting stroke survivors along with their primary caregivers from the Stroke unit at the AKUH, the participant dyads were not expected to come in for any additional visits for the study purpose other than the scheduled 5 follow-up visits at the stroke clinic. Our study started enrolling participants from January 19, 2015, and the last participant was recruited on May 15, 2015. The last follow-up was completed on June 29, 2016.

Trial Outcomes

The primary outcome measure reported was as follows: control of 3 major risk factors—BP, blood sugar, and lipids—measured via standardized methods in the central laboratory was ascertained at baseline and 6 and 12 months after discharge. All the 3 risk factors were assessed, as the proportion of participants achieving BP control (<125/85 mm Hg), blood sugar (glycosylated hemoglobin A_{1c} or HbA_{1c}<7%), and blood cholesterol (low-density lipoprotein [LDL] level<100 mg/dL).

Of the secondary outcomes, two are discussed in this paper with respect to Movies4Stroke trial protocol; others will be discussed in the subsequent paper.

Stroke-Related Mortality Among Stroke Survivors Was Ascertained at 12 Months Post Discharge

Information on mortality among stroke survivors after discharge was ascertained through a precoded and validated verbal autopsy scale. In addition, we correlated all mortality with hospital records. Mortality was further categorized as per the analysis criteria into 3 categories: stroke-related mortality, mortality (because of nonstroke complications), and out-of-hospital mortality.

Included

Mortality after discharge from the AKUH because of stroke-related complications was assessed by a review of medical records, interviews from primary caregivers of the patients, and the verbal autopsy standard procedure.

Censored

Mortality after discharge from the hospital because of competing risk, that is, cause of death not related to stroke because of, for example, head trauma, gun shot, and cancer, was assessed.

Patients who were alive after 1 year of follow-up after discharge (censored because of lack of outcome of interest or statistical considerations) were assessed.

Excluded

In-hospital mortality before patients were discharged from the hospital was a result of complications arising from an index stroke occurring before discharge into the community in a stable state, for example, iatrogenic complications, sepsis, and progression of index stroke during admission.

Moreover, the categorization of all these deaths was further validated by our team of experts including stroke specialist, epidemiologist, statisticians, and research supervisor.

Stroke Disability and Neurological Deficits Among Stroke Survivors Was Ascertained at Baseline and 6 and 12 Months After Discharge

A total of 3 different neurological functional assessment tools were used in this clinical trial, as each of them captures/measures a different parameter with respect to the functional status of stroke survivors after acute stroke:

- mRS tool is widely used by neuro physicians globally to assess functional disability after acute stroke [10-12].
- The National Institutes of Health Stroke Scale (NIHSS) tool is widely used by neurophysicians globally to objectively quantify the impairment caused by stroke [12,13].
- The Barthel Index (BI) tool is used globally by health care providers to assess the level of dependency among stroke survivors after an acute episode of stroke [12,14].

The abovementioned tools were used to assess the functional status of stroke survivors at baseline and 6- and 12-month follow-ups.

Ethics and Human Subject Protection

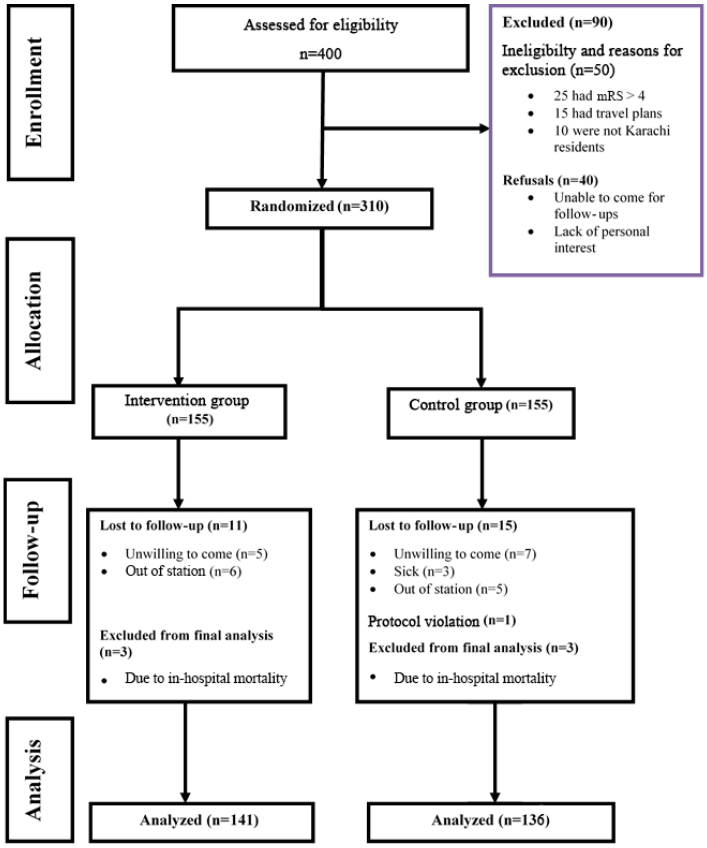
Written informed consent, in both English and Urdu, was obtained from all the study participants at the time of recruitment. The confidentiality and privacy of the participants was maintained by deidentification of the subject information. Only research staff was authorized entry into the hospital system on the computers that were used for data storage. All source documents were maintained in locked files in locked room. Fingerprint encryption was added to all sensitive data, for example, mobile numbers, app logs, and error logs. The Ethical Review Committee (ERC) of Aga Khan University, Karachi (ERC number 2890-Med-ERC-14), approved the study.

Results

Overall Trial Flow

A total of 310 stroke survivors and their caregiver dyads, ie, 620 individuals (participant dyads), were recruited over a duration of 6 months. As this clinical trial had a fixed block design, 155 participant dyads were randomized in each of the intervention and control group (310 in each group). We screened 400 participant dyads to assess eligibility; of these, 50 were not eligible, and 40 participant dyads refused to participate in the study (30% were excluded; Figure 3). The reasons for exclusions were mRS>4 (n=25), travel plans (n=15), and non-Karachi residents (n=10). The reasons for refusal were mainly the lack of ability to return for follow-up and personal interest of the stroke survivor or caregiver to participate in the study. We were able to complete information on 141 participant dyads in the intervention and 137 in the control group at the end of 1-year postdischarge follow-up. From the intervention group, 11 participant dyads were lost to follow-up at 1 year postdischarge and 3 stroke survivors died because of in-hospital mortality (before being discharged) resulting from inpatient complications from the index stroke, as compared with 15 participant dyads who were lost to follow-up and 3 who died because of in-hospital mortality in the control group. There was one protocol violation in the control group that was excluded from the final analysis.

Figure 3. Trial flow diagram. mRS: Modified Rankin Scale.



Baseline Characteristics of the Study Participants

Mean age of stroke survivors in the intervention group was 60.6 (SD 12.0) years, whereas it was 59.7 (SD 14.3) years in the control group. The caregivers were relatively younger, with the mean age of 38.7 (SD 11.7) years in the intervention group and 39.8 (SD 14) years in the control group. In our trial, most of the stroke survivors were males (109/155, 70.3%, in the intervention group vs 100/155, 65.0%, in the control group). More than two-thirds of the stroke survivors in our study had more than 5 years of education (114/155, 73.5%, in the intervention group vs 107/155, 69.0%, in the control group), with 40 of 155 (25.8%) patients being employed in the intervention group and 39 of 155 (25.1%) in the control group. More than four-fifths of our study participants were married (134/155, 86.5%) in the intervention group as compared to the control group (124/155, 80.0%), and more than half of the stroke survivors were living in a joint family system (93/155, 60.0%, in the intervention group vs 107/155, 69.0%, in the control group). Median (interquartile range) number of household members living with stroke survivors was 6 (range: 5-8) in the intervention group as compared with 7 (range: 5-10) in the control group. Median household monthly income of the stroke survivors was Rs 50,000 (US $416) in both the groups. Approximately, four-fifths of our study participants were Android mobile phone users in the intervention group (120/155, 77.4%) as compared with around two-third in the control group (99/155, 63.8%). Most variables were uniformly distributed between the two groups and not statistically significant at baseline (refer to Table 1).

Table 1. Baseline characteristics of study participants according to their group allocation (310 participant dyads)

Baseline characteristics	Intervention group (N=155)	Control group (N=155)	*P* value
Age (years) of the patient, mean (SD)	60.6 (12.0)	59.7 (14.3)	.17
Patient's gender, n (%)			.35
Male	109 (70.0)	100 (65.0)	
Female	46 (30.0)	55 (35.0)	
Age (years) of the caregiver, mean (SD)	38.7 (11.7)	39.8 (14.0)	
Source of the patient, n (%)			.26
Direct	90 (58.0)	81 (52.2)	
Referral	65 (42.0)	74 (47.8)	
Type of operating system, n (%)			.01
None	14 (9.0)	30 (19.3)	
Android	127 (82.0)	104 (67.1)	
Windows	6 (3.9)	13 (8.4)	
IOS	8 (5.1)	8 (5.2)	
Anyone at home with Android, n (%)			<.001
Yes	120 (77.4)	99 (63.8)	
No	35 (22.6)	56 (36.2)	
Desktop PC at home, n (%)			.02
Yes	143 (92.3)	130 (83.8)	
No	12 (7.7)	25 (16.2)	
Patient education, n (%)			.22
Illiterate	17 (11.0)	31 (20.0)	
Primary education	24 (15.5)	17 (11.0)	
Secondary education	36 (23.2)	34 (22.0)	
Higher secondary education	21 (13.5)	18 (11.6)	
Above intermediate	57 (36.8)	55 (35.4)	
Patient marital status, n (%)			.14
Single	3 (1.9)	9 (5.8)	
Married	134 (86.5)	124 (80.0)	
Widowed	18 (11.6)	22 (14.2)	
Patient family status, n (%)			.12
Joint family	93 (60.0)	107 (69.0)	
Nuclear family	62 (40.0)	48 (31.0)	
Monthly family income (Pakistani rupee), median (IQR)	50,000 (30,000-100,000)	50,000 (30,000-70,000)	
Patient employment status, n (%)			.45
Employed	40 (25.8)	39 (25.1)	
Unemployed	5 (3.3)	10 (6.5)	
Retired	27 (17.4)	27 (17.4)	
Housewife	43 (27.7)	50 (32.2)	
Others	40 (25.8)	29 (18.7)	
Family land ownership (acre), n (%)			.92
None	47 (30.3)	47 (30.3)	
<1	92 (59.4)	89 (57.4)	

Baseline characteristics	Intervention group (N=155)	Control group (N=155)	*P* value
Between 1 and 10	10 (6.4)	13 (8.4)	
>10	6 (3.9)	6 (3.9)	
Total household members, median (IQR)	6 (5-8)	7 (5-10)	.52
Length of hospital stay, median (IQR)	4 (3-4)	3 (3-5)	.71
Tissue plasminogen activator, n (%)			.98
Yes	7 (4.5)	7 (4.5)	
No	148 (95.5)	148 (95.5)	

Primary Outcome

Systolic Blood Pressure

At baseline, there was a uniform distribution of study participants with the two categories of systolic BP (<125 mm Hg and >125 mm Hg) in the intervention group and the control group (49/155, 50.0%, vs 48/155, 50.0%). At the 6-month visit, the distribution of study participants with a systolic BP of <125 mm Hg was similar in the intervention group and control group (36/109, 50.0% vs 36/99, 50.0%; risk ratio [RR] 0.91, 95% CI 0.62-1.32). At the final follow-up visit (at 12 months), there was a greater percentage of participants with a systolic BP of <125 mm Hg in the intervention group than in the control group (18/54, 62.0% vs 11/52, 38.0%; RR 1.58, 95% CI 0.83-2.98). However, none of these results were statistically significant (refer to Table 2).

Table 2. Systolic blood pressure.

Systolic blood pressure (mm Hg)	Intervention group, n (%)	Control group, n (%)	Risk ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.96
<125	49 (50.0)	48 (50.0)	1.00 (0.72-1.40)	
>125	106 (50.0)	107 (50.0)	1.00 (0.72-1.40)	
6-month results (N=208)[b]				.61
<125	36 (50.0)	36 (50.0)	0.91 (0.62-1.32)	
>125	73 (54.0)	63 (46.0)	0.91 (0.62-1.32)	
12-month results (N=106)[c]				.16
<125	18 (62.0)	11 (38.0)	1.58 (0.83-2.98)	
>125	36 (47.0)	41 (53.0)	1.58 (0.83-2.98)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=109) and control group (n=99).

[c]12-month results: intervention group (n=54) and control group (n=52).

Diastolic Blood Pressure

At baseline, there were slightly more participants with a diastolic BP of <85 mm Hg in the intervention group than in the control group (109/155, 51.0% vs 106/155, 49.0%). At 6 months, there was a greater percentage of stroke survivors with a diastolic BP of <85 mm Hg in the intervention group than in the control group (82/109, 55.0% vs 68/99, 45.0%; RR 1.10, 95% CI 0.92-1.30). Similar to this, at the final visit at 12 months, there was a greater percentage of participants with a diastolic BP of <85 mm Hg in the intervention group than in the control group (44/54, 55.0% vs 37/52, 45.0%; RR 1.15, 95% CI 0.92-1.42). These results failed to reach a statistically significant level (refer to Table 3).

Table 3. Diastolic blood pressure.

Diastolic blood pressure (mmHg)	Intervention group, n (%)	Control group, n (%)	Risk ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.84
<85	109 (51.0)	106 (49.0)	1.02 (0.88-1.18)	
>85	46 (49.0)	49 (51.0)	1.02 (0.88-1.18)	
6-month results (N=208)[b]				.29
<85	82 (55.0)	68 (45.0)	1.10 (0.92-1.30)	
>85	27 (46.0)	31 (54.0)	1.10 (0.92-1.30)	
12-month results (N=106)[c]				.21
<85	44 (55.0)	37 (45.0)	1.15 (0.92-1.42)	
>85	10 (40.0)	15 (60.0)	1.15 (0.92-1.42)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=109) and control group (n=99).

[c]12-month results: intervention group (n=54) and control group (n=52).

Glycosylated Hemoglobin A_{1c}

At baseline, there was a smaller percentage of participants with an HbA_{1c} level <7% in the intervention group than in the control group (88/155, 45.0% vs 105/155, 55.0%). At the 6-month visit, there was a slightly higher percentage of stroke survivors with a HbA_{1c} level <7% in the intervention group than in the control group, (81/105, 52.0% vs 74/91, 48.0%; RR 0.95, 95% CI 0.82-1.10). Similarly, at the final visit at 12 months, there was a greater percentage of participants with an HbA_{1c} level <7% in the intervention group than in the control group (36/55, 55.0% vs 30/40, 45.0%; RR 0.87, with 95% CI 0.66-1.14). However, these results failed to demonstrate statistical significance (refer to Table 4).

Table 4. Glycosylated hemoglobin A_{1c}.

Glycosylated hemoglobin A_{1c} (%)	Intervention group, n (%)	Control group, n (%)	Risk ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.03
<7	85 (45.0)	105 (55.0)	0.81 (0.68-0.98)	
>7	70 (58.0)	50 (42.0)	0.81 (0.68-0.98)	
6-month results (N=196)[b]				.47
<7	81 (52.0)	74 (48.0)	0.95 (0.82-1.10)	
>7	24 (58.0)	17 (42.0)	0.95 (0.82-1.10)	
12-month results (N=95)[c]				.32
<7	36 (55.0)	30 (45.0.0)	0.87 (0.66-1.14)	
>7	19 (65.0)	10 (35.0)	0.87 (0.66-1.14)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=105) and control group (n=91).

[c]12-month results: intervention group (n=55) and control group (n=40).

Low-Density Lipoprotein

At baseline, there was a greater percentage of study participants with an LDL level<100 mg/dL in the intervention group than in the control group (92/155, 59.0% vs 64/155, 41.0%). A similar trend was seen at the third follow-up visit: There was a higher percentage of stroke survivors with an LDL level<100 mg/dL in the intervention group than in the control group (73/106, 57.0% vs 56/90, 43.0%; RR 1.10, 95% CI 0.90-1.36). Again, a very similar trend was seen at the fifth follow-up visit: There was a greater percentage of participants with an LDL level <100 mg/dL in the intervention group than in the control group (36/51, 55.0%, vs 30/45, 45.0%; RR 1.06, 95% CI 0.81-1.39). However, these results failed to demonstrate statistical significance (refer to Table 5).

Table 5. Low-density lipoprotein.

Low-density lipoprotein (mg/dL)	Intervention group, n (%)	Control group, n (%)	Risk ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				<.001
<100	92 (59.0)	64 (41.0)	1.42 (1.13-1.78)	
>100	63 (41.0)	91 (59.0)	1.42 (1.13-1.78)	
6-month results (N=196)[b]				.33
<100	73 (57.0)	56 (43.0)	1.10 (0.90-1.36)	
>100	33 (49.0)	34 (51.0)	1.10 (0.90-1.36)	
12-month results (N=96)[c]				.68
<100	36 (55.0)	30 (45.0)	1.06 (0.81-1.39)	
>100	15 (50.0)	15 (50.0)	1.06 (0.81-1.39)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=106) and control group (n=90).

[c]12-month results: intervention group (n=51) and control group (n=45).

Secondary Outcomes

Mortality and the Number Needed to Treat

Overall, 35 deaths were reported over the course of 1-year follow-up in the Movies4Stroke trial (Multimedia Appendix 1). Mortality among stroke survivors because of stroke-related complications (included group) was higher in the control group than in the intervention group (13/155, 8.4% vs 2/155, 1.3%). The most common cause of mortality was aspiration pneumonia. Censored deaths in both the groups were caused by non–stroke-related complications and were therefore not considered a part of the included group. The results were found to be highly significant (*P*<.001). Absolute risk reduction (ARR) of mortality related to stroke-related complications was 7%, which yielded a number needed to treat (NNT) of 15. It meant that we needed to show the video-based intervention to 15 stroke survivors to prevent 1 death from stroke-related complications (refer to Table 6 and Figure 4).

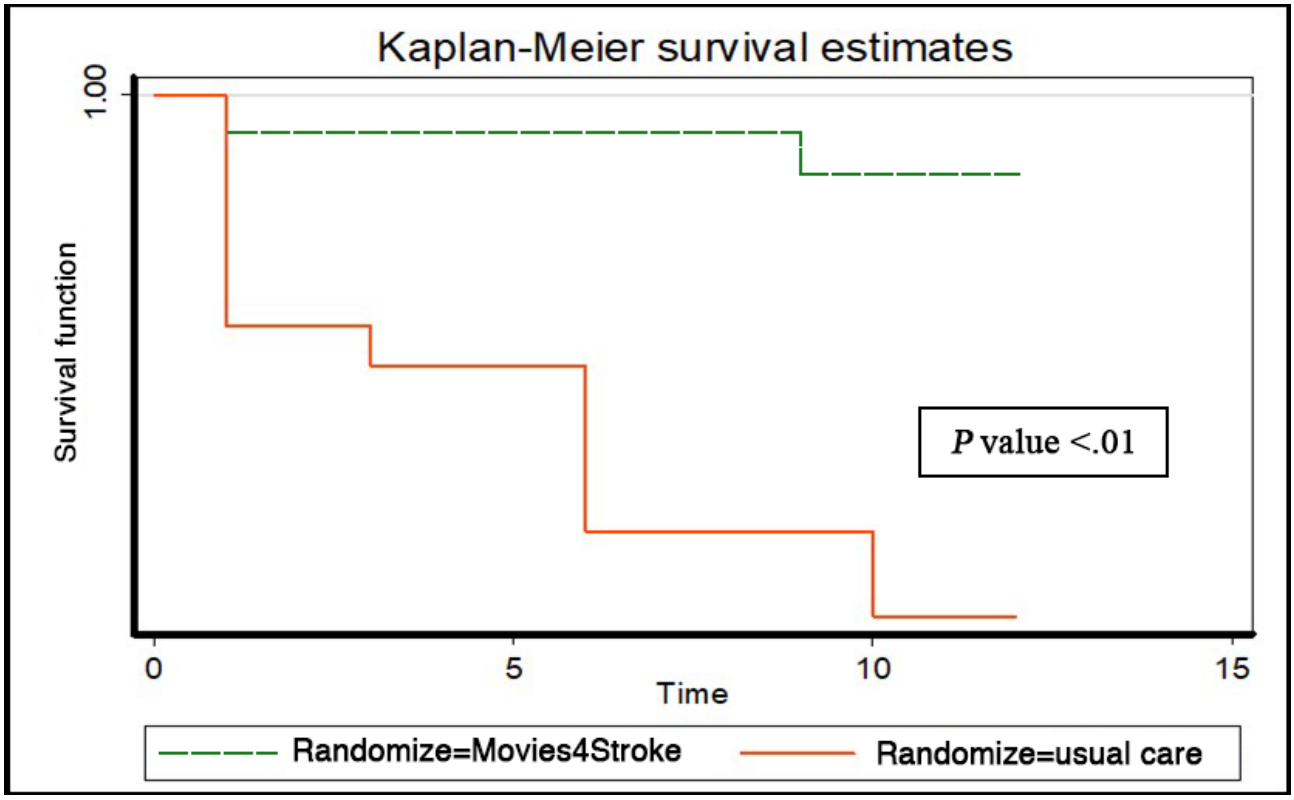
Table 6. Categorization of mortality, ARR, and NNT.

Mortality categorized	Intervention group (N=155), n (%)	Control group (N=155), n (%)	Absolute risk reduction	Number needed to treat	*P* value
Patient is alive	140 (90.3)	135 (87.1)	N/A[a]	N/A	N/A
Included	2 (1.3)	13 (8.4)	7.1	15[b]	<.001
Censored	10 (6.5)	4 (2.6)	N/A	N/A	N/A
Excluded	3 (1.9)	3 (1.9)	N/A	N/A	N/A

[a]Not applicable.

[b]Number needed to treat of 15 has been rounded off to a whole number.

Figure 4. The Kaplan-Meier survival estimates in the first year after stroke in the intervention versus control group because of stroke-related avoidable mortality.



Change in Functional Status (Disability and Severity) Among Stroke Survivors

Modified Rankin Scale

Table 7 and Figures 5 and 6 show that at baseline, as assessed by mRS, a higher percentage of stroke survivors with moderate to severe disability were present in the intervention group than in the control group (46/155, 29.7% vs 36/155, 23.2%; odds ratio [OR] 1.18, 95% CI 0.58-2.39). Similarly, at 6 months, a higher percentage of stroke survivors with moderate to severe disability were present in the intervention group than in the control group (24/135, 17.8% vs 18/129, 14.0%; OR 1.28, 95% CI 0.65-2.55). However, at 12 months, a higher percentage of stroke survivors had minimal to no disability in the intervention group than in the control group (91/128, 71.1% vs 71/120, 59.2%). At 12 months postdischarge, NNT was 9, as assessed by the mRS. This meant that we needed to show Movies4Stroke to 9 stroke survivors to achieve minimal to no disability caused by stroke after a year of follow-up.

Table 7. Modified Rankin Scale.

Modified Rankin Scale score	Intervention group, n (%)	Control group, n (%)	Odds ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.40
0-1	25 (16.1)	25 (16.1)	Reference	
2-3	84 (54.2)	94 (60.7)	0.82 (0.44-1.55)	
4-5	46 (29.7)	36 (23.2)	1.18 (0.58-2.39)	
6-month results (N=264)[b]				.40
0-1	82 (60.7)	79 (61.2)	Reference	
2-3	29 (21.5)	28 (21.7)	0.99 (0.55-1.83)	
4-5	24 (17.8)	18 (14.0)	1.28 (0.65-2.55)	
Death	0 (0.0)	4 (3.1)	__[c]	
12-month results (N=248)[d]				.07
0-1	91 (71.1)	71 (59.2)	Reference	
2-3	18 (14.1)	30 (25.0)	0.47 (0.24-0.91)	
4-5	19 (14.8)	19 (15.8)	0.78 (0.38-1.58)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=135) and control group (n=129).

[c]Odds ratio with their 95% CI could not be estimated because of the empty cell count in the intervention group.

[d]12-month results: intervention group (n=128) and control group (n=120).

Figure 5. Functional status of stroke survivors—6 months. NIHSS: National Institutes of Health Stroke Scale.

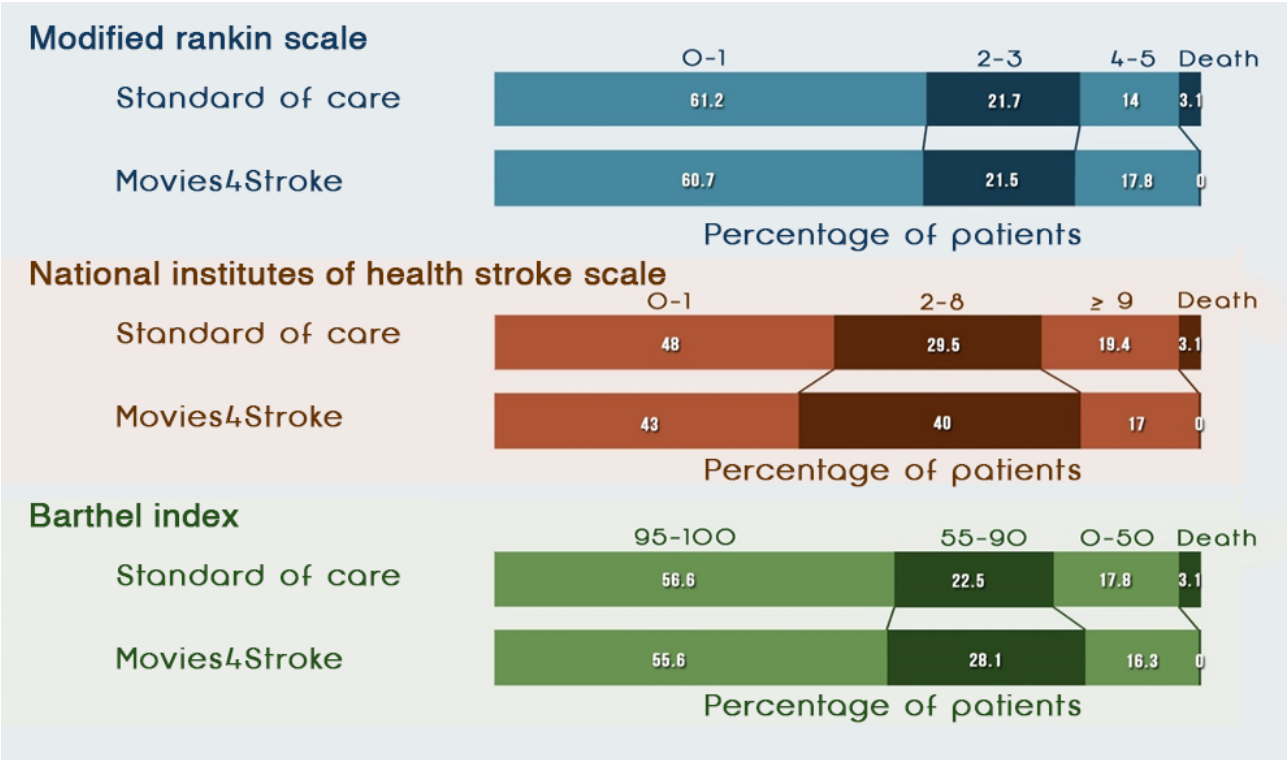
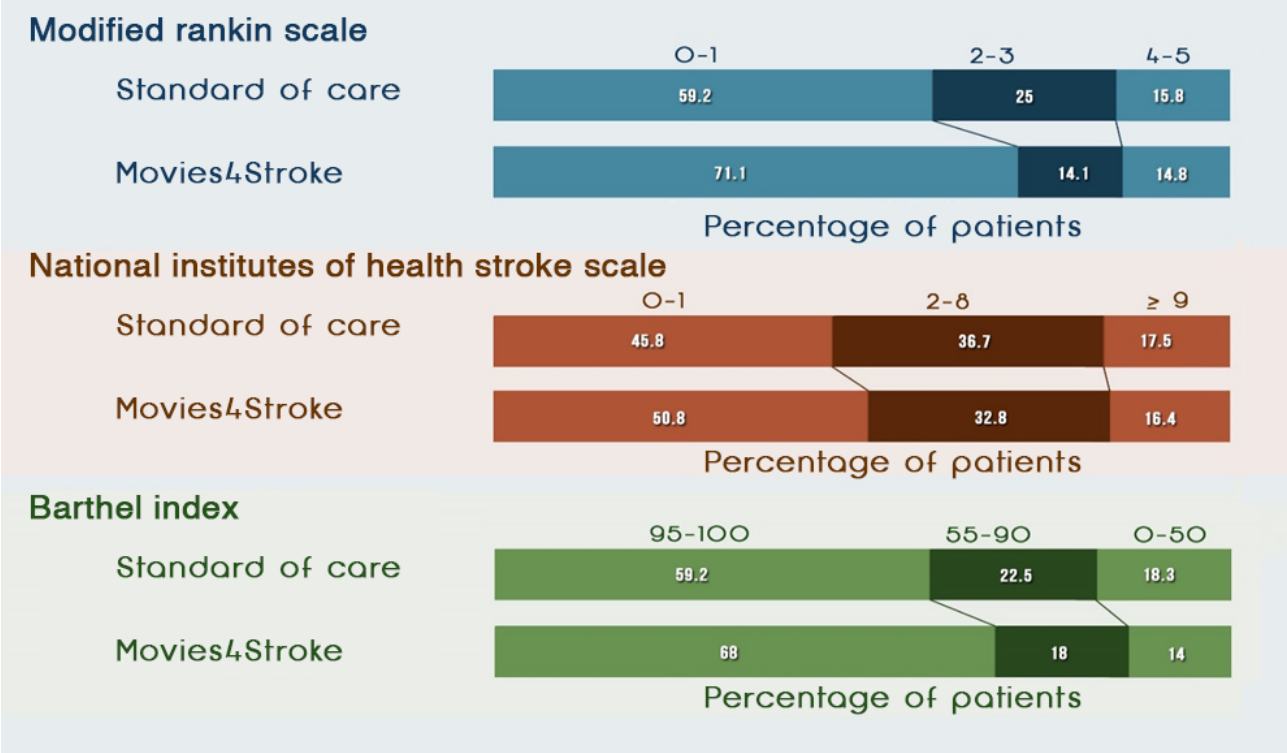


Figure 6. Functional status of stroke survivors—baseline and 12 months assessment (comparison).



National Institutes of Health Stroke Scale

Table 8 and Figures 5 and 6 show that at baseline, as assessed by the NIHSS, a higher percentage of stroke survivors had severe impairment caused by stroke in the control group than in the intervention group (72/155, 46.4% vs 61/155, 39.4%; OR 0.82, 95% CI 0.39-1.74). At 6 months, a smaller percentage of stroke survivors had severe impairment caused by stroke in the intervention group than in the control group (23/135, 17.0% vs 25/129, 19.4%; OR 0.98, 95% CI 0.50-1.92). At 12 months, a higher percentage of stroke survivors had minimal to no impairment caused by stroke in the intervention group than in the control group (65/128, 50.8% vs 55/120, 45.8%). At 12 months postdischarge, NNT was 20 as per the NIHSS assessment. This meant that we needed to show Movies4Stroke to 20 stroke survivors to have minimal to no disability caused by stroke after a year of follow-up.

Table 8. National Institutes of Health Stroke Scale.

National Institutes of Health Stroke Scale score	Intervention group, n (%)	Control group, n (%)	Odds ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.52
0-1	18 (11.6)	17 (11.0)	Reference	
2-8	76 (49.0)	66 (42.6)	1.09 (0.51-2.28)	
>9	61 (39.4)	72 (46.4)	0.82 (0.39-1.74)	
6-month results (N=264)[b]				.08
0-1	58 (43.0)	62 (48.0)	Reference	
2-8	54 (40.0)	38 (29.5)	1.52 (0.88-2.63)	
>9	23 (17.0)	25 (19.4)	0.98 (0.50-1.92)	
Death	0 (0.0)	4 (3.1)	__[c]	
12-month results (N=248)[d]				.73
0-1	65 (50.8)	55 (45.8)	Reference	
2-8	42 (32.8)	44 (36.7)	0.81 (0.46-1.41)	
>9	21 (16.4)	21 (17.5)	0.85 (0.42-1.71)	

[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=135) and control group (n=129).

[c]Odds ratio with their 95% CI could not be estimated because of the empty cell count in the intervention group.

[d]12-month results: intervention group (n=128) and control group (n=120).

Barthel Index

Table 9 and Figures 5 and 6 show that at baseline, as assessed by the BI, an equal percentage of stroke survivors had total to severe dependency in the intervention group as compared with the control group (78/155, 50.3% vs 78/155, 50.3%; OR 1.08, 95% CI 0.63-1.86). At 6 months, a smaller percentage of stroke survivors had total to severe dependency in the intervention group than in the control group (22/135, 16.3% vs 23/129, 17.8%; OR 0.93, 95% CI 0.48-1.81). At 12 months, a higher percentage of stroke survivors with minimal to no dependency were present in the intervention group than in the control group (87/128, 68.0% vs 71/120, 59.2%). At 12 months postdischarge, NNT was 12, as per the BI assessment.

As evident in Figure 7 and according to the mRS, when comparing the baseline with the 12-month follow-up visit, more survivors in the intervention group had seen the videos and had minimal to no disability at the end of the 12 months as compared with the control group. Similarly, according to NIHSS, when comparing baseline with 12-month follow-up visits, there was a higher percentage of survivors with minimal neurologic deficit at 12 months in the intervention group as compared with the control group. Similarly, for BI, when comparing baseline with 12-month follow-up visits, there was a higher percentage of survivors with had minimal to no dependency at 12 months in the intervention group as compared with the control group.

Table 9. Barthel Index.

Barthel Index score	Intervention group, n (%)	Control group, n (%)	Odds ratio (95% CI)	*P* value (overall)
Baseline results (N=310)[a]				.94
95-100	38 (24.5)	40 (25.8)	Reference	
55-90	39 (25.2)	37 (23.9)	1.11 (0.59-2.09)	
0-50	78 (50.3)	78 (50.3)	1.08 (0.63-1.86)	
6-month results (N=264)[b]				.16
95-100	75 (55.6)	73 (56.6)	Reference	
55-90	38 (28.1)	29 (22.5)	1.28 (0.71-2.28)	
0-50	22 (16.3)	23 (17.8)	0.93 (0.48-1.81)	
Death	0 (0.0)	4 (3.1)	__[c]	
12-month results (N=248)[d]				.35
95-100	87 (68.0)	71 (59.2)	Reference	
55-90	23 (18.0)	27 (22.5)	0.70 (0.37-1.32)	
0-50	18 (14.0)	22 (18.3)	0.67 (0.33-1.34)	

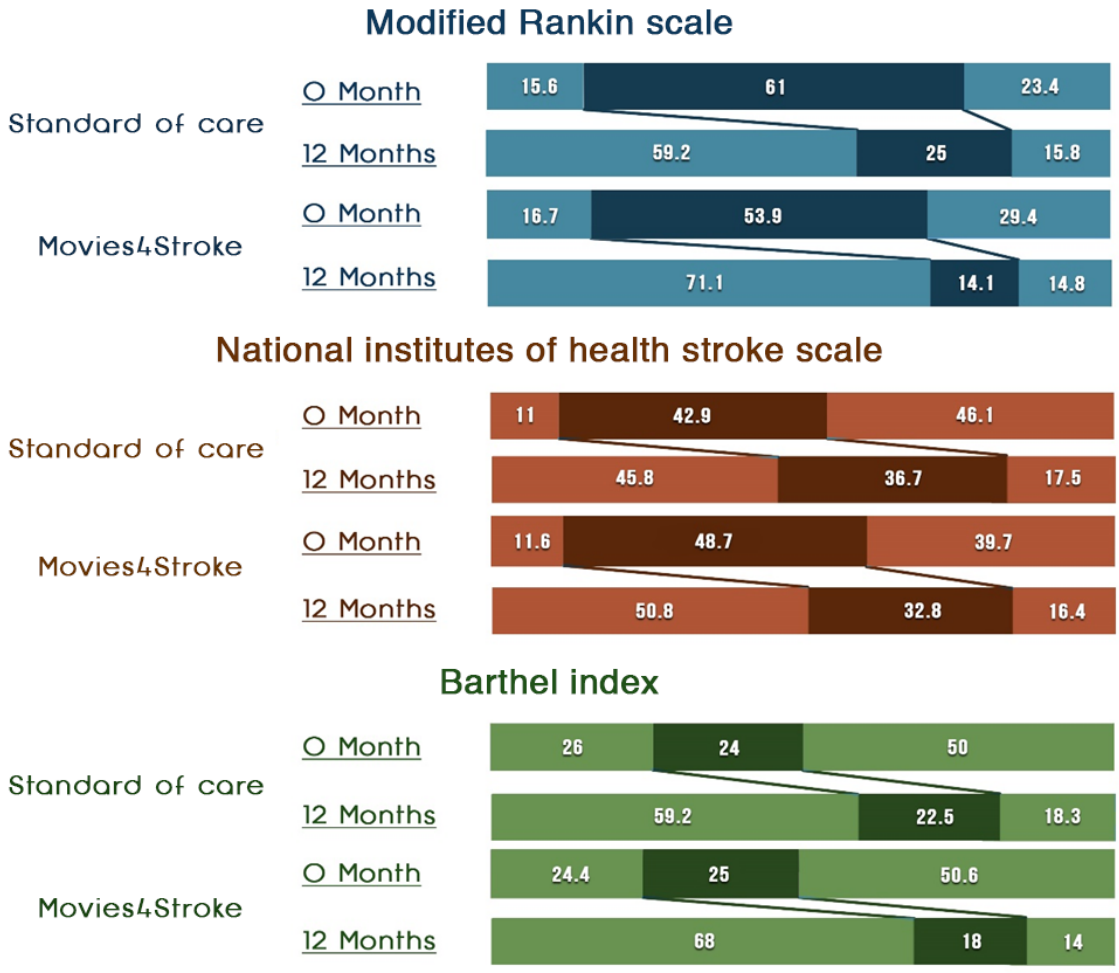
[a]Baseline: intervention group (n=155) and control group (n=155).

[b]6-month results: intervention group (n=135) and control group (n=129).

[c]Odds ratio with their 95% CI could not be estimated because of the empty cell count in the intervention group.

[d]12-month results: intervention group (n=128) and control group (n=120).

Figure 7. Functional status of stroke survivors—baseline and 12 months assessment (comparison).



Discussion

Principal Findings and Their Contextual Relevance

Movies4Stroke is a randomized controlled mHealth trial evaluating the effectiveness and safety of a phone-based intervention that showed thematically designed videos to assist the stroke survivor and caregiver dyad to get the knowledge, skills, and confidence needed to improve poststroke risk factor control, survival, and functional outcomes. The rationale of this trial was to provide repetitive high-quality survival and training to stroke survivor and caregiver dyads returning to a low- to middle-income community where rehabilitation and chronic care systems are underdeveloped. The mode of video-based IT intervention, along with competency and understanding checks and the ability to repeat and see a video, was used to assist the understanding in a literacy-challenged population that, however, had access to a cell phone. None of the trial participants were excluded because of the lack of a cell phone. This mHealth trial failed to reach its primary outcome measure of the control of hypertension, LDL cholesterol, and HbA_{1c}; however, the prespecified secondary variables of improved functional outcomes and reduced mortality were improved in the intervention group in this study because of stroke-related complications. This study demonstrated that showing the video to a literacy-challenged population in a country without any chronic care health facility saved lives. The NNT was only 15, to save 1 life, because of avoidable stroke-related complications and death. This trial provides early data on nonpharmacological intervention in stroke survivors. There are few interventions of this nature identified in a recent meta-analysis and review and none that employs mHealth in a complex, challenging, and resource-strapped setting (refer to Multimedia Appendix 2) [15-21].

Primary and Secondary Outcome Results: Mechanistic Explanations

Movies4Stroke failed to achieve its primary outcome variable of the control of primary risk variables of hypertension, LDL cholesterol, or HbA_{1c} in the intervention. There could be several reasons for these findings. First, the baseline adherence in this population was already substantially better than the general population, possibly because of the seriousness of stroke and exposure to specialist care and counseling techniques; thus, it became difficult to further improve adherence and the related improvement in risk factors. This could be explained by the Health Belief Model demonstrating that better outcomes are found in patients who understand the severity of their disease and the benefits that changing their actions would yield [22,23].

Second, in this study, to maintain long-term follow-up, the control group also had access to a 24/7 helpline, and interaction with health care personnel who assisted and resolved queries may have improved behavior in this group as well. The presence of a centralized helpline has shown to help address queries and patients cope with difficult situations [24].

Third, this was a sequential and thematic intervention where these 5-min video lessons were rolled out in order of what skill would be important for survival in the early stages as compared with the later stages of stroke. Hence at admission, the survivor and caregiver dyad were provided with skills and training to recognize life-threatening emergencies and respond to them accordingly. At the time of discharge, each dyad was taught rehabilitation and safe swallowing. Thematic movies on adherence and medication safety module were taught in the first month; thus, these preventive aspects were dealt with much later, and this might in itself be associated with learning fatigue, or perhaps, these movies were taught by the time the risk factor control had already maximized in the participants in the study.

Finally, it is difficult to design measures that capture pill compliance in the stroke population; stroke patients have diverse prescriptions that vary in the type of drug classes, number, and frequency of dosage, and no single biomarker would be applicable to all the study participants nor could electronic pill boxes capture the actual drug usage to achieve BP, glucose, or cholesterol control, as they record the number of times a box is opened. Moreover, it cannot be assumed that the participants have consumed all the pills for that dose when they open a box. However, we can see that the harder outcome measure of the control of BP, cholesterol, or blood sugar was not achieved.

In addition, these negative findings on risk factor control shed light on the importance of health theory and behavioral science designing an intervention, rather than considering just simple knowledge transfer while designing an intervention. This resonates with previous studies concluding that to achieve effective change in health systems and patient care, knowledge transfer alone is insufficient and has to be supplemented with other forms of intervention [25]. In a single-center study [26], showing just one video in an in-patient setting increased knowledge; however, it did not translate into BP monitoring in a home environment or increase physician follow-up visits. The sustained intervention in our study revealed that, at least the skills to prevent complications might have been acquired.

Nonadherence to medication has two components—intentional and unintentional nonadherence [27]. Intentional nonadherence refers to nonadherence that is deliberate and may be because of motivational factors that may be directly related to the perceived efficacy of the medicine, distrust, and the lack of knowledge, whereas unintentional nonadherence is nonadherence that is largely related to either forgetting or the lack of capacity to take the medicine. In our study, we focused on improving knowledge, empowerment, and self-efficacy, but we did not send repeated reminders to improve unintentional nonadherence. Similar results were obtained in a study implemented in Sydney, Australia, focusing on participants with coronary heart disease in which repeated lifestyle modification messages/reminders showed significant results with respect to harder outcomes such BP and cholesterol [28]. This highlights the importance of mHealth design to be multifaceted and used as a platform for re-enforcement to address behavior change with regard to adherence. It also highlights the potential of mHealth to be harnessed in reducing the burden of NCDs when interventions are designed using health theory, and they can inform effectiveness, thus achieving the millennium development goals [29,30].

Interestingly, each of our prespecified secondary outcome variables improved in this study. Secondary outcomes of Movies4Stroke trial aimed at improving functional outcomes and reducing mortality because of stroke-related complications, and the results are very promising, given the difficult context of the intervention. The mortality analysis showed that in the control group, there were 9 of 13 cases of massive aspiration pneumonias that resulted in mortality, which could have been avoided by aspiration precautions and learning tube feeding safety measures. In addition, recognizing aspiration and reporting early could have resulted in saving lives. There were 2 mortalities in the intervention group, one because of a massive recurrent stroke and the other because of aspiration. The other mortalities were not related directly to stroke-mediated complications. Given the limited nature of these observations, these findings are worthy of attention but need to be confirmed in larger cohorts with prolonged follow-up periods.

Skills to help identify, prevent, and respond to poststroke complications were taught through 5-min videos that had been rolled out in an orderly manner, with preventable early complications addressed first, followed by late complications. This method of interactive, repeated teaching increased the skill and confidence of the caregivers and thus resulted in saving lives and improving the functional outcomes and reducing disability.

Other studies have similarly reported that timely recognition and reporting of complications resulted in low mortality and improved outcomes among stroke survivors [31,32]. Through these movies, knowledge transfer helped change the skills of the caregivers rather than the adherence of stroke survivors. Along with this, Movies4Stroke might have influenced health beliefs of stroke survivors and their caregivers by helping them understand their increased susceptibility and therefore the importance of prompt action to prevent death because of complications [33,34]. Moreover, Movies4Stroke also had videos aimed at providing psychoeducational intervention and support through the helpline to the caregivers along with the procedural knowledge. These three components have been pivotal in helping prevent stress and strain in informal caregivers [19], which may also explain the active involvement and effective skill knowledge of caregivers in this study.

Owing to the varying definitions of successful stroke recovery, it is difficult to find a standard measure of recovery, which is why we used three different scales [35]. The improvement observed in functional outcomes in the intervention group might have been because of the learning model that these videos were based upon. Rehabilitation measures and approaches were described and taught in the videos. However, the demonstration of each, by registered professional physiotherapists, nurses, stroke survivors with significant disability, and speech and swallowing experts, helped augment the learning process and made it easy for patients and their caregivers to mimic and follow each step taught effectively. One of the most important aspects of these movies was watching real stroke survivors perform the exercises themselves; it acted as a morale booster and further encouraged participants to continue with the exercises. The added feature of being able to replay and rewatch these videos might have been another factor that aided their learning process, resulting in significant improvement in functional status.

These results are encouraging in several ways. First, as the extent of improvement in the functionality of stroke survivors demonstrates the ability to return to an improved functionality level with the help of only these movies and their primary caregivers without the need of a skilled nurse or a standard rehabilitation center. This is similar to the results of a trial that compared and concluded equivalent improvements in patients who received home-based rehabilitation therapy with a caregiver and others who received therapy with a professional therapist, thereby establishing home-based rehabilitation as equally effective, as shown with Movies4Stroke [36]. These video lessons filled the niche that the lack of these interventions might have created and bridged the gap between learning and implementation process [37]. Although there have been several discussions calling for attention to NCDs at national and international level to help meet the MDGs, there has also been concern regarding the high costs of treatment and recurrence of debilitating events such as cardiovascular death. These have prompted debate among the policy makers to establish ways for primary prevention, affordable treatment measures, and monitoring of NCDs [38,39]. Movies4Stroke is a step in this direction, aimed at providing better health care, and prevention through diet and healthy activity, thus curbing the alarming burden of NCDs in LMICs

Trial Strengths

The major strengths of this trial were the use of a randomized controlled trial design at a center where an internationally certified care model is followed with an algorithmic approach; hence, the results generated can be attributed to the effect of intervention.

The risk of bias was minimized by paying attention to domains that defined trial quality [19,40,41]. Selection bias was reduced by random centralized computer-based sequence generation; allocation was concealed by opaque sequentially numbered envelopes that were dispatched by CTU, which included university-based staff, which was separate from the research team. Performance and detection bias was reduced by blinded outcome assessment and cross-checks of contamination during the course of the trial and uniform training of staff on study. Attrition bias was addressed by multiple means of follow-up—maintaining good level of understanding with the participants, sending SMS reminder for follow-ups, and preserving communication through Stroke Helpline number. We were successful in keeping an overall dropout rate of less than 9%, with sensitivity analysis showing that were no significant differences between the characteristics of dropouts/those lost to follow-up and those who continued the study in both the groups (Multimedia Appendix 3). Reporting bias was reduced by reporting all possible outcomes of interest as defined in the protocol. Intention-to-treat analysis has been used to report outcomes.

To ensure compliance to the intervention, the first time, the videos were viewed in the presence of a research officer, and intervention was delivered at 100% rate, with complete verbalized understanding and unhurried visualization. To track

usage patterns at home, we remotely monitored the access and use of our app that had been installed in the mobile phone. Early results show that the rehabilitation and tube feeding videos were the highly accessed videos at home. These analyses are still ongoing.

Trial Limitations

The major limitation of our clinical trial is that it is a single-center study, chosen because of the fact that this site provided a standard of care that is algorithmic and replicable; thus, results generated can be attributed to the effect of intervention. In this study, we reported its efficacy, but the performance and potential effect size in different sites may be variable and potentially be more effective, given the usual care standards in even more resource-strapped comparative health systems, for example, the government sector, and thus, external validity is limited. Furthermore, those with more severe stroke or better health access because of socioeconomic status are more likely to visit the health systems and volunteer to participate in an educational training intervention, thus limiting direct external validity. We would definitely include nonresponse analysis in futures studies to further identify characteristics of those most likely to adopt the intervention. Another significant limitation is of contamination bias in an educational intervention. Care was taken to avoid contamination of the nonintervention group with the intervention. To ensure this, videos were shown in a separate room and not at the bedside. Given the fact that families share information, contamination was possible; however, most stroke survivors were on different schedules for follow-up visits and rehabilitation times, and so, we expected less contamination than in areas where a lot of time is spent together by families. Obviously, it is an inherent limitation of an educational intervention that blinding of participants is not possible. This intervention in a study setting required human resources in terms of a study officer and IT back up, development required human resource, and deployment required at least three staff in a study setting. To predict feasibility, we need to further analyze cost-effectiveness and realistic compliance in a clinical setting with the current patient volumes, so this limits directly recommending applicability. This study has collected data on cost-effectiveness, which is under analysis at this time.

Way Forward

In conclusion, we demonstrate the potential of mHealth interventions to save lives and reduce disability in low- to middle-income country settings; we also show that these interventions are safe and feasible, despite their complexity. Our results demonstrate the key importance of health theory in designing these complex health interventions for replicability and informing further interventions. Interventions that target compliance must have repetitive reminders for nonintentional adherence, and those that target knowledge and skills transfer must have the capacity to repeat and bolster confidence as well as provide the user the opportunity to model themselves from the materials taught, despite the lack of literacy skills to be safe. Complex interventions targeting these settings need to have a design theory in place to deliver both these aspects to be effective.

Please refer to Consolidated Standards of Reporting Trials-eHealth checklist for details regarding this Movies4Stroke trial [42].

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed Mortality Analysis.
[DOCX File , 24 KB - mhealth_v8i1e12113_app1.docx]

Multimedia Appendix 2
Non-pharmacological interventions targeting stroke survivors and their caregivers.
[DOCX File , 18 KB - mhealth_v8i1e12113_app2.docx]

Multimedia Appendix 3
Analysis of Lost to Follow Up and Mortality.
[DOCX File , 14 KB - mhealth_v8i1e12113_app3.docx]

Multimedia Appendix 4
CONSORT-EHEALTH checklist V1.6.1.
[PDF File (Adobe PDF File), 2557 KB - mhealth_v8i1e12113_app4.pdf]

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Abbreviations

AKUH: Aga Khan University Hospital
ARR: absolute risk reduction
BI: Barthel Index
BP: blood pressure

CTU: clinical trials unit
eHealth: electronic health
ERC: Ethical Review Committee
HbA_{1c}: glycosylated hemoglobin A_{1c}
IT: information technology
LDL: low-density lipoprotein
mHealth: mobile health
mRS: Modified Rankin Scale
NCD: noncommunicable disease
NIHSS: National Institutes of Health Stroke Scale
NNT: number needed to treat
OR: odds ratio
RR: risk ratio

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Original Paper

A Gig mHealth Economy Framework: Scoping Review of Internet Publications

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Abstract

Background: The gig economy (characterized by short-term contracts rather than being a full-time employee in an organization) is one of the most recent and important tendencies that have expanded through the global economic market thanks to advances in internet and communication technologies. Similarly, mobile health (mHealth) technologies have also evolved rapidly with the development of the internet and mobile apps, attracting attention globally for their health care benefits.

Objective: This study aimed to propose an integration of mHealth within the framework of the gig economy that leads to a new dimension of health care services and the proposal of a new term: gig mHealth.

Methods: A review and systematic search of articles, books, and opinions that allowed for answering the research questions were executed through the internet. In this sense, the concept of the gig economy and examples, advantages and disadvantages, were reviewed. Similarly, the general characteristics of mHealth technologies were revised. In addition, the role of technology in supporting the development of the gig economy and mHealth technologies and the interactions between them were investigated.

Results: The findings suggested that the gig economy is characterized by its flexibility in working hours, on-demand work, free agents, freelancing, freedom in the choice of work, and independent contracts. In addition, an analysis of an mHealth system indicated that it was composed of patients, specialists, nurses, and database administrators. In this system, patients and specialists or nurses are connected to cloud services for the transmission of data and medical information through a mobile app. Here, the administrators update the database and app features, among other technical tasks. Conversely, a general structure of an integrated gig mHealth system was developed. In this structure, the mHealth care services and the mHealth care activities were incorporated into a gig economy model. In addition, a practical example of an integrated view of a gig economy app in mHealth that illustrates the interaction between the patients (consumers) and providers (partners) of mHealth care services, mHealth care activities, health care professionals, and individual contractors was presented. The consumers and providers were interconnected with the health care company, brand, or firm through digital means using a mobile app or Windows platforms.

Conclusions: The analysis carried out in this study suggested the possibility of integrating mHealth within the framework of the gig economy enhancing health care service delivery and the management of health care activities. The following 4 major areas of apps proposed in the mHealth framework that can catalyze the operations using the features of the gig economy were sharing/renting medical and diagnostic equipment and resources, on-demand appointments/self-health management, on-demand health care services, and assigning health care activities/gigs to individual contractors. This integration leads to a new dimension for health care services and the proposal of a new term: gig mHealth.

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KEYWORDS

gig economy; gigs; mHealth; sharing economy; gig mHealth

Introduction

Background

A major changing trend has been observed in the work culture during the last few years. The majority of millennials and employees are shifting toward a working model that is identified by freedom in working hours, choice of work, freelancing, and small tasks (gigs), characterized by short-term contracts rather than being a full-time employee in an organization. This changing tendency is known as a gig economy, and it has been increasing rapidly. It was calculated that there were more than 5 million gig workers in the United Kingdom [1]. In addition, it was estimated that approximately 34% of the working people in the United States is the portion of the gig economy population, which is expected to reach 43% by the year 2020 [2]. This changing trend is observed across various countries, and it is impacting the work culture of organizations, products, and delivery services through the various sectors of the global economy [3]. Extensive research is needed to be able to determine the benefits of such an economy. However, the benefits, flexibility, and freedom of working in a gig economy are attracting the attention of various organizations, millennials, and researchers to investigate the possibility of integrating the concept into various systems. Previously, this conception has been applied successfully in several companies around the world: Uber, Turo, and Upwork [4-6]. Uber is a car rental company, Turo is a sharing car market place, and Upwork is a mobile platform for hiring freelancers in different fields of universal knowledge.

In relation to health care, we found that some companies such as Nomad, Enzyme, and Medely have used some ideas from the gig economy to hire doctors and nurses to perform independent and short-term jobs in hospitals [7-9]. However, in the review of the literature, no company was found that systematically applied the principles of gig economy in mHealth that integrate the use of the internet, medical sensors, mobile computing, and communication technologies for managing and delivering health care access by diverse workforces and activities [10-12].

Linking mHealth and gig economy features may enhance the performance features of mHealth and ensure effective management and delivery of health care services. Considering mHealth as a point of focus, the aim of this study was to propose the possibility of integrating mHealth into the gig economy features for the effective management of health care services. This option conducts to a new dimension for health care services and to the proposition of a new term: gig mHealth.

Gig Economy

The gig economy is a relatively new term that has attracted the attention of the world because of its accessibility to employment opportunities and to the various legal, ethical, and business complications arising from it. It has been defined from various perspectives, considering the factors of influence. A *gig* usually refers to a job or task, which often has a short-term connection with a particular business. The workers in such a scenario are employed in a specific task assigned for a particular period [13].

The gig economy also refers to an on-demand economy with independent work arising out of choice and necessity according to the McKinsey Global Institute Report, in which the independent workers are classified into 4 segments: free agents, casual agents, reluctant workers, and financially strapped workers [3]. According to this report, 162 million people who represent 20% to 30% of the working population in Europe and the United States are involved in the gig economy. This information reflects the diversity and growth of the gig economy.

Similarly, the gig economy is denoted as a sharing economy where the operational tasks in the business are divided into smaller tasks that are assigned to independent contractors who cannot be considered as employees. The business aim is to reduce the infrastructure and resource costs by sharing the work with independent workers at lower wages compared with an employee's wages. It was calculated that the gig economy was worth US $26 billion in 2015 [14].

Another approach to defining the gig economy is identified from the perspective of the types of work carried out: crowdwork and work on demand via an app [15]. In *crowdwork*, a series of tasks, which have to be completed over Web-based platforms, are outsourced to a group of individuals or organizations, and "work-on-demand via app" is a modality in which traditional working activities such as cleaning, babysitting, clerical work, software development, and lawyers are accessed directly by app users [15].

In general, the features of a gig economy consider work on demand, free agents, freelancing, independent work, flexibility in working hours, freedom of choice of work, and independent contracts.

Although the concept of the gig economy is seen by a few as a boon for the employed and unemployed, others have raised various concerns over its benefits. Therefore, there is a need for a clear understanding of its nature, implications, advantages, and underlying issues and concerns.

Role of Technology in Enhancing the Gig Economy

The advances in the internet and communication technologies are considered to be one of the most effective means through which the gig economy is developing. This has enabled the organizations to restructure their operational activities in a way that the greater share of the work is assigned to the individuals who are not the employees of the organizations, thereby reducing the operational costs. The new technologies also make it easier to organize the workforce based on the project or specific skills on a short-term contractual basis [13,16]. Unlike the days before the internet, technology has enabled organizations to find the workforce desired, pay them small amounts, and fire them when they are not needed without any obligations. Similarly, the individuals can accept any contract

of work for the time they wish and opt out without obligations. In addition, individuals from rural and remote areas can have access to the jobs at a national or an international level using internet technologies in the gig economy [17].

Developments in smartphone technology have identified new ways for accessing gig work, reshaping the market space, and providing new ways to access this market by the consumers and workers. Its ability to reach remote areas and impact a large group of workers and their livelihoods through the smartphone and other technology apps have made the gig economy one of the most preferred ways of earnings [18]. With the technology support in gig economy, new terms have been proposed such as digital labor, digital workforce, and Web-based freelancers and the need has been felt for redefining the labor policies in light of the growing size of the gig economy [19]. Furthermore, the increasing social presence of people on the Web-based platform and new business promotion techniques through social networking technologies have paved the way for advancing gig economy deployment in various industries, including transportation, hospitality, traditional services such as plumbing, tuitions, rentals, and consultations, and other businesses.

Advantages and Risks/Issues in the Gig Economy

The gig economy can significantly improve the overall employment rate and enhances the freedom and choice of work because of which it is seen as a boon to the new entrepreneur generation, as shown in the study by Burtch et al [20]. It helps the entrepreneurs to minimize the investment costs and gain the maximum output by streamlining the operations across the individual contractors at lower wages [21]. Extreme flexibility in the gig economy has worked as an advantage for the workers who are interested in having freedom in working hours, working location, and finances. In addition, computerization and globalization have enhanced the gig economy with potential benefits for deployment [22]. The gig economy also offers a platform for older people who have retired from their jobs, offering more flexibility to work. In a study conducted by Zurich UK, an insurance company, it was found that over one-third of the people older than 55 years moved to the gig economy for temporary jobs to ease the transition into retirement [23]. The gig economy can be beneficial to consumers as they can effectively and directly access various services for low costs without mediators or share costs. For example, Uber allows drivers with personal vehicles to be part of the force, helping the company to minimize the investment costs while providing benefits to the gig worker or driver, and the concept of share ride on its app reduces the cost of a ride for the consumer [24]. Similarly, a recent start-up, *InCloudCounsel*, provides various legal services offered by a group of lawyers that can be accessed by the consumers without any intermediaries [25].

On the contrary, various issues and concerns have being raised over the gig economy. One of the major issues is the perspective in which an individual or independent contractor is observed by the business. They are not considered as employees by the organizations and are not benefited from a provident fund, pension scheme, insurance, and retirement policies. In addition, the minimum wages for independent workers are rarely met, and the bulk of business risk is shifted to the workers, making them vulnerable to many risks [21,22]. Another important observation is that with the evolution of contingent work in the gig economy, new employee-employer relationships have emerged, and a question to be considered is whether or not the legal frameworks governing the workforce have updated the system with these new relationships [26]. Referring to workers as independent contractors and not as employees benefits the organizations by avoiding additional costs. This has proved to be the litmus test for the courts to determine the status of the workers [27]. It has also been suggested that entrepreneurial activity may be reduced as the gig economy offers stable employment for the employed and unemployed [20]. As it is known, safeguarding the retirement plans and savings is one of the important aspects of any employment. However, only 16% of the gig workers have retirement plan schemes, whereas 52% of the employees have access to employer-sponsored retirement plans [28].

As the gig economy is relatively new and developing rapidly, it has to be observed through various case studies and through extensive research to investigate and address the various issues surrounding it.

Review of Gig Economy Cases

There are various examples in which the gig economy has proved to be successful, effective, and efficient in delivering services and enhancing employment opportunities. To investigate the opportunities and issues that come with the application of the gig economy, some of the major cases such as Uber, Turo, and Upwork models are reviewed in the following sections.

Uber Model

Uber, a car rental company, is one of the first adopters of the gig economy, and perhaps the most widely considered example. It started in 2009 as a different alternative to common taxi services and has quickly grown to be one of the top multinational companies in the world, with an estimated worth of US $65 billion [4]. Uber is a mobile app that acts as a platform and a point of contact for the drivers and riders. Various services are offered on the platform, including premium and limousine rentals (Uber Black), less expensive rides with medium-range cars (Uber X and Uber Go), and economy services through Uber Taxi and delivery services such as food through Uber Eats. Both drivers and passengers are required to agree upon Uber's terms and conditions on the app, which declares that both are independent contractors, are subject to ratings and reviews, and the services can be denied if the ratings fall below Uber's threshold [4]. The app platform is simple and easy to use. The passengers can log in to the app and request a service for their location. An alert is raised with the nearby drivers on the Uber app, and the request can be accepted by the drivers. However, the drivers are not bound to accept all requests, giving them the freedom to work as per their convenience. If the passenger desires, the approximate fare is presented in the app before confirming a booking. Once the booking is confirmed, the driver picks up the passengers and drops them at the desired location given at the time of booking. The payment can be made through electronic wallets, cash, credit cards, or other means [29].

Turo Model

Turo is a Web-based and mobile app for car owners who do not wish to drive and can rent their cars for a day or more. It is a car-sharing marketplace, where the travelers can rent any car they want from a community of local car owners. It has its operations spread across more than 4500 cities and 300 airports with a fleet of more than 800 models. The owner's average monthly earnings are estimated to be US $720 [5]. The users can sign up on the mobile app or on the website and need to accept the terms of service. The users can then search for the car according to their needs and interests and book the car. The charges for the daily rentals are given for each car, and the price may vary with the model and year of manufacture of the car. The rental price is finalized by Turo after assessing the condition of the car. Once booked, the owners have 8 hours to accept or reject the request. The users can either pick up or request delivery of the car and then return it after completing the trip. All the cars are insured, and Turo takes all safety measures before renting out. Similarly, the car owners can register and list their car on the Turo platform. They can respond to the requests made and can either deliver or give out the car and thus can earn while not using the cars [5].

Upwork Model

This company is one of the largest Web-based and mobile platforms for hiring freelancers in a wide range of operations including Web, mobile, software development, graphic/creative designing, administrative support operations, information technology and networking, writing work, sales and marketing, data sciences and analytics, translation, legal affairs, accounting and consulting, and other tasks. With an extensive workforce in more than 3500 skill areas, freelancers across the globe are earning more than US $1 billion every year through Upwork [6]. The platform provides an easy interface not only for hiring freelancers but also for freelancing. The people who want to hire freelancers can register and start posting jobs, which are analyzed by Upwork, and a short list of likely candidates is sent to the hirers. The hirers can then browse the freelancers' profiles, review proposals, and schedule a chat before offering work. The hirers can send and receive files over the app in a secure environment and share feedback in real time. In addition, the payment process is simplified as Upwork delivers payments for freelancers in more than 170 countries through the effective global payment network, with invoicing and reporting capabilities [30]. The freelancers have the freedom to work on ideal projects and can ensure more success. A streamlined hiring process in Upwork ensures the projection of the right applicants for the job. Hourly/fixed price projects give more freedom to choose from the types of work by the freelancers. The service fee for freelancers is nominal, where 20% of the billing amount is charged for the transactions up to US $500; 10% for billings between US $500.01 and US $10,000; and 5% for billings that exceed US $10,000 [31].

These are the 3 major gig economy examples that have been growing rapidly. There are various other examples in various sectors where the gig economy has proved to be successful. Therefore, the gig economy can be streamlined into different sectors to promote easy delivery of services with a sharing economy and enhanced operational efficiency.

Gig Economy and Health Care

The health care systems have already started to attempt the gig economy, which can be observed in the temporary hiring of nurses, doctors, technicians, and other clinical specialists [32].

This trend is, among other causes, because of the increase in the costs of medical attention, the shortage of medical personnel, and the fact that many health care professionals find that the gig economy offers them more versatile and lucrative independent jobs [32,33]. One of the objectives of the gig economy in institutions dedicated to health care is to reduce labor costs, optimize the needs of medical personnel, and at the same time provide excellent medical care to patients. In general, the gig economy can offer various benefits to the health care systems [33].

On the contrary, under this modality of the economy, health systems can hire temporary professionals when they need them, and the professionals can obtain the best work opportunities adapted to their interest [32].

For example, Nomad is a Web-based platform through which independent doctors negotiate their contracts with hospitals [7]. Under this modality, both the hospital and the doctor achieve what they want, they save money, and Nomad receives a commission to facilitate the process [7]. Other platforms connecting doctors to hospitals and other health care facilities are Enzyme and Medely [8,9].

In addition, the British government has proposed to design an app for England's National Health Service that delivers on-demand health care based on the gig economy style [34].

Mobile Health

mHealth is a terminology used in the application of mobile/communication and internet technologies for the delivery of health care [10,35]. It is defined as "emerging mobile communications and network technologies for healthcare systems" [10]. It can also be described as the integration of mobile computing, communications technologies, electronics, sensors, and medical services to provide mHealth care applications [12,36,37]. In general, the definition of mHealth varies according to the areas of application, the services involved, and the technologies used. The applications of mHealth technology have been on a rapid increase in recent years, attributing to the enormous increase in the use of smartphone and internet technologies across the globe [11,35]. Various authors have identified that mHealth can have a significant impact on the management and delivery of health care services by reducing the operational costs and increasing operational efficiency [38,39]. In addition, it is convenient to point out that despite the benefits provided by the use of mHealth technologies to improve the health care delivery and motivate patients for self-care, there are risks related to the privacy and security of patient data when these technologies are used [35,40].

In general, a common mHealth structure includes 3 main actors: patients, specialists/nurses, and database administrators [11].

The patients self-handle their diseases remotely utilizing a mobile app that is linked to the cloud services for the transfer of data and information. The smart app can also be integrated (using Bluetooth, Wi-Fi, or any other connection) with biosensors or medical devices such as blood pressure monitors, glucose sensors, or other instruments. The data from the biosensors located on the patients' body can be sent to servers on the cloud using the internet connection. Then, the specialists/nurses connected to these servers on the cloud examine the collected data and return medical information based on the diagnosis results/queries placed by the patients. The administrators carry out all the technical tasks such as updating the database/app features, data entry work, and other actions. The mHealth structure involves various activities such as diagnosis, feedback, query response, data entry, data updates, and development of smart apps, among other actions. In the context of a gig economy, these activities can be simplified to smaller tasks or gigs that can be carried out or shared among several independent contractors or freelancers.

Methods

To carry out this research on the integration of mHealth systems in the context of the gig economy, a review and systematic search of articles, books, and opinions that allowed answering the research questions were executed through the internet. Only bibliographic sources that presented serious, reliable, and relevant information on the subject of research were included and analyzed.

In this search, the concept and characteristics of the gig economy, advantages and disadvantages, models, and examples of this economy were investigated. Similarly, the general features of the mHealth technologies and the possibility of integrating them into the gig economy were examined. In addition, some cases of health care systems in which some ideas related to the gig economy have been applied were considered. Similarly, the role played by the internet and mobile apps in the development of the gig economy and mHealth technologies was explored.

Results

An overview of a gig economy structure is presented in Figure 1. This figure suggests that the characteristics of a gig economy consider flexibility in working hours, on-demand work, free agents, freelancing, freedom in the choice of work, and independent contracts.

Similarly, Figure 2 shows a common mHealth structure integrated by patients, specialists/nurses, and database administrators [11]. The patients and specialists/nurses are connected to the cloud services for the transmission of data and information. According to the figure, the patients manage the disease themselves remotely using a mobile app connected to the cloud services. Analogously, the specialists and nurses linked to these services on the cloud analyze the received data from the patients and send medical information to them based on the diagnosis results and their questions. Here, the administrators update the database and app features, among other technical tasks.

On the contrary, a general structure of an integrated gig mHealth system is shown in Figure 3. In this figure, the mHealth care services and the mHealth care activities are incorporated into a gig economy system categorized by on-demand work, free agents, independent contracts, and freelancing.

In addition, a practical example of an integrated view of a gig economy app in mHealth is presented in Figure 4. This figure illustrates the interaction between the patients (consumers) and the providers (partners) of mHealth care services, mHealth care activities, health care professionals, and individual contractors.

Figure 1. Gig economy structure.

Figure 2. General mobile health framework.

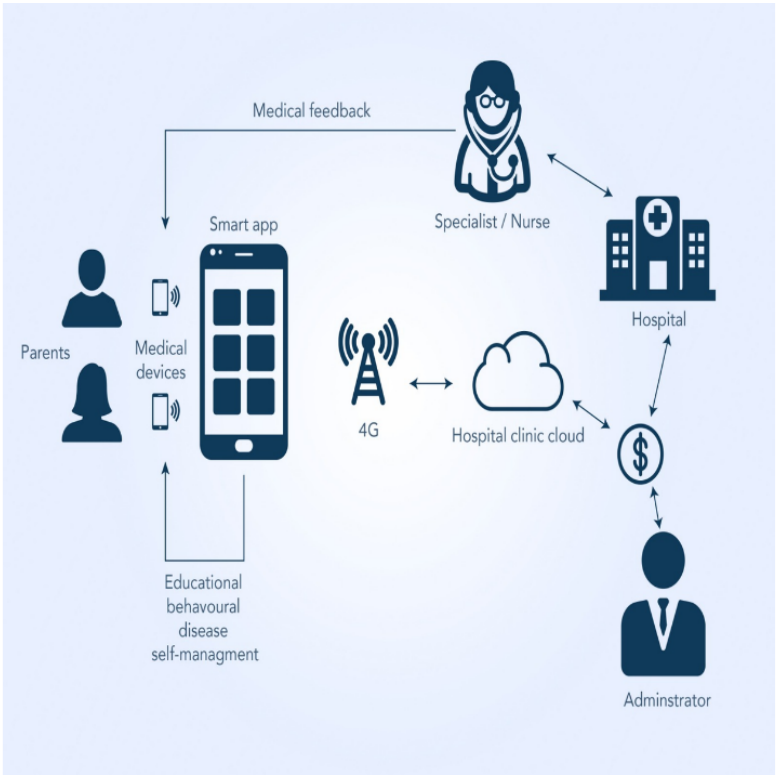


Figure 3. General gig mobile health system.

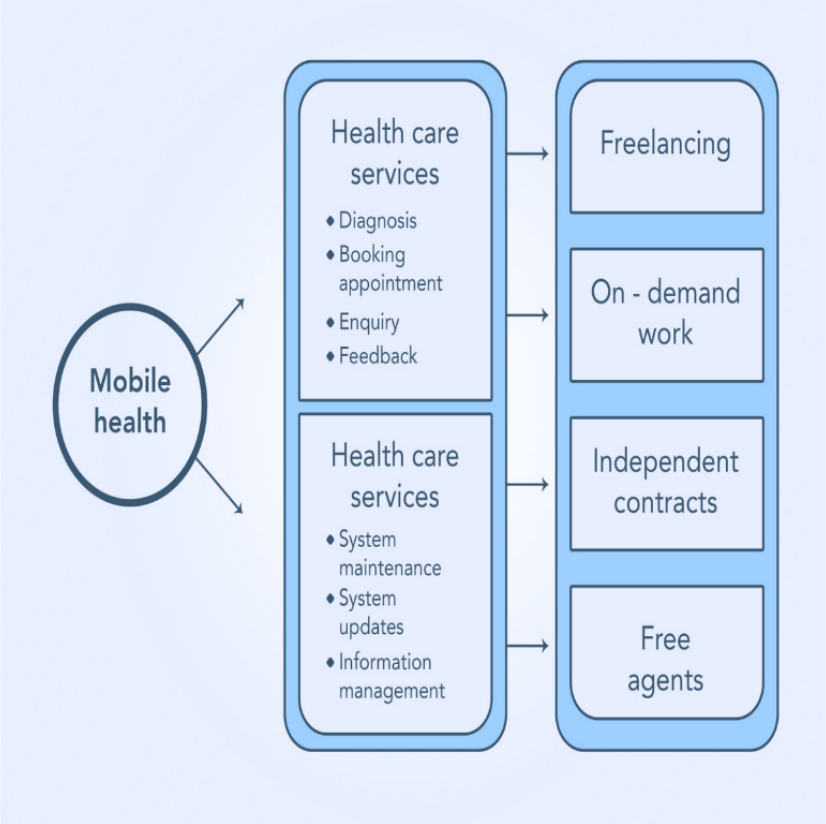
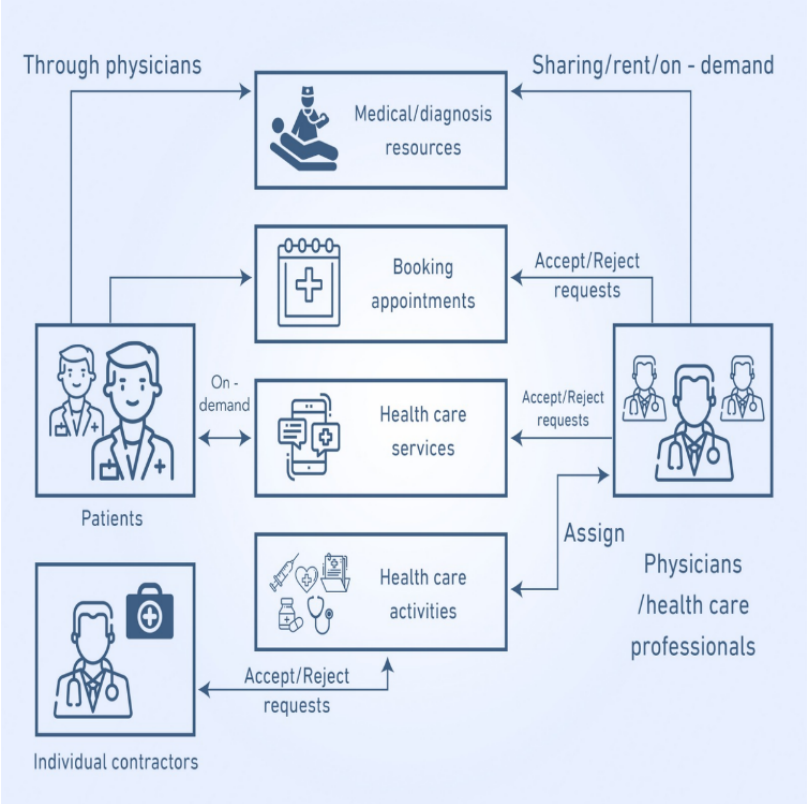


Figure 4. Gig economy adoption in a mobile health framework.



Discussion

Principal Findings

This research proposes the application of the gig economy in mHealth systems, which gives rise to a new dimension for health care services and to a new term that we have called *gig mHealth*. The gig/sharing economy can be applied in mHealth systems for effective use of resources such as medical equipment, physicians, nurses, diagnosis, and access to health care services in general. A gig mHealth dimension can be defined as "an approach of integrating the gig economy/sharing concepts such as freelancing, independent contracts, crowdwork, and on-demand works into the m-health framework, mainly in the healthcare services and activities." This integration results in the effective management of health care activities and the delivery of health care services in an mHealth framework.

As shown in Figure 3, in a general gig mHealth system, the mHealth care services (diagnosis, booking appointments, enquiry, and feedback) and the mHealth care activities (system maintenance, system updates, and information management) are integrated into a gig economy system characterized by freelancing, on-demand work, independent contracts, and free agents. In this model, the mHealth care activities and the mHealth care services can be simplified to smaller tasks (gigs), and these gigs can be outsourced or shared among many independent contractors.

To integrate the mHealth systems in a practical way with the characteristics of a gig economy similar to Uber, Upwork, Turo, and other companies, it is convenient to follow the guidelines of the so-called aggregator business model that encompasses the general principles on which the economic structures of the mentioned companies are based. This model is also called the on-demand delivery model or the Uber for X model [41-43].

According to this model, the aggregator is a firm, company, or brand such as those mentioned previously or a company that integrates mHealth systems and the gig economy, as in our particular case, which organizes or aggregates a team of suppliers or partners to provide goods/services, gigs, to a group of clients or consumers [41-43]. The provider of goods/services, gigs, or partners sign a contract with the company that specifies the conditions of service, quality, price, and commission received by the aggregator or the organizing company. It is specified that the partners may accept or reject the offer of the aggregator [42]. The contract also specifies that the company or the firm will allow the partners to contract the service through an app available on mobile phones or in a Web-based platform [41]. Similarly, the clients, who in our case are patients, will also, use the platform or mobile phones to access the services, gigs, provided by the partners of the company. It is pertinent to indicate that the aggregator or the company helps suppliers to market their services, but they are not their employees, they are partners of the business. In this model, both consumers of services and suppliers of goods/services are customers of the company in a win-win way [41]. After a service is completed, the customer or client can rate the service and the provider, and the provider can rate the customer [42].

Following the described aggregator model, an integrated view of a gig economy app in mHealth is presented in Figure 4. As shown in Figure 2, the mHealth system already has a network of physicians/nurses, health care units, database administrators, internet connections, and mobile apps connected to the hospital/clinic cloud and patients. In addition, the mHealth structure involves various activities such as diagnosis, feedback, query response, data entry, data updates, and development of smart apps, among other actions. In the framework of a gig economy, these activities can be simplified to smaller tasks or gigs that can be carried out or shared among several independent contractors or freelancers.

In this context, as shown in Figure 4, according to the aggregator model, the consumers are the patients, and the partners are the providers of mHealth care services (diagnosis, booking appointments, inquiry, and feedback), mHealth care activities (system maintenance, system updates, and information management), health care professionals (physicians, nurses, technicians, and other staff), and individual contractors. In this model, the customers and providers are interconnected with the aggregator firm, brand, or company through digital means by using a smartphone app or Windows platforms. As suggested in the figure, the providers can accept or reject the requests of the aggregator.

In addition, in Figure 4, the scope of the gig economy app in mHealth is explained considering an integrated view of the following main areas: sharing/renting medical and diagnostic equipment and resources, on-demand appointments/self-health management, on-demand health care services, and assigning health care activities/gigs to individual contractors.

In this sense, in a gig mHealth system, it is possible to share medical and diagnostic equipment and resources to make optimal use of expensive resources such as magnetic resonance imaging scanners, positron emission tomography scanners, x-ray/computerized tomography machines, and other types of equipment that are only available in large hospitals or health care centers by renting them for a certain time when necessary. This allows sharing such equipment among the network of doctors on an hourly rental basis. This possibility benefits the access of the private doctors to the diagnostic equipment when it is required, which minimizes the costs and references and improves the speed of the provision of medical care services.

Similarly, on-demand appointments/self-health management and the freedom of choosing doctors by the patients can be a major development in health care sectors that can be reached in a gig mHealth system. This allows having access to doctors at the right time and place, which is an important aspect in the delivery of health care services. In a gig mHealth system, the doctors can register on a gig economy platform, and the registered patients can access the doctor's/physician's profiles and book an appointment within minutes. This can enable the freedom of access to health care for the patients 24 hours a day and 7 days a week in any place. The platform can be embedded with various features by adopting the technology. For example, if the users are not sure whether to visit a doctor, instant health advice can be provided through the app using a chat feature. Similarly, the users can create their digital twin on the app

recording their current health condition and then access their predicted future health by the app.

Analogous to booking appointments, the users can select and book for on-demand health care services delivered at home such as dispensing medicines, physiotherapy, blood sample collection, glucose monitoring, and other services from various providers, which not only helps the patients in minimizing the costs of hospital visits but also lets them select the professionals and services based on their requirements.

In addition, various health care activities can be outsourced to individual contractors. For example, health care tasks such as vaccination can be assigned to nurses on a contractual basis where the children/patient information can be accessed from the mHealth systems and which can be updated after completing the jobs. There is even scope for outsourcing complex tasks such as major surgeries/operations that need to be performed by a health care expert. The professional experts in the mHealth system can accept/reject such proposals after examining the condition of the patients.

Among all the areas of apps examined, reviews and ratings can be used as tools to measure the abilities and capabilities of the resources. In any case, the major point of the application of the gig economy in mHealth is to simplify the health care activities/tasks into gigs/small pieces of work that can be assigned to individual contractors.

In relation to the previous ideas, it is worth mentioning that there are some examples of applications of the gig economy in the health care area. One of them is Nomad, which is a Web-based platform that connects freelance doctors and nurses to hospitals directly [7]. Through this platform, doctors and nurses negotiate their contracts, gigs, with hospitals. Nomad charges a commission for facilitating this connection. Other similar platforms are Enzyme and Medely [8,9].

As the possibility of integrating mHealth within a gig economy model represents a new technical framework that can provide benefits in health care delivery, it is necessary to carry out more research to investigate the impact of integrating mHealth real cases in the structure of the gig economy.

Conclusions

The analysis carried out in this study suggests the possibility of integrating mHealth within the framework of the gig economy, enhancing health care services delivery and the management of health care activities. The following 4 major areas of applications proposed in the mHealth framework that can catalyze the operations using the features of the gig economy are sharing/renting medical and diagnostic equipment and resources, on-demand appointments/self-health management, on-demand health care services, and assigning health care activities/gigs to individual contractors. This integration leads to a new dimension for health care services and the proposal of a new term: gig mHealth.

Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health

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Original Paper

Applicability of the User Engagement Scale to Mobile Health: A Survey-Based Quantitative Study

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Abstract

Background: There has recently been exponential growth in the development and use of health apps on mobile phones. As with most mobile apps, however, the majority of users abandon them quickly and after minimal use. One of the most critical factors for the success of a health app is how to support users' commitment to their health. Despite increased interest from researchers in mobile health, few studies have examined the measurement of user engagement with health apps.

Objective: User engagement is a multidimensional, complex phenomenon. The aim of this study was to understand the concept of user engagement and, in particular, to demonstrate the applicability of a user engagement scale (UES) to mobile health apps.

Methods: To determine the measurability of user engagement in a mobile health context, a UES was employed, which is a psychometric tool to measure user engagement with a digital system. This was adapted to Ada, developed by Ada Health, an artificial intelligence–powered personalized health guide that helps people understand their health. A principal component analysis (PCA) with varimax rotation was conducted on 30 items. In addition, sum scores as means of each subscale were calculated.

Results: Survey data from 73 Ada users were analyzed. PCA was determined to be suitable, as verified by the sampling adequacy of Kaiser-Meyer-Olkin=0.858, a significant Bartlett test of sphericity (χ^2_{300}=1127.1; P<.001), and communalities mostly within the 0.7 range. Although 5 items had to be removed because of low factor loadings, the results of the remaining 25 items revealed 4 attributes: perceived usability, aesthetic appeal, reward, and focused attention. Ada users showed the highest engagement level with perceived usability, with a value of 294, followed by aesthetic appeal, reward, and focused attention.

Conclusions: Although the UES was deployed in German and adapted to another digital domain, PCA yielded consistent subscales and a 4-factor structure. This indicates that user engagement with health apps can be assessed with the German version of the UES. These results can benefit related mobile health app engagement research and may be of importance to marketers and app developers.

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KEYWORDS

mobile health; mhealth; mobile apps; user engagement; measurement; user engagement scale; chatbot

Introduction

Background

In recent years, mobile apps addressing health and fitness issues have grown at a remarkable rate. Although there are significant advantages to health apps, such as lower health care costs and increased accessibility to health advice [1], their full potential is still untapped, mainly because of a failure to engage users in terms of sufficient and effective use [2,3].

User engagement has been recognized as a key factor in determining the success of an app [4-6] because it is linked to

the user's intention to continue using a mobile app [7,8]. Continued use, a subset of behavioral engagement, is a critical issue because of the highly competitive nature of the mobile app market [8,9]. However, it is important for researchers to move beyond user continuance behavior and examine user engagement as a broader concept [10].

Originally influenced by the user experience movement in human-computer interaction (HCI), user engagement has become a buzzword in various areas, including mobile health apps [11]. However, there is no general agreement as to what constitutes user engagement or how it is operationalized and measured [11,12].

Prior Research

Theoretical Perspectives

Although there is no user engagement theory as such, some related theories provide insights into why users engage with technology [11]. In the absence of a specific theory, researchers have relied on established theories from other disciplines [13]. Much research on user engagement has been based on Csikszentmihalyi's theory of optimal experiences, which is also known as the flow theory [11]. Particularly in the HCI and computer science literature, engagement is often seen as a subjective experience of flow [12]. Some of the attributes of flow, such as focused attention, feedback, control, and activity orientation, also occur in engagement [14]. However, it is suggested that the "degree and manifestation of these attributes may be what sets these concepts apart" (p.12) [11]. A further difference between user engagement and flow is how the 2 concepts are related to positive and negative emotions. In the flow theory, positive experience is particularly important [15], whereas user engagement is held to entail a more complex spectrum of emotions [11].

User engagement studies have also incorporated insights based on Dewey's philosophy of experience [16]. Originally, Dewey aligned his philosophy of experience to the field of education. However, his views have also been perceived as convincing and helpful in clarifying aspects of experience in the HCI world. In particular, 4 threads of experience, rooted in Dewey's philosophy, describe major aspects of users' experience with technology, which are the sensual, emotional, compositional, and spatiotemporal threads [17]. The sensual thread affects sensory engagement, the emotional thread is concerned with how users engage with the product emotionally, the compositional thread refers to users' relationships and interactions with others or with things, and the spatiotemporal thread is the aspect of space and time during the experience [17].

Concept of User Engagement

Without a doubt, engagement with technology is a multifaceted, inherently complex phenomenon [5,18,19]. Definitions of user engagement vary depending on the applications, settings, and variables of interest of user engagement research [5,13]. One of the earliest definitions proposed that "user engagement is a user's response to an interaction that gains, maintains and encourages their attention, particularly when they are intrinsically motivated" [20]. Further definitions are given by various authors (eg, [9,18-22]), and a certain overlap of aspects is apparent. For the purpose of this study, the following commonly cited principles were considered. User engagement is a quality of user experience [21,22] and is multidimensional [9,18,22]. There is no consensus concerning the meaning of the dimensions, but the cognitive, emotional, and behavioral dimensions are prevalent in user engagement literature [11,14,23]. In addition, engagement can be viewed as a process during an interaction or as a product of experience [11,14,24]. This study focused on the product- or outcome-based view where engagement attributes are crucial because they represent what a user finds naturally compelling when interacting with technology [14].

Measurement of User Engagement

Its complex nature and varying definitions make user engagement difficult to quantify [13]. We used the search terms ("user engagement" OR "consumer engagement" OR "engagement") AND ("mobile health*" OR "mobile health app*" OR "mHealth") and queried the databases PubMed, Web of Science Core Collection, and ProQuest. This search determined 3 groups of user engagement measures: self-reported methods, physiological methods such as eye tracking, and user analytics methods such as dwell time. These methods and measures are often used in combination [13].

Self-reported measures are predominant in user engagement research because they are "useful for capturing users' attitudes toward, cognitive appraisals of, and emotions surrounding their experiences of engagement with technology" (p.15) [24].

Self-reported measures target subjective user engagement by way of users' perception of technology [24], mainly through postexperience questionnaires [13,24] to measure engagement characteristics based on an interactive experience in surveys conducted with large numbers of users [25].

We found 3 studies that explicitly stated to have examined the concept of user engagement within a health app: 2 of them operationalized and measured user engagement by means of metrics [26,27] and 1 used a mixed methods approach by analyzing app usage data and conducting a satisfaction survey [5]. Other studies were conducted in similar topic areas of user engagement, for example, user experience [28] or continued intention to use [29-31].

Research Problem and Question

The issue of user engagement is a concern for providers of health apps, as insufficient engagement by users with an app affects its success rate [32,33]. It has been reported that health app users are usually not very committed to a particular app and will use it only for a short time and in a casual manner [34]. This phenomenon is known as the law of attrition and describes the situation that in any electronic health (eHealth) trial, a substantial proportion of users drop out prematurely or stop using the app [35]. For example, a retrospective cohort study of a dietary self-monitoring mobile app discovered that only 3% of 190,000 downloads resulted in a person using the mobile food journal for more than 1 week [29]. This implies that high dropout rates are natural and are a typical feature of health apps. However, study results on the reasons for this phenomenon vary

and mostly only identify the characteristics of health app users [36,37].

From an academic research perspective, there has been increasing interest from researchers in mobile health because of a growing number of health apps available. Past studies in this field can be divided into acceptance studies, design studies, and behavior change studies [1]. Nonetheless, research on the usage of health apps is still in its early stages [38].

In particular, too little attention has been paid to the conceptualization and measurement of user engagement with health apps [5,39]. Future research suggestions include features that might affect user acceptability and preferences [34], motivational factors that may lead to more sustained app usage [38], or other factors that relate to increased user engagement with commercially available health apps [26]. Furthermore, although user engagement has been conceptualized differently across the literature [11,12], a better understanding is required as to how different attributes of mobile apps influence user engagement [8]. Researchers agree that user engagement can best be operationalized by examining user system attributes that reflect an engaging experience and, therefore, constitute defining features of user engagement [24,40].

Considering the aforementioned gaps, this study sought to answer the following research question: to what extent does an existing user engagement scale (UES) yield consistent subscales in the context of health apps? As user engagement is context specific [11], for example, to the situation that the interaction triggers, and hence serves the purpose of collecting comparable data, the health app Ada is used as an example in this study. Ada was developed by Ada Health, a medical technology company based in Berlin, as a personal health guide that supports the user's health care journey with a personalized interactive chat function [41]. In 2017, this medical app had the fastest growing number of users in Europe and was ranked as the number one medical app in 130 countries worldwide [42]. Furthermore, Ada's chief executive officer has high ambitions: he and his team aim to achieve 100 million users by 2020 [42].

Methods

Scale

To answer the aforementioned research question in the best possible way, we first need to consider the scale. The recommendation when applying a self-reported measurement is to rely on previous questionnaires [24]. In the context of digital health, an eHealth engagement scale was developed [43]. We chose the eHealth scale because its characteristics are similar to ours. Both studies have an HCI setting [43], but they measured engagement with eHealth content on a website and in a laboratory context. The mobile aspect of our study is probably not as important because spatial data do not matter in both contexts. However, we still propose that through the smaller window of a phone, user engagement might be different. Therefore, this scale was not found to be an appropriate fit for this research context also because no other studies could be found that utilized this scale, causing us to question its robustness and validity.

A better fit was the UES by O'Brien et al [40], a psychometric tool used to measure user engagement with a digital system. Using empirical observations and theoretical elements of the flow theory, as well as John Dewey's philosophy of experience, the original scale has in recent years been applied to over 40 published studies in various HCI settings, such as Web news, educational technologies, social networking, or information search [13]. Few studies have used this scale in its entirety, probably because of its length and insufficient data on how to administer it; moreover, the 6-factored solution was questioned in various studies [44,45]. As a consequence, another study conducted in 2018 presented a refined scale consisting of 30 items intended to measure the 4 dimensions of user engagement in HCI settings. Table 1 describes the 4 dimensions (based on [14,19,38)]. Researchers may use only subscales of the scale; however, user engagement as a holistic construct can then not be measured [40].

Table 1. User engagement scale dimensions.

Dimension	Description
Focused attention	On the basis of some characteristics of the flow theory: focused concentration, absorption, and temporal dissociation
Perceived usability	Affective (frustration) and cognitive (effortful) aspects as a result of the interaction
Aesthetic appeal	Sensory and visual appearance of an interface
Reward	Hedonic aspects of experience, felt involvement, overall success of the interaction, and willingness to engage with the app in the future

Therefore, we proposed the following hypothesis for our study:

> *H1: The UES can be used to assess user engagement with health apps.*

Data Collection

Using the full-length UES proposed by O'Brien et al [40], we designed an online survey using EFS Survey, a software package created by Questback. We had to make 1 major adaptation to the existing UES: a translation of the questions from English to German as we conducted the survey in German-speaking countries. Not all items are suitable or compatible in another language [40]. Nonetheless, we did not make any item selections before data collection; we translated and included all the items. We slightly modified some of the wording to adapt them to the context of Ada.

We pretested the online survey under field conditions on 4 participants, using the available pretest feature of the EFS Survey. This allows pretest participants to attach comments to individual questions. After the pretest, small changes and refinements to the wording and layout were made. In addition,

the data export feature was tested to confirm that the collected data could be exported.

Data collection took place for 2 weeks in April 2018. A convenience sample as a sampling type was used. Accordingly, the link to the online survey was distributed to selected people. In addition, the snowball system was applied, whereby the participants were asked to share the survey link with their circle of friends and acquaintances. We asked participants to first download the health app Ada, use it at least once, and then relate the questions to their experience with Ada in completing the survey. We assessed the survey questions using 5-point Likert scales. The 30 questions of the UES were randomized, and information about user engagement dimensions was hidden. The English items and their corresponding translations into German can be found in Multimedia Appendix 1.

Data Analysis

When using the UES, it is suggested to perform factor analysis [40]. As the aims of this study were to understand the concept of user engagement and test the applicability of the UES to a mobile health app, a principal component analysis (PCA) with varimax rotation was performed. The main reason for choosing PCA instead of factor analysis was that the UES had originally been developed in English and that there is no German version to date.

Before conducting the main analysis, we considered several conceptual and statistical issues. These initial evaluations are of high importance because of the dependence of the quality of the data on the results of factor analysis [46]. We examined the sample size, communalities, and correlations between the items. In addition, the Kaiser-Meyer-Olkin (KMO) measure and Bartlett test of sphericity were considered.

Once this is checked, the number of extracting factors can be determined. All 3 criteria (scree test criterion, Kaiser criterion, and an a priori criterion) were discussed. Next, the factor structure was evaluated. To do so, the values of the factor loadings, which is the correlation between the original variable and its factor, were considered [47,48]. We followed the recommendation by Backhaus et al [46] and only assigned variables with loadings higher than 0.5.

After the factor structure had been defined, sum scores for each subscale were calculated. Sum scores are calculated as means for each subscale [40]. As some of the variables were reverse phrased (v_08, v_10-v_13, and v_23; see Multimedia Appendix 1), they were first recoded and transferred to the same variable so that values could be compared. Furthermore, because of the multidimensionality character of the UES, reliability in the form of internal consistency of the subscales was examined separately for each subscale using Cronbach alpha. Statistical data analysis was conducted using the statistics program SPSS version 23 (IBM).

Results

Participants and Descriptive Statistics

In total, the survey link was viewed 363 times, which translated to 73 responses. As all the questions were programmed as mandatory questions, there are no missing values; thus, none of the participants needed to be excluded from further analysis. Out of 73 participants, 36 (49%) were female and 37 (51%) were male. Their average age was 39 years (SD 15.4 years), with the youngest participant being 18 years and the oldest participant being 73 years. Multimedia Appendix 2 contains a summary of participant demographics.

Principal Component Analysis

A PCA was conducted on the 30 items using varimax rotation. PCA was determined to be suitable, as verified by multiple criteria. First, the sample size of this study, 73, was above the minimum absolute sample size of 50 [48]. Second, there were correlations below 0.3. It is recommended to exclude variables that correlate below 0.3 or correlate above 0.9 with any other variable [47,49]. However, as no variables had zero correlations below 0.3, all variables were retained for further analysis. Furthermore, there were no correlations above 0.9. Third, communalities were mostly within the 0.7 range. With a sample size of 73, communalities of around 0.7 were deemed sufficient [49]. In addition, the factorability of the items was verified by the sampling adequacy of KMO=0.858 (*meritious* according to Kaiser and Rice [50]) and a significant Bartlett test of sphericity (χ^2_{300}=1127.1; P<.001). In conclusion, based on the consideration of these criteria, factor analysis was determined to be suitable.

The next step was to obtain the factors. Overall, 4 factors had eigenvalues over Kaiser criterion of 1 and, in combination, explained 65.1% of the variance. The scree plot was ambiguous and showed inflections that would justify retaining both 2 and 4 factors. The a priori criterion indicated 4 factors [40]. Thus, 4 factors were retained because they accord with Kaiser criterion, scree plot, and the a priori criterion.

Furthermore, 5 items showed factor loadings below 0.5 (v_07, v_09, v_14, v_15, and v_26) and were therefore removed from PCA as their correlation with other variables was not strong enough. One variable, v_16, showed cross-loadings, as it loaded on factor 1 (0.533) and on factor 3 (0.582). Such variables either need to be excluded or interpreted with both factors, unless strong theoretical reasons speak against this [46]. In this case, this variable was theoretically expected to load on factor 3, and indeed, the higher factor loading of this variable was on factor 3. This variable was, therefore, kept and assigned to factor 3.

The results of the PCA are illustrated in Multimedia Appendix 3, in which the variables are listed within the respective factors in a descending order. Overall, this PCA yielded consistent subscales and a 4-factor solution as suggested by O'Brien et al [40]. Therefore, the factor labels were taken over. Only 1 of the 25 items, v_29, loaded on another factor (focused attention), as suggested by the original UES.

Factor 1, focused attention, accounted for 34% of the variance and consisted of items v_01-06 and v_29. This factor was the original UES's focused attention subscale, with the addition of 1 reward element, v_29. Factor 2, perceived usability, accounted for 14% of the variance and consisted of items v_08 and v_10-13. Factor 3, aesthetic appeal, accounted for 9% of total variance and consisted of item v_16-20. This factor was the

original aesthetics subscale. Factor 4, reward, accounted for 8% of variance and consisted of v_21-25, v_27-28, and v_30.

Sum Scales

In addition, sum scores were calculated for each factor. The factor perceived usability had the highest sum, with a value of 294; second was the factor aesthetic appeal, with a value of 275.4; third was the factor reward, with a value of 259.5; and the lowest subscale score was for the factor focused attention, with a value of 198.1. In other words, users of Ada showed the highest engagement level with perceived usability and the lowest engagement level with focused attention.

Post Analysis

Focused attention, aesthetic appeal, and reward subscale of the UES all had high reliabilities, with Cronbach alpha=.912, alpha=.852, and alpha=.910, respectively. However, the perceived usability subscale had a lower reliably, with Cronbach alpha=.693 (see Multimedia Appendix 4).

Discussion

Principal Findings

The results of this study confirm the proposed hypothesis by demonstrating that the UES developed for measuring user engagement with digital technology can be used to assess user engagement with health apps. We had to remove 5 items because of factor loadings below 0.5. Possible reasons for removing these factors are suggested in Multimedia Appendix 5. The modified 25-item version of the scale accounted for 65% of the variance in user engagement. Overall, 4 factors emerged: focused attention, perceived usability, aesthetic appeal, and reward.

In O'Brien et al [40]'s and our study, all items loaded on the same factors except for v_29 ("I felt involved in this experience"). In our study, it loaded on focused attention rather than reward. This can be explained by taking into consideration our research context of health apps and the flow theory. This item indicates absorption in the experience with Ada, and absorption is a major characteristic of the flow theory, therefore making it a good fit for the focused attention factor. Aside from this, the suggested factor structure could be replicated in this study.

Limitations

Although our findings support the use of the German UES with health apps, this study is subject to certain limitations, and results should be interpreted with caution.

First, data were collected from a sample that was not selected randomly, and the characteristics of the population were not adequately represented in the sample. In addition, the number of participants, 73, is rather small, although it is sufficient for conducting factor analysis [48].

Second, the UES was administrated and adapted to the context of this study. All items were taken from English and translated by the authors. Therefore, some items may have a slightly different meaning to respondents than the items in the original instrument. In addition, some of the items did not make sense in a non-English context and had to be removed because of low factor loadings during analysis.

The third limitation concerns the UES itself. In this study, no items were added to the original scale, so construct validity is not threatened. However, this tool might not capture all the important determinants of user engagement. In addition, adding another research method, for example, interviewing the participants, would have contributed to the interpretation of our findings.

Fourth, engagement was only measured once during a short period and not across multiple sessions, which may represent a limited view on user engagement. Further research could examine user engagement by having participants complete the scale more than once as part of the same study. Researchers could then compare engagement among participants and between iterations [40] and take a long-term view on engagement.

Furthermore, the question arises if participants engaged fully and intrinsically with the health app by being initially asked to use it at least once. Other user engagement studies in different fields have had similar problems (eg, [43,51]). Future research should try to address this issue.

Comparison With Prior Work

This study is among the first to investigate the use of the UES as a whole in the area of health apps and in the German language, so the findings cannot be compared with those of other studies. However, patterns of the UES may be compared with those of other app user engagement studies. Still, direct comparison of attributes and factors within the area of health app user engagement has to be treated with caution because of the different approaches used. This, finally, comes back to various perceptions of what constitutes user engagement and what does not.

Furthermore, the high context dependence of the defining features of user engagement are reported [11], and in the context of mobile apps, it is probably also a question of the mobile app type examined. For example, mobile app types might be divided into experiential and informational app types [52]. According to this distinction, Ada, the example of this study, falls into the category of informational apps and focuses on goal-oriented and utilitarian benefits rather than on social and hedonic benefits, as is the case for experiential app types. It has been discovered that the effect of time convenience on mobile app engagement is greater for informative mobile apps than for experiential apps [9]. Applying this to user engagement with Ada might lead to the conclusion that utilitarian benefits, such as time convenience, are better suited to explain the factor of reward than other mobile app types would have.

Conclusions

User engagement is a complex concept, and there is no general agreement as to what constitutes the phenomenon or how it is operationalized and measured [11,12]. This paper contributes in several ways to the growing literature concerning user engagement with health apps.

One major contribution of this study is the applicability of a German version of the UES [40] with a health app. On the basis

of our findings, researchers and practitioners can now further investigate the user engagement concept. Future research could build on our findings and interpret the data gathered with the UES by applying a multiple method design. Owing to its scope and complexity, researchers have taken a multidimensional view of user engagement [5,13]. In addition, further research could investigate the use of the UES with apps in general and not be limited to health apps.

Given the importance of user engagement, the findings of this study could benefit practitioners, mainly marketers and app developers, in 2 ways.

First, marketers and app developers can gain a better understanding of user engagement. Evidence suggests that one of the main challenges for successful companies in mobile environments is to find ways to keep their users engaged [4-6]. Knowing what keeps users engaged has important implications for strategic retention management [9].

Second, findings based on the self-reported measurement of the German version of the UES with Ada suggest that the attribute that drives the highest engagement among users is perceived usability. This is followed by aesthetic appeal, reward, and focused attention.

An improved understanding of the attributes that drive user engagement should help app developers and marketers in creating and marketing attractive health care apps that will be used and appreciated in the long term. This could be a vital factor in increasing health literacy among users and, therefore, a contribution toward improving public health in general.

Conflicts of Interest

None declared.

Multimedia Appendix 1
User engagement scale, German version.
[DOCX File , 31 KB - mhealth_v8i1e13244_app1.docx]

Multimedia Appendix 2
Participant demographics.
[DOCX File , 28 KB - mhealth_v8i1e13244_app2.docx]

Multimedia Appendix 3
Summary of principal component analysis results for the user engagement scale, German version (N=73).
[DOCX File , 29 KB - mhealth_v8i1e13244_app3.docx]

Multimedia Appendix 4
Reliability analysis of user engagement scale dimensions.
[DOCX File , 28 KB - mhealth_v8i1e13244_app4.docx]

Multimedia Appendix 5
Explanation of removed items.
[DOCX File , 29 KB - mhealth_v8i1e13244_app5.docx]

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Abbreviations

eHealth: electronic health
HCI: human-computer interaction
KMO: Kaiser-Meyer-Olkin
PCA: principal component analysis
UES: user engagement scale

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Original Paper

Quality Assurance of Health Wearables Data: Participatory Workshop on Barriers, Solutions, and Expectations

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Abstract

Background: The ubiquity of health wearables and the consequent production of patient-generated health data (PGHD) are rapidly escalating. However, the utilization of PGHD in routine clinical practices is still low because of data quality issues. There is no agreed approach to PGHD quality assurance; therefore, realizing the promise of PGHD requires in-depth discussion among diverse stakeholders to identify the data quality assurance challenges they face and understand their needs for PGHD quality assurance.

Objective: This paper reports findings from a workshop aimed to explore stakeholders' data quality challenges, identify their needs and expectations, and offer practical solutions.

Methods: A qualitative multi-stakeholder workshop was conducted as a half-day event on the campus of an Australian University located in a major health care precinct, namely the Melbourne Parkville Precinct. The 18 participants had experience of PGHD use in clinical care, including people who identified as health care consumers, clinical care providers, wearables suppliers, and health information specialists. Data collection was done by facilitators capturing written notes of the proceedings as attendees engaged in participatory design activities in written and oral formats, using a range of whole-group and small-group interactive methods. The collected data were analyzed thematically, using deductive and inductive coding.

Results: The participants' discussions revealed a range of technical, behavioral, operational, and organizational challenges surrounding PGHD, from the time when data are collected by patients to the time data are used by health care providers for clinical decision making. PGHD stakeholders found consensus on training and engagement needs, continuous collaboration among stakeholders, and development of technical and policy standards to assure PGHD quality.

Conclusions: Assuring PGHD quality is a complex process that requires the contribution of all PGHD stakeholders. The variety and depth of inputs in our workshop highlighted the importance of co-designing guidance for PGHD quality guidance.

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KEYWORDS

remote sensing technology; data quality assurance; patient-generated health data; wearable devices; participatory research

Introduction

The health care industry is rapidly moving toward patient-centered care, in which patients actively contribute to their health care [1]. An example of a patient-centered care model, remote patient monitoring keeps patients outside the clinical setting while monitoring their health status. In these interventions, patients actively engaged in their health care and played an increasingly important role in sharing responsibilities with health care providers [2].

Background

Health wearables are a key component of remote patient monitoring. These devices have the capability to continuously collect, process, and display health data automatically in real

time, which may improve patients' awareness of their health outside the clinical setting and enhance self-management [3].

Health wearables in the market are of 2 types: medical grade and consumer wearables. Medical wearables are designed to collect data relevant to specific health conditions, such as continuous glucose monitoring (CGM), to monitor blood glucose levels in people with diabetes. However, consumer wearables are often designed to collect general wellness data, such as fitness trackers that are used by patients to be aware of their physical activity level, sleep quality, mood, and heart rate. Some types of wearables connect to an associated mobile app to display real-time processed data, as well as to a patient portal where both patients and health care providers access passive data. Depending on the wearable platform, patients may also be required to manually enter other data types into the mobile app, in addition to the automatic data captured by the sensors in the wearable device.

Data produced by wearables are usually called patient-generated health data (PGHD), as the data collection relies on patients' (rather than clinicians') control and occurs outside the clinical environment [4]—a highly complex process. Large volumes of data collected from disparate wearables on an ongoing basis and under various situations bring possibilities for PGHD to be impacted by various technical, behavioral, operational, and organizational issues at the time of storage, transmission, analysis, or access for shared decision making that can lead to poor quality data. For example, wearable dysfunctionality [5-8], inaccurate calibration [6], incorrect manual inputs [5-9], complex data visualization [6,10], or not collecting data for a period of time [9-12] result in lack of trust in PGHD for clinical decision making. During the PGHD transmission stage, patients may share their data through a home network, their mobile wireless network, or a public wireless network, all of which might affect data transmission [5]. In addition, some of the platforms used during PGHD flow operate outside health information systems and may not be trusted because of concerns about their security and data privacy [6,9]. It is still challenging to define and implement solutions for integrating existing data in electronic medical records (EMRs) with PGHD from patients' own wearables and develop widely accepted interoperability standards for PGHD exchange [6-11]. Moreover, concerns exist regarding consumer wearables, as they are not yet regulated, and there is uncertainty about their promise in achieving the quality required in optimal PGHD collection [12,13]. Regarding human factors, an individual's intention to use wearables for general wellness tracking or for monitoring a specific health condition can strongly affect the quality of PGHD that these devices collect [8,13-15].

Health care providers may face large volumes of inaccurate, incomplete, irrelevant, and nonunderstandable PGHD, without solid principles for dealing with these data. The result is concerns about reliability and no confidence in using PGHD in routine clinical practice [16,17].

These issues of PGHD quality make it difficult to understand PGHD's usefulness for health care, and these hinder adoption of these data as a systematic part of clinical practices [18]. Owing to this, remote patient monitoring is often initiated on a small scale for a short time and focuses on a single disease. A 2018 survey of over 20,000 health care consumers in 28 countries revealed nonsignificant adoption of PGHD [19].

There is little evidence in the research and industry literature that the quality of PGHD from wearables is sufficiently well managed to enable them to be trusted as health data or that such data can be used safely and effectively in clinical care. Furthermore, health care organizations lack awareness about PGHD quality from wearable devices [13,20].

Objectives

Assuring PGHD quality requires efforts not only from health care providers but also from patients, their caregivers, and health consumers in general. Consumers, for example, have different needs from health care providers; therefore, their attitudes toward PGHD will differ, as well as the impact on data quality [21]. However, PGHD stakeholders are not limited to consumers and providers; other stakeholders, such as wearable manufacturers, contribute to PGHD transmission from outside the clinical setting, and their activities may similarly impact PGHD quality [16].

Therefore, it is critical to enhance general awareness of the quality of PGHD from wearables.

The objective of this study was to identify current challenges stakeholders face with various attributes of PGHD quality, define potential solutions to overcome those challenges, and facilitate a process where they could workshop their data quality needs and expectations with other stakeholders.

Methods

Study Design

We conducted a half-day workshop in May 2019 on the campus of an Australian University located in a major health care precinct. This was part of a larger project using a range of inputs to develop PGHD quality assurance guidance. The workshop received human research ethics approval from the University of Melbourne (Ethics ID: 18532521).

Participant Recruitment

Participants were eligible to attend the workshop, who were at least 18 years old and had experience of PGHD use in clinical care, including people who identified as health care consumers, clinical care providers, wearables suppliers, health information specialists, PGHD integration service providers, data analysts, and health service managers. Expressions of interest were sought via an open call and a Web-based registration form distributed via internal and public news and media channels, as well as professional organizations for digital health in Australia. At the point of recruitment or before, as needed, gaps were filled with personal invitations and via snowball sampling, for example, via key contacts in specific organizations where the researchers had existing relationships.

Participants

In total, 18 participants took part in the workshop. The participants included 8 health consumers and consumer

advocates, 5 clinicians, 3 health information professionals, and 2 wearable and data integration company representatives.

Workshop Structure

On-Site Registration

Each participant was given a package of stationery materials, the consent form, the Plain Language Statement, and a copy of the presentation slides.

Researcher's Presentation

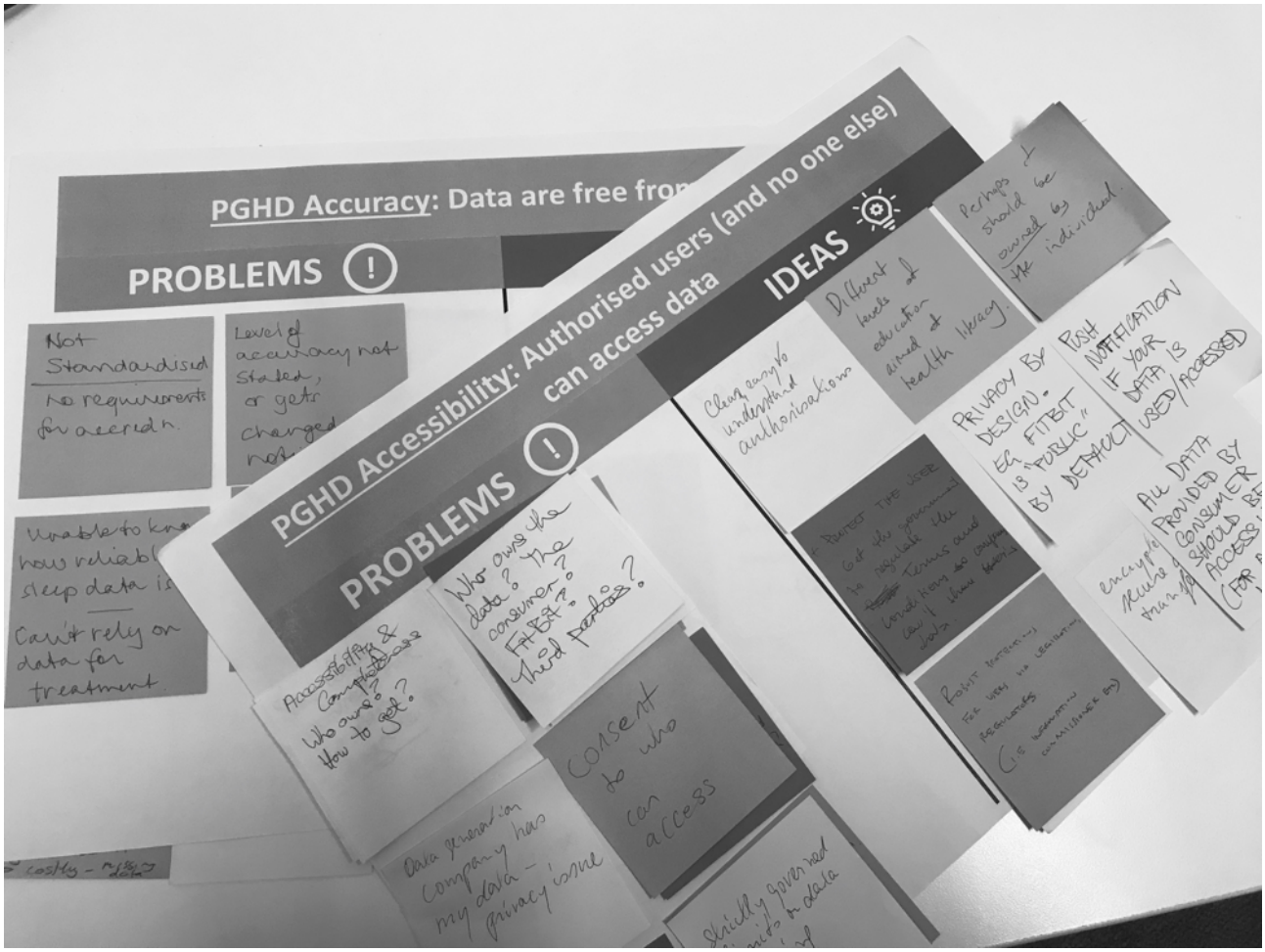
Participants were informed about the workshop purpose and its structure. In addition, findings from previous parts of the project [6,14] were elucidated. The concept of PGHD quality and its 7 aspects—accessibility, accuracy, completeness, consistency, interpretability, relevancy, and timeliness—adapted from a comprehensive data quality framework developed for clinical data quality assurance by the Australian Capital Territory [22] were explained through scenarios (Multimedia Appendix 1) to enable the participants to identify the various circumstances that might impact each PGHD quality aspect and identify the data management stage in which the quality aspect might require consideration. We used CGM devices as a medical wearable example, and we used fitness trackers as a consumer wearable example in this workshop.

Group Discussion 1

The facilitators directed participants into 4 groups, each with a cross section of different stakeholders (Figure 1). Groups discussed problems related to PGHD quality. Participants contributed verbally, wrote ideas on sticky notes, and placed these on their group worksheet (Figure 2). A total of 1 facilitator managed each group to direct discussions and assist in timekeeping. Small group discussions ran for 30 min. Thereafter, in a 15-min session, each facilitator took turns presenting to the whole room the consolidated deliberations of the facilitator's small group. The facilitators wrote the key findings on whiteboards to be available during the break.

Figure 1. Participants' discussions in 4 groups of patient-generated health data stakeholders.

Figure 2. Worksheets of patient-generated health data quality problems and ideas.



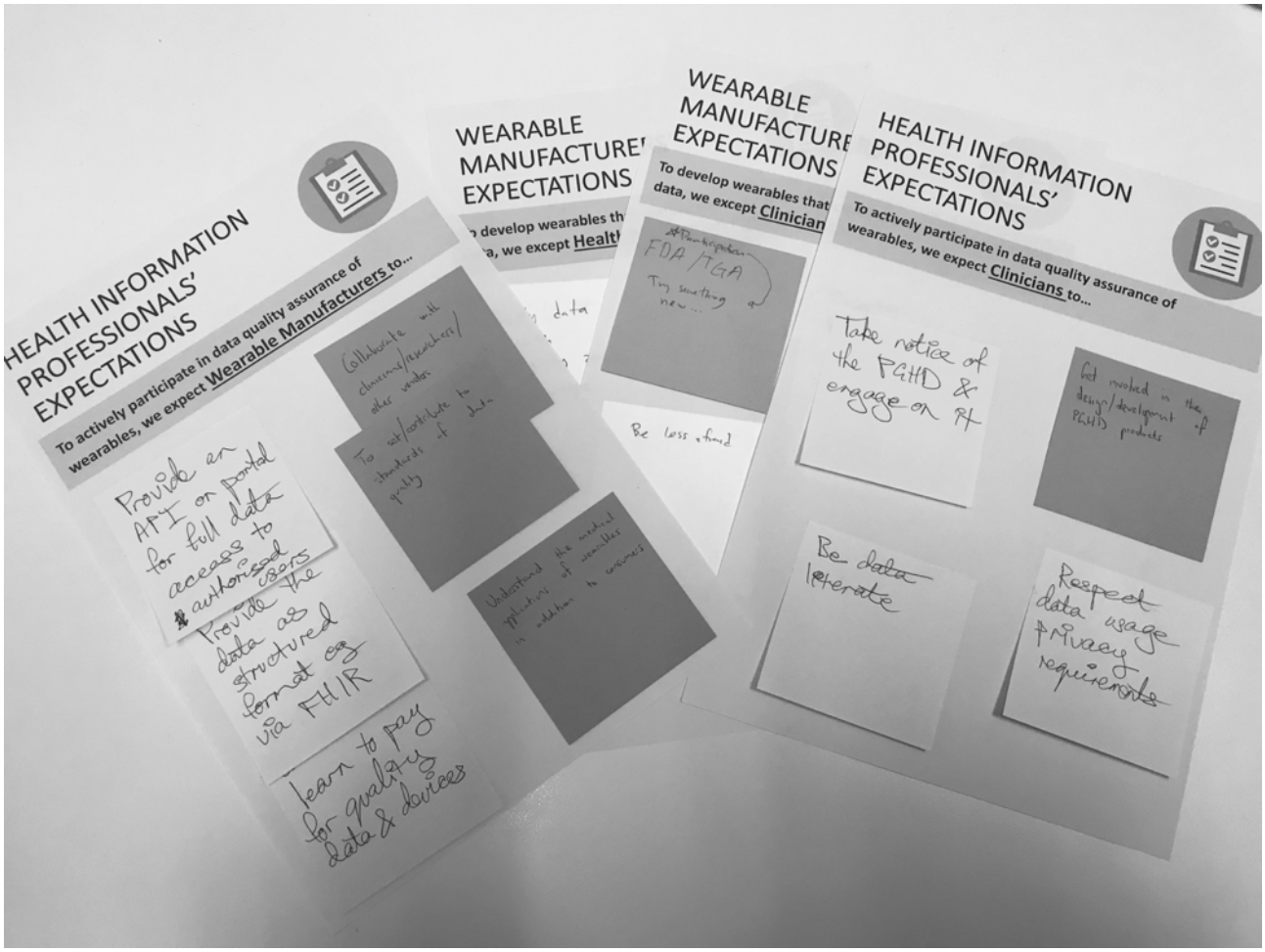
Break

Participants walked around the workshop room to view the discussion findings on whiteboards and exchange further ideas with participants, in preparation for the next part.

Group Discussion 2

The facilitators directed participants into 4 differently configured groups. Each group took on a *role* of a key stakeholder—health care consumer, health care provider, health information professional, or wearables manufacturer. Groups discussed and translated their ideas into a set of their expectations of other stakeholder groups, on worksheets (Figure 3). This task took 30 min, followed by 15 min in which each facilitator set out and spoke to the respective group's expectations on whiteboards.

Figure 3. Worksheets of patient-generated health data stakeholder's expectations.



Conclusion

The researchers pointed out the outcomes and future work implications. Participants were informed about the next steps of the research project and how they may stay engaged if they are interested.

Data Collection and Analysis

Data collection was done by facilitators capturing written notes of the proceedings as attendees engaged in participatory design activities in written and oral formats, using a range of whole-group and small-group interactive methods. The group facilitators' summing up presentations on boards and sticky notes were photographed. Deductive analysis based on 7 PGHD quality aspects (accessibility, accuracy, completeness, consistency, interpretability, relevancy, and timeliness) and inductive thematic content analysis were used as the primary data analysis methods. The initial data analysis was conducted by the PhD researcher, which was then reviewed by 3 supervisors. Thereafter, all of the 4 researchers discussed the results together in several meetings until consensus was achieved.

Results

The workshop findings are organized thematically as problems and solutions related to each health data quality dimension, as well as stakeholders' expectations of each other, to assure PGHD quality.

Data Quality Challenges and Solutions

Table 1 illustrates the current problems and potential solutions that mixed-stakeholder small groups raised for each data quality aspect.

Table 1. Patient-generated health data quality problems and potential solutions.

Definition	Problems	Potential solutions
Patient-generated health data accessibility (authorized users can access data)	• Lack of transparency on who owns the data • Lack of consent for continuous data collection and use • Lack of health consumers' access to raw data • Data hacking	• Develop data ownership principles • Design notifications in the wearable platform to alert consumers once data are accessed by others • Provide dynamic data authorization • Provide access to raw data by health consumers • Define wearable cybersecurity standards • Create data encryption techniques • Consider privacy in the wearable design • Develop layered consent for various data from different devices
Accuracy (data are free from errors)	• Inaccurate data because of the use of different wearables with different accuracy standard levels • Errors in wearable functionality • Mistakes in manual data entry • Lack of data editing functionalities	• Define accurate levels of measurements • Wearable manufacturers adopt accuracy-related feedback given by consumers and clinicians • Enable data edit functionality in the wearable platforms
Completeness (there are no data missing)	• Lack of access to internet to send the collected data • Battery problems • Incompleteness of data entered manually • Lack of data synchronization during change of time zones • Incompleteness of data because of the wearable dysfunction • Deliberate data omissions	• Design notification to provide an alert for missing data • Consumers' education and engagement
Consistency (data from different devices convey the same meaning)	• Lack of awareness of data flow and data management • Data inconsistency because of using various wearables with different platforms	• Develop data consistency checking mechanisms to correlate with other data sources • Incorporate data with the clinical workflow
Interpretability (the data presentation highlights the key message)	• Presentation of large volumes of data • Lack of contextual data from consumer wearables to supplement medical wearables data to be easily understood • Data presentations vary among different wearables	• Collect contextual data • Design standardized data presentation formats for clinicians, despite the variety of wearables used
Relevancy (the data being collected are pertinent to the standard of care)	• Different clinical judgement on data relevancy • Cyberchondria; overthinking of relevancy of collected data to a specific health condition	• Improve health literacy to understand the relevance of data to the standards of care • Provide shared understanding of data relevancy among consumers and clinicians
Timeliness (up-to-date data are available when needed)	• High volume of unfiltered data to be timely • Lack of consensus among patient-generated health data stakeholders about the definition of timeliness depending on the patient's status (stable or unstable and at risk) • Wearable design often determines when data are available	• Automation and artificial intelligence to accelerate data filtering so that important data can be available in a timely manner • Enable consumers to take responsibility for deciding when health issues need to be escalated • Design alerts for critical indicators to patients and clinicians

The findings in Table 1 show the dynamic situations in which patients collect PGHD through wearables and associated components, including mobile apps and portals. Situations are also subject to various technical, environmental, operational, and behavioral factors. These factors largely involve the design and performance of the wearable platforms, the fragmentation in clinical setting infrastructure to utilize PGHD from disparate wearables, and the stakeholders' literacy levels in their engagement with PGHD collection and use.

The participants offered solutions for each PGHD quality attribute, which can be categorized into 5 overall ideas, namely (1) concerning redesign and development of wearables in a way to allow meeting PGHD quality requirements; (2) creation of clinical and administrative policies to address data quality assurance, such as policies on PGHD ownership, standard measurements, and data management policies; (3) stakeholders' engagement and education; (4) integration of PGHD with clinical workflows and electronic health record systems, which demands creation of terminologies, data exchange protocols,

and data analytics; and (5) defining who in the workforce is responsible for PGHD quality assurance procedures.

Patient-Generated Health Data Stakeholders' Expectations

During the second group discussion, participants from each of the 4 stakeholder groups—consumers, clinicians, health information professionals, and wearable manufacturers—stated their expectations of what each of the other PGHD stakeholder groups could do to assure PGHD quality. The groups' expectations are explained in Tables 2-5. There were no expectations of health information professionals expressed by consumers and wearable manufacturers.

Table 2. Consumers' expectations of other patient-generated health data stakeholder groups.

Consumers' expectations of PGHD[a] stakeholders	Details
Clinicians	• *Consent:* Consumers expect that clinicians provide informed consent, addressing how consumers and other users can access and use PGHD securely and transparently • *Flexibility:* Clinicians are expected to adopt PGHD from new wearable platforms that consumers use and undertake processes to evaluate quality of their data • *PGHD collection strategies:* Clinicians can educate consumers on the best practices of PGHD collection and sharing • *Collaboration with wearable manufacturers:* Effective collaboration and shared responsibilities among clinicians and wearable manufacturers can lead to clear instructions for consumers in PGHD collection and sharing
Wearable manufacturers	• *Code of conduct:* Wearable manufacturers are expected to provide a transparent code of conduct to consumers to identify their rights in using the products • *Cost:* Consumers want to access their data from wearable manufacturers for free • *Transparency:* Build transparency around the purpose and use of PGHD to enable consumers to have more governance of their data • *Person-centered design:* Wearables can be developed on the basis of person-centered care models

[a]PGHD: patient-generated health data.

Table 3. Clinicians' expectations of other patient-generated health data stakeholder groups.

Clinicians' expectations of PGHD[a] stakeholders	Details
Consumers	• *Trust:* Understanding of PGHD integration into electronic medical records and combination with other clinical data, enhances honesty and enthusiasm among consumers toward the collection of accurate and complete PGHD • *Partnership:* Consumers should realize their essential partnership with clinicians in remote patient monitoring. They need to trust their clinicians' competencies as the first point of decision making for their care
Health information professionals	• *Collaborative participation:* Owing to lack of time and burnout on the clinical staff team, clinicians suggest the involvement of health information professionals to analyze and process PGHD. This step should come before PGHD are made available to the clinicians to provide meaningful information for decision making during the clinical consultation • *Data governance:* Health information professionals within health care settings should take part in developing PGHD governance strategies and inform clinicians on the best practices for PGHD use • *Consumer wearable evaluation:* Health information professionals can assess the contextual data provided by consumer wearables and inform clinicians on PGHD quality from these devices • *Technical infrastructure development:* Health information professionals can potentially invest in appropriate information technology infrastructure that enables PGHD integration with electronic medical record systems at scale
Wearable manufacturers	• *Dynamic wearable testing:* Need for routine device testing and to collaborate with clinicians to develop strategies for continuous wearable assessment through various clinical studies • *Integrity with standards of care:* Wearables should be exclusively designed for the intended purpose of use, and they should align with the standards of care in health care settings

[a]PGHD: patient-generated health data.

Table 4. Health information professionals' expectations of other patient-generated health data stakeholder groups.

Health information professionals' expectations of PGHD[a] stakeholders	Details
Consumers	• *Consistent data sharing:* Consumers can discuss their preferred wearables and associated platforms with the remote monitoring team to identify ways to share PGHD consistently. • *Data sharing authorization:* consumers are expected to authorize their data to be shared.
Clinicians	• *PGHD incorporation with other clinical data:* Clinicians can help in incorporating PGHD with other clinical data, as part of the patient record. • *Digital health literacy:* Clinicians are expected to undertake training on PGHD and wearable use.
Wearable manufacturers	• *Data exchange standards:* Wearable manufacturers should develop devices that comply with defined data exchange standards in health care settings.

[a]PGHD: patient-generated health data.

Table 5. Health wearables' manufacturers' expectations of other patient-generated health data stakeholder groups.

Health wearables' manufacturers' expectations of PGHD[a] stakeholders	Details
Consumers	• *Wearable usability feedback:* Consumers are expected to provide continuous feedback about the technical and operational issues they face in the duration of PGHD use.
Clinicians	• *New wearables adoption:* Clinicians should be less afraid to try new technologies and test various wearables via trials. • *Collaboration:* Clinicians should expand relationships with wearable manufacturers and be open to conduct research to evaluate the wearables.

[a]PGHD: patient-generated health data.

Discussion

Principal Findings

Current health data quality assurance approaches are now disrupted by PGHD challenges. Given the potential value of PGHD in health care decision support, their adoption requires an in-depth understanding of data quality.

The investigation of PGHD quality is in its infancy, and few studies have explored it [6,13,18]. Therefore, our workshop provided the participants with an opportunity to carefully investigate PGHD quality in future remote patient monitoring interventions. It was acknowledged by the participants that the process of thinking about PGHD quality and translating into solutions could enhance collaboration among PGHD stakeholders, within and outside clinical settings.

Diversity of Patient-Generated Health Data Quality Challenges and Potential Solutions

Mixed-stakeholder participant groups raised divergent problems of PGHD quality. Technical factors related to wearable design and functionality affect most of the aforementioned aspects of data quality at the PGHD collection stage. The participants recognized that a cohesive platform to integrate PGHD with current EMR systems has the potential to collect automatic and manual data entries from various wearables and associated apps, to ideally facilitate dynamic data transmission. However, more practically, operational and organizational problems are likely to occur during data transmission from the patient to the clinical setting, such as internet access, time zone, distinct data transfer protocols, and lack of data integration. Behavioral habits of consumers, as well as digital health literacy among key PGHD stakeholders, such as consumers and clinicians, are among the factors that participants identified, which can influence PGHD quality. The participant discussions further highlighted the need to create a patient-centered care model that includes defined technical standards, policies, rights, and responsibilities to ensure PGHD quality and make these data useful for clinical care.

Convergence in Patient-Generated Health Data Stakeholders' Expectations

The 4 groups of PGHD stakeholders in our workshop raised different expectations about each of the other stakeholders, whereas all participants reached consensus on the importance of promoting collaboration among stakeholders. Furthermore, participants emphasized the need for transparency on the redistribution of tasks and responsibilities given to consumers, as well as to the clinicians. Participants also stated that wearables should be designed in a way to reconcile the needs of both patients and clinicians. Another key discussion point focused on hearing the consumer's voice in improving PGHD collection. Without this voice, it may result in the consumer's lack of understanding on how to optimally contribute to PGHD collection and management processes, thus leading to poor quality data.

The scope of remote monitoring services is still limited to single programs for single diseases, and it has not yet broadened to multiple health conditions. Moreover, in current remote monitoring scenarios, PGHD flow mainly occurs among

consumers, clinicians, and wearable manufacturers, without further actions entering EMR systems or without the involvement of other specialist clinical or nonclinical staff. Presently, health information professionals within clinical settings are not full participants in the PGHD process, primarily because of the lack of integrated infrastructure, which could optimally incorporate PGHD into the health care system. This particular gap points to the need to broaden the team of stakeholders involved in the process and better define tasks for ensuring PGHD quality across the flow.

Critically, there was consensus by the stakeholder groups that PGHD management should occur in a standardized way. Different types of PGHD could become part of clinical terminology standards, made possible through national efforts. For example, specific metadata could be standardized to codify patients as source data generators.

Relation to Other Works

As stated, there is a paucity of research investigating PGHD quality for use in routine clinical practice [6,13,18]. This study included a wider range of PGHD stakeholders: consumers, clinicians, and wearable vendors, as well as health information professionals whose roles in PGHD management and quality assurance have not been investigated in previous research.

This is the first study of its kind, which brings various groups of PGHD stakeholders together to share their concerns and expectations with each other, with regard to ensuring PGHD quality. This process helped to reach a consensus among participants on clear responsibilities they could take to effectively collaborate for better patient care.

Limitations and Future Work

The workshop participants were not representing an exhaustive range of PGHD stakeholders to explore quality issues from other perspectives. Further stages of this project will involve more groups of stakeholders. The workshop was focused on PGHD quality assurance for primary use of data, which falls within clinical care. Therefore, quality issues around secondary use of PGHD, such as utilization of PGHD in biomedical research, shared care plans, and mobile health surveillance, were not discussed.

In addition, the full spectrum of consumer and medical wearables was not represented among the participants. We purposely chose CGM devices as a medical wearable example, and we chose fitness trackers as a consumer wearable example in this workshop. CGM wearables are complex devices that require both automatic and manual data entry, calibration by using conventional glucometers, and a reliable connection to mobile apps and patient portals. Patients may also need to collect lifestyle data from consumer wearables, beside the CGM data, to provide a more comprehensive picture of their health status to their clinicians.

Conclusions

This study used a participatory research method to identify (1) the problems of PGHD quality, (2) potential solutions to overcome the challenges, and (3) the PGHD stakeholders' expectations toward PGHD quality assurance. Our approach to codevelop challenges, solutions, and expectations enabled us to engage various stakeholders to jointly share experience and concerns. Active and continuous collaboration among PGHD stakeholders, from wearable development to data production and use in patient care, is vital not only to ensure the quality of the data but also the quality of the consumer's health care experience and clinical outcomes. The findings from this workshop will contribute to the development of practical recommendations toward PGHD quality assurance, which can be adopted by a wide range of PGHD stakeholders.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Workshop presentation slides.
[PDF File (Adobe PDF File), 22245 KB - mhealth_v8i1e15329_app1.pdf]

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Abbreviations

CGM: continuous glucose monitoring
EMR: electronic medical record
PGHD: patient-generated health data

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Original Paper

Factors Related to User Ratings and User Downloads of Mobile Apps for Maternal and Infant Health: Cross-Sectional Study

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Abstract

Background: Mobile health apps related to maternal and infant health (MIH) are prevalent and frequently used. Some of these apps are extremely popular and have been downloaded over 5 million times. However, the understanding of user behavior and user adoption of these apps based on consumer preferences for different app features and categories is limited.

Objective: This study aimed to examine the relationship between MIH app characteristics and users' perceived satisfaction and intent to use.

Methods: The associations between app characteristics, ratings, and downloads were assessed in a sample of MIH apps designed to provide health education or decision-making support to pregnant women or parents and caregivers of infants. Multivariable linear regression was used to assess the relationship between app characteristics and user ratings, and ordinal logistic regression was used to assess the relationship between app characteristics and user downloads.

Results: The analyses of user ratings and downloads included 421 and 213 apps, respectively. The average user rating was 3.79 out of 5. Compared with the Apple App Store, the Google Play Store was associated with high user ratings (beta=.33; *P*=.005). Apps with higher standardized user ratings (beta=.80; *P*<.001), in-app purchases (beta=1.12; *P*=.002), and in-app advertisements (beta=.64; *P*=.02) were more frequently downloaded. Having a health care organization developer as part of the development team was neither associated with user ratings (beta=−.20; *P*=.06) nor downloads (beta=−.14; *P*=.63).

Conclusions: A majority of MIH apps are developed by non–health care organizations, which could raise concern about the accuracy and trustworthiness of in-app information. These findings could benefit app developers in designing better apps and could help inform marketing and development strategies. Further work is needed to evaluate the clinical accuracy of information provided within the apps.

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KEYWORDS

mHealth; mobile apps; pregnancy; parturition; infant care; smartphones

Introduction

Increasingly, users are turning to digital technologies, such as Web-based and mobile platforms, where information regarding any topic is obtained at the touch of a button. There have been significant changes in the types of digital technologies that are available for use, and smartphones are increasingly the most popular devices for *on the go* information access [1,2]. Globally,

there were 8 billion mobile-connected devices in 2016, and this number is estimated to grow to 11.6 billion by 2021 [3]. In the United States alone, 96% of adults owned a mobile phone in 2019, out of which 81% owned smartphones [2]. Today, smartphones are used for more than the basic features of calling, texting, or even browsing the internet. Users are using these devices to seek information on a wide range of life events, including their health [4]. This cultural shift has resulted in an increased access to health-related information for laypeople and has offered them a platform to engage in behavior modification activities [1]. Smartphones are popular for their abilities to support third-party programs, commonly known as mobile apps [5]. Since their first appearance in 2008, millions of mobile apps have been designed and published for smartphones, computer tablets, and other handheld devices [6].

The ubiquity of mobile phones offers a unique opportunity to use mobile health (mHealth) for health information seeking [7]. Recently, mHealth apps have gained popularity in providing pregnancy information with easy access at little or no cost, and women are increasingly using these platforms to meet information needs during pregnancy [8-11]. A large number of surveyed pregnant women and new mothers reported the use of such apps, with nearly a quarter using these apps almost daily [12]. A majority of first-time mothers and nearly half of experienced mothers found pregnancy and childbirth apps useful in providing valuable information [13]. In addition, these apps were deemed more useful by socially disadvantaged women who may otherwise lack access to alternate educational resources [8,14].

Compared with other health topics, mobile apps for maternal and infant health (MIH) subjects, such as pregnancy, childbirth, and infant care, are some of the most frequently developed and commonly used [9,10]. MIH apps often appear on the iTunes and Google Play Store's list of most downloaded apps, and some of the apps have been downloaded over 5 million times [1]. Some of these apps have an average user rating (ie, *stars*) of 4.5 (out of 5), with higher ratings indicating a more favorable user experience. Both user downloads and user ratings offer an arbitrary indicator of the popularity, acceptability, and satisfaction with apps [15,16]. An analysis of user commentaries from women's health apps indicates that, overall, women desire apps that are easy to use, contain new information, and are motivational [17]. Therefore, as consumers increasingly use mobile apps, health care providers, app developers, policy makers, and patients may benefit from a better understanding of the underlying factors that drive user demand and popularity of MIH apps.

The rapid proliferation of mHealth apps has not been accompanied by equal attention to understanding the factors that consumers prefer or the real-world usage patterns when selecting from a multitude of available apps [18,19]. Consumers have little reliable information to refer to when seeking apps for their health needs [18,19]. Furthermore, consumer advocacy groups and other professional organizations are largely unavailable to assess the quality of these apps, given the high number of apps available in app stores [20]. Considering an overall paucity of publicly available information pertaining to health apps, users generally make decisions pertaining to app use by considering easily available attributes such as title, price, star ratings, reviews, or downloads [21]. Existing research has indicated several factors involved in the process of app selection and download. Within the context of non–health-specific apps, consumers exhibit preferences for low-priced apps, in-app purchase options, and apps with recent updates as evidenced by higher user downloads [22]. Similarly, factors that relate to high user downloads of urology apps include expert involvement in app development, optional in-app purchases, low app cost, and high user ratings [23]. However, the literature on consumer preferences for MIH apps is still rather scarce. This necessitates a better understanding of user behavior within the context of intention to use and user satisfaction with these apps.

Considering the popularity of MIH apps, it is important to understand whether app characteristics (eg, price, ratings, or update age) indicated by previous studies remain influential within the context of perceived satisfaction and intent to use these apps. Therefore, the objective of this study was to examine the relationship between MIH app characteristics (app price, update age, app store, developer type, primary category/genre, content rating, in-app purchase, and in-app advertisement) and 2 outcomes, that is, end user's perceived satisfaction (user ratings) and intent to use (downloads). Using app data from both the Apple App Store and Google Play Store, this study quantifies apps' features and characteristics that may affect end users' perceived satisfaction and intent to use. Given the specificity of MIH apps, this study also examined the influence of app developer type (ie, health care vs non–health care) on user behavior, that is, do users frequently download and rate apps developed by health care developers?

Methods

Source of Data

We measured the association between app characteristics, ratings, and downloads in a cross-sectional study of MIH apps available in the Apple App Store and Google Play Store. The dataset of MIH apps was built by scraping data from the Apple App Store [24] and Google Play Store [25] platforms using a Java-based scraper program called Node.js [26].

Scraping results returned apps in the same order as if the search was conducted by an end user. Only the first 200 app results for the Apple App Store and the first 250 app results (later reduced to 50 starting January 2017) for the Google Play Store were returned by the scraper program [27,28]. Therefore, the results of the scraping searches for this study contain apps that were higher ranked when searched and, therefore, most likely to be accessed by store visitors [23,29]. The Indiana University-Purdue University Indianapolis (IUPUI) institutional review board (IRB) approved and deemed this study as nonhuman subjects research.

Search Strategy

We followed a 3-step process to identify a list of popular MIH apps focused on health education or decision-making support to pregnant women or parents/caregivers of infant. The data reflect app store content as of March 2017.

First, we identified a comprehensive list of relevant keywords that users might enter when searching for apps related to MIH. Search terms such as *pregnancy* and *prenatal* were used as the starting point for both the app stores, resulting in a total of 699 apps. From this, we examined app descriptions to identify apps that were in English language and belonged to education, health and fitness, and medical categories, which eliminated 34.0% of the apps. Subsequently, the app results from both stores were merged and duplicates were removed, thereby eliminating another 3.0% of apps (Figure 1). This resulted in a sample of 448 unique apps from the 2 stores (261 apps from the Apple App Store and 187 apps from the Google Play Store). From the resulting apps, we selected a simple random sample of 45 apps (45/448, 10.0%) and identified 34 additional keywords related to MIH from the app descriptions (Table 1).

Next, each of the 34 keywords was entered individually into a separate search to obtain a comprehensive set of apps for potential inclusion in the study. This resulted in a total sample of 6670 apps. The resultant apps were merged and deduplicated first within stores and then across stores for a total of 4753 unique apps in the dataset (Figure 1). If an app was available on both platforms, the Google Play Store version was included for analysis because the Google Play Store provides additional metadata, such as user downloads and in-app purchase option, which are not provided by the Apple App Store [30].

Figure 1. Flowchart detailing the sample selection process.

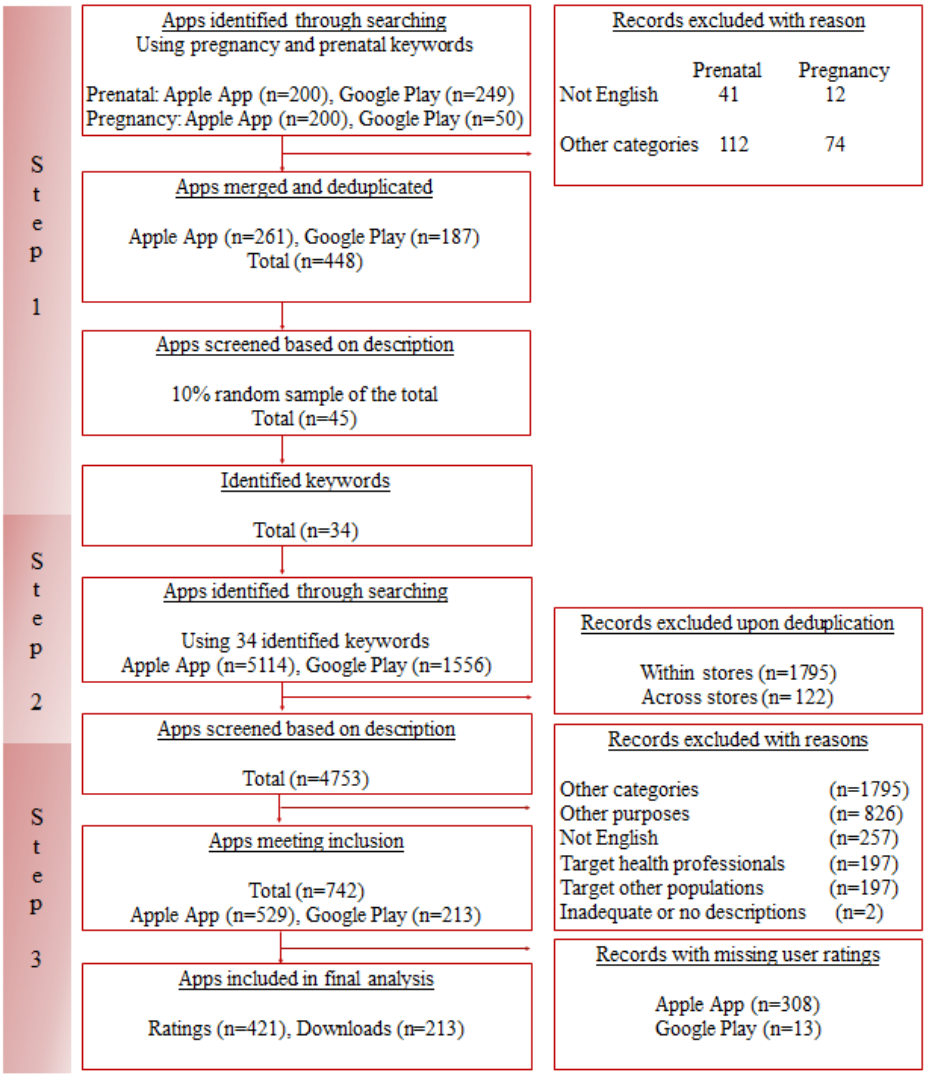

Table 1. List of keywords (N=34).

Keywords	Frequency of use within app description
Pregnant/pregnancy	170
Prenatal	63
Baby/babies	56
Child/children/childhood	29
Parents/parenting/parenthood	22
Birth	14
Mom/mum	12
Labor/delivery	8
Fetus/fetal	6
Maternal/maternity	5
Breastfeeding	4
Mother/motherhood	4
Infant	3
Obstetrics	3
Antenatal	3
Conception	3
Postnatal/postpartum	2
Gestation/gestational	2
Newborn	1
Intrapartum	1
Lactation	1

App Selection

Overall, 2 reviewers (RB and CH) independently screened the app descriptions of all retrieved apps (n=4753) for inclusion and exclusion. Disagreements were resolved through discussion and consensus. Inclusion criteria were as follows: (1) description written in English language; (2) target users judged to be pregnant women, to-be parents, and other caregivers of infant children (ie, 0-1 year old as defined by Centers for Disease Control and Prevention, 2017) [31]; (3) listed in the medical, health and fitness, books and reference, or education categories in the Apple App Store or listed in the medical, health and fitness, books and reference, education, or parenting categories in the Google Play Store; and (4) described as intending to provide health education or user decision-making support. Exclusion criteria were as follows: (1) target users judged as health professionals, providers, or students in health professions as primary users; (2) had inadequate or no description provided; (3) apps meant to be used by members or people associated with special programs or health care facilities (eg, a clinic or hospital); (4) solely calculated gestational age and/or due date; and (5) solely used to identify baby names. The detailed review of app descriptions based on the inclusion and exclusion criteria resulted in a total of 742 apps (Figure 1).

Data Extraction

For each included app, the data extracted included (1) average user rating (ie, *stars* 1 to 5), which reflects end users' perceived satisfaction; (2) number of downloads, which measures intention to use; (3) app store; (4) prices in US dollars; (5) app developer type (health care and non–health care/unknown); (6) days since last app update; (7) primary categories/genre (medical, health and fitness, and other); (8) content rating (age restricted, not age restricted, and unrated); (9) in-app purchase option (yes/no); and (10) in-app advertisement presence (yes/no). The variables number of downloads, in-app purchase option, and in-app advertisement presence were available from the Google Play Store apps only.

Data Analysis

The first outcome variable, average user ratings, was standardized as z-scores for the purpose of analysis. The Google Play Store offers continuous values to one-tenth of a point, whereas the Apple App Store rounds it to the nearest half point. To maintain consistency across stores, we converted it to a standardized z-score. Critically, the Apple App Store requires a minimum number of reviews before releasing average user ratings (ie, small numbers are suppressed), and the Google Play Store does not report ratings for unreviewed apps. Of the 742 apps in the sample, 43.3% of apps had no or suppressed user ratings. Therefore, these were all coded as missing values (n=321) and omitted from the analysis; hence, the analysis of user ratings reflects 421 apps from both stores (Figure 1). The second outcome variable, number of downloads, was available from the Google Play Store only; hence, the analysis of user

downloads consists of 213 apps from 1 store. Download numbers could only be extracted as 1 of the 12 numeric range categories. For analysis, they were collapsed into 4 categories (1-500, 501-5000, 5001-50,000, and 50,001-50,000,000).

To categorize app developer type, a manual review of developer website provided by the app stores was conducted by the primary reviewer (RB). On the basis of the description provided, developers were categorized as a health care developer if they were identified as one of the following: government agency, US hospital system, US academic medical institution, medical specialty society, nonprofit health care organization, consumer organization with health focus, US physician, third-party payer, and pharmaceutical and medical technology companies [32]. Alternatively, developers were categorized as non–health care/unknown, based on the description provided, if they were not classified into 1 of the abovementioned categories or in cases where the website was not provided. The app update age was based on the number of days since the new version was released. This was calculated by subtracting the date of the last update from the date of data extraction, March 31, 2017. Only apps belonging to health and fitness, medical, books and reference, education, and parenting genres were included in this study. Owing to small sample sizes within some categories, combined apps belonging to books and reference, education, and parenting genre were pooled into a single category (other). Content rating was classified into 3 categories: not age restricted, age restricted, and unrated. The Apple App Store apps with ratings of 4+ were categorized as not age restricted; 9+, 12+, and 17+ as age restricted; and with no rating as unrated [33]. Similarly, the Google Play Store apps with ratings of everyone were categorized as not age restricted; low, medium, and high maturity as age restricted; and with no rating as unrated [34].

First, descriptive statistics were calculated and assessed. Next, the relationship between app characteristics and end users' perceived satisfaction (user ratings) and intent to use (downloads) were examined in 2 separate regressions models. First, a multivariable linear regression assessed the relationship between app characteristics (app price, update age, app store, developer type, genre, and content rating) and standardized user ratings controlling for all other available app characteristics for both the Apple App Store and Google Play Store apps. Second, the association between app characteristics (standardized user rating, app price, update age, developer type, genre, in-app purchase, and in-app advertisement) and the number of app downloads was modeled using a series of ordinal logistic regressions for the Google Play Store apps only. Given the small sample size, the analysis of downloads could not be examined with all independent variables in a single model. Therefore, 6 models holding user ratings and price as constant with an additional independent variable were run. Statistical significance was assessed at the $P<.05$ level.

Results

App Characteristics

From the total of 421 apps that were included, 322 (75.5%) were free. Of the paid apps, the prices ranged from US $0.99 to US $10.92, with an average price of US $3.14 and a median of US $2.99. The number of days since the last update varied from 14 to 2888 (average 582 days). Only 102 (102/421, 24.2%) apps were developed by health care organizations. The average user rating was 3.79 out of 5. Furthermore, the modal category for user downloads was greater than 50,000, with 66 (66/213, 31.0%) apps (Table 2). In addition, from the 108 apps that offer in-app advertisements, as high as 104 (104/108, 96.3%) apps were offered free of cost to users, and for those that were paid, the prices ranged from US $0.99 to US $2.99.

Table 2. Descriptive statistics for independent and dependent variables.

Variables	Values
Apps included in user rating analysis (N=421)	
Average user ratings (number of stars out of 5), mean (SD)	3.79 (0.98)
App price (paid apps), mean (SD)	3.14 (2.13)
Update age (days), mean (SD)	582 (624.44)
App store, n (%)	
Apple App Store	221 (52.5)
Google Play Store	200 (47.5)
Developer type, n (%)	
Non–health care	319 (75.8)
Health care	102 (24.2)
Primary category/genre, n (%)	
Health and fitness	225 (53.4)
Medical	156 (37.1)
Other (books and reference, education, and parenting)	40 (9.5)
Content rating, n (%)	
Not age restricted	319 (75.8)
Age restricted	90 (21.3)
Unrated	12 (2.9)
Apps included in user download analysis (N=213), n (%)	
Downloads	
1-500	43 (20.2)
501-5000	52 (24.4)
5001-50,000	52 (24.4)
50,001-50,000,000	66 (31.0)
In-app purchase	
Yes	39 (18.3)
No	174 (81.7)
In-app advertisement	
Yes	108 (50.7)
No	105 (49.3)

App Characteristics Associated With User Ratings

Compared with the Apple App Store, apps from the Google Play Store had, on average, 0.33 higher star ratings (P=.005; Table 3). Compared with *other* category, apps listed under the health and fitness genre had, on average, 0.41 lower star ratings (P=.01). Other factors negatively associated with satisfaction included older apps (ie, increasing app age; beta=−.0004; P≤.001) and apps with no age restriction (beta=−.32; P=.01). After controlling for other factors, developer type did not show statistically significant associations with rating (beta=−.20; P=.06).

Table 3. Multivariable linear regression for factors associated with standardized user ratings (N=421).

Variables	Estimates	SE	*P* value
Developer type health care[a]	−0.20	0.11	.06
Google Play platform[a]	0.33	0.12	.005
Genre			
Other (books and reference, education, and parenting)	Ref[b]	Ref	Ref
Medical	−0.19	0.17	.23
Health and fitness	−0.41	0.17	.01
Update age	−0.0004	0.00008	<.001
Content rating			
Age restricted apps	Ref	Ref	Ref
Not age restricted apps	−0.32	0.13	.01
Unrated apps	−0.51	0.32	.10
Price (US $)	0.03	0.03	.35

[a]The reference level for platform iOS and for developer type not health care developer.

[b]Ref: reference.

App Characteristics Associated With User Downloads

Factors positively associated with user downloads were standardized user ratings (beta=.80; *P*<.001), in-app purchases (beta=1.12; *P*=.002), and in-app advertisement (beta=.64; *P*=.02) (Table 4). Compared with *other* category, apps listed under the medical genre had, on average, 1.63 lower star ratings (*P*<.001), and apps listed under health and fitness genre had, on average, 1.29 lower star ratings (*P*=.002). Other factors negatively associated with user downloads included price (beta=−.45; *P*=.003) and older apps (ie, increasing app age; beta=−.0008; *P*=.009). After controlling for other factors, developer type did not show statistically significant associations with downloads (beta=−.14; *P*=.63).

Table 4. Ordinal logistic regression for factors associated with user downloads (n=213).

Variables	Estimates	SE	*P* value
Standardized user rating	0.80	0.20	<.001
Price (US $)	−0.45	0.15	.003
Developer type health care	−0.14	0.30	.63
Genre			
Other (books and reference, education, and parenting)	Ref[a]	Ref	Ref
Medical	−1.63	0.46	<.001
Health and fitness	−1.29	0.42	.002
Update age	−0.0008	0.0003	.009
In-app purchase	1.12	0.36	.002
In-app advertisement	0.64	0.27	.02

[a]Ref: reference.

Discussion

Principal Findings

This study uses publicly available open-source data to assess the factors related to user ratings (perceived satisfaction) and user downloads (intent to use) for MIH apps. To our knowledge, this is the first study that quantifies app features and characteristics that relate to user ratings and downloads for MIH apps using data from the Apple App Store and Google Play Store.

The Apple App Store and Google Play Store contain hundreds of apps related to MIH, many of which have been downloaded hundreds and thousands of times. Our findings suggest that price, user ratings, in-app purchase options, and presence of in-app advertisements were impactful predictors of user downloads. For instance, less expensive apps and apps with optional in-app purchases were associated with higher user downloads. Consumers tend to prefer apps that are free or of low cost with an ability to purchase additional features or functionalities via in-app purchases, as opposed to paying a

higher price upfront [21,35]. Further examination on the quality of low-priced or free MIH apps is, therefore, needed.

Furthermore, the number of user downloads also increased with average user ratings, which suggests that perceived satisfaction with these apps is an important indicator related to new user preferences. This corroborates previous findings that most users tend to download apps with high user ratings [21,23]. Overall, consumers value Web-based word of mouth, thereby having a strong association with app sales and rankings [21,36]. However, high user ratings do not equate to quality, which is evident from an inaccurate instant blood pressure measurement app available in iTunes receiving high user ratings and positive user reviews [20].

In terms of genre, our findings suggest that apps in the health and fitness category have lower ratings and downloads, whereas apps in the medical category have fewer downloads. However, we cannot ascertain the exact reason behind why users may prefer MIH apps within specific categories over others, thereby calling for further investigation.

In addition, our results reveal that the availability of updates (ie, when was the app last updated) positively influences both user ratings and downloads. This is because updates act as a proxy of the app's evolution [23]. Further, the presence of in-app advertisements is positively associated with user downloads. Although this finding may seem counterintuitive to the popular belief that in-app advertisements may cause annoyance and distraction to the user, it may, however, provide app developers with incentives to lower their app cost [23]. Our data show that from the apps that offer in-app advertisements, a vast majority of the apps were offered for free or for very low cost to users. Furthermore, unlike a previous report [23], our findings show that apps developed by health care developers are neither associated with higher ratings nor downloads.

These results may provide some correlational information to app developers, including health care organizations, about the types of apps that people tend to download and rate higher.

Implications of Findings

Our findings could be applied to improve app design mechanisms that are currently in place for the MIH app market. Considering the sensitivity of MIH, we recommend that developers employ ways to increase health expert involvement in app design and content delivery.

A large majority (75.8%) of MIH apps included in this study were developed by non–health care organizations. This is consistent with previous reports on limited or nonexistent health expert involvement in app development within other health domains such as urology [23]. Prior studies that focus on evaluating the quality of mHealth apps have indicated missed opportunities pertaining to the timeliness and validity of the information that is being presented [6,37]. For example, out of 218 apps for the prevention of unintended pregnancy, approximately 40% of apps do not mention modern contraceptives, and from the remaining 60% of apps, less than 50% provide information on how to use them [28]. Similarly, from a sample of 10 free maternal and child health apps, only 4 apps provided information from evidence-based medical content [38].

Although these concerns have garnered attention from public agencies such as the US Food and Drug Administration (FDA), presently, the FDA only regulates apps that act as medical devices [39]. This calls for greater participation of health care organizations and other medical societies in app development, content review, and peer review process to increase app safety and accuracy [23]. It may also be beneficial for health care organizations and experts to review and *certify* health apps, similar to existing Web certification, such as the Health on the Net Foundation Code of Conduct, where the reliability and integrity of health information are evaluated against established standards [29]. Our results show no differences in user downloads between health care and non–health care organizations. Therefore, if health care organizations, in fact, provide more credible information, fewer consumers may receive this information. Hence, health care providers, app developers, and policy makers may consider strategies to review and promote apps to consumers based on information accuracy and trustworthiness.

Limitations and Future Directions

In this study, we examined MIH apps from only 2 app stores, and information available in these app stores and developers' websites were collected. However, the app stores and developers' websites remain the main source of information available to consumers too. Thus, the study uses information similar to what would normally be available to consumers in a *real-world* context before downloading an app. Furthermore, each app store limits the number of search results that are returned on scraping data from the app stores. Next, unlike the Google Play Store, the Apple App Store does not provide data on the number of downloads; hence, only apps from the Google Play Store were included to assess the factors related to user downloads. In addition, apps that were included in the user rating analysis were somewhat different from apps that were excluded. Specifically, apps that were included versus excluded from the user rating analysis differed in the distribution of developer type and content rating. No significant differences were observed on other app characteristics (app price, update age, and primary genre) between included and excluded apps. In addition, questionnaires are often used to assess users' intent to use an app. Positively, downloads are an objective measure that suggests intent to use [16,21], although we cannot state with certainty that downloaded apps may result in actual use. While categorizing the app developer type, we used the classification system based on the description provided on the developer website. It is possible that some app developers that were classified under non–health care developers may have consulted medical experts during app design. In addition, for app developers that were classified as health care developers, there was no known way to quantify the level of involvement by medical experts.

We suggest future studies focus on establishing consistent guidelines for the disclosure of health care professional's participation and measures to quantify it. We also recommend future studies apply the same approach to other health topics

and compare their results with this study. Although we found associations of app characteristics with perceived satisfaction and intent to use, we were not able to identify their impact on learning or behavior change because of app use. Therefore, we recommend future research and inquiry to focus on collecting data from users pertaining to their learning and behavior impact from app use. At present, we lack a standardized format/clinical guideline for the evaluation of accuracy of clinical content or included topics within apps, which necessitates further study and recommendations in this area.

Conclusions

A large majority of MIH apps were developed by non–health care organizations, which raises concern about the clinical accuracy and quality of MIH app content. No differences in ratings or downloads were observed between health care and non–health care organizations. Therefore, if health care organizations, in fact, provide more credible information, fewer consumers may receive this information. Health care providers, app developers, and policy makers may consider strategies to review and promote evidence-based and trustworthy apps to consumers.

mHealth apps are increasingly becoming popular and can be used as a tool for MIH care delivery. However, the design and delivery of effective MIH apps still remain a challenging issue. Considering the lack of standard guidelines for app development, or selection, users typically consider publicly available app characteristics to make decisions pertaining to app use and satisfaction. Therefore, we examined the relationship between app characteristics, perceived satisfaction, and intent to use by using cross-sectional data from 2 app stores. We observed that app price, update age, user ratings, in-app purchases, and in-app advertisements are important predictors for intent to use, whereas update age is an important indicator for perceived satisfaction. Most importantly, our findings revealed that apps developed by health care developers were neither associated with higher perceived satisfaction nor intent to use. Knowledge of factors related to ratings and downloads may benefit app developers and help inform future marketing and development strategies.

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Authors' Contributions

The primary author RB proposed and completed this study as part of her doctoral dissertation. The coauthors JRV, BED, TC, and CAH (chair), who are all members of the dissertation committee, contributed significantly to the acquisition, analysis, and interpretation of data; to rigor of the methodology and analysis; and to write the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

FDA: Food and Drug Administration
IRB: institutional review board
IUPUI: Indiana University-Purdue University Indianapolis
MIH: maternal and infant health
mHealth: mobile health

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Review

Perspectives of People Who Are Overweight and Obese on Using Wearable Technology for Weight Management: Systematic Review

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Abstract

Background: Obesity is a large contributor to preventable chronic diseases and health care costs. The efficacy of wearable devices for weight management has been researched; however, there is limited knowledge on how these devices are perceived by users.

Objective: This study aimed to review user perspectives on wearable technology for weight management in people who are overweight and obese.

Methods: We searched the online databases Pubmed, Scopus, Embase, and the Cochrane library for literature published from 2008 onward. We included all types of studies using a wearable device for delivering weight-loss interventions in adults who are overweight or obese, and qualitative data were collected about participants' perspectives on the device. We performed a quality assessment using criteria relevant to different study types. The Cochrane risk of bias tool was used for randomized controlled trials. The Risk of Bias in Non-randomized Studies - of Interventions (ROBINS-I) was used for nonrandomized studies. The Oxman and Guyatt Criteria were used for systematic reviews. We used the critical appraisal checklist for qualitative studies. Data were extracted into a data extraction sheet and thematically analyzed.

Results: We included 19 studies: 5 randomized controlled trials, 6 nonrandomized studies, 5 qualitative studies, and 3 reviews. Mixed perceptions existed for different constructs of wearable technologies, which reflects the differences in the suitability of wearable technology interventions for different individuals in different contexts. This also indicates that interventions were not often tailored to participants' motivations. In addition, very few wearable technology interventions included a thorough qualitative analysis of the participants' view on important features of the intervention that made it successful.

Conclusions: This study highlights the importance of determining the type of intervention most suitable for an individual before the intervention is used. Our findings could help participants find a suitable intervention that is most effective for them. Further research needs to develop a user-centered tool for obtaining comprehensive user feedback.

Trial Registration: PROSPERO CRD42018096932; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=96932

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KEYWORDS

wearable electronic devices; wearable technology; wearable device; mobile health; digital technology; weight loss; wearable; activity tracker; obesity; overweight

Introduction

Obesity is an increasing but preventable chronic health problem affecting over half of the world's adult population and costing the United States an estimated US $147-$210 billion per year [1]. Obesity is a complex issue involving various interacting factors including a person's upbringing, lifestyle, environment, and genetics. Numerous strategies for losing weight have been developed over the past decades, which mainly focus on reducing calorie intake and increasing energy expenditure.

Ownership of smartphones has increased among every demographic group including low-income populations, accompanied by a rapidly growing wearable sector [2]. There are many technologies available that can facilitate the delivery of weight management interventions, for example, wearable devices and smartphone apps. In more recently developed products, the wearables and apps can be synced through Bluetooth for long-term data tracking [3]. In combination with an effective weight management intervention, technologies can help weight loss through various means, for example, by promoting physical exercise, monitoring food consumption, or encouraging interuser communication and support [4].

Several health behavior theories can be used to design more effective weight loss interventions, for example, the self-determination theory, social cognitive theory, and elaboration likelihood model. These theories suggest that behavioral change is based on an individual's reception to things people encounter in their environment. A key aspect is whether the intervention is received favorably by the target audience [5]. It is important to understand what individuals who are overweight and obese value about wearable technology for delivering weight management interventions. This information can be used for the future design of efficient weight loss interventions assisted by wearable technology.

Studies have been conducted to assess the effectiveness of wearables or mobile apps to increase physical activity and decrease sedentary behavior [6]. However, few have investigated their efficacy in achieving desired health outcomes [7]. Even fewer have investigated how these devices are perceived by users [8].

This review aims to review user perspectives on wearable technology for weight management in people who are overweight and obese. Additionally, discrepancies in opinions of participants and investigators that may have contributed to this difference were reviewed. This review answers the following question: From a user feedback perspective, what makes wearable technology efficacious for weight management?

Methods

Protocol and Registration

A protocol was registered with PROSPERO (CRD42018096932), with the review structure following PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Multimedia Appendix 1).

Research issues identified and prioritized by members of the public in a workshop at the European Scientific Institute in July 2017 were used to guide the focus of this study. As data collection was executed via published literature, ethical approval was not required for this review.

Eligibility Criteria

We included studies on participants who were obese or overweight and above the age of 18 years. "Overweight" was defined as having a body mass index of 25-29.99 kg/m^2 or as defined by the study, and "Obese" was defined as having a body mass index of ≥30 kg/m^2.

Interventions included were digital wearable technologies used for monitoring or managing weight. Devices needed to have a clear use case for these activities, and we included studies examining the effectiveness of these devices for this purpose.

Comparators included traditional behavioral weight loss approaches, usual care, another intervention, or no intervention. Studies that did not have a comparator were also included if they met the other inclusion criteria.

Outcomes were barriers and facilitators for management weight and factors influencing the design, development, and deployment of wearable technologies for delivering interventions.

We included all types of studies where qualitative data were collected about the participant's feedback on the device. Documents written in English that were published after 2008 were included.

Information Sources

We searched the electronic databases PubMed, Medline, Scopus, Embase, and the Cochrane Library from 2008 onward. Data prior to 2008 were not included because they did not consider the rapid change in the use of smartphone technology and its influence on the development of wearable technology.

Search

A combination of keywords and index terms related to items in the PICO (Participants, Interventions, Comparators, Outcomes) approach were used to search for relevant papers. A librarian was consulted for advice on the searches. PubMed was the first database searched after a list of keywords and Medical Subject Headings terms were chosen. The search was then adjusted and modified for subsequent databases. Search strings for all databases can be found in Multimedia Appendix 2. In databases where index terms did not exist, keywords were used instead.

Study Selection

Duplicate articles were first removed using EndNote X8 software (Clarivate Analytics, Philadelphia, PA), and then any remaining duplicates were deleted manually. Two further screens were completed using endnote according to the eligibility criteria: (1) any field contains "device*" or "mobile" or "track*" or "technolog*" or "electronic," "not child*," "not adolescent*," and "weight*" and (2) abstract contains "overweight" or "obes*." Following the second screen, the titles and abstracts of all remaining studies were screened individually by two reviewers. Any discrepancies between the two reviewers

were resolved by discussion. A list of studies for full-text reading was produced. The inclusion and exclusion criteria were used to select relevant studies. A final list of eligible studies was created when ineligible studies were excluded following reading the full-text papers. Reference lists of included studies were searched, and no further eligible studies were identified.

Data Collection Process and Items

A standardized data extraction sheet was used to extract data. The extracted data included the title, research question, data sources, how the data were analyzed, main findings, and conclusions. During the data extraction process, a reflection of the gathered evidence on the research question was also created.

Assessment of Methodological Quality

All eligible studies in the final list underwent a methodological quality assessment. Different assessment tools were used for different study designs. The risk of bias of included randomized controlled trials was evaluated using the Cochrane Collaboration Risk of Bias Tool. The quality of the evidence in the nonrandomized studies was assessed using Risk of Bias in Nonrandomized Studies of Interventions (ROBINS-I). The quality of review articles was assessed using the Oxman and Guyatt Criteria for a quality rating of systematic reviews. Qualitative studies were assessed using the critical appraisal checklist for qualitative research studies according to Treloar et al [9]. Each item in the assessment criteria was given a score of 1 if it was fulfilled (a negative item is considered fulfilled if it is avoided) in the article, and a score of 0 if was not fulfilled or if there was insufficient evidence to make a clear statement. Where a criterion was not considered by the study, it was marked as not applicable. The total score of each study was calculated by dividing the number of items included by the number of applicable items, yielding a score between 0 and 1. The methodological quality was considered low if the score was between 0 and 0.5 and high if the score was between 0.51 and 1.

Synthesis of Results

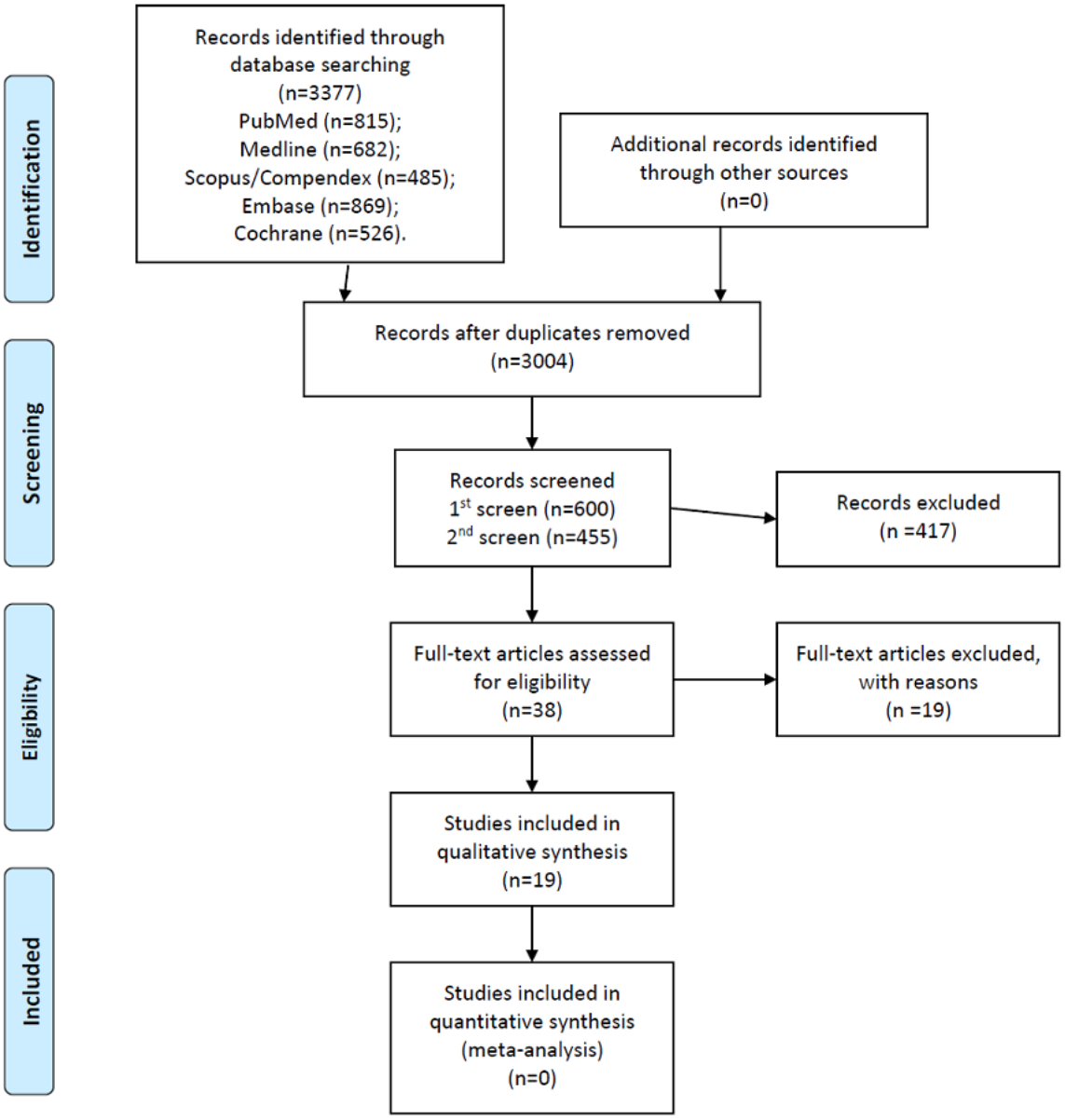
Once data extraction was completed, the findings were grouped into themes based on their context. Data within the same theme were compared, and similarities and differences were identified between studies. A meta-analysis of the studies could not be carried out due to heterogeneity in the type of interventions and the nature of the research question, which focuses on user feedback.

Results

Study Selection

The searches identified 3377 publications (Figure 1). After the removal of duplicates, 3004 relevant publications remained. Screening these results using keywords in the title and abstract led to 455 articles. The abstract of all 455 articles were read manually, which led to the identification of 38 potentially eligible publications. All 38 articles underwent full-text reading, which resulted in the inclusion of 19 studies [4,7,8,10-25]. The reasons for exclusion were the lack of an intervention (n=5), nontarget group of participants (not all overweight or obese; n=4), lack of a mention of specific features of wearable technology (n=4), lack of appropriate measurement of the experimental outcome (n=3), wrong type of wearable technology used during the intervention (n=1), and wearable technology used only as a means of intervention delivery (n=1, Multimedia Appendix 3).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) study flow diagram.



Study Characteristics

The study duration ranged from 3 weeks to 24 months [22], with 6 months being the most common intervention period [12,17,23]. The most common way to deliver the wearable device intervention was by a mobile app [11-15,17,20,23]. Ten studies collected postintervention user feedback by conducting interviews or group discussions [10-12,15,21].

All studies included some aspects of the social cognitive theory (Table 1). Self-determination [10-13], adaptive goals [10,13-15], and social support [10,12,14,18,22] were among the most frequently mentioned behavioral theories mentioned for designing the intervention. Some studies incorporated additional constructs, for example, the importance of cultural facilitators [11]. One study paired participants to give each other direct support and a sense of competition [14].

Table 1. Central motivation theory in included studies.

Central motivation theory identified in participants' responses	Included study
Social support/competition	• Donnachie et al (2017) [10] • Lee and Kim (2016) [22] • Mummah et al (2016) [12] • Laing et al (2014) [18] • Eisenhauer et al (2016) [19] • Burke et al (2009) [23] • Carter et al (2013) [24] • Choo et al (2016) [14]
Self-determination	• Donnachie et al (2017) [10] • Maglalang et al (2017) [11] • Robinson et al (2013) [16] • Mummah et al (2016) [12] • Naslund et al (2016) [13]
Adaptive goals	• Donnachie et al (2017) [10] • Hekler et al (2017) [15] • Naslund et al (2016) [13] • Martin et al (2015) [21] • Burke et al (2009) [23] • Choo et al (2016) [14]

Methodological Quality

The methodological quality of the included studies was relatively weak, with 4 of 19 studies scoring below 0.5 (Tables 2-5). Overall, RCTs received the lowest score for methodological quality due to the general lack of allocation concealment and blinding. This is due to the nature of the wearable device intervention, which, in most cases, requires the researcher to give instructions to participants in the intervention group on how to use the device correctly. Similarly, participants must also understand the intervention they were given to abide by the details of the wearable technology intervention. However, two studies used blinding of investigator/assessor to increase study accuracy [18,21].

Table 2. Quality scores for randomized controlled trial calculated using the Cochrane Collaboration Risk of Bias Tool.

Study	Random sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Selective reporting	Score
Carter et al (2013) [24]	1	0	0	0	1	0.40
Bentley et al (2016) [17]	1	0	0	0	1	0.40
Laing et al (2014) [18]	1	1	1	1	1	1.00
Martin et al (2015) [21]	1	0	1	1	1	0.80
Burke et al (2009) [23]	1	0	0	1	1	0.60

Table 3. Quality scores for nonrandomized studies (Risk of Bias in Nonrandomized Studies - of Interventions [ROBINS-I]).

Study	Confounding	Selection of participants	Classification of interventions	Deviations from intended interventions	Missing data	Outcome measurement	Selection of the reported result	Score
Choo et al (2016) [14]	1	0	1	1	0	0	0	0.43
Korinek et al (2017) [15]	1	1	1	1	0	0	1	0.71
Lee and Kim (2016) [22]	1	0	1	1	0	0	0	0.43
Naslund et al (2016) [13]	1	1	1	1	0	1	1	0.86
Eisenhauer et al (2016) [19]	1	0	1	1	1	1	1	0.86
Robinson et al (2013) [16]	1	0	1	1	1	1	1	0.86

Table 4. Quality scores of the qualitative studies (critical appraisal checklist for qualitative research studies).

Study	Purpose clear	Rationale appropriate	Conceptual framework	Ethical implications	Sampling strategy	Data collection procedures	Data organization	Data analysis	Reliability and validity in data collection and analysis	Progression from research question to conclusions	Score
Donnachie et al (2017) [10]	1	1	1	1	1	1	1	1	1	1	1.00
Huberty et al (2015) [20]	1	1	1	0	1	1	1	1	1	1	0.90
Maglalang et al (2017) [11]	1	1	1	1	0	1	1	1	1	1	0.90
Mummah et al (2016) [12]	1	1	1	1	1	1	0	1	1	1	0.90
Karduck et al (2018) [25]	1	1	0	1	0	1	1	1	1	1	0.80

Table 5. Review articles selected as per the Oxman and Guyatt criteria.

Study	Questions and method clearly stated	Comprehensive search methods	Inclusion explicit	Validity of primary studies	Assessment of the primary studies reproducible	Variation in the findings analyzed	Findings of the primary studies combined appropriately	Conclusions supported by the data cited	Overall risk
Bardus et al (2015) [7]	1	1	1	0	N/A[a]	1	1	1	0.86
Khaylis et al (2010) [8]	1	1	1	0	N/A	1	1	1	0.86
Lyzwinski et al (2014) [4]	1	1	1	1	1	1	1	1	1.00

[a]N/A: not applicable.

Results of Individual Studies and Synthesis

Several themes were found, which are described below.

Self-efficacy

Participants found pedometers to be "a catalyst that enabled a new or renewed sense of self" [10]. Others expressed that a Fitbit accelerometer helped them "progress...from despair to self-efficacy" [11] and "improved participant's self-efficacy in making healthy behavior changes" [11]. Participants in another study commented that they were "inspired" to increase their vegetable consumption [12]. Similarly, wearable devices have been "empowering" because they "helped create a sense of accomplishment from being more active and collecting more steps" [13]. On the other hand, a study found that participants who were more externally motivated failed to develop self-efficacy and were more likely to discontinue use of the device postintervention [10].

Goal Setting

Having a "goal" to work toward was identified by participants as a motivation to use the wearable. For example, participants commented that instantaneous feedback from the pedometer enabled them to "determine precisely how far they were from their goal" [10]. Some users perceived the device as a challenge: "It was like the one on one with myself and the Fitbit" [13]. In one study, "personal goal setting and monitoring" received the best feedback [14]. Variation in goals was also popular; one study showed that "100% of participants liked receiving different daily goals" [15]. However, some reported a "feeling of disappointment when unable to fulfil step targets" and discontinued use after the program [10].

Awareness

Participants commented that pedometers provided them with "an awareness of their (in)activity levels, which they felt they could not contest" [10]. Some felt that the mere presence of the app on their mobile phone and having to photograph and record foods "raised awareness of what they had been eating." In addition, at times, this information resulted in changes in decision making regarding future eating [16]. Participants in other studies agreed that wearable mobile health devices "make you think and do things differently" [17] and are "helpful for increasing awareness of physical activity" [12]. Using a wearable "increases awareness of unhealthy food choices or portion size" [18] and "improved self-awareness about physical activity, water intake and portion sizes" [19]. Moreover, it provided an opportunity for the participants to "look at" their sleep quality (and confirm bad sleep quality) [20].

Feedback

Some participants felt that pedometer feedback gave them "personally relevant information and a meaningful rationale for increasing their activity levels" [10]. Others, while interested in receiving notification messages, "varied notably in their desired frequency" [12] of such notifications. "Encouraging messages" were appreciated by participants in a study, who felt that the messages "compelled (them)...to work towards their daily step goal" [13]. Similar results were also found in other studies, where participants "enjoyed receiving feedback on their progress," "enjoyed the reminder feature" [18], "found specific suggestions helpful" [21], and "found the daily text messages...to be positive resources for self-monitoring eating and activity" [19]. In one study, participants identified the feedback they received from researchers as "their biggest motivator to wearing the sensor" [20]. Similarly, "feedback on physical activities" was one of the two features that had the highest satisfaction level [14].

Social Network and Communication

This construct received mixed feedback from users. Some participants found that the "interactional context" was one of the greatest sources of motivation; they felt that "connection to a group they valued" combined with a "perceived need/desire to report back to this group" kept them going [10]. The importance of meaningful connection was reflected in another study where researchers found that a more direct and closer relationship (eg, opposite sex, same occupation, and shared workspace) between the competing users resulted in more positive physical characteristic changes [22]. Users also "liked comparing their physical activity with other participants," which "provides relevance to their self-monitoring" [19]. The two studies that received the most positive feedback on communication and competition were studies conducted in men only [10,19]. Most participants were interested in competing with others and "liked the way [the app] ranked everybody" [12]. However, some were "not interested in competing against friends and family outside of the study," since "they might become discouraged if they were too far behind" [12]. Likewise, in two other studies, the overall use of the social networking feature was minimal, and satisfaction with the social networking service was low [14,18].

Acceptability in Social Settings

Participants were in favor of wearable devices and reported that the device was "socially acceptable." They could "record in any public setting without having to let others know that they were self-monitoring" [23]. Smartphones gave them a "higher level of comfort using the study equipment in social settings" [24]. In some social situations, however, use of a mobile phone has been regarded as "inappropriate" and this decreased use [16].

Having Fun

In one study, participants commented that "self-monitoring with the pedometer provided an optimal challenge, which was fun/enjoyable in itself" [10]. Participants in other studies reported wanting "ideas" in the intervention that overcame the "boredom" of repeating the same activities repeatedly [12]. Similarly, in another study, participants who adhered to using wearable technology reported that it was "fun to use" [18], while the majority who gave up reported that it was "tedious" [18,19].

Suitability and Attractiveness of the Wearable Device

Comfort and appearance were among the primary considerations for using a device. Overall, participants found wearable technology "easy to use, portable and non-intrusive" [10]. Some commented that the device was "easy to incorporate into their everyday lives," and, in some cases, linked it directly to adhering to increased exercise or dieting [17]. In addition, 30% of participants in one study even commented that they "would not have volunteered for the trial if there had been no offer of using a smartphone" [24]. In a study where three wearable devices were compared, the device that was the most comfortable received the highest satisfaction. In the same study, "appearance" was commonly referred to by female participants [20]. Some concerns about wearable technology included "frustration that it did not include more user-friendly software" [23], "desired better accuracy and precision in all aspects of the activity monitor" [19], and "challenges with...learning to use the Fitbit" [13].

Discussion

Principal Results

This review found 19 studies that reported user perspectives of wearable technology for weight management in people who are overweight and obese. It provides insight into what people have found to be helpful for their weight management when using a wearable device. Several themes were found, including "self-efficacy," "goal setting," "physical awareness," "feedback," "social comparison," "acceptability in social settings," "enjoyability," and "attractiveness of hardware." Participants had different views on "self-efficacy" and "goal setting," indicating the importance of identifying and tailoring interventions to individual motivations in order to facilitate technology adoption. Furthermore, specific design elements were identified by users as decreasing their likelihood of adopting the technology. For example, while a smartphone was considered an attractive means of intervention delivery, users sometimes found it inappropriate in social settings. Users also found some types of devices, such as waist-worn ones, not comfortable enough to be worn all the time. Feedback from the device indicating that it had been worn properly was also appreciated by users.

Limitations

The methodological quality of the included studies was relatively weak, with 4 of 19 studies scoring below 0.5. Most studies had a relatively short duration, with an average of 6 months, which means that they could not provide evidence for the long-term effectiveness of wearable technology. Long-term adoption of technology and sustained weight loss are challenging. Only a few studies conducted a thorough qualitative analysis of the participants' views to help identify essential features of the intervention that made it a successful weight loss intervention. A carefully charted tool for obtaining comprehensive user feedback may be the first step to achieving this.

A strength of this review is that we followed, where possible, the comprehensive Cochrane Collaboration methods for systematic reviews. A limitation of this review is that we did not hand search journals or the grey literature. However, a comprehensive search of electronic databases was conducted to find relevant studies.

Implications for Policy and Practice

The effect of different theories varies when approaching different groups of individuals, including hard-to-reach populations. For example, cultural factors play a significant role in treating at-risk ethnic minorities, and special adaptations may be required in treating patients with a mental illness. In addition, interventions targeting rural populations may require special attention to access disparity and seasonal exercise level fluctuation. Sources of motivation also play a part in achieving optimal results, and intervention programs need to be tailored to individuals with different needs. Hence, it may be worth considering introducing a preintervention assessment to make sure participants are introduced to an intervention that suits their individual needs.

Future Research

For future studies to provide more meaningful information on user feedback, the criteria used by researchers in qualitative data collection should be specified. Participants might then be guided to provide a more in-depth and comprehensive reflection on their intervention experience and on the features they felt were helpful or needed. This information is much needed for the future development of wearable technology for weight loss to meet the specific needs of people who are overweight or obese. Comfort and appearance were important considerations for using a device. Thus, further research should develop wearable devices that are comfortable to wear and acceptable in social settings, for example, digital glasses.

Conclusions

Our review found mixed views on the effective use of wearable technology for weight loss interventions. This highlights the importance of determining the type of intervention most suitable for an individual before the intervention is used.

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Authors' Contributions

EM conceived the study objectives and oversaw the original study protocol. RH reviewed the initial study protocol, made amendments as per this manuscript's methods, executed the review independently (with peer review on study inclusion), and drafted the final manuscript on her own. EM provided feedback to RH, and RH incorporated all feedback. MV rewrote the paper and made major revisions based on peer-review feedback. The final manuscript was approved by all authors. EM is the guarantor.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 16 KB - mhealth_v8i1e12651_app1.docx]

Multimedia Appendix 2
Full search strategies used.
[DOCX File , 15 KB - mhealth_v8i1e12651_app2.docx]

Multimedia Appendix 3
Eligibility stage exclusions.
[DOC File , 425 KB - mhealth_v8i1e12651_app3.doc]

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Abbreviations

PICO: Participants, Interventions, Comparators, Outcomes
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
ROBINS-I: Risk of Bias in Nonrandomized Studies - of Interventions

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Original Paper

Activity Tracker–Based Metrics as Digital Markers of Cardiometabolic Health in Working Adults: Cross-Sectional Study

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Abstract

Background: Greater adoption of wearable devices with multiple sensors may enhance personalized health monitoring, facilitate early detection of some diseases, and further scale up population health screening. However, few studies have explored the utility of data from wearable fitness trackers in cardiovascular and metabolic disease risk prediction.

Objective: This study aimed to investigate the associations between a range of activity metrics derived from a wearable consumer-grade fitness tracker and major modifiable biomarkers of cardiometabolic disease in a working-age population.

Methods: This was a cross-sectional study of 83 working adults. Participants wore Fitbit Charge 2 for 21 consecutive days and went through a health assessment, including fasting blood tests. The following clinical biomarkers were collected: BMI, waist circumference, waist-to-hip ratio, blood pressure, triglycerides (TGs), high-density lipoprotein (HDL) and low-density lipoprotein cholesterol, and blood glucose. We used a range of wearable-derived metrics based on steps, heart rate (HR), and energy expenditure, including measures of stability of circadian activity rhythms, sedentary time, and time spent at various intensities of physical activity. Spearman rank correlation was used for preliminary analysis. Multiple linear regression adjusted for potential confounders was used to determine the extent to which each metric of activity was associated with continuous clinical biomarkers. In addition, pairwise multiple regression was used to investigate the significance and mutual dependence of activity metrics when two or more of them had significant association with the same outcome from the previous step of the analysis.

Results: The participants were predominantly middle aged (mean age 44.3 years, SD 12), Chinese (62/83, 75%), and male (64/83, 77%). Blood biomarkers of cardiometabolic disease (HDL cholesterol and TGs) were significantly associated with steps-based activity metrics independent of age, gender, ethnicity, education, and shift work, whereas body composition biomarkers (BMI, waist circumference, and waist-to-hip ratio) were significantly associated with energy expenditure–based and HR-based metrics when adjusted for the same confounders. Steps-based interdaily stability of circadian activity rhythm was strongly associated with HDL (beta=5.4 per 10% change; 95% CI 1.8 to 9.0; *P*=.005) and TG (beta=−27.7 per 10% change; 95% CI −48.4 to −7.0; *P*=.01). Average daily steps were negatively associated with TG (beta=−6.8 per 1000 steps; 95% CI −13.0 to −0.6; *P*=.04). The difference between average HR and resting HR was significantly associated with BMI (beta=−.5; 95% CI −1.0 to −0.1; *P*=.01) and waist circumference (beta=−1.3; 95% CI −2.4 to −0.2; *P*=.03).

Conclusions: Wearable consumer-grade fitness trackers can provide acceptably accurate and meaningful information, which might be used in the risk prediction of cardiometabolic disease. Our results showed the beneficial effects of stable daily patterns of locomotor activity for cardiometabolic health. Study findings should be further replicated with larger population studies.

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KEYWORDS

mobile health; metabolic cardiovascular syndrome; fitness trackers; wearable electronic devices; Fitbit; steps; heart rate; physical activity; circadian rhythms; sedentary behavior

Introduction

Background

Wearable consumer-grade fitness trackers are becoming more widespread every year. The market and number of wearables are expected to more than double from an estimated 527 million devices worldwide in 2017 to more than 1.1 billion in 2022 [1], achieving a market size of US $27 billion by 2022 [2]. These wearables are equipped with multiple sensors and can monitor and record biometric and locomotor activity data, including steps, heart rate (HR), blood volume pulse, electrodermal activity, skin and body temperature, respiration rate, oxygen saturation, electrocardiography, and sleep patterns. Apart from providing direct information about an individual's physical health status (eg, body temperature), some of these physiological and behavioral characteristics can be considered as risk factors or markers related to different diseases. For example, increased resting HR (RHR) is an important risk marker of cardiovascular disease [3,4], and insufficient physical activity (PA) is a risk factor of major noncommunicable diseases [5,6]. At the same time, activity metrics have potential value in risk prediction of other health conditions, including mental disorders [7,8] and neuropsychiatric illness [9]. As greater adoption of wearables can enhance personalized health monitoring, scale up population health screening, and facilitate early detection of some diseases, research should explore associations between metrics derived from consumer-grade wearables and clinical and biological health markers. Multisensor and continuous data available from fitness trackers at second-by-second or minute-by-minute resolution allow the retrieval of various metrics and exploration of their clinical significance. In this work, we focused on the association between wearable data and biomarkers of cardiovascular and metabolic diseases, which are the leading causes of mortality and disability worldwide [10].

Related Work

The risk of sedentary behavior and the beneficial effects of PA for cardiometabolic disease have been extensively studied in different populations [11-22]. Large cross-sectional studies demonstrated reliable evidence that sedentary time and PA measured objectively with wearable accelerometers are strongly related to most cardiometabolic biomarkers, including waist circumference, BMI, high-density lipoprotein (HDL) cholesterol, triglycerides (TGs), fasting blood glucose (BG) level, high-sensitivity C-reactive protein (CRP), and blood pressure independently from major confounders. Most studies measured average daily duration of sedentary behavior and PA in minutes with research-grade actigraphs; however, the observation period in these studies did not exceed 7 consecutive days. Key differences in findings concern the significance of light-intensity PA and moderate-to-vigorous PA (MVPA) as protective factors for cardiometabolic disease independent of sedentary time. Different levels of PA were found to vary in significance in specific population groups. For example, light-intensity PA was found to be beneficial for cardiometabolic health in American Hispanic adults with type 2 diabetes [17], although it did not appear to have a beneficial effect in older adults without known diabetes [22]. However, the overall beneficial role of PA has not been questioned.

Several studies explored the association between rest/activity rhythms measured by wearables and indicators of cardiometabolic disease [23-28]. Continuous activity tracking permits the assessment of circadian patterns, revealing possible irregularities and disruptions. To our knowledge, there are only a few studies that have investigated the associations of regularity in activity rhythms, measured as interdaily stability (IS), with cardiometabolic risk or related biomarkers. Paudel et al [23] studied rest/activity rhythms in 2968 community-dwelling older men and found that lower regularity in circadian activity was associated with an increased risk of peripheral vascular disease events (such as acute arterial occlusion, rupture, or dissection) independent of age, race, smoking status, walking for exercise, history of cardiovascular events, and even a number of cardiovascular risk factors, including diabetes, blood pressure, total cholesterol, and HDL cholesterol. Sohail et al [24] studied actigraphic data from 1137 older adults and found that IS was related to several key components of the metabolic syndrome. In particular, higher IS was associated with lower blood pressure, higher HDL cholesterol, lower risk of being obese (defined with BMI), or having diabetes (according to medical history) independent of total daily PA and other confounders. Another study did not find significant associations between IS and blood pressure and cholesterol level (including HDL) in patients with diabetes [25]. One more study reported the negative relationship between IS and systolic blood pressure (SBP) and diastolic blood pressure (DBP) [26]. In addition, two studies tested the association of IS with BMI, which was found to be significant in one study [27] and nonsignificant in the other [28].

Most research on consumer-grade fitness trackers with multiple sensors are intervention studies focused on their value in promoting PA in different populations [29-31] or monitoring studies of patients with different health conditions [32,33]. Despite great enthusiasm for fitness trackers, the current evidence does not consistently indicate significant or long-term effects of using wearables for the promotion of greater PA and habitual behavior change [34-38]. However, fewer studies have

explored the associations between multidimensional data from fitness trackers and clinical and biological markers. Li et al [39] analyzed data collected with Intel Basis smartwatches from 43 individuals over the course of 152 days on average. Initially, the authors demonstrated that elevated HR and skin temperature were strongly associated with elevated CRP, a biomarker of inflammatory response. To identify transitions between healthy and ill states, they used fraction of outlying values of HR and skin temperature, which were calculated with the peak detection method. Second, the authors found that both daytime HR (DayHR) and difference between DayHR and nighttime HR (NightHR) were positively correlated with steady-state plasma glucose level, indicating differences between insulin-sensitive and insulin-resistant individuals. Price et al [40] analyzed comprehensive health data of 108 individuals, including activity tracking with Fitbit wearables. However, along with modest compliance of using wearables (only 64% of the participants met the criterion of a minimum of 40 days of observation), authors did not find any significant correlations between average energy expenditure (calories) and biomarkers. Lim et al [41] analyzed data from 233 volunteers, combining activity tracker data of 3 complete days and multiple cardiovascular and metabolic disease clinical markers. They found that higher RHR was significantly associated with most clinical markers, including higher BMI, waist circumference, DBP and SBP, TG and BG levels, and lower HDL cholesterol, whereas a higher step count was significantly associated only with lower BMI, waist circumference, and TG.

Objectives

Wider adoption of consumer-grade fitness trackers compared with research-grade wearables stimulates the exploration and testing of activity metrics, which might be used for risk prediction of cardiometabolic disease. Compared with previous research, we, first, focused on working-age population; second, harnessed activity tracking for a longer period to analyze regularity of circadian activity rhythms; and, third, used fasting blood samples to get cardiometabolic biomarkers. This allowed us to go beyond standard metrics available from consumer-grade fitness trackers. Thus, the objective of this study was to investigate the associations between different activity metrics retrievable from a consumer-grade fitness tracker and major modifiable biomarkers of cardiometabolic disease, relying on prolonged activity monitoring.

Methods

Study Design and Participants

The data used in this paper were obtained from a workplace cohort study conducted in Singapore by the Nanyang Technological University (NTU) [42]. In total, four organizations agreed to join the study: two from the transport industry, a cooling plant, and a university. Healthy volunteers from these organizations were invited to participate in the study via meetings, workplace posters, and emails (for more details on the recruitment process, refer to the study by Dunleavy et al [42]). The NTU institutional review board approved the study protocol and informed consent form (IRB application reference: 2015/2601).

Measurements

Health Outcomes: Cardiometabolic Disease Risk Biomarkers

In accordance with the American Heart Association guidelines [43,44], cardiometabolic syndrome is determined by an abnormal condition of the following characteristics: waist circumference (or waist-to-hip ratio), blood pressure, TG, HDL cholesterol, and BG. Hence, we considered the following clinical biomarkers in this study: BMI, waist circumference, waist-to-hip ratio, SBP, DBP, fasting levels of total cholesterol, HDL and low-density lipoprotein (LDL) cholesterol, TG, and BG.

Standardized self-report questionnaires were used to collect sociodemographic and health behavior characteristics. Trained staff performed clinical measurements, such as height, weight, and waist and hip circumferences, according to a standard protocol using standardized tools [15]. Height was measured using a stadiometer (Seca 217) to the nearest 0.1 cm, and weight was measured in light clothing using a digital scale (Seca 874) to the nearest 0.1 kg. Waist and hip circumferences were measured using a stretch-resistance tape (Seca 201). Waist circumference was measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest (hip bone). Hip circumference was measured at the maximum circumference over the buttocks. BMI was calculated as weight in kilograms divided by the square of height in meters. Waist-to-hip ratio was calculated as the ratio between waist and hip circumferences. Blood pressure, in accordance with the National Health and Nutrition Examination Survey protocol [45], was measured over the right arm using an appropriate cuff size with an automatic digital blood pressure monitor (Dinamap Pro100V2; Criticon). The average value of the 3 readings taken with 2-min intervals was used.

Venous blood samples were collected from participants in a fasting state (at least 8 hours) by trained phlebotomists. A maximum of approximately 11 mL of blood was drawn into 2 tubes—8 mL in plain and 3 mL in fluoride tubes. Blood samples were transported immediately, in cooler boxes (4°C), to an internationally accredited laboratory for analysis. Blood samples were processed using the hexokinase method for plasma glucose and enzymatic methods for serum lipids on a COBAS 6000 analyzer, using kits supplied by Roche Diagnostics. LDL cholesterol was estimated using the Friedewald equation for those with TGs ≤ 4.52 mmol/L [46], whereas for the rest, values estimated by the direct method were used. Serum 25-hydroxyvitamin D concentrations were measured using the chemiluminescence immunoassay method on a Cobas e 411 analyzer with kits supplied by Roche Diagnostics.

Explanatory Variables: Activity Tracker–Based Metrics

Fitbit Charge 2 devices (a consumer-grade fitness tracker) were used in the study to collect activity data. The accuracy of Fitbit devices in collecting activity data has been tested in multiple studies [47-51]. According to a systematic review [49], studies have indicated that Fitbit wearables were likely to provide comparatively accurate (ie, similar to research-grade monitors) measures of step counts and sleep duration in free-living conditions. However, Fitbit wearables less accurately measure

energy expenditure, underestimating sedentary time and overestimating time spent in MVPA [49,51].

Participants wore Fitbit devices on their wrists for a period of 23 days. As the first and the last days of wearing the fitness tracker were partial days, the total observation period was 21 days (3 weeks) of continuous tracking. Participants were instructed to wear the Fitbit tracker all day and to remove only when taking a shower or to charge it. In addition, participants were instructed to open the Fitbit mobile app and allow it to synchronize with the tracker once every mealtime and to not change any settings in the Fitbit app for the period of the study. To check the completeness of the activity tracking, we counted the number of hours per day with recorded HR data. Participants with a minimum of 14 days with greater than or equal to 18 valid hours each (maximum of 6 missing hours per day) were included for further analysis.

The fitness tracker records the data to the participant's own Fitbit account through the official Fitbit mobile app on the participant's mobile phone. The data were saved on Fitbit's own server, and participants gave consent for Fitbit to send their data to our data collection server, after which the data were automatically retrieved and saved by the server. Our data collection server was situated within NTU's network on a password-protected computer located within the Culture Science Institute's Bio-Cognitive Laboratory. The server maintained a list of registered Fitbit accounts and sent daily requests through the Web application program interface to retrieve data from Fitbit's own server database. Fitbit Charge 2 algorithmically derives and records the following variables from raw sensor data: steps, distance, elevation, calories, HR, and a number of sleep characteristics. Steps, distance, elevation, and calorie data are available at an intraday level in minute-by-minute intervals. Intraday HR data are available at 5- or 10-second intervals.

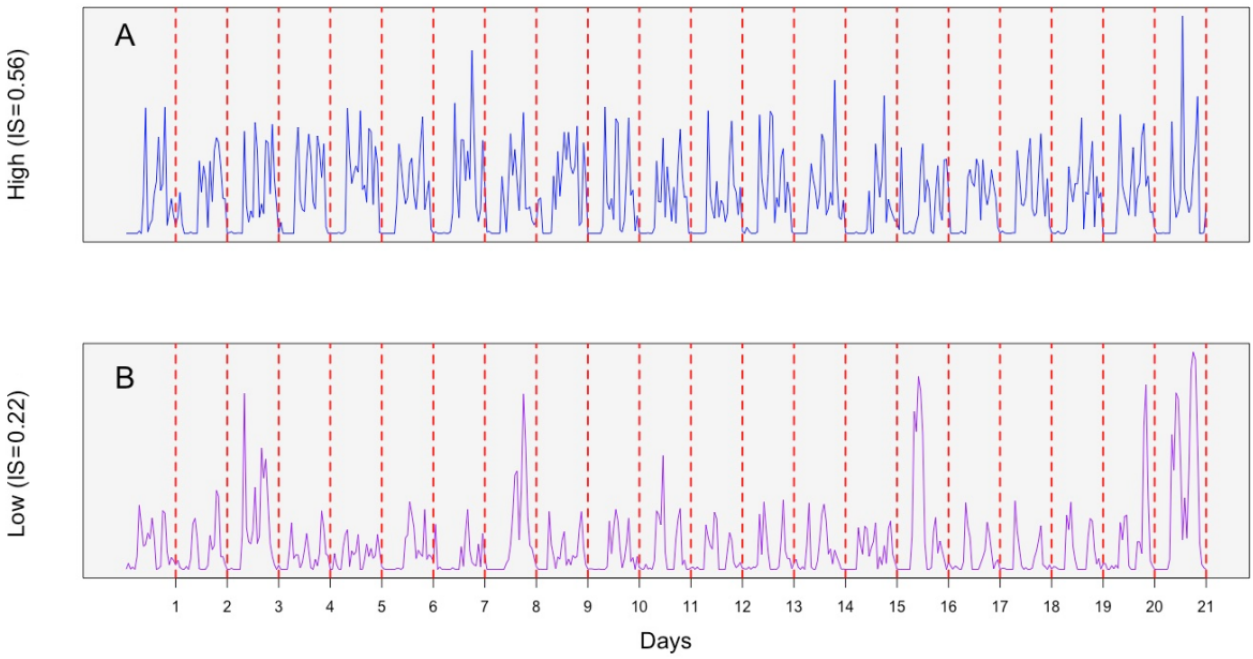
The following wearable-derived activity metrics were considered in the study: daily average steps, daily average HR, RHR, DayHR, NightHR, delta of RHR (dRHR), circadian delta of HR (cdHR), IS of locomotor activity, interdaily variation (IV) of locomotor activity, daily average sedentary time, and daily minutes of light-, moderate-, and vigorous-intensity PA.

To determine RHR, DayHR, and NightHR from the fitness trackers, we followed the approach proposed by Lim et al [41]. RHR was calculated as the average HR of 15-min intervals with less than or equal to 100 steps. DayHR was obtained by averaging HR values between 2 pm and 4 pm, whereas NightHR sampled time points between 2 am and 4 am. dRHR is the difference between average HR and RHR. cdHR is the difference between DayHR and NightHR.

We followed the common conception of sedentary behavior and defined sedentary time as "any waking behavior characterized by an energy expenditure ≤1.5 metabolic equivalents (METs), while in a sitting, reclining, or lying posture" [52]. Hence, to determine sedentary time, we excluded all sleep intervals and calculated a daily mean of total minutes with less than or equal to 1.5 METs.

IS is a nonparametric measure that evaluates the stability/similarity of activity patterns across a series of 24-hour cycles, that is, the extent to which an individual consistently follows some regular activity pattern from day to day. IS was calculated as the variance of the average steps-based 24-hour daily profile divided by the total variance of all days' 24-hour profiles [53]. Higher IS indicates that an individual has a more stable circadian pattern over the course of observation period regardless of the overall level of activity, and lower IS indicates less stability in circadian activity distribution (see Figure 1).

Figure 1. Steps tracking charts. Individuals with relatively high (A) and low (B) interdaily stability but similar total daily steps. x-axis: time in days. y-axis: steps count. IS: interdaily stability of locomotor activity rhythm.



To calculate IV of locomotor activity, we obtained a steps-based daily profile of coefficients of variation for each hour in a 24-hour cycle and took an average of these coefficients. Thus, IV indicates the average hour-by-hour variation of daily activity across the observation period regardless of the overall level of activity. We proposed this metric as alternative to IS, which aims to assess the same phenomena with a different approach.

The daily duration of light-intensity PA and MVPA was determined according to the PA guidelines of US Department of Health and Human Services [54], where moderate-intensity PA corresponds to energy expenditure from 3.0 to 6.0 METs, vigorous-intensity PA is above 6.0 METs, and light-intensity PA is below 3.0 METs. We sampled minutes within these intervals separately and took an average of the daily sum of these minutes.

Data Analysis

We clustered participants according to their normalized average 24-hour profiles of steps using k-means cluster analysis (k=3) to identify groups of participants with similar activity patterns. Normalization of data allowed us to ignore individual differences in the absolute daily number of steps and focus on the temporal pattern of activity distribution. We used steps data for cluster analysis because step counts are probably the most accurate Fitbit metric [49].

An additional analysis was done to determine whether a longer period of tracking provides more stable estimates of RHR than estimates of RHR sampled from 3-day windows. For this analysis, we used the Kolmogorov-Smirnov test to compare the distribution of RHR values from a full period with the distribution of RHR values sampled from ten 3-day windows for each participant. Then the fraction of *failed* tests (with $P<.05$, meaning that distributions are significantly different) was calculated for each participant and on the study sample level.

Spearman rank correlation was used to explore preliminary associations between continuous activity metrics and continuous biomarker metrics. A correlation network based on Spearman coefficients [40] was plotted to display significant associations between activity metrics and clinical biomarkers.

Multiple linear regression analysis was used to determine the extent to which each metric of locomotor activity is associated with clinical biomarkers. For all models, adjustments were made for age, gender, ethnicity (3 categories: Chinese, Malay, or Indian), education, and shift work (shift worker or not). Thus, each regression model includes one explanatory variable (activity tracker–based metric) and aforementioned covariates. In addition, pairwise multiple linear regression analysis was used to investigate the significance and mutual dependence of activity metrics when two or more of them were found to be significant predictors of the same outcome from the previous step of the analysis. Pairwise multiple regression was used instead of including all predictors at once because the sample size limits the number of predictors that can be included in a regression model according to the *one in ten* rule of thumb (minimum 10 cases per predictor). Linear model (*lm*) function in R was used to execute computation (see Multimedia Appendix 1 for the R code used for data processing and analysis).

Results

Characteristics of Participants

A total of 464 full-time employees (aged ≥21 years) were recruited and enrolled in the study (Figure 2). Of these, 334 participants were followed up at 12 months, and blood samples were collected from 214 of them. Three months later, 87 volunteers were issued with consumer-grade fitness trackers to continuously record their biometric and locomotor activity data. These participants were randomly selected among those who confirmed they were going to be at work for 3 weeks (ie, not planning to be on vacation or on a business trip). In total, 87 participants were tracked for 21 days. Three participants were excluded because of incomplete activity data (see Table 1). One participant was excluded from the sample because of extremely high daily locomotor activity (average daily steps above 24,000) compared with others. Thus, we had 83 participants with activity data eligible for further analysis. In addition, there was 1 participant with missed waist circumference and blood pressure measurements. One outlier was excluded in the regression models of TG, BG, and LDL. The final sample for body composition measures was 83 (or 82 for some outcomes because of missing data), and 70 for blood test analysis (or 69 without the outlier).

Table 2 summarizes the characteristics of participants. The mean age of participants was 44.3 years (range 22-65 years), and the majority of them were male (64/83, 77%). The average step count was 10,865 steps per day (median 10479.4), and HR and RHR were 76 (median 75) and 70 (median 69), respectively (see Multimedia Appendix 2 for the differences in activity-tracker-based metrics between shift and nonshift workers).

Figure 2. Participants flow diagram. BG: blood glucose; DBP: diastolic blood pressure; HDL: high-density lipoprotein; LDL: low-density lipoprotein; SBP: systolic blood pressure; TG: triglyceride; WC: waist circumference; WHR: waist-to-hip ratio.

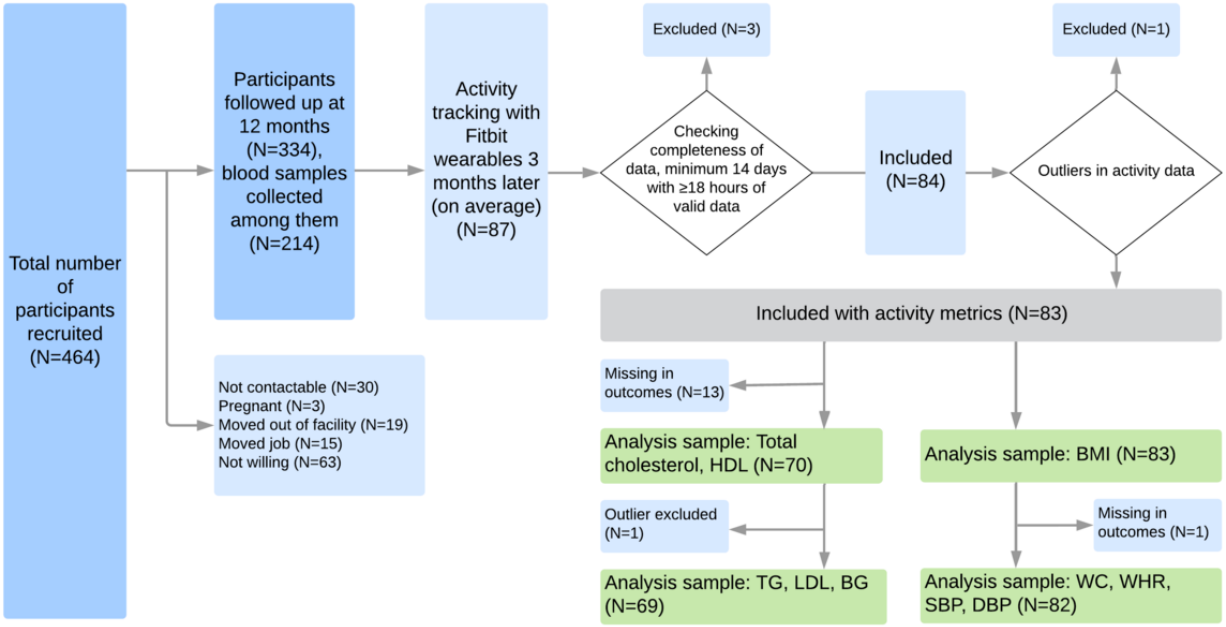


Table 1. The distribution of the number of valid days (1702 days in total) among participants (N=84).

Number of valid days	Number of participants
21	53
20	15
19	10
18	3
16	1
15	1
14	1

Table 2. Summary statistics of participants.

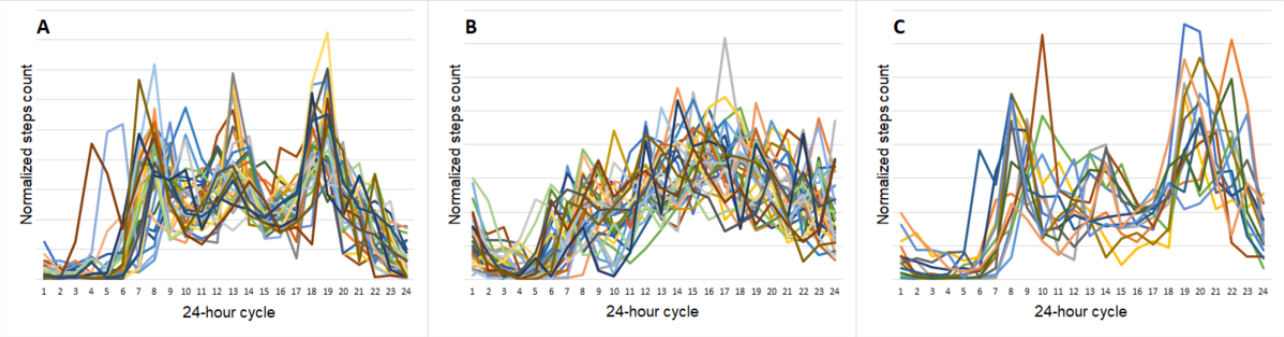
Variable	Values
Sociodemographic characteristics	
Age (years; n=83), mean (SD)	44.3 (11.9)
Gender, n (%)	
Male	64 (77)
Female	19 (23)
Ethnicity, n (%)	
Chinese	62 (75)
Indian	13 (16)
Malay	8 (9)
Education, n (%)	
Below university degree	54 (65)
University degree	29 (35)
Shift worker, n (%)	
No	42 (51)
Yes	41 (49)
Health outcomes: cardiometabolic disease biomarkers, mean (SD)	
BMI (kg/m^2; n=83)	24.6 (4.4)
Waist circumference (cm; n=82)	82.9 (13.2)
Waist-to-hip ratio (n=82)	0.86 (0.08)
Systolic blood pressure (mm Hg; n=82)	119.9 (13.6)
Diastolic blood pressure (mm Hg; n=82)	71.8 (10.7)
Total cholesterol (mg/dL; n=70)	215.7 (34.6)
High-density lipoprotein (mg/dL; n=70)	57.5 (15.7)
Low-density lipoprotein (mg/dL; n=69)	129.1 (27.5)
Triglyceride (mg/dL; n=69)	133.4 (77.4)
Blood glucose (mg/dL; n=69)	96.6 (14.6)
Explanatory variables: activity tracker–based metrics (n=83), mean (SD)	
Steps (per day)	10,865 (2775)
Interdaily stability of locomotor activity rhythm	0.28 (0.11)
Interdaily variation of locomotor activity	1.31 (0.23)
Heart rate (bpm)	76.3 (7.6)
Resting heart rate (bpm)	70.6 (8.1)
Delta of resting heart rate (bpm)	5.7 (1.9)
Daytime heart rate (bpm)	81.5 (9.1)
Nighttime heart rate (bpm)	64.1 (8.1)
Circadian delta of heart rate (bpm)	17.4 (5.7)
Sedentary time (min/d)	787.9 (99.3)
Light-intensity PA[a] (min/d)	1202.9 (60.2)
Moderate-intensity PA (min/d)	205.4 (55.1)
Vigorous-intensity PA (min/d)	31.6 (16.1)
Moderate-to-vigorous PA (min/d)	237.1 (60.2)

[a]PA: physical activity.

We obtained 3 groups of sizes—35, 34, and 14 individuals, respectively—using k-means cluster analysis. Visualization of normalized 24-hour activity profiles (Figure 3) showed that clusters differ in the number of activity peaks, having 3 (morning, lunch, and evening), 2 (morning and evening), or 0 clear peaks throughout a day. The absence of clear peaks in the average activity profiles from the B cluster might be the result of both stable and evenly distributed activity or irregularity and inconsistency in the daily activity of the participants from this cluster. As data clustering indicated a meaningful division of participants, cluster membership was also used as a single categorical predictor of cardiometabolic disease biomarkers in further analysis.

Finally, an additional analysis of stability of RHR indicated that RHR estimated within 3-day windows is different from RHR estimated from the full period (3 weeks) in half of the cases. The sample level fraction of *failed* Kolmogorov-Smirnov tests was 0.49 (*P* values of all Kolmogorov-Smirnov tests are presented in Multimedia Appendix 3). Therefore, we used RHR estimated from the full period in further analysis.

Figure 3. Visualization of normalized average 24-hour activity profiles by clusters. A: first cluster (N=35); B: second cluster (N=34); C: third cluster (N=14). Each line represents an individual within a cluster. x-axis: hours in a daily cycle. y-axis: average number of steps normalized by an individual sum of steps in average 24-hour profile.

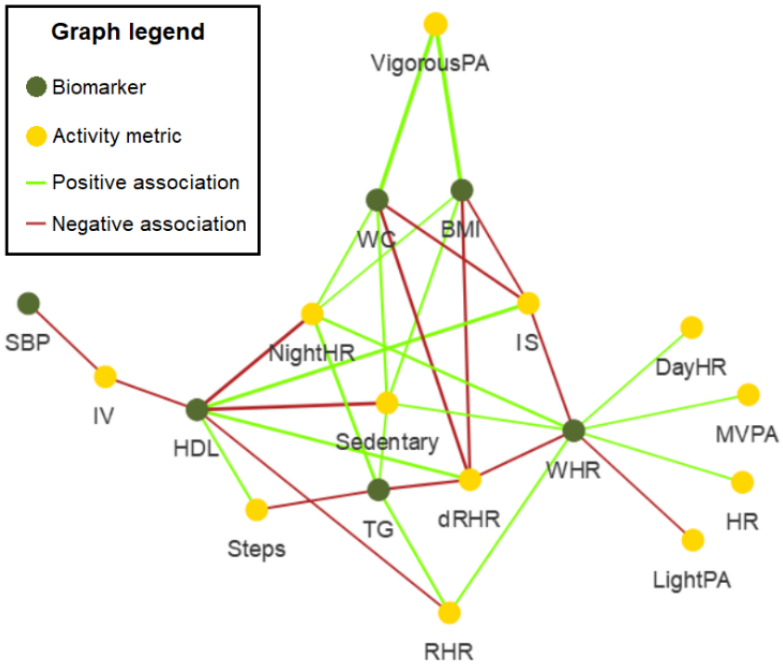


Associations Between Activity Tracker Metrics and Cardiometabolic Disease Biomarkers

Exploratory correlation analysis (Figure 4) showed there were a number of significant monotonic associations (absolute values of Spearman rank correlation coefficients varied from 0.22 to 0.38) between activity metrics and continuous biomarker values. Only 6 of 10 cardiometabolic biomarkers were significantly associated with activity tracker–based metrics: BMI, waist circumference, waist-to-hip ratio, SBP, HDL, and TG. Almost all activity metrics were associated with some biomarkers, except for moderate-intensity PA and cdHR. Sedentary time, NightHR, dRHR, and IS had the greatest number of significant associations with biomarkers.

Further regression analysis showed that a number of activity metrics were significantly associated with BMI, waist circumference, waist-to-hip ratio, HDL, and TG, although there were no significant associations for LDL, BG, blood pressure, and total cholesterol (Table 3).

Figure 4. Correlation network of cardiometabolic disease biomarkers and activity tracker metrics. Only associations significant at $P<.05$ were displayed. Width of lines is proportional to absolute value of Spearman coefficients that vary between 0.22 and 0.38. BG: blood glucose; DayHR: daytime heart rate; DBP: diastolic blood pressure; dRHR: delta of resting heart rate; HDL: high-density lipoprotein; HR: heart rate; IS: interdaily stability of locomotor activity rhythm; IV: interdaily variation of locomotor activity; LDL: low-density lipoprotein; MVPA: moderate-to-vigorous physical activity; NightHR: nighttime heart rate; PA: physical Activity; RHR: resting heart rate; SBP: systolic blood pressure; TG: triglyceride; WC: waist circumference; WHR: waist-to-hip ratio.



Blood biomarkers of cardiometabolic disease were significantly associated with steps-based metrics only. The number of daily steps was negatively associated with TG (beta=−6.8 per 1000 steps; 95% CI −13.0 to −0.6; *P*=.04), so participants with more daily steps had lower levels of TG. IS was negatively associated with TG (beta=−27.7 per 10% change; 95% CI −48.4 to −7.0; *P*=.01) and positively associated with HDL (beta=5.4 per 10% change; 95% CI 1.8 to 9.0; *P*=.005), so participants with higher IS had higher levels of HDL and lower levels of TG. Note that the significant associations between IS and blood biomarkers were independent of all confounders, including shift work. Patterns of circadian activity were also significantly associated with blood biomarkers of cardiometabolic disease independent of all confounders, including shift work. Participants from cluster *B*, whose daily activity was distributed more evenly without clear peaks, had worse indicators of cardiometabolic health, lower HDL (beta=−9.7; 95% CI −17.4 to −2.0; *P*=.02) and higher TG (beta=66.0; 95% CI 24.1 to 107.9; *P*=.003), compared with participants from clusters *A* and *C* with clear 2- or 3-peak patterns. Subsequent pairwise multiple analysis for HDL showed that IS remained a significant predictor when additionally adjusted for cluster membership, whereas cluster membership became nonsignificant (see Multimedia Appendix 5). Pairwise multiple regression analysis for TG indicated that IS remained a significant predictor after adjustment for steps and cluster membership; steps remained significant after adjustment for cluster membership, but it lost significance after adjusting for IS; and cluster membership remained a significant predictor after adjusting for IS and steps (see Multimedia Appendix 5).

Body composition biomarkers of cardiometabolic disease were significantly associated with metrics based on energy expenditure and HR-based metrics. Sedentary time was positively associated with BMI (beta=.1; 95% CI 0.003 to 0.2; *P*=.047), so participants with more sedentary time had a higher BMI. However, this association had borderline significance. Vigorous-intensity PA was positively associated with BMI (beta=.7; 95% CI 0.2 to 1.1; *P*=.01) and waist circumference (beta=1.9; 95% CI 0.6 to 3.2; *P*=.005), so participants with more time spent in vigorous-intensity PA had a higher BMI and a higher waist circumference. RHR was positively associated only with waist-to-hip ratio (beta=.02; 95% CI 0.001 to 0.03; *P*=.04), whereas dRHR (the difference between overall average HR and RHR) was negatively associated with BMI (beta=−0.5; 95% CI −1.0 to −0.1; *P*=.01) and waist circumference (beta=−1.3; 95% CI −2.4 to −0.2; *P*=.03). Lower RHR in relation to overall HR was associated with lower BMI and waist circumference values. Subsequent pairwise multiple analysis for BMI indicated that sedentary time together with vigorous-intensity PA remained significant predictors, as well as vigorous-intensity PA together with dRHR, whereas sedentary time paired with dRHR became nonsignificant (see Multimedia Appendix 5). Pairwise multiple analysis for waist circumference demonstrated that vigorous-intensity PA together with dRHR remained significant predictors after mutual adjustment (see Multimedia Appendix 5).

Table 3. Associations between wearable-based metrics of physical activity and common cardiometabolic disease risk markers.

Activity tracker-based metrics[a]	Blood biomarkers				Body composition					
	High-density lipoprotein		Triglyceride		BMI		Waist circumference		Waist-to-hip ratio	
	Beta (95% CI)	*P* value	Beta (95% CI)	*P* value	Beta (95% CI)	*P* value	Beta (95% CI)	*P* value	Beta (95% CI)	*P* value
Steps (×1000)	—[b]	—	−6.8 (−13.0 to −0.6)	.04	—	—	—	—	—	—
Interdaily stability of locomotor activity rhythm (×0.1)	5.4 (1.8 to 9.0)	.005	−27.7 (−48.4 to −7.0)	.01	—	—	—	—	—	—
Cluster B	−9.7 (−17.4 to −2.0)	.02	66.0 (24.1 to 107.9)	.003	—	—	—	—	—	—
Sedentary time, minutes (×10)	—	—	—	—	0.1 (0.003 to 0.2)	.047	—	—	—	—
Vigorous-intensity physical activity, minutes (×10)	—	—	—	—	0.7 (0.2 to 1.1)	.01	1.9 (0.6 to 3.2)	.005	—	—
Resting heart rate, bpm (×10)	—	—	—	—	—	—	—	—	0.02 (0.001 to 0.03)	.04
Delta of resting heart rate, bpm	—	—	—	—	−0.5 (−1.0 to −0.1)	.01	−1.3 (−2.4 to −0.2)	.03	—	—

[a]The table shows unstandardized coefficients (beta), 95% CI, and exact *P* values of activity metrics as predictors of cardiometabolic disease biomarkers in multiple linear regression models. For each predictor, adjustments were made for age, gender, ethnicity, education level, and shift work. Only significant coefficients reported. Coefficients of adjusted covariates are omitted. The full results are provided in Multimedia Appendix 4. For steps, the effect is for each additional 1000 steps; for IS, the effect is for each 0.1 change in score; for sedentary time and vigorous-intensity physical activity, the effects are for each additional 10 min of time spent in respective activity; for RHR, the effect is for each additional 10 bpm.

[b]Nonsignificant coefficients are omitted. The full results are provided in Multimedia Appendix 4.

Light-intensity PA, moderate-intensity PA, MVPA, average HR, DayHR, NightHR, cdHR, and IV did not indicate any significant associations with cardiometabolic disease biomarkers.

Discussion

Principal Findings

We explored the relationships between metrics of locomotor activity and regularity in circadian rhythms derived from a consumer-grade fitness tracker and risk biomarkers of cardiometabolic disease in a multiethnic Asian working population in Singapore. We found that blood biomarkers of cardiometabolic disease (HDL cholesterol and TGs) were significantly associated with steps-based activity metrics (daily steps, IS, and different patterns of circadian activity), whereas body composition biomarkers (BMI, waist circumference, and waist-to-hip ratio) were significantly associated with energy expenditure–based and HR-based metrics (sedentary time, vigorous-intensity PA, RHR, and dRHR). These associations were significant, independent of age, gender, ethnicity, education, and shift work. One of our principal findings is that the stability of circadian activity rhythm was significantly associated with blood biomarkers of cardiometabolic health independent of shift work, which along with jet lag is considered the strongest disruptor of normal circadian biorhythms and bears a higher risk of developing cardiovascular diseases [55,56], metabolic syndrome, and type 2 diabetes [57,58]. Moreover, the association between IS of circadian rhythm and HDL cholesterol and TGs did not depend on the overall activity level (the number of daily steps), which indicates that a stable activity rhythm may be beneficial for cardiometabolic health at any level of activity. Patterns of circadian activity were also strongly associated with blood biomarkers, which means that some daily regimes may be more beneficial for cardiometabolic health than others regardless of the stability of these regimes. Finally, we found that vigorous-intensity PA was positively associated with BMI and waist circumference, meaning that participants who spent more time engaging in vigorous-intensity PA had higher BMI and waist circumference. Overall, these results contribute to the sparse but growing evidence on, first, the benefits of regular and stable locomotor activity for cardiometabolic health, and, second, the potential public health value of consumer-grade fitness trackers in population health monitoring and cardiometabolic disease risk prediction.

Strengths and Limitations

This study has several strengths. First, a reasonably long period of continuous activity tracking (21 days) was involved, which enabled a more precise assessment of the stability and regularity of circadian activity as well as the level of habitual PA and HR in different states and conditions. Second, we used a wide range of measures based on different wearable data, which evaluated

everyday activity in a comprehensive way. Third, we used IS, a nonparametric measure of the activity rhythm, instead of more common parametric measures. IS is not based on any assumptions about the pattern of the rhythm and hence allows assessment and comparison of the regularity of circadian activity between individuals with different lifestyles. Fourth, regarding clinical measurements, we followed standard operating procedures and collected fasting blood samples, which allowed us to use TGs and fasting BG as biomarkers. Finally, in the statistical analysis, we used linear regression models adjusted for a range of potential confounders, including age, gender, ethnicity, education, and shift work, which allowed us to robustly estimate the linear effect of wearable-derived predictors on continuous measures of biomarkers.

The main limitations of the study are the relatively small sample size (N=86), time gap (3 months on average) between clinical measurements and activity tracking period, and the limited accuracy of Fitbit wearables in measuring energy-expenditure metrics. As we studied a working population that did not change their job over the course of the study, it is acceptable to assume that their behavior and activity patterns were habitual and stable over time. Although we cannot exclude the influence of other multiple contextual factors on the locomotor activity of participants between clinical measurements and activity tracking, such a time gap is not unusual in cohort studies that include an activity tracking component [26]. We found that study participants were highly active in terms of time spent in MVPA, having on average 237 min per day of MVPA and more than 30 min per day of vigorous-intensity PA, much more than meeting PA guidelines [54]. These estimates should be interpreted with caution because Fitbit wearables tend to progressively overestimate the time spent in higher intensity activities [49]. Another limitation is the threshold of a minimum daily wearing time of Fitbit trackers to include a day into the analysis—set to at least 18 hours per day (75% of daily time). This threshold may affect the results of the analysis because missing 6 hours per day is still a significant gap. However, the use of the less strict time gap compared with, for example, 4 hours that is common in actigraphy research brings our study closer to real-life conditions and enables us to explore the potential of consumer-grade wearables in health risk prediction more realistically. In addition, given that the overall observed level of activity (steps) is quite high, we assume that most missing hours did not affect the active phases of the monitored days. An additional limitation concerns the definitions of HR-based metrics, which should be appraised with caution because there is no formal theory-based rationale underpinning them. For example, sampling HR between 2 pm and 4 pm for measuring DayHR can be affected by proximity to a postprandial period or other daily events. Finally, this study has a cross-sectional design, which limits the possibility of making causal inferences.

Comparison With Previous Research

The results of our study are mostly consistent with previous research. First of all, data of fitness tracker–based metrics obtained in our study, namely daily steps and RHR, were similar to the data from the recent study in the same population (Singapore residents) [41].

Second, our findings complement the extant literature on the effects of objectively measured sedentary time and PA on cardiovascular and metabolic health. We found that more daily steps were significantly associated with lower TG after adjustment for confounders, which is consistent with a previous study [41]. Furthermore, correlation analysis indicated that longer daily sedentary time was associated with higher BMI, higher waist circumference, higher waist-to-hip ratio, higher TG levels, and lower HDL [11-22]. However, contrary to previous research, only the association between sedentary time and BMI remained marginally significant after adjustments for age, gender, ethnicity, education, and shift work in the regression models. We hypothesize that this may be because of insufficient power of our study compared with previous research as well as because of the lower accuracy in measuring calorie expenditure by Fitbit wearables compared with research-grade actigraphs. In addition, we did not find associations between cardiometabolic disease biomarkers and light-intensity PA, moderate-intensity PA, or MVPA. Moreover, contrary to previous findings, our analysis showed that participants spending more time engaging in vigorous-intensity PA had a higher BMI and waist circumference. This may potentially be explained by overweight participants already being concerned with their body condition and thus spending more time exercising during the study. Alternatively, this finding may potentially be related to the limited accuracy of Fitbit wearables in measuring energy expenditure and the tendency to overestimate the time spent in higher intensity activities [49], which may have substantial impact on the result.

Third, we found that RHR metrics were associated with body composition markers of cardiometabolic disease risk, including BMI, waist circumference, and waist-to-hip ratio, but not with blood biomarkers, which partially replicates earlier evidence [3,41]. Note that RHR was associated only with waist-to-hip ratio, whereas dRHR was associated with BMI and waist circumference. A lower number of significant associations might be explained by the insufficient power of the sample size (86 vs 233 participants) or the time gap between clinical measurements and activity tracking. However, having a longer period of activity tracking compared with the study by Lim et al [41] (21 days over 3 days) suggests that our estimates of RHR are more stable than their study. RHR sampled and estimated within a 3-day period is more sensitive to random fluctuations, for example, because of higher activity on 1 day, and, therefore, can have more skewed distribution compared with RHR obtained from a longer period.

Finally, harnessing longer activity tracking, we explored the effects of regularity in circadian activity rhythms on cardiometabolic disease biomarkers, going beyond standard metrics available from consumer-grade fitness trackers. Nevertheless, our findings are consistent with the previous studies investigating the clinical value of activity rhythms in respect of cardiometabolic risk or related biomarkers [23,24]. Our data indicate a strong positive association of IS with HDL cholesterol and a significant negative association with TG, both independent of sociodemographic confounding factors and when adjusted for steps or different activity patterns. Despite a much smaller sample size, our study has several advantages in contrast

to previous research. First, both studies were limited by an elderly population, and one study considered only older men, whereas we studied working-age population (aged 21-65 years). Second, both studies used research-grade actigraphs, whereas we used consumer-grade fitness trackers and obtained similar results. Consumer-grade wearables are much more affordable and common among the general population and, therefore, have a higher potential value for public health, enabling predictive health monitoring on a population scale. Third, the duration of activity tracking in both studies did not exceed 7 days, whereas we collected wearables' data for 21 days. Longer tracking enables one to more precisely infer an average profile of daily activity and estimate the IS. Fourth, only Sohail et al [24] directly analyzed relationships between IS and cardiometabolic disease risk markers, but they collected nonfasting blood samples and so could not investigate associations with TG and BG. Thus, our study is the first to report a significant association between steps-based IS and TG, an important blood biomarker of metabolic syndrome.

Possible Mechanisms

How might rhythms of locomotor activity be related to cardiometabolic health? Circadian rhythms are cyclic biochemical processes with a 24-hour period, which play a crucial role in physiology and metabolism [59]. Circadian biorhythms are controlled by molecular circadian clocks, which are present in many cells and synchronize internal biological functions with environmental conditions [60]. External stimuli, called Zeitgebers, mainly light and food intake, can change the phase of a circadian oscillator and entrain circadian clocks. Hence, the misalignment of Zeitgebers and intrinsic circadian clocks entail consequences for metabolic processes and health. Experimental studies in humans demonstrated that circadian misalignment (shift of active phase from habitual time) imposes adverse cardiometabolic implications—decreased leptin, increased glucose, increased arterial pressure [61], and also disruption in free fatty acids and TGs [62]. Disruption of normal circadian rhythms because of shift work, chronic jetlag, artificial light, or poor sleep impacts human health and increases the risk of many diseases, including obesity, type 2 diabetes, and various cardiovascular diseases [56,63,64]. According to a recent review, locomotor activity modulates the molecular clock in skeletal muscle, affecting both the amplitude and phase of circadian rhythms [65]. Besides, it was found that the muscle molecular clock does not synchronize rapidly with the changes in the behavioral cycle [62]. Here, relying on previous research and our findings, we cautiously assume that unstable locomotor activity rhythms, even because of commuting to work, breaks, or any other locomotor activity occurring at different times, do not allow circadian clocks to align with these activity rhythms and establish a stable internal biorhythm and, therefore, provoke disruptions in metabolic functioning. Moreover, as IS is a nonparametric measure, we may assume that stable and regular rhythms in locomotor activity, regardless of shift work and alignment with day-night cycle, contribute to better cardiometabolic outcomes.

Conclusions and Future Research

Wearable fitness trackers enable the collection of biometric data, such as steps, HR, and sleep characteristics, at a low cost and at a population scale, which might have clinical value and public health implications. Our findings suggest that consumer-grade fitness trackers can provide insightful information with respect to the risk factors of cardiometabolic disease. We employed the measure of IS in circadian activity rhythms based on steps and show that this metric can be used for personalized risk prediction. With wearables, people can monitor their biometrics and activity, enabling early detection of deviations in digital biomarkers. In addition, wearables can be used to increase control over modifiable behavioral and lifestyle risk factors of cardiometabolic disease.

The molecular mechanisms underlying the effects of activity rhythms on the risk biomarkers of cardiometabolic disease require additional longitudinal and experimental studies, and results need to be confirmed in other populations. Future research examining the utility of consumer-grade fitness trackers should focus on the prognostic prediction of health outcomes in free-living conditions using wearable data and recent advances in machine learning. The development of highly accurate predictive algorithms that combine different data and digital markers in a single model is one of the main targets in this field.

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Authors' Contributions

YR conceived the idea for the paper, conducted data processing and analysis, and wrote the original draft. TQ helped with data processing, provided methodological guidance, and reviewed the paper. AR and GD curated data collection and provided insightful comments on the paper. GD, JC, and GC reviewed the paper and provided insightful comments on the paper. JC, GC, and SK provided overall supervision of the project and secured the funding.

Conflicts of Interest

None declared.

Multimedia Appendix 1
R code for Fitbit data processing and analysis.
[ZIP File (Zip Archive), 6 KB - mhealth_v8i1e16409_app1.zip]

Multimedia Appendix 2
Differences in activity tracker–based metrics between shift and nonshift workers.
[PDF File (Adobe PDF File), 22 KB - mhealth_v8i1e16409_app2.pdf]

Multimedia Appendix 3
Analysis of stability of resting heart rate sampled from 3-day windows (*P* values of Kolmogorov-Smirnov tests).
[XLSX File (Microsoft Excel File), 24 KB - mhealth_v8i1e16409_app3.xlsx]

Multimedia Appendix 4
Full results of regression analysis.
[PDF File (Adobe PDF File), 109 KB - mhealth_v8i1e16409_app4.pdf]

Multimedia Appendix 5
Pairwise multiple regression analysis.
[PDF File (Adobe PDF File), 79 KB - mhealth_v8i1e16409_app5.pdf]

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Abbreviations

BG: blood glucose
cdHR: circadian delta of heart rate
CRP: C-reactive protein
DayHR: daytime heart rate
DBP: diastolic blood pressure
dRHR: delta of resting heart rate
HDL: high-density lipoprotein
HR: heart rate
IS: interdaily stability
IV: interdaily variation
LDL: low-density lipoprotein
MET: metabolic equivalent
MVPA: moderate-to-vigorous physical activity
NightHR: nighttime heart rate
NTU: Nanyang Technological University
PA: physical activity
RHR: resting heart rate
SBP: systolic blood pressure
TG: triglyceride

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Original Paper

Correction: Iterative Adaptation of a Mobile Nutrition Video-Based Intervention Across Countries Using Human-Centered Design: Qualitative Study

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In “Iterative Adaptation of a Mobile Nutrition Video-Based Intervention Across Countries Using Human-Centered Design: Qualitative Study” by Isler et al (JMIR Mhealth Uhealth 2019;7(11):e13604), the manuscript title was published incorrectly.

The original version of the manuscript was published with the incorrect title as:

> *Iterative Adaptation of a Maternal Nutrition Videos mHealth Intervention Across Countries Using Human-Centered Design: Qualitative Study*

The correct manuscript title is:

> *Iterative Adaptation of a Mobile Nutrition Video-Based Intervention Across Countries Using Human-Centered Design: Qualitative Study*

The correction will appear in the online version of the paper on the JMIR website on January 24, 2020, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Original Paper

Why We Eat What We Eat: Assessing Dispositional and In-the-Moment Eating Motives by Using Ecological Momentary Assessment

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Abstract

Background: Why do we eat? Our motives for eating are diverse, ranging from hunger and liking to social norms and affect regulation. Although eating motives can vary from eating event to eating event, which implies substantial moment-to-moment differences, current ways of measuring eating motives rely on single timepoint questionnaires that assess eating motives as situation-stable dispositions (traits). However, mobile technologies including smartphones allow eating events and motives to be captured in real time and real life, thus capturing experienced eating motives in-the-moment (states).

Objective: This study aimed to examine differences between why people think they eat (trait motives) and why they eat in the moment of consumption (state motives) by comparing a dispositional (trait) and an in-the-moment (state) assessment of eating motives.

Methods: A total of 15 basic eating motives included in The Eating Motivation Survey (ie, liking, habit, need and hunger, health, convenience, pleasure, traditional eating, natural concerns, sociability, price, visual appeal, weight control, affect regulation, social norms, and social image) were assessed in 35 participants using 2 methodological approaches: (1) a single timepoint dispositional assessment and (2) a smartphone-based ecological momentary assessment (EMA) across 8 days (N=888 meals) capturing eating motives in the moment of eating. Similarities between dispositional and in-the-moment eating motive profiles were assessed according to 4 different indices of profile similarity, that is, overall fit, shape, scatter, and elevation. Moreover, a visualized person × motive data matrix was created to visualize and analyze between- and within-person differences in trait and state eating motives.

Results: Similarity analyses yielded a good overall fit between the trait and state eating motive profiles across participants, indicated by a double-entry intraclass correlation of 0.52 (P<.001). However, although trait and state motives revealed a comparable rank order (r=0.65; P<.001), trait motives overestimated 12 of 15 state motives (P<.001; d=1.97). Specifically, the participants assumed that 6 motives (need and hunger, price, habit, sociability, traditional eating, and natural concerns) are more essential for eating than they actually were in the moment (d>0.8). Furthermore, the visualized person × motive data matrix revealed substantial interindividual differences in intraindividual motive profiles.

Conclusions: For a comprehensive understanding of why we eat what we eat, dispositional assessments need to be extended by in-the-moment assessments of eating motives. Smartphone-based EMAs reveal considerable intra- and interindividual differences in eating motives, which are not captured by single timepoint dispositional assessments. Targeting these differences between why people think they eat what they eat and why they actually eat in the moment may hold great promise for tailored mobile health interventions facilitating behavior changes.

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KEYWORDS

mHealth; eating; motivation; mobile app; EMA; in-the-moment; disposition; trait; state

Introduction

Background

Food is almost ubiquitous in our everyday life, and *eating* is one of the simplest yet most complex behaviors [1-3], involving up to 200 decisions a day [4]. The motives for and functions of eating in everyday life play a crucial role in promoting healthy eating behaviors [5]. A deeper understanding of the underlying mechanisms and causes of human food choices is indispensable for designing and facilitating effective primary interventions to counteract the obesity epidemic [6] and its associated health risks [7-9]. The questions "what we eat" and also "why we eat, what we eat" are therefore of great importance for promoting normal eating behavior and preventing the development of obesity and eating disorders.

Everyday human eating behaviors are regulated by numerous motives [10,11] that range from physiological factors [12,13], psychological factors (such as positive or negative emotional states [14-17] and social reasons [18-20], to various situational factors such as food's smell or appearance [21-24]. Thus, in addition to hunger, there are other compelling reasons for choosing and eating certain food items.

As eating motives are multidimensional, assessing eating motives is a major challenge. Most psychometric measures focus on specific motives, such as the Motivation to Eat Scale, which assesses 4 core motives (pleasure, coping with negative affect, being social, and complying with others' expectations [25]), or the Dutch Eating Behavior Questionnaire, which includes eating in response to negative emotions and in response to external sensory cues as 2 core motivations for eating [24]. A more comprehensive conceptualization of eating motives is provided by the Food Choice Questionnaire (FCQ), which encompasses 9 different food choice motives for everyday life of which the taste, appearance, and smell of food were rated as the most important motives for food choices, followed closely by healthiness, affordability, and availability [26-29]. However, as the FCQ does not include important motives such as social or physiological motives, The Eating Motivation Survey (TEMS) was developed to cover a more extensive set of 15 basic eating motives [10,11], including eating because of liking, habit, need and hunger, health concerns, convenience, pleasure, tradition, natural concerns, price considerations, visual appeal, sociability, weight control concerns, negative affect regulation, and concerns about social norms and social image, which have been found consistently across different groups [10,30], contexts [31], and countries [11,32].

Although these current psychometric measures capture multiple motives, they commonly assess eating motives as time and situational invariant dispositions (or traits), asking for *typical* reasons, for example, why respondents usually eat what they eat [10,29]. These dispositional measures capture why people think they eat what they eat. However, daily eating situations can differ greatly, for example, depending on time and place [15,33,34]. It is, therefore, likely that eating motives will vary in the moment of eating, both across and within individuals.

The rise of mobile health (mHealth) and mobile technology in medicine and public health offers great possibilities for capturing in-the-moment experiences, including eating motives in both real life and real time [22,33-38]. Smartphones are a particularly promising method of assessing eating events and eating motives in the moment because of the high level of global penetration and the ease of installing apps in all kinds of mobile devices [39,40]. Assessing eating motives in the moment offers important conceptual and methodological advantages compared with classical single timepoint dispositional measures [41]. Specifically, participants do not need to recall eating motives for each past eating event to derive a judgment about their typical eating motives. Considering the daily multitude of eating occasions, people are unlikely to accurately recall all their relevant reasons for eating and so must reconstruct their eating motives when gauging their typical eating motives [42-47]. Even when people manage to do this accurately, they still need to aggregate the different reasons across multiple eating occasions to infer their typical reasons [48]. Initial evidence on self-to-peer comparisons of eating motives [49] shows that people might have biased conceptions of their dispositional eating motives. Hence, current dispositional measures for assessing eating motives may be substantially affected by memory and aggregation biases [48,50].

Using an in-the-moment, that is, event-based, ecological momentary assessment (EMA) approach [38,51-53], eating motives can be repeatedly and comprehensively assessed when an eating event occurs, which ensures a high measurement accuracy and maximizes ecological validity [50,54-56]. In contrast to signal-content protocols, participants in event-based protocols determine for themselves when the event occurs and initiate an assessment [57,58]. Some approaches are even developing methods to automatically detect an eating event, see for example eButton [59] or automatic ingestion monitor [60]. This alleviates the problem of memory and aggregation bias associated with the conventional "single-shot" assessment of eating motives. However, research determining the correspondence of in-the-moment assessments with single timepoint dispositional measures is scarce [51,61-64] and to our knowledge has not been addressed with regard to eating events and their underlying motives.

This Study

The aim of this study was to examine differences between why people think they eat (trait motives) and why they eat in the moment of consumption (state motives) by assessing 15 different basic eating motives [10] measured by (1) a single timepoint dispositional (trait) and (2) a 1-week in-the-moment (state) assessment of eating motives using smartphone-based EMA [52,54,65].

Profile similarity indices are used to analyze whether and to what degree the 15 trait eating motives concur with the 15 state motives [66,67]. The omnibus index reflects a proxy of the overall fit between the trait and state eating motive profiles. Furthermore, profiles can be similar in respect of 3 major characteristics: their shape, scatter, and elevation. A large shape similarity indicates that the same motives score on average high (or low) within the trait and state profile. A large scatter similarity indicates that the variability between the 2 eating motive profiles is relatively comparable. A high elevation similarity indicates that the average of the 15 motives is similar between the trait and state measure [66,67]. These similarity indices can be applied on different levels of analyses to assess inter- and intraindividual differences in profile similarity, including the between-person, between-motive, and the within-person level.

We developed a new visualization tool called the *SMART-Profile-Explorer* to comprehensively analyze and visualize high-dimensional data. The Web-based SMART-Profile-Explorer can be used interactively to sort, filter, and visualize these data, making the data available to other scientists and facilitating communication and data sharing [68].

Methods

Study Guidelines

This study was part of the research project, SMARTACT, funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung). The study adhered to the guidelines of the German Psychological Society (Deutsche Gesellschaft für Psychologie) and the Declaration of Helsinki. The University of Konstanz's Institutional Review Board approved the study protocol, and it is in accordance with ethical guidelines and regulations. All participants gave written informed consent before participation.

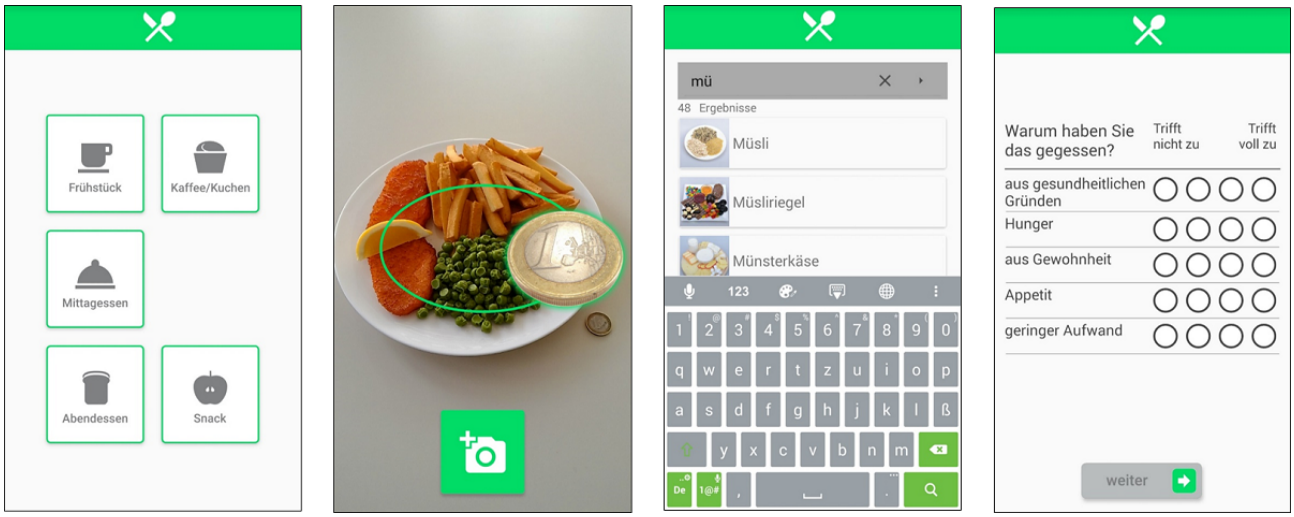
Participants

In total, 35 individuals participated in the study (88.6% female, *n*=31), with a mean age of 25.49 years (SD 5.70; range 19-41 years) and an average body mass index of 22.51 kg/m^2 (SD 5.51; range 15.43-42.87 kg/m^2). No participants dropped out of the study.

Procedure

Participants were recruited through leaflets distributed at the University of Konstanz and postings on Facebook groups. Participants were invited to the laboratory for individual introductory sessions. At the baseline session, participants completed a questionnaire assessing 15 dispositional (trait) eating motives based on a single-item version of TEMS [10] and demographic variables. We used the mobile app, SMARTFOOD, which was developed as part of the research project SMARTACT [69], to record these motives in the moment of consumption [36]. The participants were provided and familiarized with the smartphones (ASUS Padphone Infinity, Android 5.0.2) and research app during the introductory session. They were asked to record all eating events for 8 consecutive days using the SMARTFOOD app (Figure 1). Specifically, they were asked to record the meal type (Figure 1, left), to take a picture of their meal (Figure 1, second from left), and to classify what they ate using a drop-down menu (Figure 1, third from left). Additional courses and leftovers were also recorded by taking pictures. In addition, participants rated 15 reasons why they ate what they ate based on the brief TEMS (Figure 1, right). As compensation, participants could choose between receiving €25 or course credits (3 hours).

Figure 1. Screenshots of the SMARTFOOD app for assessing eating events and the 15 eating motives.



Measures

The 15 eating motives were surveyed using a single-item version of TEMS (see Multimedia Appendix 1), in which a single item represented each of the motives, including *liking*, *habit*, *need and hunger*, *health*, *convenience*, *pleasure*, *traditional eating*, *natural concerns*, *sociability*, *price*, *visual appeal*, *weight control*, *affect regulation*, *social norms*, and *social image* [10]. In the single timepoint dispositional assessment (trait motives) and at every time participants logged a meal or snack (state motives), they were asked to answer the question "I eat what I eat because of..." by rating each of the 15 motives on a Likert scale ranging from (1) "strongly disagree" to (4) "strongly agree."

Analytical Procedure

To statistically compare trait with state eating motives, repeatedly assessed state motives were averaged across all eating occasions. Profile similarity was analyzed according to 4 different similarity indices: overall profile similarity by double-entry intraclass correlations (ICC_{de}), shape similarity (r) by Pearson correlations, scatter similarity (Var_D) by raw differences between profile variances, and elevation similarity (M_D) by raw differences between profile means [66,67]. Findings were analyzed by paired *t* tests and Pearson correlation analyses for each motive. Effect sizes were classified by using Cohen *d* [70]. All analyses were conducted with IBM SPSS (*version 24*). Furthermore, the SMART-Profile-Explorer was used to visualize and compare the resulting trait and state eating motive profiles at the different levels of data analyses [71] [72].

Results

Eating Occasions

In total, 888 eating occasions were recorded during the 8-day EMA period. By using a participant-identified approach [34,73], 231 (25.8%) eating occasions were classified as breakfast, 194 (21.8%) as lunch, 25 (2.8%) as afternoon tea, 209 (23.5%) as snacks, and 229 (25.8%) as dinner.

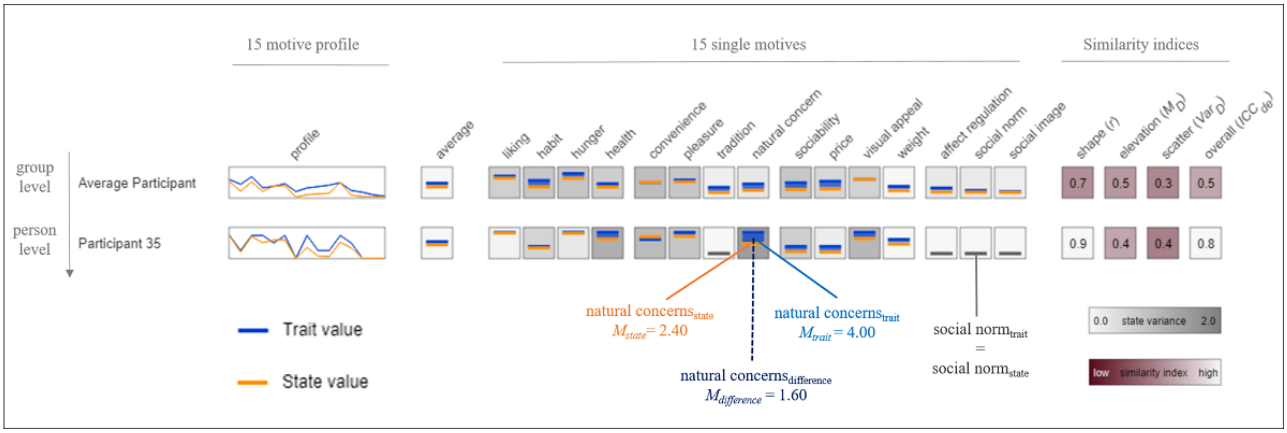
State and Trait Eating Motives: The Visualized Person × Motive Data Matrix

The data from each participant and eating motive were visualized in a matrix using the SMART-Profile-Explorer, which is illustrated in Figure 2. Statistical indices and individual trait and state motive profiles are additionally summarized in Multimedia Appendices 2 to 4. The visualized person × motive data matrix encompasses 3 dimensions: (1) the between-person level, displaying aggregated state and trait motives across participants and motives, (2) the between-motive level, for comparing pairs of trait and state motives within each of the 15 motives across all participants (vertical comparison), and (3) the within-person level, allowing a comparison of the 15 trait and state eating motives within a single participant (horizontal comparison). The 3 profile similarity indices were calculated, respectively, and averaged means of the 15 trait and state eating motives are additionally displayed as the last lines of the matrix.

Within the visualized person × motive data matrix, for the group and for each participant, the first left column shows the individual trait (blue line) and state eating motive profile (orange line). The second column depicts the average trait (blue dash) and state (orange dash) values aggregated across the 15 eating motives for the group and each participant, respectively. Columns 3 to 17 display the 15 trait (blue dash) and 15 state (orange dash) eating motives separately. Values within each data box can range from 1 (dash at the bottom) indicating a low value for the respective motive to 4 (dash at the ceiling) indicating a high value for the motive. The difference between the trait and state motive values is further visualized by the size of a colored square between the trait and state motives. The greater the difference, the larger the colored square, whereas the depth of the square's color is determined by how pronounced the motive is. In addition, the white-gray background of the motive data boxes changes to visualize the observed variability of each state eating motive. A darker shading indicates a greater variance across the longitudinal in-the-moment assessment for the state motive and, hence, a greater within-person motive fluctuation across time. In addition, columns 18 to 21 display the 4 similarity indices shape (r), elevation (M_D), scatter (Var_D), and the overall similarity index (ICC_{de}), with lighter colors indicating a high similarity value and darker colors indicating a low similarity value on the respective index.

Illustrating the visualized data matrix exemplarily (see Figure 2) shows that participant 35 scored high on the overall similarity with ICC_{de}=0.8. More specifically, the separate indices revealed r=0.9 for shape similarity as well as M_D=0.4 for elevation and Var_D=0.4 for scatter similarity. Focusing on the single eating motive *natural concerns*, participant 35 scored higher in the trait (M_{trait}=4.00, blue dash) than in the state assessment (M_{state}=2.40, orange dash). This difference of 1.60 is further visualized by the colored square. As participant 35's trait motive for *natural concerns* was more pronounced than the state motive, the square is colored in blue. The comparatively dark gray background color of the data box indicates a high observed state variance across the in-the-moment assessment of *natural concerns* with *Var*=1.49 (for more details, see Multimedia Appendix 4).

Figure 2. Illustration of the visualized person x motive data matrix and similarity indices for the 15 trait and state eating motive profiles. The first line displays data for the average participant (between-person level). The second line displays data for a single participant (No. 35) (within-person level). D=Difference score (trait value—state value).

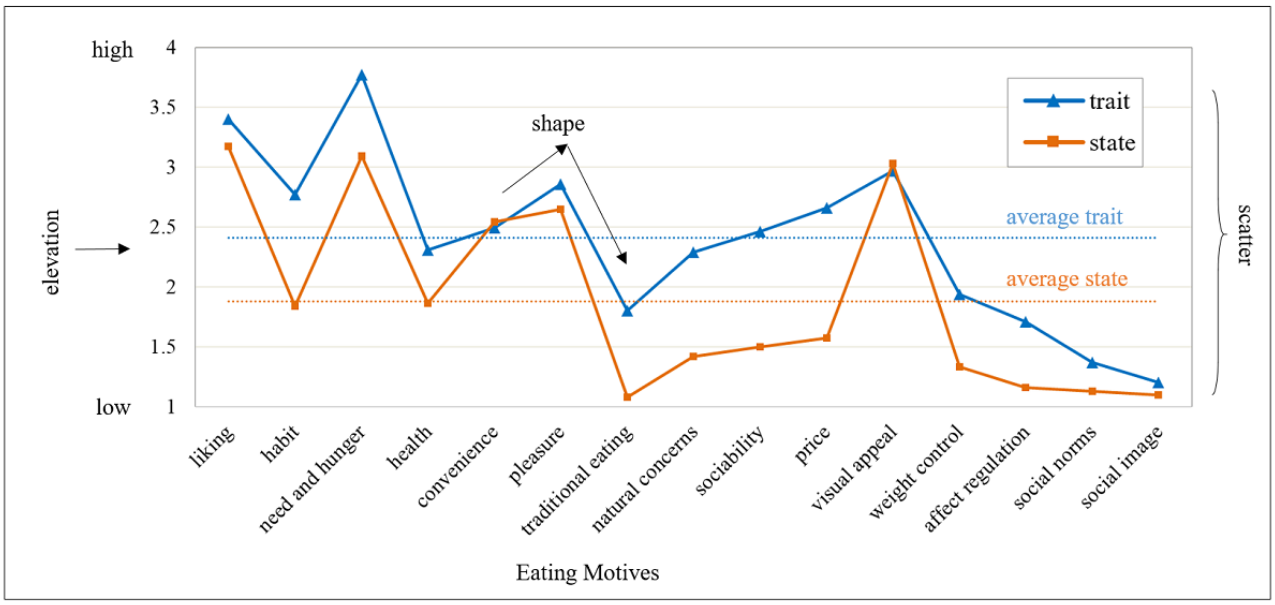


State and Trait Eating Motives: The Between-Person Level

Figure 3 illustrates the averaged eating motive profiles of the 2 assessment approaches. The omnibus index of profile similarity yielded a good overall similarity between the trait and state eating motive profiles across participants with ICC_{de}=0.52 (P<.001). Thus, 27% of the observed variance in state eating motive profiles is explained by respective trait eating motive profiles.

The shape of the averaged trait and state motive profiles coincides with r=0.65, P<.001, indicating a comparable rank order across participants. However, trait and state motive profiles differed substantially in respect to the observed elevation (M_D=0.53). Trait motives were rated higher on average than state motives, M_{trait}=2.41, SD 0.31; M_{state}=1.88, SD 0.23; t_{34}=9.02; P<.001; d=1.97. In terms of scatter similarity, the average ratings ranged from 1.20 to 3.77 for trait and from 1.09 to 3.12 for state motives, indicating comparable scatters for both assessment methods. The average scatter index yielded a raw variance difference of Var_D=0.33.

Figure 3. Average (typical) profile of the 15 trait and state eating motives with ICC_{de}=0.52, P<001. Ratings ranged from (1) “strongly disagree” to (4) “strongly agree.” Motives are arranged according to their rank order observed for The Eating Motivation Survey.



State and Trait Eating Motives: The Between-Motive Level

Of 15 eating motives, 12 were rated significantly higher on average when assessed as trait motives as compared with state motives, indicating a consistent pattern of results with the found overall elevation differences. Large differences between trait and state eating motives (d>0.8) were found for *price*, *sociability*, *need and hunger*, *traditional eating*, *habit*, and *natural concerns*. Moderate mean level differences (d>0.5) emerged for *weight control*, *affect regulation*, *health*, *pleasure*, and *liking*, whereas a small effect size (d>0.3) emerged for *social norms*. Despite these elevation differences, positive correlations were found for 9 out of 15 eating motives, indicating that participants who had a higher trait eating motive also tended to exhibit higher average state scores for the respective eating

motive (for more details, see Multimedia Appendix 2). The highest correlations between state and trait eating motives (r≥0.50) were found for *visual appeal*, *weight control*, *affect regulation*, *natural concerns*, and *price*. State-trait correlations within the medium effect size range (r>0.30) were observed for *pleasure*, *sociability*, *convenience*, and *health*. Comparing the variability for each pair of trait and state eating motives showed that some motives such as *sociability*, *weight control*, *traditional eating*, and *affect regulation* showed large variances in the trait (*Var*≥0.64) but low variances (*Var*≤0.19) in the state assessment. Inversely, motives such as *visual appeal*, *pleasure*, *convenience*, *health*, and *natural concerns* showed large variances (*Var*≥0.67) in both the trait assessment and the state assessment (*Var*≥0.41), indicating relatively high situational and/or between-person fluctuations.

State and Trait Eating Motives: The Within-Person Level

In Figure 4, participants are arranged according to their overall profile similarity (ICC_{de}), with participant 35 displaying the highest and participant 22 the lowest profile similarity. This omnibus index yielded a high overall similarity for 7 of the 35 participants, with ICC_{de}≥0.80. Thus, at least 64% of the observed variance in the state profile was explained by the respective trait profile. In addition, 15 participants showed a substantial profile similarity with at least 25% of the observed state variance explained by the trait variance (ICC_{de}≥0.50). However, the remaining 13 participants showed only a low overall similarity between state and trait eating motive profiles, with less than 25% of the variance explained. The shape of the individual trait and state motive profiles coincides with r≥0.80 for 13 participants, indicating a highly similar rank order of the 15 eating motives within these participants. Furthermore, 16 participants showed a substantial rank order similarity with r≥0.60, and 6 participants showed a comparable low shape similarity with r≤0.40. Trait and state eating motive profiles differed substantially within participants for the observed elevation. At both group and individual levels, trait motives were rated higher on average than state motives. Specifically, 20 of the 35 participants scored half a point higher on the 4-point rating scale in the trait compared with the state assessment, whereas only 2 participants rated the state motives (slightly) higher than the trait motives. Comparing the variability between state and trait eating motives by using the index scatter shows substantial interindividual differences in intraindividual trait-state similarity. A total of 11 participants showed an average overall raw variance difference of Var_D≥0.5, indicating a substantial scatter difference between state and trait motives within these participants. Conversely, 13 participants showed a difference in variance of 0.2 or lower.

In addition, comparing the 4 similarity indices at the intraindividual level shows marked interindividual differences. For example, the eating motive profiles of participants 35 and 13 yielded the same overall similarity (ICC_{de}=0.80), but their elevation and scatter values still differed. Comparing their motive profiles shows that the differences were located at different state-trait motive pairs. While participant 35 overestimated the importance of *natural concerns* when asked about the usual relevance for choosing food as compared with the relevance in the concrete eating situation, participant 13 showed an overestimation for the importance of *price* for his or her daily food choices. Hence, zooming in at the motive and person level revealed distinct individual similarity patterns leading to considerable differences in similarity between eating motives, as well as between and within individuals.

Discussion

Principal Findings

This study examined differences between why people think they eat what they eat (trait motives) and why they eat in the moment of consumption (state motives) by assessing 15 different basic eating motives measured by (1) a single timepoint dispositional (trait) and (2) an in-the-moment (state) assessment using smartphone-based EMA.

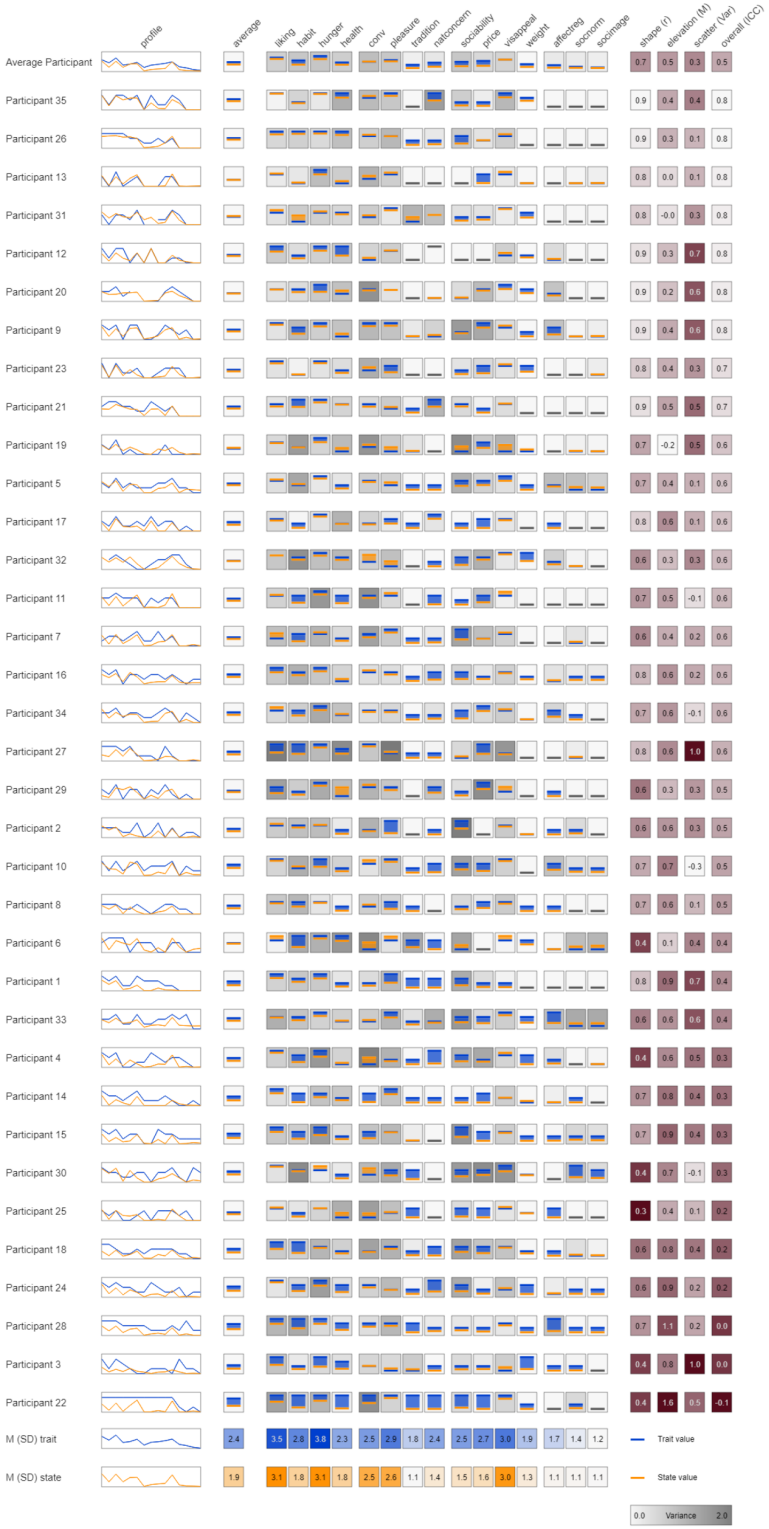
Examining the aggregated EMA data across eating occasions and participants, we found that in-the-moment assessed eating motives generally mirrored eating motives assessed through the classical single timepoint approach. Specifically, at the between-person level, the similarity indices including overall similarity, shape, and scatter indicated a comparable rank order between motives and a comparable variance pattern. A positive relationship was also found at the between-motive level, indicating that individuals who scored higher in the dispositional assessment also scored higher when assessing the same motive in the moment of eating.

However, the single timepoint assessed trait motives clearly differed in their mean level from in-the-moment assessed state eating motives, as indicated by the similarity index elevation. Compared with the state assessment, the trait assessment significantly overestimated 12 out of 15 eating motives. Interestingly, not only core motives such as *need and hunger*, *price*, *habit*, *sociability* but also motives such as *natural concerns* or *traditional eating* were rated far more importantly when people indicated why they typical eat than when asked in the moment of consumption. Similarly, motives such as *health*, *weight concerns*, or *affect regulation* were overestimated in the trait assessment. Mean levels for state and trait motives only concurred for the motives *convenience*, *visual appeal*, and *social image.Convenience* and *visual appeal* were both important reasons for eating, and the high mean values in the state and trait assessment indicate that they are generic motives, influencing eating on most occasions, across participants, and in a wide range of different contexts. Conversely, the low observed mean values for *social image concerns* in both assessments suggest that these concerns are limited to specific eating situations. This is in line with research on impression management, which suggests that eating behavior can serve a role of showing oneself to be a particular type of person in certain social situations [74-76]. For example, in specific situations such as eating with an unfamiliar man, women are more inclined to create an impression of femininity by restricting food intake to increase the desirability by presenting a feminine social identity [74].

Analyses on the within-person level showed pronounced interindividual differences in intraindividual patterns between trait and state motives (see also Figure 4). Some participants had a very good notion of why they eat, as their trait and state motives converged. For example, participant 35 gave highly accurate estimations for 14 out of 15 motives. Only sustainability concerns were less characteristic in the moment of eating as participant 35 believed when gauging his/her typically eating motives. However, other participants (eg, participant 22) showed a considerable divergence across almost all 15 eating motives. Thus, using an in-the-moment assessment of eating motives suggests that people show clear discrepancies between why they think they eat and why they actually eat in-the-moment.

These discrepancies between experienced and remembered eating motives are of crucial importance for future interventions. Research indicates that what we remember seems to be more predictive for our future behavior than what we experience [45,46,77-81]. However, as this research shows, remembered (ie, dispositional) eating motives do not accurately represent in-the-moment experiences. For instance, one might assume that health concerns primarily guide one's own eating behavior, but when it comes to the actual moment of eating, taste or visual appeal of a tempting food affects the actual food choice to a higher degree. Identifying and addressing these discrepancies between why people think they eat and why they actually eat in the moment indicates important starting points for changing eating behaviors. Especially, when we aim to implement mHealth interventions that are characterized by acting *in-the-moment*, it is of crucial importance to target processes and experiences of the eating situation itself.

Figure 4. Visualized full person x motive data matrix. Participants are arranged in descending order according to the overall motive profile similarity (ICC_{de}) from high (top) to low (bottom).



Implications of These Findings

The observed overestimation of the influence of motives in the moment of consumption through dispositional assessments might reflect different methodological issues affecting single timepoint measurement of trait motives and longitudinal assessment of state motives, heterogeneous mechanisms and causes, or the complexity and multidimensionality of eating behavior in day-to-day life [82,83]. One might argue that people tend to view themselves favorably and therefore, overestimate the typical eating motives that they see as desirable. A recent study showed that the 15 eating motives differ in their perceived desirability [49], with *hunger*, *health*, and *liking* being perceived as highly desirable motives, whereas *social image*, *social norms*, and *affectregulation* are seen as particularly undesirable. For desirable motives, participants rated their own motives as higher

than their peers, whereas the opposite pattern emerged for undesirable motives, indicating unrealistic optimism in eating motives [49]. In this study, trait eating motives were generally more pronounced than state motives, including desirable (eg, need and hunger) and undesirable ones (eg, affect regulation). Hence, social desirability concerns are unlikely to explain the observed pattern of results. Admittedly, to derive a judgment about their typical eating motives, people need to recall and aggregate the different reasons across multiple eating occasions. Numerous studies have shown that people often use heuristics to form judgments about their behavior and characteristics [84-86]. In particular, participants might have used the representativeness heuristic as a mental shortcut to evaluate their typical eating motives, which might have caused the observed overestimations. In addition, measurement issues may have inflated the magnitude of trait motives or deflated the magnitude of state motives. For example, response biases to the mobile EMA scales such as underreporting of momentary experiences of eating motives across assessments might have contributed to the lower mean levels. Furthermore, enduring trait motives could shape the actual eating behavior and as a consequence limit the occurrence of specific state eating motives. For example, an individual with a pronounced weight control motive at the trait level might avoid tempting food choices altogether (eg, sweets and snacks) and therefore, she or he is less likely to report state weight control motives. Although avoidance of food items or eating situations might be caused by motives such as weight control, tradition, or social norms, in most cases, people probably opt for alternatives (eg, an apple instead of chocolate) and thus, trait and state motives would covary.

To consider the real-life situational fluctuations in eating behaviors [15,33,87] and prevent retrospective recall biases [45,77,88], a smartphone-based EMA approach was used to assess eating motives in the moment. Although it is admittedly true that in-the-moment approaches offer advantages over conventional single timepoint methods, especially in terms of their ecological validity [54,89], they are also accompanied by increased expenditure for both participants and researchers. Especially in the case of eating, participants must log every eating occasion over a prolonged period to generate representative data, which in turn leads to methodological and statistical challenges for researchers [90]. For instance, research is challenged with finding new, elaborated methods of analyzing the resulting high-dimensional data [90,91]. Developing methods that force data analyses to go beyond aggregated mean values and consider the between- and within-person levels is, therefore, an important achievement in the field of mHealth.

The additional analysis on the person and motive level, which was facilitated through the SMART-Profile-Explorer, acknowledges these person- and situation-specific differences in eating motives. The interplay between inter- and intraindividual differences that emerged from these findings could only result from a comprehensive analysis that incorporates different aggregation levels, rather than focusing on overall means and between-person effects. The implemented visualized person × motive data matrix fosters this approach by facilitating an analysis that is close to the raw data. This approach aims to not only increase data transparency in terms of open data appeals [68] but also to illustrate underlying patterns and dynamics of eating motives. Focusing not just on between-person but also on within-person variability is crucial for gaining more detailed insights into psychological processes and counteracting the "threat to the conceptual integrity" of psychological research elicited through a mismatch between theory and research practice [92]. We are convinced that a deeper understanding of human food choice behavior can only be achieved by integrating between- and within-person effects and combining findings at the motive and person level.

Strengths and Limitations

To our knowledge, this study is the first that directly compares a single timepoint dispositional assessment of eating motives with an in-the-moment assessment of the same motives in the same individuals by using a smartphone-based EMA to derive conceptual conclusions. Furthermore, these findings are indicative for planning and designing effective health interventions. To promote healthy eating behavior and counteract the associated health risks of the rising obesity epidemic [93-95], the interplay between person, situation, and eating motive needs to be considered to improve intervention effectiveness by identifying critical cues, moments, and target groups.

Although these findings expand the current state of research and provide important implications for health interventions, they must be viewed in consideration of 2 main limitations that should be accounted for in future research. Although the sample size is comparable with other studies in eating research [15,22,96,97], it is small, and the participants were predominantly white, female, and highly educated. Moreover, future research is needed to investigate preceding situations that might also determine eating behavior, such as buying, choosing, or preparing food, to draw reliable conclusions and shed further light on explanations for the differences found between dispositional and in-the-moment eating motives.

Conclusions

In general, this study found a substantial overlap between the dispositional and in-the-moment assessment regarding eating motives. However, elevation markedly differ between the 2 assessment approaches and the majority of eating motives are overestimated in the dispositional assessment. A more detailed analysis of the interplay between person and motive revealed interindividual differences in intraindividual similarity patterns. Hence, for a comprehensive understanding of why we eat what we eat, dispositional assessments need not only to be extended by comprehensive EMAs that take place in the moment but also to be analyzed at the between- and within-person level. Capturing these individual dynamics in eating motives is crucial to develop tailored dietary interventions to intervene in the critical moments of situations that determine eating behavior.

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Authors' Contributions

BR and HS developed the study concept. All authors participated in the generation of the study design. DW conducted data analyses, and MB developed and implemented the visualization tool for the data with input from DW, KV, and BR. The manuscript draft was prepared by DW and BR and finalized with comments from HS, KV, LK, KZ, and GS. All authors approved the final version of the manuscript for submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Single-item version of The Eating Motivation Survey.
[PDF File (Adobe PDF File), 376 KB - mhealth_v8i1e13191_app1.pdf]

Multimedia Appendix 2
Statistical characteristics of trait and state eating motives on the between-motive level.
[PDF File (Adobe PDF File), 295 KB - mhealth_v8i1e13191_app2.pdf]

Multimedia Appendix 3
Profiles of the 15 eating motives for each individual.
[PDF File (Adobe PDF File), 413 KB - mhealth_v8i1e13191_app3.pdf]

Multimedia Appendix 4
Profile similarity indices for trait and state eating motives at the within-person level.
[PDF File (Adobe PDF File), 210 KB - mhealth_v8i1e13191_app4.pdf]

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Abbreviations

EMA: ecological momentary assessment
FCQ: Food Choice Questionnaire
ICC_{de}: double-entry intraclass correlation
mHealth: mobile health
TEMS: The Eating Motivation Survey

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