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Original Paper

Formative Evaluation of Participant Experience With Mobile eConsent in the App-Mediated Parkinson mPower Study: A Mixed Methods Study

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Abstract

Background: To fully capitalize on the promise of mobile technology to enable scalable, participant-centered research, we must develop companion self-administered electronic informed consent (eConsent) processes. As we do so, we have an ethical obligation to ensure that core tenants of informed consent—*informedness*, *comprehension*, and *voluntariness*—are upheld. Furthermore, we should be wary of recapitulating the pitfalls of “traditional” informed consent processes.

Objective: Our objective was to describe the essential qualities of participant experience, including delineation of common and novel themes relating to informed consent, with a self-administered, smartphone-based eConsent process. We sought to identify participant responses related to *informedness*, *comprehension*, and *voluntariness* as well as to capture any emergent themes relating to the informed consent process in an app-mediated research study.

Methods: We performed qualitative thematic analysis of participant responses to a daily general prompt collected over a 6-month period within the Parkinson mPower app. We employed a combination of *a priori* and emergent codes for our analysis. *A priori* codes focused on the core concepts of informed consent; emergent codes were derived to capture additional themes relating to self-administered consent processes. We used self-reported demographic information from the study’s baseline survey to characterize study participants and respondents.

Results: During the study period, 9846 people completed the eConsent process and enrolled in the Parkinson mPower study. In total, 2758 participants submitted 7483 comments; initial categorization identified a subset of 3875 germane responses submitted by 1678 distinct participants. Respondents were more likely to self-report a Parkinson disease diagnosis (30.21% vs 11.10%), be female (28.26% vs 20.18%), be older (42.89 years vs 34.47 years), and have completed more formal education (66.23% with a 4-year college degree or more education vs 55.77%) than all the mPower participants ($P < .001$ for all values). Within our qualitative analysis, 3 conceptual domains emerged. First, consistent with fully facilitated in-person informed consent settings, we observed a broad spectrum of comprehension of core research concepts following eConsent. Second, we identified new consent themes born out of the remote mobile research setting, for example the impact of the study design on the engagement of controls and the misconstruction of the open response field as a method for responsive communication with researchers, that bear consideration for inclusion within self-administered eConsent. Finally, our findings highlighted participants’ desire to be empowered as partners.

Conclusions: Our study serves as a formative evaluation of participant experience with a self-administered informed consent process via a mobile app. Areas for future investigation include direct comparison of the efficacy of self-administered eConsent with facilitated informed consent processes, exploring the potential benefits and pitfalls of smartphone user behavioral habits on participant engagement in research, and developing best practices to increase *informedness*, *comprehension*, and *voluntariness* via participant coengagement in the research endeavor.

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KEYWORDS

informed consent; research ethics; mobile applications; smartphone; Parkinson disease

Introduction

Informed consent of participants is fundamental to the ethical practice of clinical research. Disclosure, voluntariness, and decisional capacity make up the core of valid informed consent processes [1-3]. Since the adoption of the Declaration of Helsinki in 1964, regulatory authorities in countries around the world have further codified the elements of informed consent, for example the 8 requirements described in the US Code of Federal Regulations, title 45, section 46.116 [4]. However, despite widespread consensus on the importance of informed consent and broadly on the elements included therein, ensuring research participants are truly informed remains a challenge to researchers worldwide [5].

Most of what we understand about the effectiveness of informed consent has come from studies of research participant informedness in the context of clinical trials. In their 2009 systematic review, Falagas and colleagues analyzed 30 studies of participant understanding following informed consent in clinical care and clinical trial settings between 1961 and 2006 [6]. They found that participant understanding of key elements of informed consent, such as the purpose of the treatment or study, the voluntary nature of treatment or research, the ability to withdraw, and the risks and the benefits of participation, was “adequate” (>80% of the participants having understanding graded in the study’s highest classification category) in only about half of the studies they reviewed.

In their 2014 systematic review of literature from 2006-2013 about participant informedness in clinical research, Montalvo and Larson identified risk factors for poor comprehension of informed consent topics such as low literacy, lower educational attainment, non-English speaking (for studies conducted primarily in English), and mental illness [7]. Yet, across the 27 studies reviewed, participants of diverse demographic descriptions demonstrated poor comprehension of core clinical research study concepts. For example, persistent therapeutic misconception, which is when participants do not appreciate that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether they may potentially benefit. These findings further highlight the scale of the challenge researchers face in designing effective informed consent processes.

Increasing attention has been given to improving participant understanding in clinical research. In their 2004 systematic review of the use of multimedia to improve participant informedness, Flory and colleagues found that multimedia approaches did not consistently improve understanding, a finding echoed by Ryan and colleagues in their systematic review on the same topic for the Cochrane Database in 2008 [5,8]. Instead, Flory and colleagues suggest the use of “simple” language, allowing for sufficient time to evaluate information and the opportunity to clarify misunderstandings as ways to achieve adequate participant comprehension. Others have advocated for repeated exposure to study information as a

method of improving informedness [9]. Many have advocated for a multipronged approach incorporating these diverse approaches to improving informedness, including the US National Quality Forum (NQF) and the US Agency for Healthcare Research and Quality (AHRQ). Within clinical care, NQF advocates for the use of universal symbols and pictures, specifies that written informed consent documents be at a US fifth-grade reading level (age 11) or lower, and endorses “teach back” interactions to improve informedness [10]. AHRQ has created the Informed Consent and Authorization Toolkit for Minimal Risk Research, which incorporates “plain language” explanations with audiovisual reinforcement of key concepts (eg, pictures) coupled with “teach back” interactions [11]. Efforts to enact these suggestions have been hampered by both the time and technology required for implementation.

Mobile platforms hold promise for improving informed consent as they are enabled with visual, auditory, and tactile modes of information presentation facilitating myriad modalities of interaction, for example, listening and watching video, navigating an interactive decision tree. They also offer a scalable and customizable approach to informed consent interaction to researchers. These technologies are well suited for providing just-in-time information and facilitating self-paced learning, allowing for repeated self-directed exploration of consent topics by prospective participants.

In addition to their potential as a facilitator of informed consent processes, smartphones are enticing research tools. Smartphones are increasingly ubiquitous, now owned by 58% of US adults, including 47% of those with a household income of less than US \$30,000, potentially democratizing access to research participation [12]. Rich in sensors, from gyroscopes to temperature sensitive touch screens, and enabled to collect information that is both granular and continuous, smartphones offer tremendous promise for the monitoring and assessment of human health. Furthermore, smartphones are designed to be secure, with encryption and identity protection features essential to the ethical conduct of research. Unsurprisingly, by offering a dynamic, customizable, and responsive platform for engaging participants in research and enabling rapidly scalable, longitudinal investigations, these devices are being heralded as a potential boon to human health researchers [13].

To facilitate the promise of smartphones for research, Sage Bionetworks has developed a scalable, self-guided eConsent process incorporating many of the suggested elements and approaches for improving participant comprehension described previously [14]. Here we present a mixed methods investigation of participant reaction to an implementation of this eConsent within the Parkinson mPower study, an app-based, entirely remote research study focused on tracking within-day fluctuations in certain Parkinson disease symptoms. In this new research setting, is participant engagement fulfilled? Are the challenges with traditional informed consent recapitulated? Do participants raise novel concerns or identify opportunities within the informed consent process afforded by mobile platform based

studies? Utilizing open-response feedback solicited by a daily general prompt from an adult population self-reporting having Parkinson disease or not, our analysis serves as a formative evaluation of the diversity of participant experience with independent eConsent and identifies themes for further evaluation.

Methods

We assessed a convenience sample of participant reaction to the eConsent implementation within the Parkinson mPower mobile study using a mixed methods approach.

To enroll in Parkinson mPower, prospective participants download the free and openly available Parkinson mPower app from the Apple App Store; download requires an iPhone model

4s or a more advanced version. The study received attention in the popular press when opened, including at the annual Apple product launch [15]. Several Parkinson advocacy groups also publicized the study, including the Michael J Fox Foundation [16]. Therefore prospective participants may have learned about the study from any number of public sources; there was no direct recruitment of prospective participants. Parkinson mPower is an open study; after download, prospective participants attest to meeting the study's inclusion criteria (age 18 or older, US residents, and are comfortable with reading and writing in English) and self-administer the study's eConsent process. The development of Sage's eConsent, including formatting and use of icons and animations, has been previously described [14]; topics addressed in the mPower eConsent are summarized in Table 1.

Table 1. mPower electronic informed consent (eConsent) content.

Topic	Points addressed
Welcome	Orientation to topics to be covered in eConsent
We'll test your understanding	There will be a quiz before enrollment Contact information in case you have questions
Activities	Overview of study activities You can skip if do not want to answer or complete
Sensor data	With your permission, study will gather data from wearable fitness device or HealthKit Will not access other applications, photos, contacts, text, or email
Data processing	Coding of study data Combination of data with that of other participants Data will not be sold, rented, or leased
Data protection	Coding and encryption
Data transfer and use	Transfer to US-based analysis platform With your permission, your data can be shared with researchers worldwide
Time needed	Time needed to perform study activities Notification options
Study surveys	Overview of topics to be covered in surveys Reminder that all questions are optional
Study activities	More detail about study tasks
Withdrawal	Participation is voluntary Withdrawal procedures and contact information Data persistence after withdrawal
Issues to consider (screen 1)	Not a treatment study Do not do anything that makes you uncomfortable If others see study notifications on your phone, they may realize you are enrolled
Issues to consider (screen 2)	Possible emotional impacts of participation Risks that are not known at this time will be disclosed as they are identified
Risk to privacy	Separation of personally identifying information from coded data Who will have access to personally identifying information Risks of cross border transfer
Sharing options	Participant designates if they would like their study data shared only with Sage and its research partners, or broadly with qualified researchers worldwide

Following the eConsent process, prospective participants must pass a 5-question summative evaluation before being allowed to enroll in the study ([Multimedia Appendix 1](#)); those not receiving a perfect score are redirected to the beginning of the eConsent for review. There is no limit to the number of times prospective participants can review the study information within the eConsent process and attempt the quiz. Following the quiz, participants view the long form consent document, sign this document, and are emailed their signed form. From that email, participants confirm their email address and are enrolled in the study. Ethical oversight of the study was provided by the Western Institutional Review Board (WIRB #20141369).

We performed qualitative analysis on free-text comments submitted by enrolled participants to the daily study prompt "In

what ways would you improve or change mPower?" during the first 6 months following the release of the Parkinson mPower app (March 9 to September 9, 2015). Participants providing comments included in this analysis may have been enrolled for the entire study period or for some portion thereof. The open response field does not have a character limit; participants were free to skip the prompt and remain enrolled in the mPower study. This feedback was decoupled from study data collected from the core research activities and surveys.

During the study period, 9846 people completed the eConsent process and joined Parkinson mPower. Of those enrolled, 2758 (28.01%, 2758/9846) participants submitted 1 or more responses to the daily open prompt, for a total of 7483 open-responses. Initial categorization excluded 3608 responses (48.22% of total

responses). Excluded responses were explicitly not informative (eg, “No comment,” “N/A,” “idk [I don’t know]”), broadly nonspecific in content (eg, emoticons, “Done,” “Good”) , or unable to be interpreted (eg, “Yyg,” “Buhv”). Tech or bug reports (eg, frozen screen, button not working, prompt not audible), which were monitored, categorized, and addressed in real time, were also excluded.

We employed a combination of *a priori* and emergent codes to analyze the remaining 3875 responses (51.78% of total responses) submitted by 1678 distinct participants (17.04% of total participants). We used the 8 requirements of informed consent listed in the US Common Rule as *a priori* codes [4]. Emergent codes, for example, “the role of the control participant,” were derived as we identified novel or recurrent response content following first-pass examination of all responses submitted. Following initial development by the research team, the code book was iteratively reviewed and refined by a primary coder and an independent coder using a subsample of responses until a finalized code book was agreed upon.

Using the finalized code book, 1 or more codes was assigned to each response. The primary coder coded all responses; the independent coder verified the reliability of code assignment through examination of a random subsample of 775 (20.00%) of responses. Presumed participant typographical errors were reviewed and discrepancies resolved by consensus. We extracted findings within each code, categorized these findings into broader themes, and cross-compared. After reaching consensus on the number and spectrum of refined themes, we again examined responses to ensure thematic consistency, completeness, and robustness of the themes identified.

Participants optionally completed a demographic survey shortly after enrollment and self-report diagnosis of Parkinson disease or not, age, sex, and educational attainment among other variables [17]. We employed descriptive statistics to characterize group-level demographic information available about all those submitting responses, as well as subgroup description of those

submitting coded responses, as compared with the totality of enrolled mPower participants.

Results

Sample Characteristics

We received 7483 responses from 2758 of 9846 enrolled mPower participants. Among the 28.01% of mPower participants who submitted any response to the open prompt (“responders”), 79.30% (2187) submitted 1 or 2 responses (mean 2.71, median 1, range 1-151 responses per respondent).

Participants were presented an additional optional demographic survey following enrollment and self-report being persons with Parkinson disease (PWP) or controls; those declining to respond were included as controls. The mPower study data collection has been previously described [17]. Among responders, 2672 (96.88%) additionally answered at least one question within the demographic survey. 1895 (71.92%) responders self-identified as persons without PD (control) and 740 (28.08%) self-identified as persons with PWP. Responders who provided demographic information were significantly more likely to be PWP, female, older, and have completed more formal education as compared with the entire pool of mPower participants (Table 2).

Through initial categorization, we identified 3875 responses for coding submitted by 1697 participants, 1171 (69.00%, 1171/1697) of whom self-identified as controls and 507 (29.88%, 507/1697) of whom as PWP (19, 1.12% did not respond). These germane responses varied in length from 1 to 388 words (mean 21.93 words, median 16.00 words) and 6 to 2006 characters (mean 116.80 characters, median 84.00 characters). Multiple codes were assigned to 623 responses (16.07% of germane responses) further reflecting the richness of feedback received. Again, responders submitting germane responses were more likely to be PWP, female, older, and have completed more formal education as compared with all mPower participants (Table 2).

Table 2. Demographic characteristics of participants completing one or more demographic survey questions: all mPower participants versus responders and all mPower participants versus germane responders.

Demographic characteristics	All mPower participants	Responders ^a	Germane responders ^a
	n=9846	n=2635	n=1678
Self-reported diagnosis, n (%) Parkinson disease	1414 (14.36)	740 (28.08)	507 (30.21)
	n=9986	n=2662	n=1695
Sex, n (%) female	2152 (21.55)	686 (25.77)	479 (28.26)
Age, mean years	35.90	41.75	42.89
	n=10,048	n=2672	n=1697
Education, n (%) ≥ 4-year college degree	5781 (57.53)	1620 (60.63)	1124 (66.23)

^aP value versus all mPower participants; $P < .001$.

Qualitative Analysis of Open-Response Data

Participant Comprehension

We selected *a priori* codes to target participant comprehension within the open-response data as the core purpose of the eConsent is to facilitate participant comprehension. Responses echoed many of the challenges reported in “traditional” informed consent processes; however, because of our methodological approach, we were not able to provide metrics for comparison with qualitative studies of participant comprehension in traditional settings [6].

Purpose

Some responders made statements clearly illustrating their understanding of the core purposes of the study:

I am encouraged to be on cutting edge of using technology to improve health for people...We can truly learn about disease through this better knowledge of symptoms in real time. [Participant d8ca]

I feel that this app on this iPhone is fantastic because it allows the average person to get involved with PD research, instead of perhaps 3000 to 5000 research subject(s) worldwide. [Participant 00de]

However, others expressed misunderstandings, as in this example of therapeutic misconception, that is, that the app may have therapeutic benefit for Parkinson disease, whereas it was designed to track symptoms:

How do I know that this kind of mental activities and exercises work for Parkinson's disease? All this activities help with that? [Respondent 0244]

Responders expressed variable appreciation of the link between the purpose of the study and study procedures. For example, here the responder does not connect one of the core aims of the study, to capture within-day variation in Parkinson disease symptoms, with the periodicity of study activities:

...it seems like (completing study activities and surveys) two or three times a week would be an adequate measure of the change in symptoms. [Respondent 53ee]

Voluntary Nature of the Study and the Right to Withdraw

The right to skip activities and survey questions, as well as the right to withdraw, is highlighted throughout the eConsent process, with 2 of the 5 mPower post-eConsent comprehension quiz questions focused on this topic. Responses belied a spectrum of understanding of respondent rights as research participants to limit or stop participation. Among those fully appreciating their right to self-regulation, in addition to the autonomy expressed, we commonly noted an invested, informing communication style as if the participants viewed themselves as coinvestigators.

I am on a three day vacation. I will only be doing the memory and tapping and voice. [Respondent b383]

I am not feeling well and am going to bed early. Will I not finish all my activities today. [Respondent 0e8e]

However, not all participants appeared confident in their right to self-regulate their participation.

I'm going to take time off starting now, but will be back in a couple of months if that's permissible. [Respondent d0ae]

Risks and Benefits

The majority of statements coded in this category relate to the emotional experience of participation, a topic that is stressed as both one of the primary risks and primary benefits of participation by the eConsent process. Participants clearly comprehended this risk or benefit and were unhesitating in sharing their experience through the open-response prompt.

Respondents expressed enthusiasm, stated being happy to participate, being stimulated by being part of the research, excited, and curious. Expressions of altruism and agency were common.

I very much like participating. I feel as if I am helping to reach an overall outcome. [Respondent a88e]

I don't have Parkinson's but am happy to participate in the study if it helps to find help for those who have it. [Respondent c073]

Negative emotional expressions were also common and ranged from boredom to frustration, stress, disappointment, and anxiety and guilt when study activities or surveys were missed.

The memory question gets hard very quickly. It is hard on the ego... [Respondent d9cc]

I just feel that if I forget (to complete study activities)...it's going to make me feel even worse that I have PD. [Respondent ddb1]

For both PWPDP and controls, study participation prompted deep contemplation of life with Parkinson disease.

...After going through that last series of questions though I'm going to quit this program. I don't like going through all those symptoms that I don't have yet. I don't want to think about what may be coming... [Respondent 2945]

This study is helping me accept the reality of my brother's Parkinson's diagnosis and what lies ahead for him. [Respondent 934e]

We emphasized throughout the eConsent that there were no anticipated individual-level benefits expected from participating in the study, although participants would be able to track their own data, export, and share it if they chose. Respondents cited access to their own data as the primary benefit of participation and expressed frustration with any limitations to their access.

I can't get the program to let me look back over more than a week of data. Is that my ineptness or part of the program (?) I was hoping over the years to come to see the course. [Respondent 2e3c]

The “benefit” of data tracking was often described in more nuanced terms by PWPDP respondents.

I'm going to be very interested in seeing the test results over time. I think I'm losing ground and that

my results are not as good now as they were when I first began. [Respondent 2b84]

A handful of responses highlighted risks that were not specifically addressed in the eConsent process. Apart from

battery life, these risks are not unique to mobile studies; however, they may arise more commonly in entirely remote, app-mediated studies (Table 3).

Table 3. Risks raised by responders not highlighted within the electronic informed consent (eConsent) process.

Finding	Example response
Feeling uncomfortable, identifiable completing study activities	<i>The walking exercise is a bit embarrassing around others.</i> [Respondent bfb3] <i>...Ahhhhing loudly in public causes considerable concern and consternation.</i> [Respondent f56a]
Apparent contradiction of treating clinician	<i>I can't figure out why my gait score is low...Maybe...it is indicating something that really isn't related to PD. I walked for my movement specialist yesterday and it looked great. He is (from a renowned hospital).</i> [Respondent 4419]
Battery life	<i>When the app is tracking the walking/gait, the phone battery drains to 50% by mid day.</i> [Respondent 9cb6]

Privacy and Confidentiality

Because of the novel approach to data capture and transfer within this app-mediated study, data handling, storage, transfer, privacy, and data confidentiality are a major focus of the eConsent. Proportionally, nearly 3 times as many PWPDP commented on these topics as compared with controls (PWPDP n=47, 9.27% of PWPDP germane responders; controls n=37, 3.16% of control germane responders). Participants' limited understanding of study procedures often complicated their comments about privacy and confidentiality.

iOS reported that you're recording my location data all the time. What is the reason for that? [Respondent fab5]

I am concerned about you accessing my microphone when I'm not aware of it. Make it clear that you cannot do so at any time. [Respondent 7dd8]

Study Procedures

Participants expressed a lack of clarity regarding study procedures. The majority of these responses focused on how to complete study activities and surveys, including activity timing and frequency. While lack of clarity on study procedures is not a unique challenge to remote, app-mediated research, participants' approach to resolving their confusion may be. Although we listed study contact information (phone, email, and physical address) within the eConsent, written and signed consent document, and the app itself, 319 respondents submitting germane responses (19.01% of germane respondents) chose to ask questions about study procedures through the open-response prompt at least once, perhaps viewing it as a conduit for direct, immediate communication with study staff, as if texting.

Why is the study not asking me to walk carrying the phone? I'm confused. [Respondent 1e51]

Additionally, artifacts of the participant's own phone model's impact on available study activities were misunderstood as procedural design, a challenge unique to app-mediated research.

I was wondering why I get a walking test, as a healthy participant, but my husband, who has Parkinson's, does not get that test. [Respondent 62cb]

Contact With Study Staff

As previously discussed, some respondents may have felt they were "texting" the study team through the open-response field. We identified a dozen responses that contained email addresses, phone numbers, and full names in addition to numerous requests without identifying information for study staff to contact the respondent directly, as in this response:

(This particular study activity) cancels me out. Please help! Email me at (redacted) ASAP. [Respondent c6ab]

The Definition and Role of Controls

According to the study design, both PWPDP and controls were invited to complete the same study surveys and activities. The role of control participants is explicitly addressed in the eConsent and written consent, as well as in the eligibility criteria. However, myriad comments addressed the definition and role of controls, with 594 control respondents (50.73% of control germane respondents) raising questions or concerns about their role as controls and their potential impact in the study; no PWPDP respondents commented on this theme.

Responses fell into 4 categories: confusion about whether controls were desired members of the study, if the study "knew" who was a control, reiteration of "healthy" status, and suggestions on how to fix the "control confusion." Lack of clarity on the control group definition and role led to questions about the study app's design, performance, and the overall study's design.

The initial survey has a question that asks if I have ever been diagnosed with Parkinson's disease: whether I answer yes or no it then asks a bunch of questions that seem to assume that I have and am being treated for Parkinson's. It's confusing and makes it seem like the survey is broken. [Respondent 5aa5]

(For us) participating that do not have Parkinson's, some questions are unclear. The option to skip is available but I actually found myself checking the study requirements again just to be certain was eligible. [Respondent a7b4]

Governance Challenges in Remote Research, App-Mediated Studies

Through emergent coding, we identified informed consent process themes that may have arisen either due to the remote setting of the Parkinson mPower study, its app-mediated design, or due to both of these factors in tandem.

Participant Engagement

One of the dominant themes within the coded responses was participant engagement in the research ecosystem; the open-response prompt, “In what ways would you improve or change mPower,” was designed to engage participants in this way. However, we were impressed by the depth and breadth of suggestions offered and, moreover, with the ways in which these suggestions could impact informed consent concepts and processes. How to improve motivation to participate and the role of participants as research partners were at the forefront of comments.

Motivators

Respondents asked generally for “motivators” or “incentives” to encourage their participation. They specifically called out data access, feedback from the research team, gamification, and group or team participation as motivators to sustain their interest. There were no responses that mentioned financial incentives or transactional incentives (eg, physical “gifts”) other than data access.

I lost interest/motivation and stopped recording for a while...I think seeing my long term trends would help me stay motivated. [Respondent 5b31]

Please give feedback - are you still doing this study? I need some motivation if you want me to continue...How about a message to all the participants? [Respondent 5f9e]

One suggestion is an incentive program...Incorporate tangible goals and visual reward either through points or badges. Establish goals for members so that they accomplish each task in a certain time for bonus rewards. [Respondent 8e33]

Make everything a game. Make it interactive and fun. Even though kids are the ones supposed to be playing games to learn, it makes it easier for adults too. It also makes it fun and makes me want to come back to finish the task every day...even the smallest rewards are still rewards and humans thrive to be rewarded. [Respondent 59f9]

At least one participant noted that in a condition for which apathy is a symptom, as in Parkinson disease, fostering motivation to participate is of particular importance.

It would probably mess up your double-blind nature or privacy but it is my experience that those of us with Parkinson's will often show up and be more consistent when we are involved in a group rather than as individuals because of our inherent lethargy and apathy. [Respondent c1ce]

Citizen Science

Respondents rejoined the open-response prompt as lay scientists. Frequently responses included hypotheses about why the respondent's own scores might be high or low, or observations about factors that might affect study performance:

Time of day affects performance irregardless (sic) of medication. Memory activity better in morning (after coffee!). [Respondent 9a05]

Additionally, responders expressed their own desired purposes for the study, most commonly that the purpose should include the diagnosis and treatment of Parkinson disease.

I think it would be good to include tests that tell you if we may have Parkinson's, so we could go to a doctor and have ourselves checked. [Respondent 4d46]

(I would like) Feedback from experts on any improvements to my medication. [Respondent 16f3]

Speaking to the subtheme of alternative purposes for the study, 183 respondents (10.91% of germane respondents) asked for feedback from the study about their own study data. Proportionally, this request was 4 times more common among PWP (n=117, 23.08% of PWP germane respondents) as compared with controls (n=66, 5.64% of control germane respondents).

I am puzzled by the gait and balance exercise. I walk 35 steps and get a score of (number redacted). What does that mean? [Respondent f4da]

Respondents especially desired to compare their results with those of other participants, seemingly to derive greater understanding of their own disease course.

An updated (way to) compare your symptoms with others (names excluded) would be cool. As an early onset patient, I wonder how I am fairing compared with people like me. [Respondent 345a]

If I could see my results compared with another would help me understbnd (sic) better how this is affecting me. [Respondent 856c]

Presentation of Information

Despite our sincere efforts to design the eConsent as a multimodality informed consenting process for a broad audience, respondents had suggestions for improvement. Responders made specific suggestions for refining the presentation of information throughout the eConsent, calling out the need to increasing the clarity of the eConsent process by adding detail and audiovisual materials to aid understanding, adapting the eConsent more completely for those with visual impairment, and through simplifying the language used throughout the eConsent.

If you expect people with some high school to use this app you will have to simplify the vocabulary & cut out the jargon... [Respondent ebab]

Discussion

Principal Findings

Our qualitative analysis of participant open-response feedback provides an initial description of the essential qualities of participants' experience with a self-administered eConsent. We find our qualitative assessment of particular value not only for thematic comparison of the "lived experience" with an entirely remote mobile eConsent with existing understanding of traditional informed consent processes, but also for identifying novel and emergent themes in eConsent that may have consequences for the content contained therein.

Despite attention to presentation, content flow, and the use of icons, animations, and video as well as the volume of the information presented, we identified broad thematic consistency with gross challenges observed in in-person, fully facilitated informed consent processes. We were unable to comment on the relative degree to which participant misconception persists in self-administered eConsent as compared with traditional facilitated consent; now that we have established thematic consistency between participant experiences with the 2 modalities of consent, comparison between the approaches could be undertaken in a controlled study.

Respondents showed variable appreciation of core elements of informed participation, for example therapeutic misconception. This finding was of particular interest to our research team. Although therapeutic misconception is 1 of the most commonly discussed challenges in informed consent, researchers have previously suggested that the setting of clinical research within the academic medical center environment leads to participant conflation of research participation with clinical care [18,19]. What motifs, beyond physical setting, used both in traditional informed consent and eConsent, lead to therapeutic misconception and what approaches can be trialed to target it in remote research settings? Additional investigation is warranted.

Another stumbling block to informed and engaged participation highlighted within the open-response data was the struggle with the definition and role of the control participant. We found little discussion of this challenge within the literature, perhaps because within in-person studies, control participants are reassured frequently—albeit perhaps not consciously or deliberately—by study staff of their role and importance. It will be critical to the success of remote, app-mediated research to find balanced ways of reinforcing to control participants the requirements of their role and reaffirming their importance to research outcomes.

App-mediated research poses unique privacy and confidentiality concerns for research participants that may have implications for the content of consent. Overall, these risks were not commonly commented on by control subjects, but more than 9% of PWPD submitting responses touched on this topic. We did not find evidence in the literature of known differences with privacy and security concerns between "case" and control research participants in traditional clinical research settings. We wonder if PWPD may be more concerned about privacy and

confidentiality than control participants due to their older age as compared with controls (which may engender greater skepticism of mobile technology.) Alternatively, could we observe this trend because PWPD, due to their disease status, have greater awareness and concerns about the spectrum of potential misuse of their data? Research to tease apart if the privacy and confidentiality considerations of affected populations results from rightful awareness and concern or some other source is clearly needed as the spectrum of app-mediated research studies diversifies.

Technology blurs the line between research participation and every day smartphone interaction. We attempted to design for this shift in the fundamental context of research, but were still surprised by the evidence we found of the powerful influence of habit. The risk raised by participants of being identifiable when completing study activities in public, although not unique to app-mediated research, may be exacerbated by it. For example, participants, conditioned to responding to their smartphones, may immediately move to fulfill study activities upon receiving automated notifications without pausing to contemplate if they are in an "appropriate" setting for engagement. Furthermore, the frequency of "texting" of study staff through the anonymous response field was eye opening for our research team. These "habits" have clear implications for the content addressed in the informed consent process, from highlighting the risks of identifiability to clarifying the mechanisms of study staff contact. Attention should be paid by mobile study designers to the mechanisms for study staff contact that are included in app-based studies as well as the selection and design of open-response prompts or fields. Consideration of texting or short message service (SMS)-based study contact during designated "office hours" may be a solution, although the privacy and confidentiality risks posed by texting interactions within the context of human subjects research should be assessed.

Among the dominant benefits of participation identified by respondents were the positive emotions generated by their participation including altruism and agency. At the same time, participants did not hesitate to ask for "motivators" or "incentives" to encourage their participation. The balance between intrinsic and extrinsic motivating forces in human subjects research leans away from extrinsic motivators—most commonly financial incentives—and skews heavily to intrinsic motivation as a way of avoiding the hazards of undue influence and involuntary participation [20-23]. By contrast, app "stickiness"—the ability of an app to bring its audience back time and again—is viewed as essential to successful app design [24]. As we start to recognize participants' habitual patterns of smartphone interaction, we must guard against designs that angle toward undue influence and recognize the multifold challenges of creating app-mediated research that is engaging but not coercive, honoring the core consent principle of voluntariness in research.

One possible solution to the balance between intrinsic and extrinsic motivators is harnessing participants' eagerness to engage as coinvestigators. One of the great promises of mHealth research is coengagement of participants and researchers. This promise is noteworthy for governance and ethics professionals

as it has potential for improving participant comprehension and retention. Based on the volume and diversity of the responses we reviewed, participants are ready and able to share their insights and ideas with researchers. We plan further development of interactive study features to more actively and reciprocally partner with study participants.

Limitations

We focused the development of our eConsent for mHealth studies on facilitating disclosure, comprehension, and voluntariness for participants independently self-administering consent for research. The eConsent has a deliberately structured format and carefully curated content designed to maximize participant understanding and engagement. Our design is openly and freely available through GitHub (GitHub, Inc). Parameters limiting the application of our work include that the eConsent prototype has been designed for use in low risk studies, with populations that have smartphones and are comfortable using them.

Within the Parkinson mPower study, respondents report having completed significantly more formal education as compared with the US general population. The study participant pool also skews strongly male as compared with the US general population. The sample of respondents is somewhat more balanced, but still skews heavily male as compared with the US general population. Germane respondents were further

differentiated from the total pool of Parkinson mPower participants by reporting more formal education, having a Parkinson disease diagnosis, and being older than the total pool of participants. Based on these factors, our results may highlight the interests of PWPD, men, and those who are more highly educated over those of a more representational sample.

Conclusions

This analysis of participant open-response feedback provides a preliminary snapshot of the consent landscape of entirely remote research administered through smartphones. While acknowledging the limitations of using general open-response feedback to address specific study questions, we identified several formative themes worthy of further consideration within informed consent in the emerging field of app-mediated research [25]. We found that, as in fully facilitated informed consent processes, ensuring participant comprehension continues to be a challenge in eConsent; now that thematic consistency has been established qualitative comparison of these 2 approaches with informed consent is warranted. We documented several study governance themes that may be exacerbated by, if not entirely unique to, app-based remote research settings, especially several ripe for inclusion in the risks and benefits of this and future similar studies. Finally, we highlighted opportunities for participant engagement that may specifically foster informedness and comprehension in remote research studies.

Conflicts of Interest

None declared.

Multimedia Appendix 1

[PNG File, 62KB - [mhealth_v5i2e14_app1.png](#)]

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Abbreviations

PWPD: persons with Parkinson disease

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Original Paper

“Back on Track”: A Mobile App Observational Study Using Apple’s ResearchKit Framework

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Abstract

Background: In March 2015, Apple Inc announced ResearchKit, a novel open-source framework intended to help medical researchers to easily create apps for medical studies. With the announcement of this framework, Apple presented 5 apps built in a beta phase based on this framework.

Objective: The objective of this study was to better understand decision making in patients with acute anterior cruciate ligament (ACL) ruptures. Here, we describe the development of a ResearchKit app for this study.

Methods: A multilanguage observatory study was conducted. At first a suitable research topic, target groups, participating territories, and programming method were carefully identified. The ResearchKit framework was used to program the app. A secure server connection was realized via Secure Sockets Layer. A data storage and security concept separating personal information and study data was proposed. Furthermore, an efficient method to allow multilanguage support and distribute the app in many territories was presented. Ethical implications were considered and taken into account regarding privacy policies.

Results: An app study based on ResearchKit was developed without comprehensive iPhone Operating System (iOS) development experience. The Apple App Store is a major distribution channel causing significant download rates (>1.200/y) without active recruitment. Preliminary data analysis showed moderate dropout rates and a good quality of data. A total of 180 participants were currently enrolled with 107 actively participating and producing 424 completed surveys in 9 out of 24 months.

Conclusions: ResearchKit is an easy-to-use framework and powerful tool to create medical studies. Advantages are the modular built, the extensive reach of iOS devices, and the convenient programming environment.

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KEYWORDS

mHealth; mobile health; anterior cruciate ligament injury

Introduction

In March 2015, Apple Inc (Cupertino, CA, USA) announced the launch of ResearchKit, an open-source framework shipped with iPhone Operating System (iOS) 8.3, aiming at revolutionizing medical research studies to its developer community. Medical researchers around the world paid attention to this hot topic addressing their daily challenges [1]. The

preview was followed by a 4-week-long waiting time until further documentation, and the framework itself was released to the public [2,3]. The source code is distributed under an open-source license via GitHub (GitHub, Inc) [4].

Immediately after Apple’s announcement, a controversial discussion regarding the impact, significance, and potential risks started in the public and scientific community. Enthusiasts stress how easy it is to recruit participants and that participating

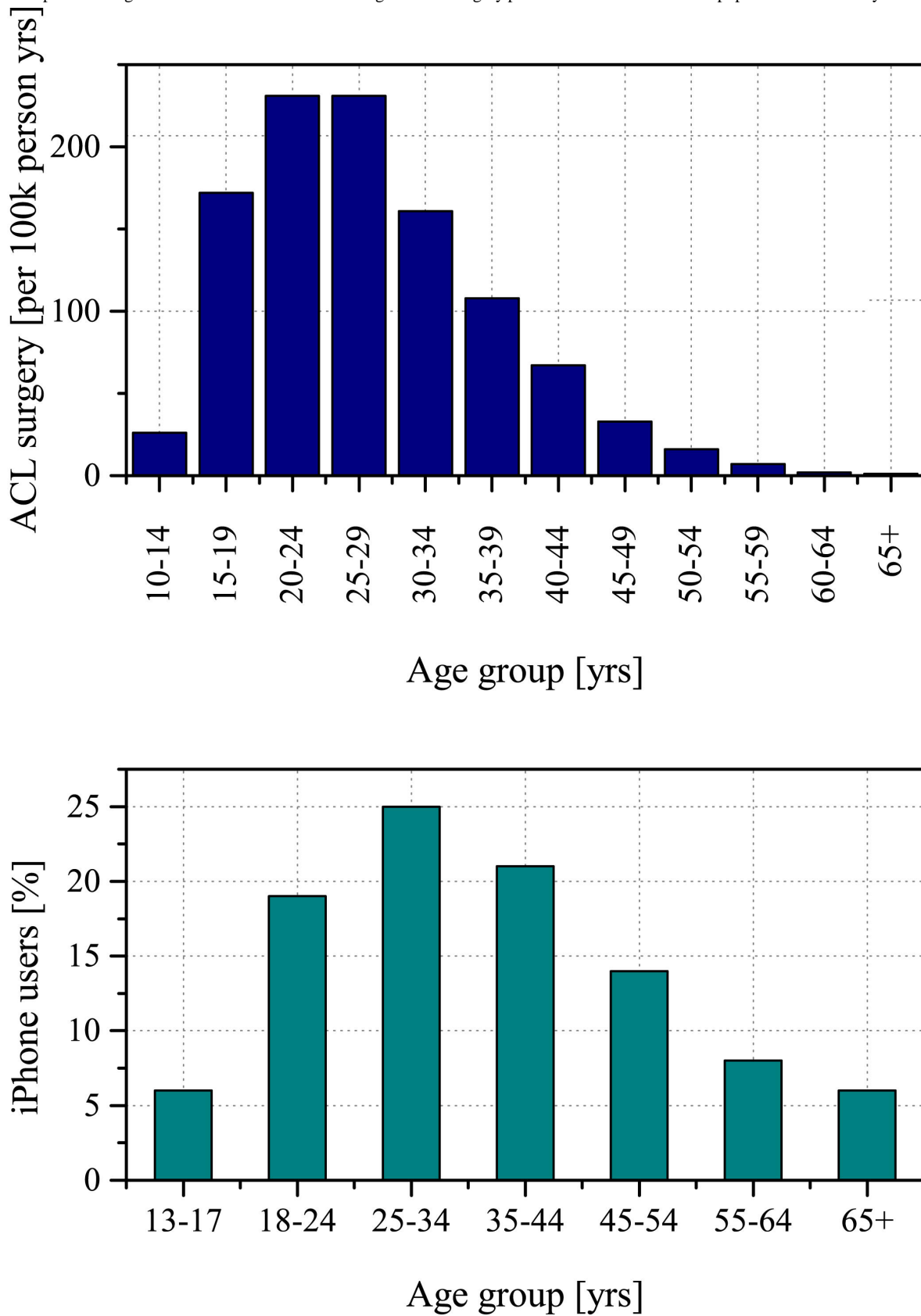
becomes as simple as posting on Facebook. Furthermore, it is argued that the data may be more realistic when gathered in daily life instead of an unrealistic laboratory setting. The sensor data provided by the iOS devices will potentially unveil new hypothesis and perspectives on certain diseases. Optimists predict that millions of people will participate in medical studies in the near future only because it becomes simple and accessible. The major advantage of Apple and ResearchKit is its broad market share with millions of potential participants [5]. The main concern of critics is the quality of the gathered information. Missing possibilities to confirm a participant's illness and challenges in matching sensor data, that is, step count, with physical activity levels are only two objections commonly mentioned [6]. Apart from that, iPhone users are more likely to be higher educated and have a higher income than the average population [7,8]. This bias is another concern often discussed by critics [9]. Our aim was to present a study designed with Apple ResearchKit and provide insights of the development process to other researchers who are interested in this novel framework.

Methods

Study Selection

A research topic to be investigated with Apple ResearchKit was carefully chosen. Due to the preselected group of potential participants and the nature of mobile device studies, the bias of a study depends on the topic [10]. Studies have shown that iPhone users are generally higher educated, have a higher income, and are younger than the average population in developed countries [7]. Ruptures of the anterior cruciate ligament (ACL) occur predominantly in young and active people, and no studies have shown significant correlation between income or education and ACL tears [11-13]. Figure 1 shows the age distribution of iPhone users [14] and ACL [15] surgery in New Zealand. It is concluded that ResearchKit is an appropriate data collection method because the age groups predominantly affected by ACL tears match the predominant age groups of iPhone and potential ResearchKit users. Furthermore, it is proposed that patients are more likely to share information regarding a sports injury via a mobile app than data on psychiatric or severe chronic diseases. Based on these assumptions, a decision-making study evaluating the outcomes of different treatment options for acute ACL tears was performed.

Figure 1. Comparison of age distribution in iPhone users and age of ACL surgery patients taken from a national population-based study in New Zealand.



Study Design

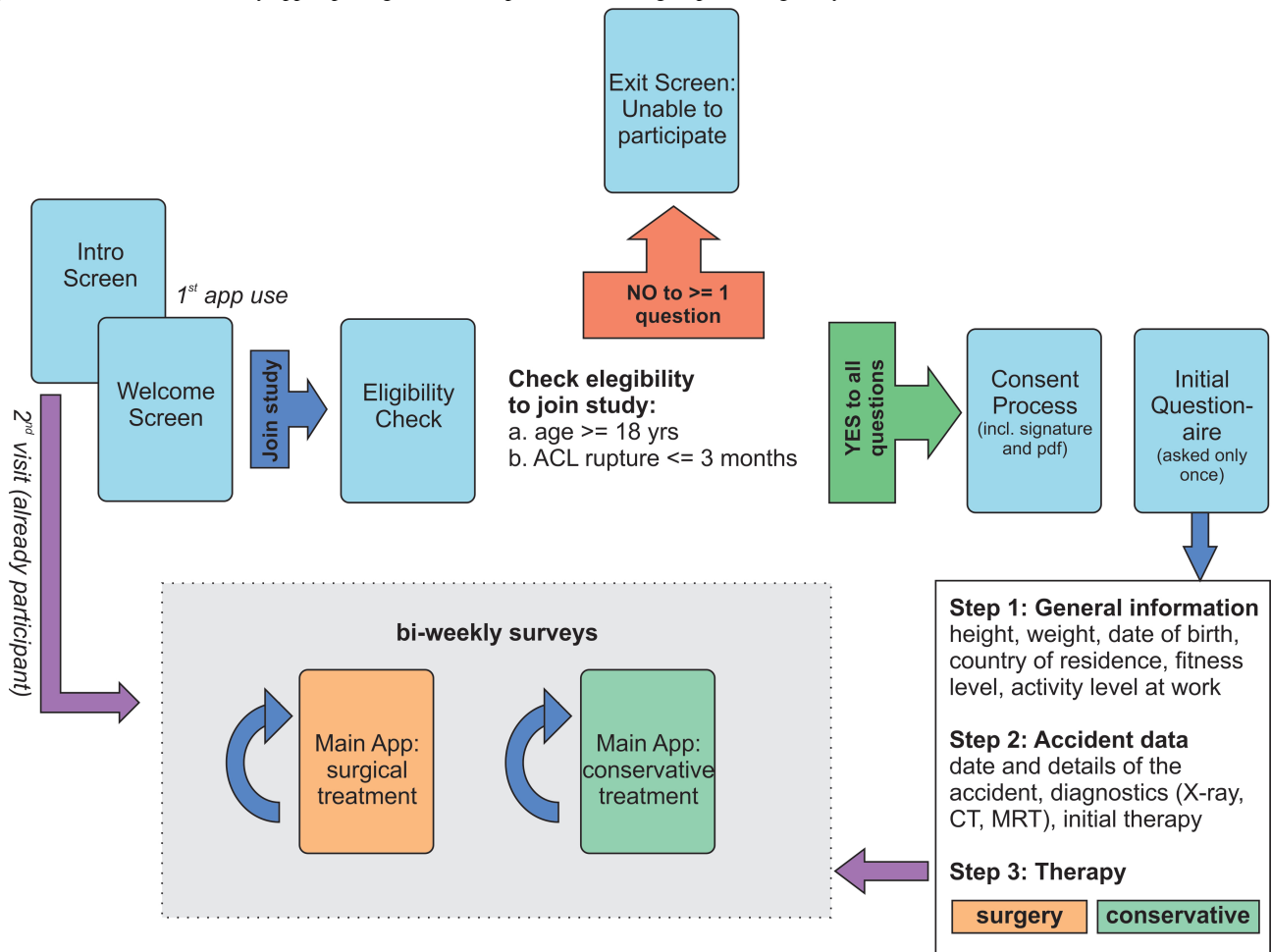
The study was designed as an observational study collecting data through surveys. The purpose of the study was to evaluate treatment options by capturing patient satisfaction and subjective

observations. This allowed the comparison of various treatments based on their outcomes. The app was programmed in 3 languages (German, English, and Spanish) and distributed internationally via the Apple App Stores, thus allowing identification of international differences in ACL therapy. By

choosing every country or region with at least one of the apps languages as the official language, it was deployed in 53 regions. Figure 2 presents the workflow of the first mandatory steps

when starting the app for the first time. This includes an eligibility check, consenting, and an initial questionnaire.

Figure 2. Workflow of the study app depicting the consent process, initial sign-up, and eligibility check.



Technical Development

Modular Concept

The ResearchKit framework provides a modular concept to build research apps. Most apps are distinguishable into 4 sections. Following an intro screen with general information on the study, a consent process is started. Apple ships everything necessary for a digital informed consent in the framework. This step is followed by an initial questionnaire collecting personal information and disease-relevant data, such as diagnostic procedures and previous and current therapies. In case these modules are completed successfully, the participant is registered

and may take part in the study through the main app. A main app may be customized according to the investigators’ needs. With ResearchKit, Apple provides easy-to-use modules to create surveys and profiles, access sensor data, and display scores on a dashboard [16]. Well-known features from other apps such as push notifications are also quickly integrated.

The ACL rupture study app presented in this study comprised a survey with 9 questions that have been validated in previous studies. Figure 3 displays these questions. The question in the green box was only asked while a participant received a conservative treatment.

Figure 3. Questions of the bi-weekly survey. The question in the green box was only asked when the participant received a conservative treatment.

Survey questions:

Have you had surgical treatment or is a surgical procedure planned?

1. Do you have a feeling of instability? (yes/no)
2. How much pain do you feel during daily activities? (VAS 10)
3. Are you still wearing a brace? (yes/no)
4. How do you rate the overall function of your knee during daily activities? (1-10 score)
5. How does the pain in your knee limit your activities? (1-10 score)
6. How do you rate the overall effect of your knee on your daily life? (score 1-10)
7. Are you actively doing sports again?

If yes (question 7):

8. How often per week? and 9. Which sports?

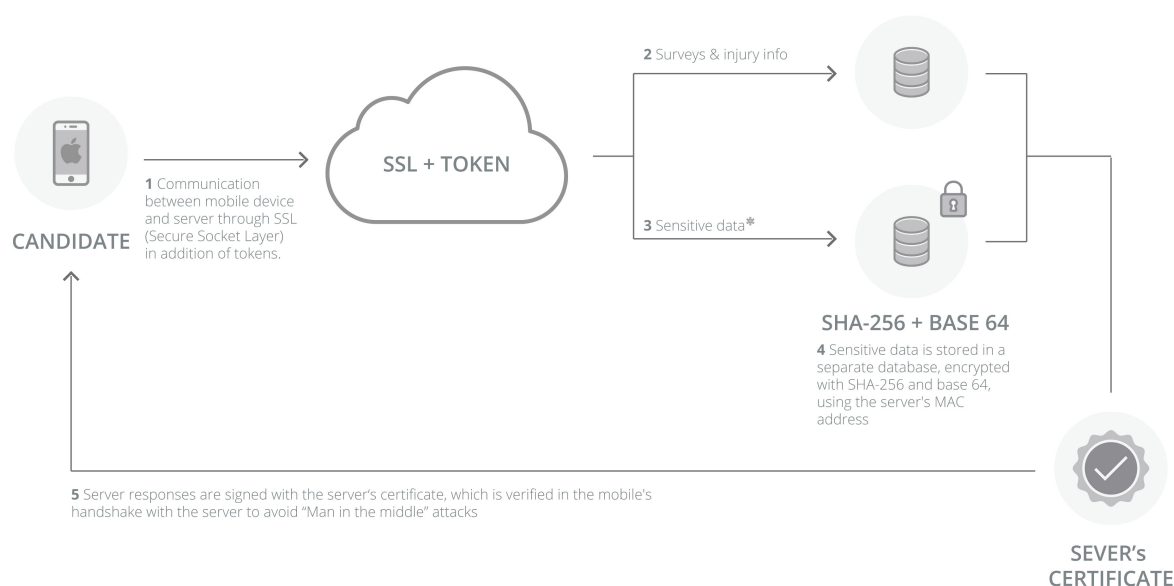
Programming Environment

Xcode (Apple Inc, Cupertino, CA, USA) was required to develop iOS apps and thus was also necessary to develop ResearchKit apps. It was distributed free of charge as proprietary software. ResearchKit itself was open source and installed locally for development purposes by cloning the GitHub repository [4].

Server Security

A server with Ubuntu 14.04 (Canonical Ltd, London, UK) as operating system was set up on the intuitional site to ensure that all data were physically stored in a secure data center in Germany. A Linux, Apache, MySQL, and PHP (LAMP, PHP: Hypertext Preprocessor) system including PHP 5.5 and MySQL

5.5 was installed. All communication between mobile device and institutional server was realized via Secure Sockets Layer (SSL). Different databases were used for sensitive data (name, email, and signature) and study data (surveys and information). Server side encryption was realized using `mcrypt_create_iv()`, which created a padding vector, padded the serialized value, and encrypted the result using base64 and the padding vector. Afterward it hashed this encrypted value using the media access control (MAC) address of the server. This allowed for the data only to be decrypted on the encryption server. Finally, it encoded with base64 an array containing the JavaScript Object Notation (JSON) encoding of the padding vector, original value, and MAC address. This value was stored in the database. The security concept is depicted in [Figure 4](#).

Figure 4. Security concept for data storage and communication.

* Sensitive data are candidates contact information such as full name, email and consent signature

Language Support

Localizable strings were used in this study to realize multilanguage support for the ACL rupture app. ResearchKit supported this commonly used technique in iOS development. Strings were placed in separate language files with a unique identifier used to place the strings at the appropriate location in the app. Initially, the app was designed in English. By using the concept of localizable strings, language support for Spanish and German was added by duplicating the English language file and adapting it for the other 2 languages. Changes to the graphical user interface and design were only necessary when adding language support for a language that was not based on the Latin or similar typeset, that is, Chinese or Japanese. Hunt et al [17] showed that language barriers had a significant impact on clinical studies. To overcome these barriers it was necessary to provide a multilanguage version of an app to collect reliable data internationally.

Ethics and Data Protection

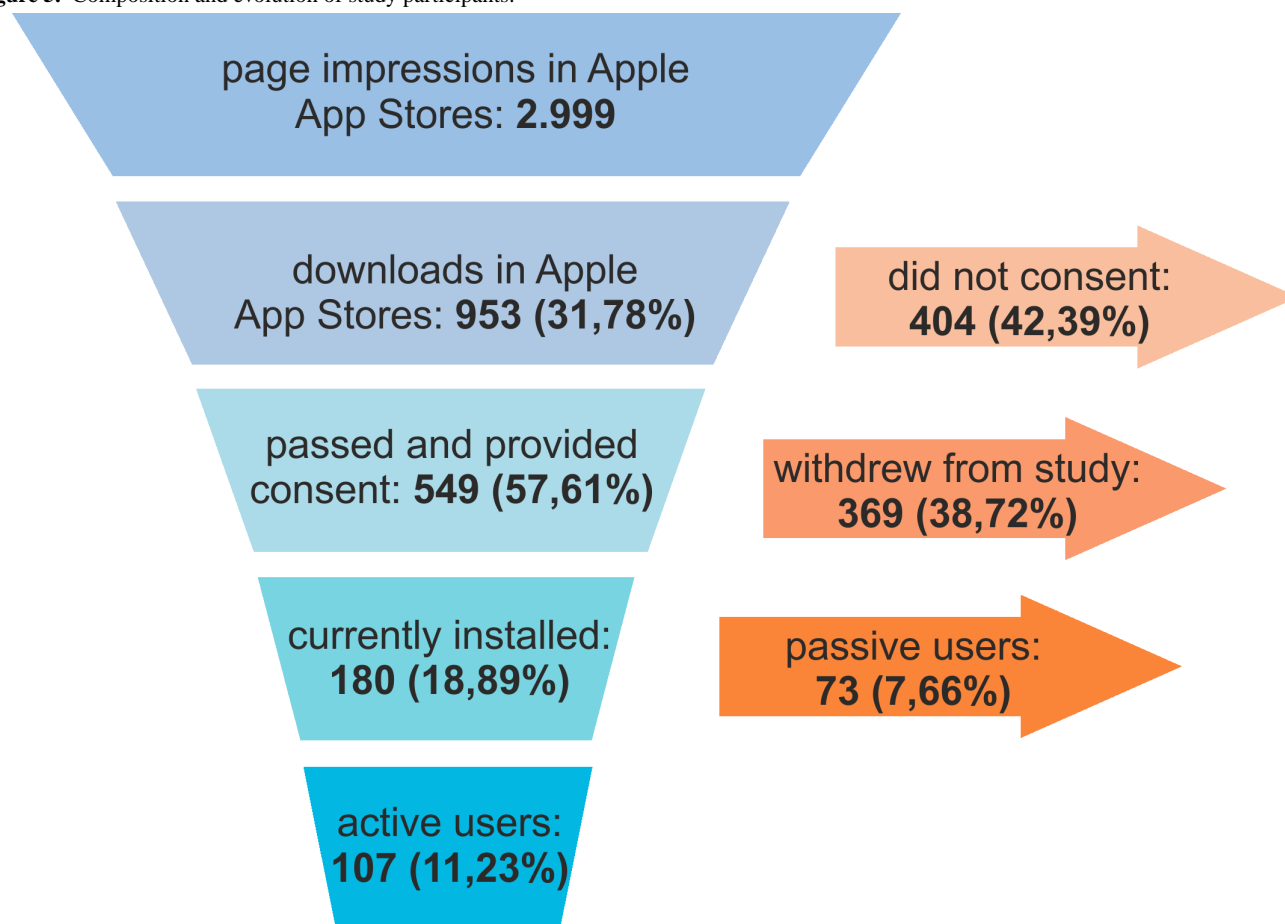
This study was approved by the local ethics committee and registered with the German Clinical Trials Register (DRKS-ID: DRKS00009270). The approval was mainly based on the thorough implementation of German data protection laws. Due to the fact that the app server, all data, and the study center were based in Germany, only German data protection laws and retention policies applied for the app, although study participants were located worldwide. Supervision was carried out by German local and federal authorities.

Results

A first ResearchKit app to investigate the decision-making process in the treatment of ACL tears was developed. The app had multilanguage support and was distributed through Apple App Stores. It was added to the portfolio of all App Stores in regions and countries with German, English, or Spanish as the official language, thus resulting in 53 regional stores.

Within 9 months of recruitment, the App Store website was accessed 2999 times and the app was downloaded 953 times (31.8% conversion rate, 953/2999). A total of 549 participants (57.6% of all downloads, 549/953) completed the consent form successfully and joined the study. Currently, the app is installed on 180 iOS devices (18.9%, 180/953) and 107 participants (11.2%, 107/953) are actively participating in study activities at the moment. A participant is considered to be actively participating when still enrolled in the study and having completed the last 2 surveys. Figure 5 depicts the composition and evolution of participants. In this ongoing study, 424 surveys were completed within a total duration of 9 months (1.57 per day).

Preliminary data show downloads from 21 of 53 regions with a majority of these originating from Germany, Austria, and Switzerland (85%, 91/107). A gender analysis of all participants showed a ratio of 74:26 in favor of the male sex. The predominant age group was 25-34 years (54%, 58/107). No participants older than 56 years were registered for the study.

Figure 5. Composition and evolution of study participants.

Discussion

The idea of conducting medical studies via the Internet and by using mobile devices is not new [18-21]. Previously, this technique was used to improve communication, data collection, and data quality in studies with participants known personally to the investigators, that is, somehow they are affiliated with the study center. A major advantage and novelty of ResearchKit is the ability to conduct studies and recruit participants unrelated to the study center. Furthermore, ResearchKit simplifies the process of developing such apps and thus makes this technology affordable for research groups around the world.

Mobile apps allow for groups of people to participate in medical studies, which are underrepresented in conventional studies, such as young and active people or those living in remote locations [16]. Researchers also hope to address patients suffering from mental illnesses with new mobile study apps. This specific target group has been difficult to reach with conventional studies [22].

Opening up mobile app development to a large community and conducting large-scale studies for thousands of participants imply the necessity for quality assurance on both sides. The quality of medical mobile apps has been discussed for several years [23]. Recently, the Food and Drug Administration announced to implement stricter regulations for medical apps. Although this announcement targeted apps, it might possibly harm patients through misleading, unfiltered, or incorrect

information; the quality of study apps might also decrease with the rapidly increasing number. This issue needs to be addressed by independent institutions that check and certify mobile study apps [24]. In addition, ethics committees have to be educated on the new technologies and the implications of an increasing number of studies conducted via mobile devices. The quality of ResearchKit apps may benefit from the fact that the framework is open source. Researchers who are new to the field can avoid pitfalls by using a well-tested platform with many contributors.

According to the National Health Service (NHS) study in the United Kingdom, development costs currently range from £1000 to £30,000 depending on the extent and functionality of the desired app [16,25,26]. The modular design concept of ResearchKit reduces the initial development cost of mobile apps, as well as the following maintenance cost. Furthermore, the cost per participant of a mobile app study is significantly lower compared with that of conventional studies [27].

Moreover, the acceptance of mobile health care studies in the general public may possibly increase with Apple's involvement in this sector. According to a recent study, medical students and junior doctors are very enthusiastic about mobile health (mHealth) solutions. Future development in this sector may very likely be driven by this peer group [28].

In the last decade, browser-based Internet surveys were the most common technology used for study surveys in the United States [29]. This trend will shift toward mobile devices in the near

future. A thorough understanding of this technology, with its risks and benefits, is needed by all parties involved in the process. This includes ethics committees, data protection officers, data storage and security specialists, app developers, public relations officers, medical researchers, and participants.

Recruitment and retention of participants may also change in contrast to browser-based surveys. All traditional recruitment methods that are currently used to win participants for Web-based survey studies, that is, Google AdWords, Facebook ads, social media and forum posts, newspaper ads, TV, radio, flyers, and doctors, can also be used for mobile phone-based study apps. However, participant retention is low with browser-based Web-based surveys [30]. This may improve with mobile phone-based study apps. Especially, the push-notification function of iOS devices, which is easily implemented in ResearchKit apps, allows the investigators to send notifications, reminders, and information directly on a participant's mobile device.

Apart from that, this study revealed that passive recruitment was insufficient to enroll large numbers of participants. New recruitment channels have to be tapped. Solely relying on passive recruitment—meaning active participants who might find the study app through search engines—does not allow conducting large big data studies. Furthermore, keeping up the motivation to participate is challenging. Possible solutions are an instant feedback of study results, a gamification approach, or providing relevant treatment information.

Comparison With Prior Work

Only very few prior scientific studies have been published explicitly reporting on experience and first steps with Apple ResearchKit. Mobile-device-based health care studies are numerous [21,24,31]. Data have to be gathered and analyzed in order to compare the ResearchKit studies with different methods and techniques.

The mPower study was created and launched within the beta phase of Apple ResearchKit. Bot et al recently published preliminary results [32]. The percentage of consenting participants (34.5%) was reported to be significantly lower than that determined in this study (57.6%, 549/953). The resulting percentages of active participants, however, are comparable between both studies, with 10.9% in the mPower study and 11.2% (107/953) in this study.

Conclusions

Apple ResearchKit provides an interesting tool to easily create and distribute medical research apps that are simple to access and use for the public. The concept of a major company developing and promoting software, which targets this issue, is new. Many questions regarding this novel technology remain unanswered. Further investigations, especially regarding bias and public acceptance, need to be performed. Data quality and validity have to be evaluated in the further course in order to derive reliable conclusions for future mHealth developments. In addition, novel approaches to acquire participants and preserve the initial motivation to participate have to be found in order to reduce dropout rates.

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Conflicts of Interest

None declared.

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Abbreviations

ACL: anterior cruciate ligament
iOS: iPhone Operating System
LAMP: Linux, Apache, MySQL, PHP
PHP: Hypertext Preprocessor
SSL: Secure Sockets Layer

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Original Paper

Mixed-Methods Analysis of Factors Impacting Use of a Postoperative mHealth App

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Abstract

Background: Limited communication and care coordination following discharge from hospitals may contribute to surgical complications. Smartphone apps offer a novel mechanism for communication and care coordination. However, factors which may affect patient app use in a postoperative, at-home setting are poorly understood.

Objective: The objectives of this study were to (1) gauge interest in smartphone app use among patients after colorectal surgery and (2) better understand factors affecting patient app use in a postoperative, at-home setting.

Methods: A prospective feasibility study was performed at a hospital that principally serves low socioeconomic status patients. After colorectal surgery, patients were enrolled and given a smartphone app, which uses previously validated content to provide symptom-based recommendations. Patients were instructed to use the app daily for 14 days after discharge. Demographics and usability data were collected at enrollment. Usability was measured with the System Usability Scale (SUS). At follow-up, the SUS was repeated and patients underwent a structured interview covering ease of use, willingness to use, and utility of use. Two members of the research team independently reviewed the field notes from follow-up interviews and extracted the most consistent themes. Chart and app log reviews identified clinical endpoints.

Results: We screened 115 patients, enrolled 20 patients (17.4%), and completed follow-up interviews with 17 patients (85%). Reasons for nonenrollment included: failure to meet inclusion criteria (47/115, 40.9%), declined to participate (26/115, 22.6%), and other reasons (22/115, 19.1%). There was no difference in patient ratings between usability at first-use and after extended use, with SUS scores greater than the 95th percentile at both time points. Despite high usability ratings, 6/20 (30%) of patients never used the app at home after hospital discharge and 2/20 (10%) only used the app once. Interviews revealed three themes related to app use: (1) patient-related barriers could prevent use even though the app had high usability scores; (2) patients viewed the app as a second opinion, rather than a primary source of information; and (3) many patients viewed the app as an external burden.

Conclusions: Use patterns in this study, and response rates after prompts to contact the operative team, suggest that apps need to be highly engaging to be adopted by patients. The growing penetration of smartphones and the proliferation of app-based interventions are unlikely to improve care coordination and communication, unless apps address the barriers and patient perceptions identified in this study. This study shows that high usability alone is not sufficient to motivate patients to use smartphone apps in the postoperative period.

KEYWORDS

mHealth; colorectal surgery; smartphone apps

Introduction

Surgical complications, particularly after colorectal surgery [1], result in increased resource utilization, readmissions, and lower patient satisfaction [2-7]. Unplanned readmissions are especially problematic, leading to increased mortality [8] and an estimated cost of US \$17.4 billion dollars annually for Medicare alone [9]. Expedited care and enhanced recovery pathways have led to shorter hospital stays than with traditional care for a variety of surgeries [10-14], but this allows less time for healthcare providers to monitor for complications and educate patients. Despite moves toward earlier discharges, there is increasing pressure from public and private payers to reduce readmissions for an expanding number of admission diagnoses [15,16]. The transition from in-hospital care to home care, and the management of home care, are increasingly recognized as important factors that can influence the rate of readmissions [17]. Early recognition of complications may allow outpatient management in some cases. In this setting, tools that promote postdischarge self-care and early recognition of complications are particularly appealing.

Mobile health (mHealth) tools offer the potential to improve postdischarge care. Rapid advances in communication and computer technologies during the last few decades have allowed for the development of healthcare tools based on mobile computers and communication devices, which have the potential to influence many facets of healthcare [18]. Smartphones are increasingly common, with 64% of the US population owning a smartphone, and 62% of smartphone owners report getting information about a health condition on their device [19]. Together, software stores for the two most popular mobile platforms, Apple Inc's iOS and Google Inc's Android, offer over 100,000 health-related apps [20], but many of these tools lack a solid evidence base for their use [21-24].

mHealth interventions, consisting of both mHealth tools and the surrounding systems that provide and support them, have shown benefits in the management of some chronic health conditions [25]. For example, mHealth apps have been successfully utilized in outpatient clinics to improve blood glucose control in diabetics, and improve patient outcomes [26,27]. The use of apps for patient follow-up in human immunodeficiency virus/acquired immune deficiency syndrome and tuberculosis clinics has the potential to reduce the number of patient visits, thereby reducing the burden on the health care system [28]. Additionally, mHealth apps have proven successful in patient education to promote physical activity and healthy diets [29,30]. The above studies suggest a possible role for the use of mHealth interventions in perioperative care; however, studies regarding the use of mHealth apps in surgical settings remain limited. A recent study by Sanger et al [31] assessed patient perceptions of mHealth apps for postoperative wound monitoring, and found that patients believed mHealth tools would be useful for wound monitoring and that these tools could

improve follow-up, communication, and triage. Another study by Semple et al [32] demonstrated the feasibility of using an mHealth app for monitoring patient ratings of the quality of their recovery. Despite these recent studies, the factors that affect the use and utility of mHealth interventions in the postoperative period remain unknown.

Methods

We performed a descriptive feasibility study in which we used semistructured interviews, a standard technology usability score, chart review, and app use metrics to assess patient perceptions and use of a postoperative symptom-tracking smartphone app. Institutional Review Board approval was obtained prior to beginning the study and written informed consent was obtained from all subjects at enrollment.

Mobile Health App

The mHealth app used in this study was developed by an industry partner (Seamless Mobile Health, Inc) and is based on an algorithm previously developed by our group, based on a systemic review and meta-analysis [33]. The app was designed to function on three mobile operating systems including Android (version 2.0 and newer, Google Inc, Mountain View, CA), iOS (version 4.0 and newer, Apple Inc, Cupertino, CA) and Blackberry OS (version 10.2.1 and newer, Blackberry Ltd, Waterloo, ON). The app is intended for daily postoperative self-reporting by patients, and the main functionality is a symptom tracker which asks a series of questions about symptoms that can be warning signs after colorectal surgery. The symptom tracker also allows the patient to take a picture of their surgical wound and record their temperature each day. The app delivers an on-screen reminder to patients that they need to fill out the questions if they have not already done so by a set time of day. After answering all questions (the photograph and temperature features can be skipped), the app automatically gives patients one of three responses: (1) *no issues, continue current care*; (2) *concerning issues, call surgical team*; or (3) *emergently concerning issues, go to emergency room (ER)*.

The wording of both the questions and responses was developed through an iterative design process and literacy evaluation was performed to develop an after-hospital care plan based on the same algorithm. Goals of this process were to make the after-hospital care plan accessible and patient-centered, while improving communication and patient knowledge. Although the design process included patient interviews, formal validation of the app (and the after-hospital care plan on which it was based) with regard to these design goals was not performed.

In this study, patient responses were encrypted and then automatically uploaded to a secure, encrypted online portal. Responses that could not be immediately uploaded due to the lack of an Internet connection were cached on the patient's device and uploaded once a connection was available. Patients

were instructed that members of the treatment team would not be notified of any issues reported through the app, and that patients needed to respond to app cues as they felt appropriate. Upgrades to the app were made throughout the study period to correct technical issues, but the overall app design, questions given to patients, and algorithm remained constant throughout the study.

Subjects and Setting

This study was conducted at Ben Taub Hospital, a large urban county hospital in Houston, TX which principally serves patients with low socioeconomic status. We recruited postoperative adult patients who had undergone colorectal surgery for both traumatic and nontraumatic causes, during the admission in which they were identified. Inclusion criteria included: English or Spanish as the primary language, ability to obtain a mobile device capable of running the app, and capacity to consent for self. Exclusion criteria included: pregnancy; incarceration; and desire by the primary team to not have the patient participate due to medical complexity, enterocutaneous fistula, or length of stay. Spanish-speaking patients were not included until a Spanish language version of the app became available 5 months after the study began. Enrollment, teaching, and follow-up for Spanish speaking patients was performed via an interpreter. Patients who did not have a phone but wanted a family member or friend to fill out the app were allowed to participate.

After identification by twice-weekly inpatient census review, patients were introduced to the study by members of the treatment team using a standardized script. In order to protect patient privacy, only patients desiring to hear more about the study were approached by a member of the study team. Informed consent was obtained and each patient went through a brief, standardized orientation with the app, led by the same member of the research team. Patients were shown how to use the app on a device used in the study and were asked to perform a teach-back on their own device. Patients were then instructed to use the device daily for at least two weeks after discharge. Patients who were enrolled and completed follow-up, regardless of how often they used the app, were given US \$10 as compensation for participation.

Data Collection

At the time of study enrollment, patients completed a brief demographic survey. Immediately after performing the teach-back of the app on their device, patients were asked to rate the app using the System Usability Scale (SUS). The SUS is a validated, 10-item Likert scale survey that assesses the usability of technological tools and generates a composite score with a maximum of 100 points [34,35].

Follow-up with patients occurred at either the routine postoperative clinic visit (typically 2-3 weeks after discharge) or by phone if we were unable to meet with patients in a clinic. If we could not contact patients on our initial attempt, we made two additional attempts and left phone messages when possible. At follow-up, we performed a semistructured interview (Interview Guide found in [Multimedia Appendix 1](#)) which asked both direct and open-ended questions related to app use. In addition to the semistructured interview, the SUS was repeated

at the time of follow-up. Interviews were conducted by a single investigator. For patients who reported not using the app, we did not use the interview guide and instead focused solely on reasons for not using the app. Interviews were conducted with family members that were present, if they accompanied the patient to the clinic visit. Detailed field notes of the interviews were collected, and data was delimited at the time of collection, with direct quotations of informative responses recorded. Audio/visual recordings and interview durations were not collected. The authors met after each set of 5 interviews to review the data and determine if data saturation had been achieved. Field notes were not reviewed by study participants and participants were not asked to provide feedback on the findings of this study.

At 30 days after discharge, we reviewed patients' charts to look for phone calls related to the surgical intervention, ER visits, and readmissions. Using the online portal, we collected the total number of times each patient used the app, responses to all questions in the tracker, and the recommendation given to the patient each time they used the app.

Data Analysis

Two members of the research team independently reviewed the field notes from follow-up interviews and extracted the most consistent themes. To facilitate theme extraction, patient responses were stratified based on the number of times the patient had used the app after discharge. All members of the team were then given the field notes, as well as the themes suggested by the two initial reviewers, and modifications were made to the themes (as deemed appropriate by group consensus). Descriptive statistics for the use metrics, SUS, and demographic surveys were calculated using Stata 13.1 (StataCorp LP, College Station, TX).

Results

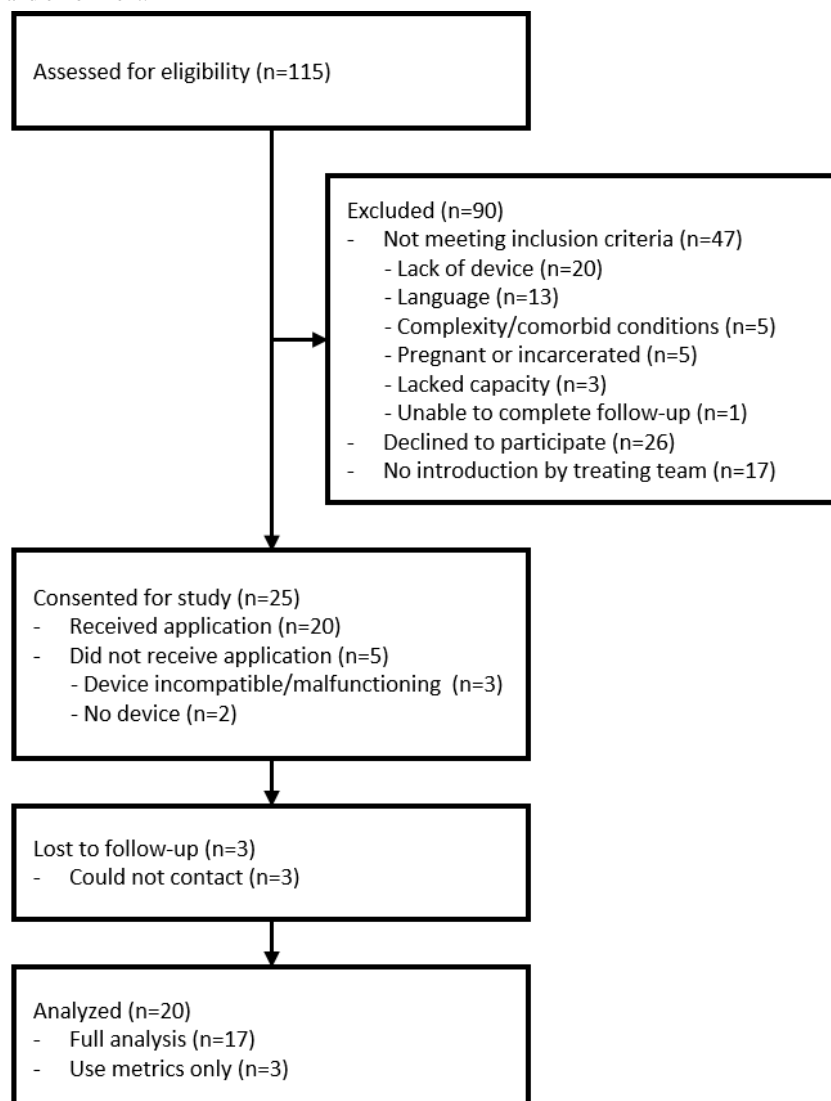
Subjects

Over a 1-year time period (December 15, 2013 to December 15, 2014), we screened a total of 115 patients ([Figure 1](#)). We identified a total of 68 patients who were eligible for participation, however the treating team was unable to introduce the study to 17 patients. The majority of patients that did not meet inclusion criteria either did not have a suitable device (n=20) or spoke a language not supported by the app at the time of screening (n=13). Of the remaining 51 patients approached by the treatment team, 26 declined to participate and 25 wanted to be enrolled. Of those 25 patients, 2 were unable to have their devices brought to the hospital and 3 had devices that were incompatible with the app. This left a pool of 20 patients who were able to receive the app. Demographics for these 20 patients are shown in [Table 1](#). We were unable to contact 3 patients for follow-up interviews, but app use metrics and data from the 30-day chart review were available for all 20 patients. Among the 17 patients for whom we did complete follow-up, 2 reported not using the app, resulting in an abbreviated interview in which only reasons for nonuse were discussed. There was a total of 15 patients for whom the semistructured interview was completed and the follow-up SUS was collected.

Table 1. Patient demographics.

Characteristics	Number =0 or 1 uses	Number >1 use
All Patients	8	12
Gender		
Male	3	9
Female	5	3
Age (years)		
29 or younger	3	3
30-44	3	5
45-64	2	4
Marital status		
Single	4	5
Married and/or living with a partner	4	5
Separated/divorced	0	2
Race/ethnicity		
White	2	3
Black, African-American, African-Caribbean, African, or nonwhite Hispanic or Latino	3	4
Hispanic or Latino - white	3	4
Other	0	1
Residents in house		
Lives alone	1	2
Two people	2	5
Three or more people in household	5	5
Schooling		
No formal educational credential	1	2
High school diploma or equivalent	3	1
Some college or trade school, no degree	2	7
College graduate (bachelor's degree)	2	2
Employment		
Working full-time or part-time	5	6
Unemployed or laid off	2	6
Disabled, not able to work	1	0
Income		
<US \$20,000/year	2	4
US \$20,000-\$59,999/year	5	7
>US \$60,000/year	1	1

Analysis of this data revealed three themes: *usability and actual use*, *the app as a second opinion*, and *internal versus external motivation*.

Figure 1. Patient screening and enrollment.

Usability and Barriers to Actual Use

The majority of patients gave the app high quantitative ratings for usability. Interviews and use metrics revealed a more mixed assessment of usability and lower-than-desired use. Immediately after initial use, patients gave the app a median SUS score of 95 (interquartile range [IQR] 86-98). Among patients who reported using the app at least once after discharge, the median SUS score was 95 (IQR 83-98) at the time of follow-up.

Ten of 15 patients (67%) reported that the app fit into their day-to-day routine easily and did not take very much time. Statements included:

Didn't have to fit in, only took a couple seconds.

It's fine because I'm done with my morning routine and haven't started my lunchtime routine yet.

Whenever I had time I just did it.

A week after I got out, the grenade [surgical drain] had doubled its drainage, so I used it at the fairgrounds [patient was attending a rodeo when he noticed increased drainage].

Four of 15 patients (27%) felt that the app did not fit in well because the reminder came at the wrong time, or they simply forgot to fill it out. These patients did not remember that the time of the reminder could be changed, with one respondent stating, "If the reminder was in the evening, it would have been better."

Finally, one patient (1/15, 7%) felt that the app fit into his routine better on some days than others, stating, "It fit in OK, just some days were good, some were bad [and on bad days] the app was just not happening."

Despite high usability ratings and perceptions that the app fit into their daily routines, the majority of patients did not use the app daily after discharge, as instructed. Use metrics collected in the online portal showed that six patients (6/20, 30%) did not use the app at all and two patients (2/20, 10%) only used it once. Twelve patients (12/20, 60%) used the app more than once, with a median of 7 times (IQR 6-31.5). Four of these patients used the app more than 25 times. During the interview, two patients with zero recorded uses in the portal reported that they had used the app, with one stating that her Internet connection had malfunctioned. Use metrics are summarized in [Table 2](#). Of the three patients who could not be reached for follow-up, two

had no record of app use and one had used the app eight times. A summary of the number of patients who used the app and responded for follow-up is given in [Table 3](#).

During interviews, when asked if they had any problems while using the app, 8 of 15 patients (53%) responded affirmatively. The problems patients reported were variable, but fell into three broad categories: (1) app issues or technical problems with the app (bugs), including, “started becoming buggy on me [...] reset itself when I was in the middle of answering questions” and, “every time I tried to use it, I’d forget about the picture, and when the picture wouldn’t go through I’d say, ‘oh, God’ and give up.”; (2) patient/user issues, such as not answering a question before attempting to move to the next question because the patient was, “speeding through it,” and difficulty entering

the app directly from the notification/reminder; and (3) system issues or problems with how the app fit into self-care and the care system, including difficulty with an Internet connection (“just my Internet was tripping”), feeling unable to take a wound photograph because a surgical dressing was in place (“because I was already bandaged up”), and inability to reach a physician by phone when told to call.

The clinical impact of low use can be seen in ER visits by patients enrolled in this study. Eight of 20 patients (40%) had unplanned ER visits within 30 days of discharge. Of those 8 patients, 5 (63%) presented with symptoms that could have been addressed by the app. On the day of their ER visit, none of the 5 patients used the app to check their symptoms.

Table 2. Number of app uses and surgical diagnoses.

Number of times app used	Number of patients					
	Trauma	Cancer	Diverticulitis	Inflammatory bowel disease	Appendicitis	Total
0	2	3 ^a	1 ^b	-	-	6
1	2	-	-	-	-	2
2-10	5	-	1	1	1	8
>25	-	3	1	-	-	4

^aTwo of these patients did not receive the app on their own device but had a child with a mobile device on which the app was installed. The third patient had no recorded uses in the portal, but reported having problems with her Internet connection, and stated that she used the app three times.

^bThis patient reported using the app 2-3 times, and he denied problems with his Internet connection.

Table 3. Number of patients who used the app and responded to follow-up.

Category	Number of patients	Percentage
Enrolled	20	100%
Completed follow-up	17	85%
>1 use reported by patient	16	80%
>1 use recorded by portal	14	70%
Completed follow-up and reported use	15	75%

App as a Second Opinion

The second theme relates to patients’ perceptions of the role the app had in their postoperative care and how they responded to recommendations given by the app. While the first theme relates to barriers to using the app, this theme relates to barriers to clinical effect. Patients felt that the app served as a second opinion or accessory source of information rather than a primary source of information, and thus did not always follow recommendations given by the app. Some patients struggled with how to properly input data and respond to recommendations based on unclear data, but used their own judgment to make decisions about when to seek help. Patients also frequently skipped the two data fields (wound photograph and temperature) with options to be skipped, lowering the amount of clinically actionable data that was collected.

Overall, patients reported that they trusted the recommendations given by the app. When asked directly, 11 of 15 patients (73%) reported that they trusted the recommendations, 3 patients (20%)

reported that they did not trust the recommendations, and 1 patient (7%) was unsure. Patients trusted the app for different reasons:

Yes, because it was stuff that I didn't know that I thought was right.

When the app tells you you need to call, you do what it says. It was kinda a second opinion you know.

I felt that it would tell me what to do if I needed to.

Yes, because it said I was on the red team.

Yes I do because it helped me a lot.

Kinda a little security thing, if anything going on, tells you who to contact.

Despite reporting that they trusted the app, many patients did not follow the recommendations given. Ten of the 16 patients (63%) who used the app received a recommendation to call the surgical team, but only 4 of those 10 (40%) called when prompted. Patients who did not follow the recommendation could be split into three categories. Two patients simply felt

they knew better than the app and made statements such as, “I thought I knew better.”

Three patients were unsure of the significance of their symptoms and decided to see how they changed over time. In one instance, a colorblind patient who thought his wound might be red stated, “I wasn’t hurting in any way and my daughter wasn’t absolutely sure it was red.” A single patient reported wound drainage, which prompted a recommendation to call, but the patient had just been seen in the ER and evaluated for the same symptom so she decided not to call.

In contrast, the four patients who did call when prompted did so either because they were unsure and wanted extra information, or because they felt obligated, with one patient stating, “I had to do something.”

Patients took photographs of their wounds a median of 0% (IQR 0-54) of the time. Patients reported two main reasons for not taking wound photographs. Three of 15 patients (20%) reported that it was not convenient to take down their dressing to take a photograph if they were filling out the app at a different time than when they changed their wound dressing. An additional three patients reported that they did not feel comfortable viewing their wound:

- I hated looking at it, most of the time I took pictures with the wound covered.*
- I dunno, I'm just, I think because of the ostomy bag, I'm a little timid about taking photos.*

An additional two patients (2/15, 13%) felt that it was difficult to appropriately position themselves for the photograph. One patient (1/15, 7%) did not take pictures because the app crashed when he tried to take a picture, one was not motivated to take pictures, and one felt that it was not important because the topic was not repeatedly stressed during his educational orientation.

Patients recorded their temperature more frequently, with a median of 50% (IQR 14-90) of the time. In most instances that patients did not record their temperature, they reported not having a thermometer at home. Of note, some patients recorded a temperature even when they did not have a thermometer and one patient stated that, “I kinda fibbed” and did not actually measure his temperature because, “I don’t know, I didn’t feel sick.”

Internal Versus External Motivation

The third theme relates to patients’ motivations to use the app. Seven of the 15 patients (47%) reported being able to fill out the app every day, while 8 stated that they could not. Patients gave a variety of reasons to use or not use the app, summarized in Table 4. In general, patients who used the app daily had internal motivators such as feeling connected to the app in some way or believing that the app benefited them in some way. Three of the 4 patients who used the app more than 25 times had undergone surgery for cancer. Table 2 shows the reasons patients underwent surgery divided by number of uses. Patients who used the app less frequently viewed the app as an external burden, which they would not use in the face of barriers.

Table 4. Reasons for using/not using the app.

	Relevant quotes
Reasons for daily use	
Patients felt app was personal	“Because asked about my symptoms.” “Because it said I was on the red team.”
Provided sense of security	“Kinda a little security thing, if anything going on, tells you who to contact.” “Good for me because when I check everything it tells me everything is ok.”
Felt that it would benefit research study	“I like it because maybe this way you can get some more information.”
Boredom	“A lot of times when I got bored.”
Reasons to not use daily	
Time constraints	“Just running up and down.” “I was too busy.”
Postoperative pain	“Due to my surgery, I was in a lot of pain.”
Fatigue	“Too tired.” “Didn’t feel like doing it.”
Memory	“Probably cause I forgot. I could swear I'd done it that day, then noticed the calendar wasn't filled out one day when I did it.”
Technical issues	No specific quotes

Discussion

mHealth interventions such as smartphone apps have the potential to revolutionize care coordination and communication, but limited data exist on their use in perioperative settings [18].

We found that most enrolled patients could use a postoperative symptom-tracking app and believed that it was easy to use, but a significant number did not actually use the app. Our results indicate that mHealth interventions must be designed to account for a variety of patient factors that can impact use, and we have

extended previous work by exploring these factors in the postoperative, at-home setting using a qualitative descriptive approach. These factors can be understood using the integrative model of behavioral prediction, and analyzing our results using this framework has provided several important lessons which we feel are important for developing apps targeted at postoperative patients. Ultimately, we believe that mHealth apps should be designed with patient beliefs and attitudes in mind, and those apps should use validated content and content delivery methods that can improve patient trust, activation, and use of the intervention.

A recent study by Sanger et al [31] suggested that mHealth apps designed to improve management of postdischarge complications need to enhance knowledge, self-efficacy, and communication. The same authors have recommended that postacute care apps should meet accessibility, usability, and security needs, encourage patient-centeredness, facilitate more and better communication, and facilitate personalized management [36]. Our study expands the understanding of how some of these factors may influence app use, by interviewing patients who had used a postoperative care app. The content in the app used in this study was designed with the goals of improving knowledge and communication with a high degree of patient centeredness, but was not formally validated in these domains. As such, suboptimal patient engagement in this study may be secondary to inadequacy in these previously suggested domains, or due to failure of the intervention to address other modulators of engagement such as patient attitudes and perceived norms.

Our study has some similarities to a recent study by Semple et al [32], but also had several differences. While both studies assessed the feasibility of using a patient-centered app in the postoperative period, we focused on factors that impact use. The significantly lower use rates found in our study likely stem from multiple factors. First, patients participating in our study were initially approached in the postoperative period, whereas patient in the Semple et al study were enrolled in the preoperative period. However, a large number of patients in our study were undergoing surgery for trauma or nonelective indications and therefore could not be enrolled in the preoperative period. In our study, patients were given the app at the time of enrollment rather than at a subsequent time point. Second, patients in our study were expected to provide their own device rather than using a device provided by the research team. The novelty of a free device may have led patients in the Semple et al study to use the app at an increased rate, which may not continue after patients stop recognizing the free device as a reward. Data from Liu et al [37] suggest that a one-time reward may improve initial engagement but that this engagement will not be sustained. Third, patients in the Semple et al study were given an educational booklet to guide their use of the app, while patients in our study were instructed to use the app's *Help* section if they had questions. Finally, the patient population likely differed significantly between the two studies. Our study took place at a large public hospital, which principally serves low socioeconomic status patients, and was not limited to English speakers. These differences are consistent with the reality that that mHealth interventions are not composed solely

of smartphone apps or other tools, but also of the systems that provide and support them. Factors such as the timing and method of app distribution, the intensity of education surrounding the app, and even the app's integration in the care pathway can all impact patient use because they affect attitudes and perceptions toward app use, as well as a patient's perception of their control over the app. These latter factors likely have a significant impact on patient engagement and must be accounted for when comparing interventions.

This study is notable for a low recruitment rate, reflective of its pragmatic design. The three largest groups of patients who were screened but not enrolled were patients who did not wish to participate in the study (26/115, 22.6%), patients who did not have a suitable device (20/115, 17.4%), and patients who were not introduced to the study by the treating team (17/115, 14.8%). Failure of the treating team to introduce the intervention indicates the need to target treating teams with training on any new intervention, to address concerns by the treating team about the intervention's limitations and integration in the current work flow, and to design interventions that integrate well in current workflows [38,39]. Limitations in device availability should diminish with increasing use of smartphones, but participation can also be increased by expanding the number of platforms on which a given mHealth app can run, or providing suitable devices to patients when needed. This study focused on app use after enrollment rather than barriers to recruitment, meaning it has limited ability to define strategies to improve patients' desires to enroll in mHealth interventions. A recent review from O'Connor [40], however, suggests that perceived quality of the intervention, the approach to recruitment, patient personal lives and values, and patients' personal agency and motivations can all impact recruitment to mHealth studies. The findings in this study can be understood using the integrative model of behavioral prediction, which is the latest formulation of the reasoned action approach, that includes the theory of reasoned action and the theory of planned behavior [41]. In the context of a postdischarge mHealth app, the integrative model suggests that patient use of the app and responses to the app cues (behavior) are driven by the patient's intention to use the app and respond appropriately (moderated by their actual control over doing so). The patient's intention to use the app is based on their attitude toward use, their perception of whether or not use is normal, and their perception of their own ability to use the app. Underlying these factors are the patient's beliefs about using the app, beliefs about whether or not app use is normal, and their beliefs about their ability to use the app. Comments from participants in the current study emphasize the importance of moving mHealth apps from novelty features to expected norms of clinical care.

The three themes found in our study can all be considered, using the integrative model as a framework. The first theme we encountered related to patients' app use rates in the setting of high usability ratings. High quantitative usability ratings are likely consistent with high perceived control; patients who indicate high usability likely feel that they have the capacity to use the app. Reasons for use/nonuse can then be attributed to attitudes toward use (eg, a patient in pain may not want to use the app because they feel that it is a burden), perceived norms

(eg, a patient calls when prompted because they feel that is the correct action), or actual control (eg, a patient having technical issues does not use the app). The second theme was viewing the app as a second opinion, which stems largely from behavioral and normative beliefs. Patients who described the advice given by the app as authoritative, or who stated that responding to the app was the correct behavior, also reported calling when prompted. Patients who reported feeling that they knew better than the app were unlikely to respond as directed. The third theme was internal versus external motivation, which fits with the concept of behavioral beliefs. Patients who had internal motivation to use the app (eg, patients with an oncologic diagnosis) or believed that it would be beneficial (eg, patients who reported that it provided them a sense of security) reported higher use, consistent with use being driven by a favorable attitude toward use.

Lessons Learned

We believe that there are several lessons to be learned about mHealth intervention design and implementation. These lessons are applicable to academicians, clinicians, and software developers alike.

First, mHealth interventions should be designed with consideration of patient views on the intervention's level of authority or their trust in the intervention. In this study, viewing the app as authoritative was associated with following directions provided by the app, but multiple patients reported not viewing the app as authoritative. This study did not attempt to assess elements which influence patient views on an intervention's authority, but there are likely multiple factors involved. O'Connor et al [40] suggests that a lack of trust in the information included in a digital healthcare intervention, and the lack of a clinic endorsement and support of the intervention, may pose barriers to patient engagement. For interventions with poor quality content or in cases where patients are not informed of the content's source, we theorize that patient trust will be lower than for interventions with high quality content that is presented with a clinician's endorsement of its accuracy, or an explanation of its empiric basis. Commercially available apps related to asthma, cardiovascular disease, breast cancer, pain management, headaches, eating disorders, and a variety of other topics consistently lack an appropriate empirical basis [21-23,42-44]. Evidence-based content may improve trust in an intervention and thus drive engagement, but only if the patient is informed of the content's origin. In this study, patients did not universally view the app as authoritative despite the empirical grounding of the content, but no specific effort was made to inform patients of the content's origin. We believe mHealth content should be empirically grounded and that mHealth interventions should be designed to inform patients of that empiric basis.

Second, postoperative mHealth interventions need to be adaptive to specific patient attitudes, concerns, and perceptions that may arise in the postoperative period. For example, multiple patients reported feeling uncomfortable viewing their wounds, stating that they did not like the appearance of their wounds. This discomfort appears to have decreased appropriate use of the app's wound photo functions. One patient reported

photographing their wound without first removing the bandage, indicating that discomfort with the wound rather than the inconvenience of taking the photograph likely hinders use of this function for some patients. Use of both the app and this specific function may have improved for these patients if the intervention had assessed comfort with the appearance of postoperative wounds, and provided patients who expressed discomfort with reassurance regarding the appearance of wounds and the normalcy of feeling uncomfortable when viewing such wounds. Similarly, patients who are internally motivated to recover from surgery may need minimal reinforcement to use any additional tools offered, but patients who have lower internal motivation for surgical recovery may view the app as an external burden, and might need further assurances of how the app can benefit them. The majority of our heaviest users had oncological diagnoses, suggesting that the degree of concern with potential outcomes may modulate use in this setting. Future work in postoperative care apps should further explore factors specific to this setting (eg, presence of wounds, concerns about surgical outcomes) and how they modulate engagement via mHealth interventions. Richer understanding of the interplay between such factors will allow for the creation of interventions that address individual concerns in a way that promotes engagement.

Third, while usability is important, perceptions of convenience within one's routine are equally important. Multiple patients stated that they felt too busy to use the app or that they could not use it when they felt sick. These statements may be allusions to the perception that an app is inconvenient or too distinct from what one does during a routine day. A study by Anderson et al [45] revealed patient preferences to have customizable settings including different tactile, visual, and auditory alarm choices to serve as reminders for app use. Passive data collection (ie, taking pictures) may also be preferable to active data collection that requires manual entry of information (ie, typing information), as this option reduces the effort required and time spent on app use [46]. Incorporating these features into future app development may improve the convenience of app use by integrating use into daily routines and making periods of app use shorter.

Finally, comparing our results with the available literature, we believe that implementation is critical. mHealth apps alone should not be viewed as mHealth interventions, but rather as a component of mHealth interventions. App use was lower in our study than when patients were given an app preoperatively [32], indicating that preoperative introduction of mHealth interventions is superior, but may not be feasible in an acute-care setting. Likewise, intensive education surrounding the app and distribution of educational materials with the app may improve engagement, but may be difficult to achieve in some clinical settings. We believe that optimal outcomes can only be realized when both the app and surrounding intervention target patient beliefs and attitudes, which affect patient intentions and ultimately behavior.

Limitations

This study provides insights into factors that can affect patient engagement via mHealth interventions in the postoperative period, but has some limitations. First, the intervention was

offered only in the postoperative period, which resulted in a significant number of patients not having phones available, thereby limiting participation. Second, we only interviewed patients who chose to participate, which limits our conclusions about reasons patients might refuse to use mHealth apps. Third, multiple patients responded to structured interview questions in ways that were inconsistent with their actual use of the app. These responses raise the possibility that patients were attempting to rationalize their behavior or appease the interviewer rather than convey their true impressions of the app. Interview data obtained in this study are inadequate to determine the intent of patient responses. Fourth, we did not assess all of the concepts included in the integrative model (eg, intention), which partially limits our ability to analyze our data using this model. Fifth, the app used in this study has not been validated with regard to its ability to communicate or enhance knowledge, or with regard to its usability (beyond the SUS), limiting the assessment of how these factors may have influenced use. Finally, this was a feasibility study with a small sample size and limited power to infer quantitative differences between patients who used the app frequently and those who used the

app infrequently. Despite these limitations, we believe that this study does provide novel insights into factors which influence app use, and thus can benefit clinical scientists and app developers. Similarly, this study was pragmatic, focusing on an intervention that could be provided in a postoperative setting, making our findings clinically important.

Conclusions

mHealth interventions have the potential to improve care coordination and communication after surgery. In this study, patients thought that an mHealth app that tracked symptoms after colorectal surgery was highly usable, yet actual use fell short of goals. Multiple factors appear to influence app use in this setting, including patients' opinions of the app's benefit and authority, the source of patients' motivations, and patients' perceptions of the relative importance of using the app. The integrative model of behavioral prediction provides a framework for understanding these factors and can provide insight into how to develop and test future mHealth interventions. Our future work will use the lessons we have learned in this study to optimize patient engagement via perioperative mHealth interventions.

Authors' Contributions

Dr Naik, Dr Berger, and Dr Suliburk provided critical aspects of study vision and design. Dr Naik, Dr Berger, Dr Suliburk, and Dr Alore critically revised the paper for intellectual content. Dr Scott is the first author of the manuscript, contributed to data collection and analysis, and was the primary drafter of the manuscript, tables, and figure. Dr Scott and Dr Naik performed the initial analysis of qualitative data and Dr Berger and Dr Suliburk jointly resolved any discrepancies. All authors give final approval for the version to be published.

Conflicts of Interest

Dr Scott holds a trainee grant from the Cancer Prevention and Research Institute of Texas (RP140102). Dr Suliburk holds a Gordon and Betty Moore Foundation Early-Career Investigator Award (#4603). Dr Naik receives support from a VA Health Services Research and Development Center of Innovation grant (CIN 13-413). This study was sponsored by Seamless Mobile Health, Inc. Sponsorship was limited to access to app, patient compensation, and the cost of a mobile hot-spot used to allow patients to download the app. The authors retained full editorial rights and have no other commercial interest with the sponsor. The Department of Veterans Health was not a performance site for this study and was not involved with any research activities associated with the commercial sponsor.

Multimedia Appendix 1

Semistructured interview guide.

[[PDF File \(Adobe PDF File\), 35KB - mhealth_v5i2e11_app1.pdf](#)]

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Abbreviations

ER: emergency room

IQR: interquartile range

mHealth: mobile health

SUS: System Usability Scale

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Original Paper

Apps for People With Rheumatoid Arthritis to Monitor Their Disease Activity: A Review of Apps for Best Practice and Quality

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Abstract

Background: Rheumatoid arthritis (RA) is a chronic inflammatory arthritis requiring long-term treatment with regular monitoring by a rheumatologist to achieve good health outcomes. Since people with RA may wish to monitor their own disease activity with a smartphone app, it is important to understand the functions and quality of apps for this purpose.

Objective: The aim of our study was to assess the features and quality of apps to assist people to monitor their RA disease activity by (1) summarizing the available apps, particularly the instruments used for measurement of RA disease activity; (2) comparing the app features with American College of Rheumatology and European League against Rheumatism (ACR and EULAR) guidelines for monitoring of RA disease activity; and (3) rating app quality with the Mobile App Rating Scale (MARS).

Methods: Systematic searches of the New Zealand iTunes and Google Play app stores were used to identify all apps for monitoring of RA disease activity that could be used by people with RA. The apps were described by both key metadata and app functionality. App adherence with recommendations for monitoring of RA disease activity in clinical practice was evaluated by identifying whether apps included calculation of a validated composite disease activity measure and recorded results for future retrieval. App quality was assessed by 2 independent reviewers using the MARS.

Results: The search identified 721 apps in the Google Play store and 216 in the iTunes store, of which 19 unique apps met criteria for inclusion (8 from both app stores, 8 iTunes, and 3 Google Play). In total, 14 apps included at least one validated instrument measuring RA disease activity; 7 of 11 apps that allowed users to enter a joint count used the standard 28 swollen and tender joint count; 8 apps included at least one ACR and EULAR-recommended RA composite disease activity (CDA) measure; and 10 apps included data storage and retrieval. Only 1 app, Arthritis Power, included both an RA CDA measure and tracked data, but this app did not include the standard 28 tender and swollen joint count. The median overall MARS score for apps was 3.41/5. Of the 6 apps that scored $\geq 4/5$ on the overall MARS rating, only 1 included a CDA score endorsed by ACR and EULAR; however, this app did not have a data tracking function.

Conclusions: This review found a lack of high-quality apps for longitudinal assessment of RA disease activity. Current apps fall into two categories: simple calculators primarily for rheumatologists and data tracking tools for people with RA. The latter do not uniformly collect data using validated instruments or composite disease activity measures. There is a need for appropriate, high-quality apps for use by rheumatologists and patients together in co-management of RA.

KEYWORDS

mHealth; mobile applications; telemedicine; self-management; rheumatoid arthritis

Introduction

Rheumatoid arthritis (RA) is a systemic inflammatory disease characterized by a symmetrical polyarthritis due to immune-mediated inflammation of synovial tissue [1,2]. The symptoms include painful and swollen joints with fatigue and morning stiffness. Uncontrolled polyarthritis can damage cartilage and bone [1,2]. Therefore, long-term treatment with disease-modifying antirheumatic drugs to control inflammation is required, ideally under the supervision of a rheumatologist [1]. The disease course can be unpredictable, with periods of relatively lower disease activity interspersed with flare-ups. Treatment response is also unpredictable with marked individual variation in drug effectiveness or adverse effects, and there are changes in efficacy over time. Regular follow-up and monitoring of patient disease activity to guide treatment is required to achieve RA remission or low disease activity state [3] and patient-centered care is important in the optimal management of RA [4]. Guidelines recommend that rheumatologist assessment of RA disease activity should include some or all of the validated measures of disease activity or patient physical function, and a composite disease activity measure, such as the Disease Activity Score including 28 joints (DAS28) [3,5].

Mobile health (mHealth) is a rapidly growing area of health care delivery, where mobile devices, particularly via mobile apps on smartphones, are used to support medical and public health practice [6]. mHealth apps may be useful tools for patient self-management, as well as for facilitating improved communication between patients and health care providers [7]. In the United States, over two-thirds of adults own a smartphone [8]. mHealth is therefore increasingly accessible, and there are now numerous health-related smartphone apps available [9,10]. For chronic conditions such as RA, mHealth may provide a way for patients to become more actively involved in their disease management. In a Portuguese study, 86 of 100 people with RA agreed that a smartphone app for RA self-management would be useful [11]. Younger age, current smartphone ownership, and use of email, Internet, and short messaging services were all associated with willingness to use apps for RA self-management. A small Japanese study reported that patient self-reported disease activity data using validated instruments correlated well with rheumatologist-assessed RA disease activity [12]. Furthermore, there is some evidence that mHealth interventions such as smartphone apps may improve outcomes for people with other chronic diseases [7,13,14].

With an increasing number of mHealth apps available, potential users need to be able to determine the quality of health-related apps. A systematic literature review demonstrated that many health apps did not adhere to evidence-based guidelines and did not involve medical experts during development [15]. When assessing app quality, users currently have little information beyond the description of the app and a star rating. Therefore, they may rely on an app that is not based on best practice or

medical evidence and could even be unsafe. As mHealth apps become pervasive, it is important that users can make informed decisions about the apps they use.

Recently, the Mobile App Rating Scale (MARS) was developed as a tool for classifying and rating the quality of mHealth apps [16]. The 23 items in the MARS were identified from a review of existing criteria for rating app quality. Each item was rated on a 5-point scale (1=inadequate, 2=poor, 3=acceptable, 4=good, and 5=excellent) with descriptors provided for each anchor rating. The MARS grouped the items in 4 categories: engagement (5 items), functionality (4 items), aesthetics (3 items), and information quality (7 items), as well as 1 subjective quality scale (4 items). The MARS was scored with a mean for each of the categories and an overall mean score. The MARS demonstrated good internal consistency and inter-rater reliability and provided a reliable method to rate and compare mobile apps [16,17].

Since mHealth apps have the potential to allow people with RA to monitor their RA disease activity, it is important to assess the features and quality of smartphone apps currently available. Apps that collect disease activity data using validated disease activity instruments may be useful in facilitating management with a rheumatologist by measuring medically credible RA activity between visits and potentially enabling some care to be provided via telehealth [18,19].

The objective of this study was to determine whether there are existing high-quality apps for monitoring RA disease activity that use validated, recommended measurement instruments, have functionality to share these data with the treating rheumatologist, and are currently available for public use. The specific aims of this review were to assess the features and quality of apps designed to assist people to monitor their RA disease activity by: (1) summarizing the available apps and the key features, particularly the instruments used for measurement of RA disease activity; (2) comparing the app features with guidelines for monitoring of RA disease activity; and (3) rating app quality according to the MARS. This will enable informed decisions about app use and may identify gaps or deficiencies in the mHealth apps for RA disease activity monitoring currently available.

Methods

App Identification

A systematic search of the New Zealand iTunes and Google Play stores was conducted on April 1, 2016, to identify all potentially relevant apps. The search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews [20]. Search terms included “arthritis” OR “rheumatoid” OR “RA” OR “rheumatoid arthritis” OR “rheumatic.” The app store description of each identified app was read and compared with the inclusion and exclusion criteria. Apps were included if they

were: (1) a smartphone-based app; (2) capable of running on Android or iOS operating systems; (3) in English language; (4) useful for people with RA or to assist clinical care of people with RA; and (5) available for download in the New Zealand app store (iTunes or Google Play). Apps were excluded if: (1) a condition other than RA was targeted; (2) app content was for information, education, or reference only (ie, no data entry); (3) the app included only treatment algorithms; or (4) it was explicitly only for clinician use. When an app was found in both the Google Play and iTunes store, both versions were included so any differences between operating systems could be identified. Android apps (New Zealand Google Play store) were downloaded and tested using 2 Samsung Galaxy J1 Ace phones equipped with Android version 5.1.1. iOS apps (New Zealand iTunes store) were downloaded and tested using iPhones (4s and 6) with iOS 9.1 installed.

Since the New Zealand app stores may not include all potentially relevant apps, the United States, the United Kingdom, Australia, and Canada iTunes stores were also searched for eligible apps

by conducting the search using the terms “rheumatoid arthritis” on the website fnd.io [21]. “Rheumatoid arthritis” was used as the sole search term, as this returned almost all apps found in the main search and did not identify any additional apps.

Data Extraction

The following data about all apps were recorded: app name, platform (Android, iOS), developer, current version, size, cost, number of installs, and user star ratings. Functional features were noted descriptively.

Comparison of Apps to Rheumatoid Arthritis Management Recommendations

App adherence with relevant recommendations for monitoring of RA disease activity in clinical practice from the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) was evaluated [3,5]. This was determined by operationalizing the recommendations and determining whether present or not present in each app (Table 1).

Table 1. Recommendations from the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) for rheumatoid arthritis (RA) disease activity monitoring.

Organization	Recommendation	Instruments required	Composite disease activity score	Adherence by app present if:
ACR ^a [5]	The use of ACR-recommended validated composite measures of disease activity is needed to treat to target in clinical practice.	PtG ^c , PhG ^d , HAQ ^e , 28TJC ^f , 28SJC ^g , CRP ^h , ESR ⁱ	Patient-driven tools: PAS ^j ; PAS-II ^k , RAPID-3 ^l Patient + provider: CDAI ^m Patient + provider + laboratory: DAS28 ⁿ , SDAI ^o	One or more of composite disease activity scores were calculated by the app, using the validated component instruments.
EULAR ^b [3]	The use of validated composite measures of disease activity, which include joint assessments, is needed in routine clinical practice to guide treatment decisions. Measures of disease activity must be obtained and documented regularly, as frequently as monthly for patients with high or moderate disease activity or less frequently (such as every 6 months) for patients in sustained low-disease activity or remission.	PtG, PhG, HAQ, 28TJC, 28SJC, CRP, ESR	PAS, PAS-II, RAPID-3, SDAI, CDAI, and DAS28 (CRP or ESR)	One or more of composite disease activity scores were calculated by the app, using the validated component instruments. Users were able to record disease activity on multiple occasions with data recorded and retrievable within the app.

^aACR: American College of Rheumatology.

^bEULAR: European League Against Rheumatism.

^cPtG: patient global assessment of disease activity.

^dPhG: physician global assessment of disease activity.

^eHAQ: health assessment questionnaire.

^f28TJC: 28 tender joint count.

^g28SJC: 28 swollen joint count.

^hCRP: C-reactive protein.

ⁱESR: erythrocyte sedimentation rate.

^jPAS: patient activity scale.

^kPAS-II: patient activity scale II.

^lRAPID-3: routine assessment of patient index data.

^mCDAI: clinical disease activity index.

ⁿDAS28: disease activity index.

^oSDAI: simple disease activity index.

App Rating Using the MARS

All apps were rated by two independent reviewers (HT and BW) using the MARS [16]. Before app assessment, the two reviewers discussed the use of the MARS in the context of apps for people with RA. The target group was determined to be “all people with RA aged 18 years or older; some familiarity with smartphone technology.” As recommended by the developers of the MARS, the reviewers considered all items of the MARS and confirmed that all were applicable to apps for RA, and that no additional app-specific items were required [16]. The reviewers also viewed the training video developed by Stoyanov et al.

Before assessing all the apps identified in the search, both reviewers assessed and discussed an excluded app to ensure shared understanding of the MARS items and process. The reviewers then independently rated all apps using the MARS. Before scoring each app, the reviewers used each app for at least ten minutes to gain an adequate understanding of the app functionality. Apps were tested on April 11, 2016, using the app version downloaded on April 1, 2016. Any issues or uncertainties about specific apps were discussed, and consensus was reached.

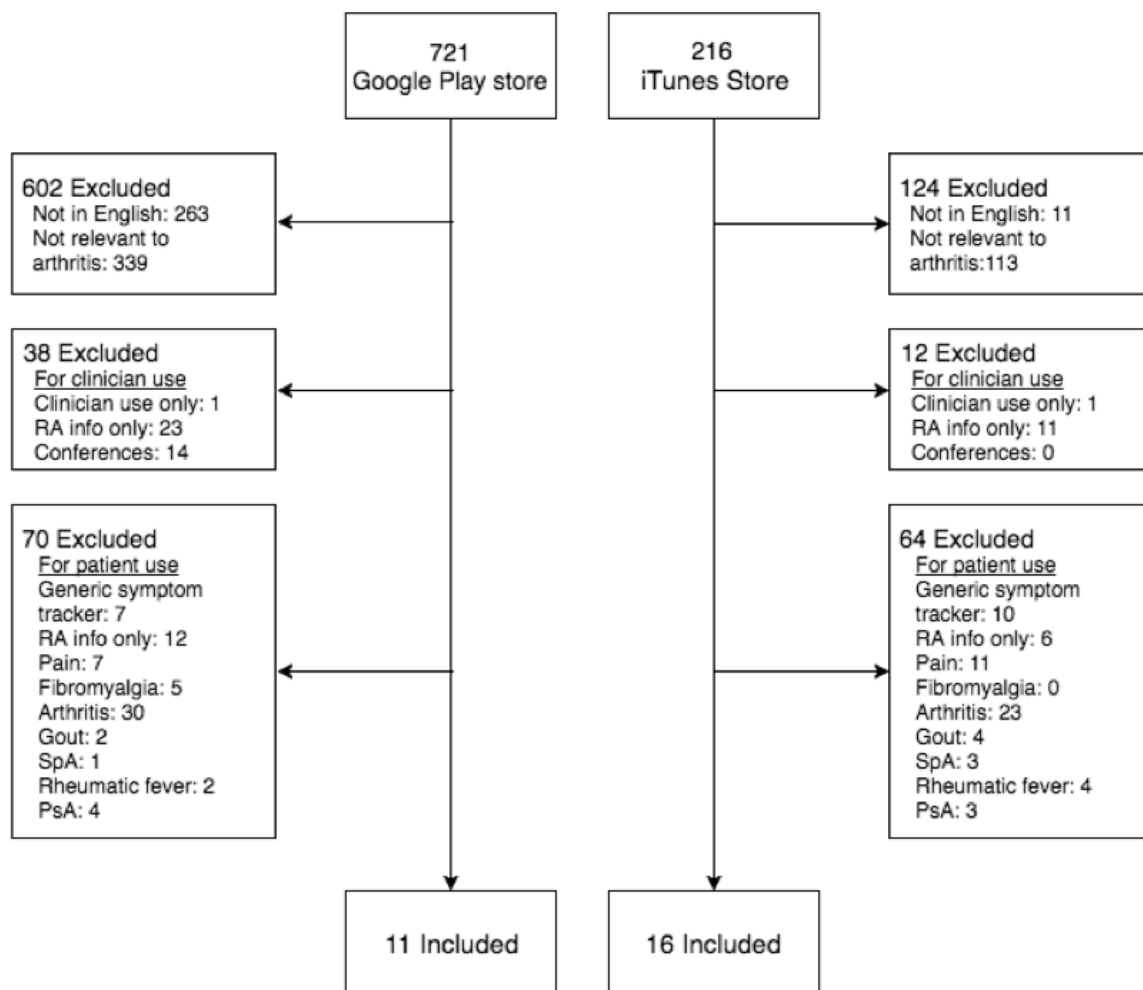
Scores were calculated for each MARS item, along with a total mean score. The mean score from two reviewers was calculated. No apps had been tested in clinical studies. Therefore, MARS item 19 “evidence base” was excluded from calculations. Inter-rater reliability of the MARS subscales and total quality score were calculated using the intraclass correlation coefficient (ICC) in SPSS Version 20.0 (IBM Corp; 2-way random-effects model of absolute agreement between single ratings).

Results

Systematic Search for Apps

The search retrieved 721 Android apps from the Google Play store. Of these, 710 were excluded, leaving 11 apps for analysis (Figure 1). A total of 216 iOS apps were retrieved from the iTunes app store. After exclusion of 200 apps, 16 apps remained for analysis. No further apps were found in the find.io search of the United States, the United Kingdom, Australia, and Canada iTunes stores. As 8 apps were available in both operating systems, a total of 19 different apps were included, of which 18 were free apps (Rheumatoid Arthritis Diary was available for NZD \$6.39 for Android and NZD \$6.49 for iOS).

Figure 1. Flow diagram of systematic search and selection of app from Google Play and iTunes stores.



Characteristics and Functions of Included Apps

The information on app platform, developer, version, and size are shown in Table 2. Since no apps had different functionality between operating systems, the apps are presented only once in Tables 2-6. The app description, target user (as derived from the app store description), Android installs, and Android star rating are shown in Table 3. None of the iOS apps included had the minimum of 5 reviews from users in New Zealand required on the New Zealand iTunes store before a star rating is provided. Table 4 shows joint count data entry and main functionality in the apps. Eleven apps allowed users to enter a joint count, either

by selecting joints on a homunculus (n=4) or by entering the number of joints (n=7). Seven of these apps included the standard 28 swollen and tender joint count and primarily functioned as disease activity measure calculators, with no capacity to store or track data. The remaining 4 apps with other joint counts (Cliexa-RA, myRA, RheumaTrack RA, and RAPA) all had additional patient-focused functions, such as recording fatigue, and storage and tracking of imputed data. Fourteen apps included calculation of a RA disease activity measure. Six apps allowed export of patient data, including via email (n=5), spreadsheet (n=2), or to a website (n=2).

Table 2. Operating system, developer, version, and size of included apps.

App	Operating system	Developer	iOS version ^a	iOS size (MB)	Android version ^a	Android size (MB)
Arthritis Power	iOS	Jeffrey Curtis	1.2.1	3.5	–	–
Cliexa-RA ^b	iOS	CN4CE, LLC	1.01	12.6	–	–
DAS Calculator for Rheumatologists	iOS	Greg Fiumara	1.13	0.596	–	–
DAS28 ^c -Rheumatoid Arthritis	Android	Tantor Systems	–	–	2.5	0.52
DAS28 Calculator	iOS	Rheumatology LMU	2.1	0.654	–	–
DAS28 Calculator	Android	Owl Studios	–	–	2.1	1.4
DAS28/ACR-EULAR criteria	iOS	Keiji Matsui	3.1	0.2	–	–
DAS28 Free	Android	Esdras Beleza de Noronha	–	–	1.0.	0.762
myRA	iOS	Crescendo Bioscience Inc	1.7	3.3	–	–
myRAteam	Android, iOS	MyHealthTeams Inc	10.10.0	4.7	10.10.a	1.8
RA Helper	Android, iOS	Modra Jagoda	2.1	4.9	1.2	3.4
RAISE	Android, iOS	Publicis Development-Arthritis Ireland	1.0.3	16.7	1.0.3	7.3
RAPA ^d	Android, iOS	Jacsomedia Ltd	1.0.	3.7	4	2.0
Rheuma Helper	Android, iOS	Modra Jagoda	2.3	3.3	2.3	2.7
Rheumatoid Arthritis Diary	Android, iOS	cellHigh	1.6.7	15	1.6.4	2.6
Rheumatoid Arthritis Patient Companion	iOS	Point of Care	3.27.6	10.4	–	–
RheumaTrack RA	Android, iOS	Axovis GmbH	2.0.7	10.5	2.0.9	5.6
RheumInfo HAQ ^e -II Calculator	iOS	Bitcurve Systems	1	1.2	–	–
TRACK and REACT	Android, iOS	Arthritis Foundation	1.8	5.6	1.3	2.2

^aversion available on April 1, 2016.

^bRA: rheumatoid arthritis.

^cDAS28: disease activity score 28 joints.

^dRAPA: RA Patient Application.

^eHAQ: health assessment questionnaire.

Table 3. Description, target user, Android installs, and star rating of included apps.

App	Description	Target user	Android in-stalls ^a ($\times 10^4$)	Android star rating
Arthritis Power	Input data to monitor disease	People with arthritis	–	–
Cliexa-RA ^b	Input data to monitor disease	People with RA	–	–
DAS Calculator for Rheumatologists	DAS28 calculator	Clinicians	–	–
DAS28 ^c -Rheumatoid Arthritis	DAS28 calculator	Clinical practice or trials	10-50	4.1
DAS28 Calculator	DAS28 calculator	Not stated	–	–
DAS28 Calculator	DAS28 calculator	Not stated	1-5	3.4
DAS28/ACR-EULAR criteria	Various calculators	Not stated	–	–
DAS28 Free	DAS28 calculator	Clinicians	1-5	3.6
myRA	Input data to monitor disease	People with RA	–	–
myRAteam	Social media for people with RA	People with RA	1-5	4.5
RA Helper	Input data to monitor disease	People with RA	1-5	4.3
RAISE	Patient monitor exercise and pain levels	People with RA	0.1-0.5	2
RAPA ^d	Input data to monitor disease	People with RA	0.1-0.5	4.7
Rheuma Helper	Calculator with info for rheumatologists	Clinicians	0.1-0.5	4.4
Rheumatoid Arthritis Diary	Input data to monitor disease	People with RA	0.05-0.1	–
Rheumatoid Arthritis Patient Companion	Input data to monitor disease	People with RA	–	–
RheumaTrack RA	Input data to monitor disease	People with RA	10-50	4.2
RheumInfo HAQ ^e -II Calculator	HAQII calculator	Not stated	–	–
TRACK and REACT	Patient monitor exercise and pain levels	People with RA	10-50	3.3

^aInstall data available only for Android in Google Play store, as of search date on April 1, 2016.

^bRA: rheumatoid arthritis.

^cDAS28: disease activity score 28 joints.

^dRAPA: RA Patient Application.

^eHAQ: health assessment questionnaire.

Table 4. Joint count and other functionality of included apps.

App	Joint count		Data entered	Composite disease activity measure	Other functions
	Number	Measure			
Arthritis Power			Medication, sleep, exercise, fatigue	✓	Email data, export to website
Cliexa-RA ^a	26	S ^e , T ^f	Medication	✓	
DAS Calculator for Rheumatologists	28	S, T		✓	
DAS28 ^b -Rheumatoid Arthritis	28	S, T		✓	
DAS28 Calculator	28	S, T		✓	
DAS28 Calculator	28	S, T		✓	
DAS28 Free	28	S, T		✓	
DAS28/ACR-EULAR criteria	28	S, T		✓	
myRA	44	p ^g	Medication, lab ^e		Reminders, email data, RA info ^f
myRAteam			Free text		Within app social media function
RA Helper			Medication, lab		Reminders
RAISE			Pain, activity,		Email data, RA info
RAPA ^c	28	S	Work, fever	✓	RA info
RheumaHelper	28	S, T		✓	RA info
Rheumatoid Arthritis Diary			Medication, lab, pain, symptoms, activity, triggers, sleep, mood		Email data, export to spreadsheet
Rheumatoid Arthritis Patient Companion			Medication, lab, mood, symptoms, activity	✓	Reminders, share data with clinician, RA info
RheumaTrack RA	52	S, P	Medications, morning stiffness, work, exercise, infection	✓	Email data, export to spreadsheet
RheumInfo HAQ ^d -II Calculator				✓	
TRACK and REACT			Medication, stiffness, joint function, social, exercise, energy	✓	Export to website

^aRA: rheumatoid arthritis.

^bDAS28: disease activity score 28 joints.

^cRAPA: RA Patient Application.

^dHAQ: health assessment questionnaire.

^eS: swollen.

^fT: tender.

^gP: pain.

^eLab: laboratory data.

^fRA info: rheumatoid arthritis information.

Comparison of Apps to Rheumatoid Arthritis Management Recommendations

App inclusion of the component measurement instruments, composite disease activity measures calculated, and app functionality to record and retrieve data over time (as recommended by ACR and EULAR [3,5]) are shown in Table

5. Eight apps included at least one recommended composite measure of RA disease activity. Only 1 of these 8 apps provided the formulae for calculation of the composite disease activity measures (RheumaHelper), which were confirmed to be the correct formulae. Ten apps included a function allowing data to be recorded and retrieved. One app, Arthritis Power, included both 1 composite disease activity measure and allowed data

recording and retrieval, but this app did not have functionality to record a 28 tender or swollen joint count.

Table 5. App inclusion of the rheumatoid arthritis (RA) activity measures and component measurement instruments.

App	ACR and EULAR-endorsed instruments or laboratory measures	ACR and EULAR-recommended composite disease activity measure	Equation provided for composite disease activity measure	Allows users to record and retrieve disease activity data on multiple occasions
Arthritis Power	PtG ^c , Pain VAS ^d	RAPID-3 ^j	No	History, graph
Cliexa-RA ^a	PtG, ESR ^f			History, graph
DAS Calculator for Rheumatologists	PtG, CRP ^g , 28SJC ^h , 28TJC ⁱ	DAS28 ^m	No	
DAS28-Rheumatoid Arthritis	PtG, ESR, CRP, 28SJC, 28TJC	DAS28	No	
DAS28 Calculator	PtG, CRP, 28SJC, 28TJC	DAS28	No	
DAS28 Calculator	PtG, 28SJC, 28TJC	DAS28	No	
DAS28 Free	PtG, CRP, 28SJC, 28TJC	DAS28	No	
DAS28/ACR-EULAR criteria	PtG, Pain VAS, ESR, CRP	DAS28, CDAI ^l , SDAI ^k	No	
myRA	ESR, CRP			History, graph
myRAteam				History
RA Helper	ESR, CRP			History, graph
RAISE				History, graph
RAPA ^b	Pain VAS			History, graph
RheumaHelper	PtG, CRP, 28SJC, 28TJC	DAS28, CDAI, SDAI	Yes	
Rheumatoid Arthritis Diary	ESR, CRP			History, graph
Rheumatoid Arthritis Patient Companion				History, graph
RheumaTrack RA				History, graph
RheumInfo HAQ-II Calculator	HAQ ^e			
TRACK and REACT	Pain VAS			History, graph

^aRA: rheumatoid arthritis.

^bRAPA: RA Patient Application.

^cPtG: patient global assessment of disease activity.

^dVAS: visual analog scale.

^eHAQ: health assessment questionnaire.

^fESR: erythrocyte sedimentation rate.

^gCRP: C-reactive protein.

^h28SJC: 28 swollen joint count.

ⁱ28TJC: 28 tender joint count.

^jRAPID-3: routine assessment of patient index data.

^kSDAI: simple disease activity index.

^lCDAI: clinical disease activity index.

^mDAS28: disease activity index 28 joint count.

MARS Rating of Apps

MARS ratings for included apps are shown in [Table 6](#). The ICC for MARS ratings was greater than or equal to 0.69 for all MARS sections. For overall MARS ratings, the ICC was .93 (95% CI 0.76-0.98) for Android apps and .82 (95% CI 0.55-0.94) for iOS apps, confirming good inter-rater reliability. The overall MARS scores for the apps ranged from 1.98 to 4.62, indicating large variation in the quality of apps. Engagement

(1.6-4.8) and aesthetics (1.17-4.67) showed greatest variability. Of the 6 apps that scored $\geq 4/5$ on the overall MARS rating, only 1 (RheumaHelper) included a composite disease activity score endorsed by ACR and EULAR, but this app did not have a data tracking function. Of the other 5 apps scoring $\geq 4/5$ on the overall MARS rating (myRA, RAISE, myRAteam, Rheumatoid Arthritis Patient Companion, and RheumaTrack RA), 2 allowed entry of CRP and ESR but no other validated RA disease activity instruments were included in these apps. Arthritis Power, the

only app that included an ACR and EULAR–recommended composite disease activity score and tracked results had an overall MARS score of 3.41.

Table 6. Mean mobile app rating scale (MARS) ratings of included apps.

App name	MARS ^a categories											
	Engagement (5 items)		Functionality (4 items)		Aesthetics (3 items)		Information (7 items)		Subjective (4 items)		Overall MARS mean score	
	Android	iOS	Android	iOS	Android	iOS	Android	iOS	Android	iOS	Android	iOS
Arthritis Power		3.60		3.13		3.33		3.58		2.25		3.41
Cliexa-RA ^b		3.20		4.00		3.83		3.42		2.38		3.61
DAS Calculator for Rheumatologists		3.00		5.00		4.00		3.40		2.63		3.85
DAS28 ^c -Rheumatoid Arthritis	1.70		3.25		2.17		3.25		1.50		2.59	
Das28 Calculator		2.70		4.38		3.50		3.35		2.13		3.48
Das28 Calculator	1.60		3.00		1.17		2.00		1.25		1.94	
DAS28/ACR-EULAR criteria		1.70		3.75		1.33		2.33		1.25		2.28
DAS28 Free	2.20		4.38		3.00		2.92		2.25		3.13	
myRA		4.80		4.50		4.67		4.50		4.38		4.62
myRAteam	4.50	4.50	3.63	3.63	4.00	4.00	4.33	4.33	4.25	3.75	4.11	4.11
RA Helper	2.20	2.20	4.00	4.00	4.17	4.17	2.42	2.42	1.50	1.50	3.20	3.20
RAISE	4.00	4.00	4.38	4.38	4.34	4.34	4.25	4.25	3.25	3.25	4.24	4.24
RAPA ^d	2.40	2.40	3.00	3.00	2.67	3.00	3.34	3.34	1.75	1.75	2.85	2.93
Rheuma Helper	3.60	3.60	4.88	4.88	4.33	4.33	4.25	4.25	4.00	4.00	4.26	4.26
Rheumatoid Arthritis Diary	3.60	3.60	2.50	2.50	1.83	1.83	3.08	3.08	2.50	2.50	2.75	2.75
Rheumatoid Arthritis Patient Companion		4.40		3.63		4.00		4.58		3.13		4.15
RheumaTrack RA	3.80		4.63		4.50		4.42		4.50		4.34	
RheumInfo HAQ ^e -II Calculator		2.20		4.13		2.67		2.80		1.38		2.95
TRACK and RE-ACT	3.90	3.90	2.75	2.75	2.83	2.83	3.75	3.75	2.63	2.63	3.31	3.31
Reliability of MARS rating												
Two-way random effects ICC using absolute agreement between single ratings (95% CI)	0.93 (0.77-0.98)	0.92 (0.79-0.97)	0.87 (0.60-0.96)	0.83 (0.57-0.94)	0.91 (0.69-0.97)	0.87 (0.47-0.96)	0.83 (0.51-0.95)	0.83 (0.51-0.94)	0.80 (0.43-0.94)	0.69 (0.15-0.89)	0.93 (0.76-0.98)	0.82 (0.55-0.94)

^aMARS: mobile app rating scale.

^bA: rheumatoid arthritis.

^cDAS28: disease activity score 28 joints.

^dRAPA: RA Patient Application.

^eHAQ: health assessment questionnaire.

Discussion

Principal Findings

This review of apps for monitoring disease activity in people with RA showed that there are broadly two categories of apps available: apps for calculation of validated disease activity measures and those for people with arthritis to track symptoms. Many symptom-tracking apps did not use validated instruments. Apps that focused on calculations of a disease activity measure tended to only perform that function. One app, myRAteam, provided an environment in which people with RA could connect and share updates about their symptoms. Other less commonly encountered app functions included setting reminders and information sharing with a clinician, either via email or through a linked app. The latter is essential for an app to facilitate telehealth. Six apps allowed email or sharing of data, and only 1 of these apps provided a mechanism for sharing specifically with a clinician. This indicates a lack of apps suitable for large-scale telehealth management of RA.

Only one app, Arthritis Power, included both a symptom-tracking function and calculation of an ACR and EULAR-recommended composite measure of RA disease activity. However, Arthritis Power did not include a joint count function. Some apps appear to perform both functions, but include an incorrect version of a disease activity measure, for example, a 28 swollen joint count without a tender joint count (eg, RAPA). Overall, 14 apps provided a composite disease activity score, but only 8 apps used the correct component instruments to calculate the composite disease activity measure and therefore provided an ACR- and EULAR-recommended composite measure. A common reason for measures to not meet the latter criterion was the use of a joint count that did not specify tender and swollen as the joint abnormalities of interest or did not count the 28 joints required for a DAS-28. Some apps recording joint symptoms may be useful for people with RA to monitor their symptoms, but could not be used in a remote monitoring telehealth care service. People with RA wishing to monitor their own symptoms should be encouraged to choose apps, which use validated instruments and have a tracking function, such as Arthritis Power.

There were no apps that scored $\geq 4/5$ on the overall MARS and included all ACR and EULAR endorsed disease activity instruments. This could be because apps are designed with either people with RA or rheumatologists as target users where patients do not usually perform joint counts and doctors would not usually need to store patient data in a mobile phone. The MARS scores had a wide range indicating highly variable quality of apps in terms of user experience. Future app development should occur with cooperation between software developers and key stakeholders. Software developers should optimize user experience in collaboration with people with RA, while doctors can ensure app adherence with best-practice evidence-based medicine. Item 19 of the MARS, "evidence base," was excluded from all calculations because no apps had been studied in clinical trials, as specified by Stoyanov et al [16]. Therefore any future apps developed for RA disease activity monitoring should be assessed in clinical trials to determine the impact on

clinical outcomes for people with RA and cost-effectiveness and undergo external quality review [22].

Limitations

This study had a number of limitations. Only apps available in New Zealand app stores and in English language were included. An app for patient-led monitoring of RA disease activity has been developed in Japanese, which includes ACR and EULAR recommended instruments and diseases activity measures [12]. However, a preliminary search of the iTunes stores of 4 other English-speaking countries with the term "rheumatoid arthritis" suggested that the search of the New Zealand app stores has captured all relevant apps in the English language.

App quality was assessed using the MARS. The MARS is a recently developed tool and has not been extensively validated. However, it has now been used in several other app evaluations [17,23,24], and as in this study, the MARS has consistently proven good inter-rater reliability. App quality was also assessed by considering whether apps complied with ACR and EULAR RA management recommendations. There may have been other criteria that could have been used to assess app quality. Assessment of data security is not included in the MARS but is one commonly considered criterion of health software quality not included in this study [25]. Data security considerations are of utmost importance but will need to be considered within the regulatory requirements of the country in which the app is being used. The integration of health behavior theory concepts into app design and function, which has been used as a measure of quality, was also not considered in this study [26,27].

The recommended RA composite disease activity (CDA) scores include those with exclusively patient-reported outcomes (eg, RAPID 3 and PAS) and those that combine patient-reported outcomes and physician-performed tender and swollen joint counts. Remote telehealth monitoring of disease activity for people with RA assumes either that disease activity is derived from patient-reported outcomes or that patient self-performed joint counts will provide sufficiently accurate assessments of RA disease activity. Patient-performed joint counts do correlate moderately with physician-performed joint counts [28]. However, further validation of the assumption that patient-performed joint counts will be sufficient for longitudinal measurement of RA disease activity is required.

Comparison With Prior Work

The findings of this study suggest that currently available RA apps for RA disease activity monitoring are of variable quality and generally do not comply with RA management guidelines. Many other studies of health apps have found that most apps do not comply with evidence-based guidelines [29-31]. Like RA, inflammatory bowel disease requires ongoing management by a specialist physician and has a variable, unpredictable clinical course. A comprehensive analysis of apps for inflammatory bowel disease (IBD) identified that only 54% (14/26) provided a symptom-tracking function and only 19% (5/26) had medical input during app development [32]. Eight apps were specifically for providing information about IBD. When information about IBD included in these apps was compared with the minimum information set of 14 statements

recommended to be shared with people with IBD, only 38% of these statements had complete coverage in the apps [32]. Similarly, a review of apps for people with gout, another common form of chronic arthritis, found only 1 of 6 relevant apps included all recommendations for patient-focused quality care of gout [33]. These studies suggest that the lack of a comprehensive, guideline-compliant app for RA is part of a wider paucity of high-quality health apps available.

The inclusion of persuasive principles, aimed to support positive behavioral change, has been considered as a measure of app quality in a recent systematic analysis of apps for chronic arthritis [34]. In the 28 assessed apps, a mean of only 5.8 of 37 persuasive principles per app was found with social support techniques (eg, social media, user forums) and sophisticated dialogue support techniques (eg, praise, rewards) largely absent. This suggests that the design process for future for RA should consider evidence-based persuasive techniques.

Conclusions

This review indicated the lack of high-quality apps available to assist in the management of RA, particularly the longitudinal assessment of RA disease activity. Only 1 app of the 19 identified in this study had functionality to allow both calculation of a validated composite disease activity measure and tracking of the calculated patient data. No available apps

meet the aforementioned criteria along with inclusion of 28 tender and swollen joint counts. Thus, current apps fall into two categories: simple calculators for rheumatologists and data tracking tools for people with RA. The latter do not uniformly collect data using validated composite disease activity measures. Apps that were rated highly according to the MARS tended to collect only patient-reported outcomes.

The rheumatology professional workforce is inadequate to meet current population rheumatology health care needs. Since demand for care is predicted to increase, adoption of different models of care provision will be necessary [18,35,36]. These are likely to include telehealth and an increased emphasis on participatory health care where people with RA are active agents in the management of RA. Developing apps that are attractive, engaging, simple to use, and having functionalities relevant to the clinical management of the health condition will require collaboration between rheumatologists, people with RA, app developers, and health systems, and due consideration of local regulatory environment, health service delivery, and user experience [22]. Once apps are developed, assessment of the validity and accuracy of self-performed joint counts will be required along with demonstration of equivalent health outcomes for people with RA whose care is provided with a mixed face-to-face and telehealth approach.

Authors' Contributions

HT and RG wrote the draft manuscript. All authors discussed the draft and provided comments and suggestions for change. All authors approved the final report.

Conflicts of Interest

None declared.

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Abbreviations

ACR: American College of Rheumatology
Apps: applications
CDA: composite disease activity
CDAI: clinical disease activity index
DAS28: disease activity score 28 joints
EULAR: European League Against Rheumatism
HAQ: health assessment questionnaire
ICC: intraclass correlation coefficient
Lab: laboratory data
MARS: mobile app rating scale
mHealth: mobile health
NZ: New Zealand
P: pain
PAS: patient activity scale
PAS-II: patient activity scale II
PhG: physician global assessment of disease activity
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PtG: patient global assessment of disease activity
RA: rheumatoid arthritis
RA info: rheumatoid arthritis information
RAPID-3: routine assessment of patient index data
SDAI: simple disease activity index
T: tender
28TJC: 28 tender joint count
28SJC: 28 swollen joint count

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Original Paper

Support for Sustainable Use of Personal Health Records: Understanding the Needs of Users as a First Step Towards Patient-Driven Mobile Health

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Abstract

Background: The tethering of a personal health record (PHR) to an electronic medical record (EMR) may serve as a catalyst in accelerating the distribution of integrated PHRs. Creating shared health records for patients and their health care professionals using self-administered functions of EMR-tethered PHRs is crucial to support sustainable use of the system.

Objective: This study assesses the factors related to active use of a self-administered function (Health Notes) in an EMR-tethered PHR (Health4U) in a tertiary academic hospital.

Methods: This research is a cross-sectional study conducted in a tertiary academic hospital in South Korea. The enrollees included adults aged 19 years and older with experience accessing Health4U in the 13-month period after June 2013. The primary outcome was the adoption of Health Notes in accordance with the number of chronic diseases. Socio-demographic variables were included as confounding factors.

Results: Subjects 71 years of age and older were less likely to become active users of Health Notes than those 30 years and younger. Moreover, compared with men, women had 44% and 40% lower tendencies to become Health Notes users and active users, respectively. Those who accessed the desktop page and/or mobile page had higher tendencies to become users of Health Notes. We found a consistent increase in the odds ratio as the number of chronic diseases increased in the active users. When considering specific diseases, patients who had cancer or chronic kidney disease had higher tendencies to become users of Health Notes.

Conclusions: Patients with a greater number of chronic diseases tended to use PHR more actively, and used the self-administered function. Women and the elderly may have lower tendencies to actively use PHR. Therefore, items specific to the health of each demographic—women, the elderly, and those with chronic diseases—should be carefully considered to support sustainable use of PHRs.

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KEYWORDS

electronic health record; medical informatics; personal health record; hospital information systems

Introduction

Google Health was discontinued in January 2012, less than 3 years after its inception [1,2]. Google's original intent was to disseminate consumer-centric values that it had successfully established in other areas within the field of health care by providing users with an opportunity to access all personal health records (PHRs) and useful health information. However, Google soon realized that, in contrast to its initial expectation, people who used the service were limited to a small number of users with interests in information technologies [1]. Google's candid confession clearly suggested the limitations of a standalone PHR.

In a symposium organized by the American Medical Informatics Association's College of Medical Informatics in 2005, participants concluded that an electronic medical record (EMR)-tethered PHR can provide greater value than a standalone PHR [3]. A standalone PHR presents many challenges, particularly with information accountability; as information entry is solely dependent on the users' ability to periodically update their information, failure to do so will likely be ineffective [3,4]. Conversely, if PHRs were connected to EMRs, patients would have the benefit of being able to take advantage of a system that automatically generated their personal health information during their visitation to the hospital via the connected Hospital Information System. Compared with a standalone PHR, higher-quality and objective information can be provided by an EMR-tethered PHR. In addition, this type of system can process hospital data in diverse formats and can provide the data directly to the patients [5]. However, patients may lack initiative to manage their medical information actively if they are only given information that is automatically generated by the EMR, and if they are not provided with perceptive value to use PHRs [3]. Therefore, EMR-tethered PHRs should offer a convenient way for both patients and physicians to create a shared records database and provide self-administered features, which may be the first step in supporting the sustainable use of

PHRs, in terms of providing patients with consumer-centric values [6,7].

Although EMR-tethered PHRs have been attempted in many medical institutions, only a few studies have been conducted on how the system can be served to improve self-administered functions. We can overcome the shortcomings of EMR-tethered PHRs by analyzing the gap between patients' needs and self-administered functions, in an effort to sustain users' interest.

This study explored the features of EMR-tethered PHRs used in Seoul National University Bundang Hospital (SNUBH) in South Korea, and investigated the demographics of the frequent users of the self-administered features in EMR-tethered PHRs. Based on the findings, this study also suggests additional functions that can be incorporated into the system of EMR-tethered PHRs in the future.

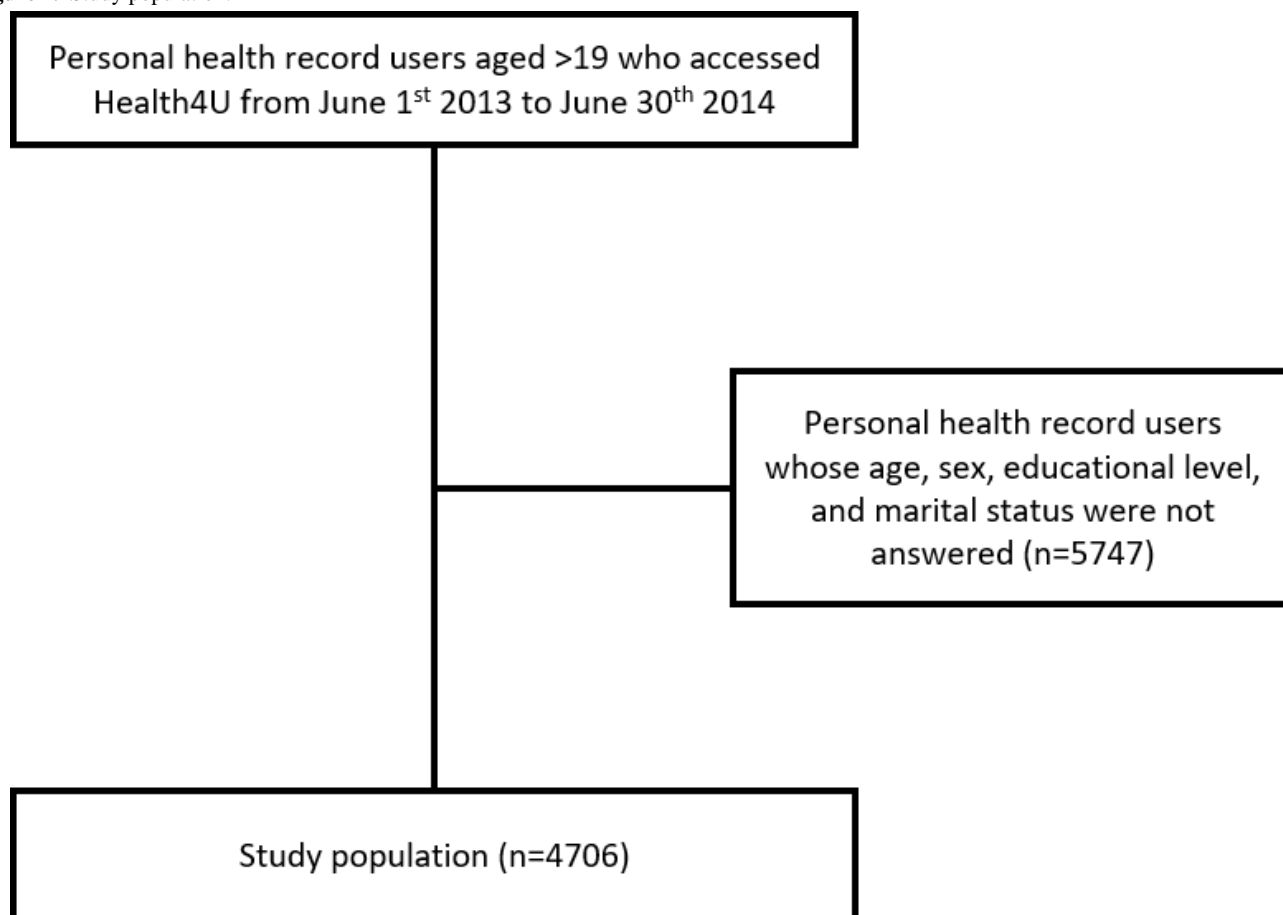
Methods

Development Process of Electronic Medical Record-Tethered Personal Health Records

A task-force team was established to conduct a needs-analysis and develop PHRs with the name of *Health4U*. Health4U was established based on the needs of users, mainly composed of five parts: visit history, prescription history, drug notification, laboratory results, and management of self-administered component (called the *Health Notes*). Patients can record their daily blood pressure, blood sugar, amount of exercise, and body weight in the Health Notes [8].

Study Population

This study used cross-sectional data extracted from a clinical data warehouse of SNUBH. The enrollees were selected from adults aged 19 years and older with prior experience accessing Health4U in the 13-month period after June 2013, when the service was first initiated. A total of 4706 users of Health4U were included in this study (Figure 1).

Figure 1. Study population.

Observation and Statistical Analysis Method

The following socio-demographic variables were included: age, gender, educational level, marital status, religion, method used to access Health4U, and main services utilized. Age was divided into 10-year increments for comparison. Educational level was categorized into three groups: middle school and lower, high school degree, and college degree and above. The access method was also divided into three groups: access by mobile application only (mobile-only group), access by personal computer website only (desktop-only group), and access with both (desktop-mobile group). The services used for the analysis included the number of views for treatment history, prescription information, medication reminders, test results, and Health Notes.

Users of Health4u were defined as individuals who accessed the system once or more. Users of Health Notes were defined as those who used the feature once or more, and nonusers were defined as those who did not use Health4U. Active users of Health Notes were defined as those who used the feature three times or more. The factors associated with becoming a Health Notes user or active user were investigated using univariate analyses.

Diseases that the Health Notes users had can be considered as important factors for improving the self-administered features of EMR-tethered PHRs. In this study, diabetes, hypertension,

dyslipidemia, obesity, and chronic kidney disease were included as representative chronic diseases, and acute coronary syndrome was included as a representative acute disease.

A multivariate logistic regression analysis was performed to adjust for potential confounding factors. In the first model, an analysis was conducted using the number of chronic diseases that showed a *P*-value of less than 0.25 as a covariate in a univariate analysis. In the second model, an analysis was performed using each disease as a covariate. *P*-values of less than 0.05 were considered statistically significant, and Stata 13.0 (Stata Corp., College Station, TX, USA) was used for statistical analyses. This study was approved by the Institutional Review Board at the SNUBH. The requirement of informed consent was waived because we used nonidentified retrospective data.

Results

Use of Health4U

Among the 4706 users of Health4U included in this study, 373 users accessed both the mobile application and the website, while 2459 users accessed the mobile application only, and 1874 users accessed the website only. The age groups were distributed between 10-21%. Men used Health4U more than women (2444/4706, 51.93%; [Table 1](#)).

Table 1. Baseline characteristics.

Characteristics	Number	Percentage
Age		
19-30	500	10.62
31-40	974	20.70
41-50	989	21.02
51-60	965	20.51
61-70	654	13.90
71 or more	624	13.26
Gender		
Male	2444	51.93
Female	2262	48.07
Education level		
Middle school and lower	330	7.01
High school degree	1489	31.64
College degree and above	2887	61.35
Having spouse		
No	864	18.36
Yes	3842	81.64
Modes of access		
Mobile only	2459	52.25
Desktop only	1874	39.82
Both	373	7.93
Components (mean)		
View visit history	6.17	
View prescription history	2.39	
View drug notification	3.47	
View laboratory result	14.15	
View Health Notes	5.43	

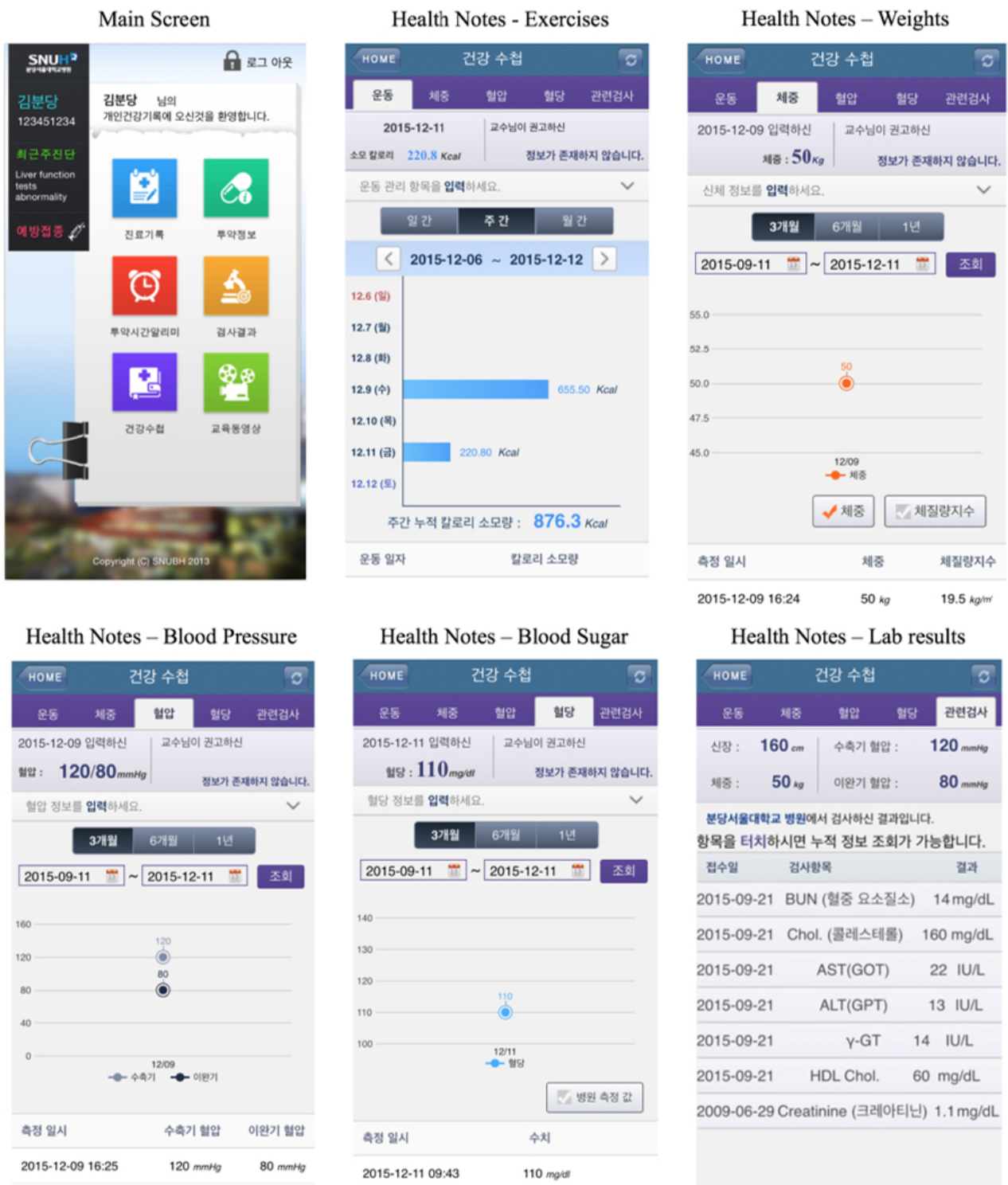
The function most commonly utilized by the users was to view test results, with an average of 14.15 views. The need for viewing Health Notes was third most commonly used, with an average of 5.43 views.

Self-Administered Functions of Health4U (Health Notes)

Health Notes were developed to include five main components (Figure 2). Users can input their daily amount of exercise to

compare it to their doctor's recommendations. Amounts of exercise can be monitored weekly and monthly, and users can manage their daily weight, height, blood pressure, and blood sugar. Additionally, users can monitor these data every 3, 6, and 12 months, and can also see their laboratory results related to their diseases.

Figure 2. Main screen of mobile Health4U, and five key components of Health Notes: amount of exercise, weight and height, blood pressure with measurement time, blood sugar with measurement time, and laboratory results relevant to users' current medical status.



Analysis of the Health Notes Completion Traits

Both users and active users of Health Notes were an average of >3 years younger than nonusers and nonactive users, respectively. The age group of 61 years and older had a lower tendency to become users of Health Notes compared to the 19-30-year age group. Women completed Health Notes 50% less frequently than men, and the group with an educational level of college degree and above completed Health Notes more than the group with middle school education or below. The

desktop-only group and the desktop-mobile group had higher tendencies to become users of Health Notes, compared with the mobile-only group.

Regarding disease association, those who had diabetes, dyslipidemia, cancer, obesity, chronic kidney disease, or acute coronary syndrome had higher tendencies to become users or active users of Health Notes. Those who had a greater number of chronic diseases had higher tendencies to become users and active users of Health Notes (Multimedia Appendix 1).

After adjusting for covariates in the first model, the age group of 61 years and older had a lower tendency to become users of Health Notes; the age group of 71 years and older had a lower tendency to become active users than the age group of 30 years and younger. Compared with men, women had 44% and 40% lower tendencies to become Health Notes users and active users, respectively. The desktop-only group or desktop-mobile group had higher tendencies to become users of Health Notes, and the desktop-mobile group had a higher tendency to become active

users than the mobile-only group. Although we found a consistent increase of odds ratios as the number of chronic diseases of Health Notes users increased, the results showed a statistical significance when they had 1 chronic disease or 3 chronic diseases. Regarding active users, we found a consistent increase of odds ratios as the number of chronic diseases increased, with statistical significance when they had 1 or more chronic diseases (Table 2).

Table 2. Multivariable analysis of the factors associated with completing Health Notes in Health4U (Model 1).

Variable	Health Notes Usage		Health Notes Active Usage	
	Adjusted Odds Ratio (95% CI)	P-Value	Adjusted Odds Ratio (95% CI)	P-Value
Age				
19-30	1		1	
31-40	0.91	.71	0.80	.54
41-50	0.92	.78	0.83	.62
51-60	0.82	.51	0.99	.99
61-70	0.43	.018	0.54	.18
71 or more	0.24	.001	0.28	.02
Gender				
Male	1		1	
Female	0.56	<.001	0.60	.009
Education level				
Middle school and lower	1		1	
High school degree	1.22	.66	1.66	.50
College degree and above	1.35	.51	1.65	.48
Having spouse				
No	1		1	
Yes	0.91	.64	0.67	.14
Modes of access				
Mobile only	1		1	
Desktop only	1.66	.002	1.29	.25
Both	7.01	<.001	5.94	<.001
Number of chronic diseases				
0	1		1	
1	1.68	.007	2.41	<.001
2	1.72	.065	2.77	.003
3	6.83	<.001	6.99	.001
4	8.78	.164	1	Not applicable

In the second model, it was found that the difference in age, gender, and method of access was similar to that of the first model; the group with cancer and chronic kidney disease had

higher tendencies to become Health Notes users or active users (Table 3).

Table 3. Multivariable analysis of the factors associated with completing the health notes in Health4U (Model 2).

Variable	Health Notes Usage		Health Notes Active Usage	
	Adjusted Odds Ratio (95% CI)	P-Value	Adjusted Odds Ratio (95% CI)	P-Value
Age				
19-30	1		1	
31-40	0.88	.64	0.77	.45
41-50	0.90	.72	0.84	.64
51-60	0.80	.45	0.980	.96
61-70	0.40	.011	0.53	.16
71 or more	0.23	.001	0.24	.012
Gender				
Male	1		1	
Female	0.56	<.001	0.58	.008
Education level				
Middle school and lower	1		1	
High school degree	1.29	.58	1.89	.32
College degree and above	1.42	.44	1.80	.35
Having spouse				
No	1		1	
Yes	1.12	.58	1.51	.13
Modes of access				
Mobile only	1		1	
Desktop only	1.63	.003	1.32	.21
Both	6.58	<.001	5.45	<.001
Diabetes				
No	1		1	
Yes	1.24	.347	1.39	.25
Dyslipidemia				
No	1		1	
Yes	1.36	.19	1.58	.12
Cancer				
No	1		1	
Yes	1.38	.031	1.57	.021
Obesity				
No	1		1	
Yes	2.11	.072	1.77	.29
Chronic Kidney Disease				
No	1		1	
Yes	2.75	.001	4.00	<.001
Acute Coronary Syndrome				
No	1		1	
Yes	1.39	.24	1.26	.53

Discussion

In this study, we have revealed a significant association between the use of a self-administered function of an EMR-tethered PHR and the number of chronic diseases the users had. Regarding specific diseases, patients who had cancer or chronic kidney disease had higher tendencies to become users or active users of Health Notes. Additionally, we found that those who were 61 years and older had a lower tendency to become Health Notes users compared to those who were 30 and younger. Men were more likely to become Health Notes users than women, and those who accessed the desktop page were more likely to become Health Notes active users compared to those who only accessed the mobile page.

Differences in Health Notes Completion by Age

Our findings, with respect to the generation gap in the use of Health Notes, were similar to a previous study [9,10]. Accordingly, older adults lacking experience with technology encountered greater problems using PHRs [9,10]. Elderly people tend to have lower income and lower literacy for new technology compared to younger people, as indicated by previous studies [11,12]. A previous study also revealed that low-income elderly would not receive benefits from PHRs due to poor technical skills, low literacy, and limited cognitive/physical ability [13,14]. Due to the differences in PHR usage by age, which can lead to health inequality between generations, a feature must be developed to enhance the accessibility and usability of Health Notes for older adults.

Differences in Health Notes Completion by Gender

Women had a lower tendency to become Health Notes users or active users. A report by the Broadband Commission Working Group revealed that there exists a gap in the use of information technology between men and women, and that approximately 200 million fewer women (compared to men) access information technology on the Internet globally [15]. Therefore, items specific to women's health, or efforts to promote campaigns that target women, should be developed to overcome gender differences in Health Notes usage. PHR functions for health care during pregnancy and postmenopausal periods are viable options.

Differences in Health Notes Completion by Method of Access

The group that used Web-based PHRs tended to be active users of Health Notes, highlighting the importance of allowing users to easily administer their own health information. Most of the items that can be entered into Health Notes require measurement equipment, such as individual physical measurements, as well as blood pressure and blood sugar. Such equipment is often placed in the vicinity of a personal computer (in a home or office), making it more likely that the resulting information is entered by accessing the Web-based PHR; after measuring their values, it is relatively easy for patients to enter this information directly into the PHR system. When using the mobile PHRs, health information must be entered using a smartphone's virtual keyboard. Using this method, information can be entered from anywhere, especially when personal computers are not an option.

Differences in Health Notes Completion by the Presence of Chronic Diseases

In the first model, we found that those who had more chronic diseases tended to become active users of Health Notes. This study indicates that patients with chronic diseases have a higher desire to use Health Notes. However, a previous study revealed that it has remained impossible to conclude that the use of PHRs can be effective for improving chronic diseases [16].

In addition, a previous study on the use of the Internet in diabetes management suggested that the frequency of website use for diabetes management decreased over time [17]. Taken together, although patients with a chronic disease tend to actively use PHRs, it is insufficient to assert that using such a feature (when installed in an existing PHR) can translate to significant improvements in health outcomes. Patients with chronic diseases may also encounter barriers to the continual use of PHRs. One solution to this problem might be to provide patients with easy opportunities to visualize how the management of their blood pressure, body weight, and blood sugar can affect their chronic disease by relying on more specific values (eg, cardiovascular risk scores) and providing these values to patients. For example, if diabetic patients are provided with their annual test results (including a retinal examination, microalbuminuria test, and renal function test), as well as imaging tests taken at the hospital (eg, carotid sonogram, coronary angiography, and brain magnetic resonance imaging/angiogram) and a comprehensive report, they may become more motivated to actively manage their health via PHRs.

In the second model, which analyzed each disease separately, patients with cancer or chronic kidney disease had higher tendencies to become users or active users of Health Notes. However, it was found that health diaries lacked a sufficient number of items to help cancer patients manage their health. One future option could be to implement a feature in which cancer patients under treatment can record their health conditions, or a feature that reminds cancer survivors that it is time for postcancer examinations. One study demonstrated that the rates of mammogram screening and flu vaccination increased when a reminder was provided via a standalone PHR for health maintenance [18]. Other insufficient items were observed for the management of chronic kidney disease. A feature that could inform the residual renal function would be helpful for sustaining the interest of patients with chronic kidney disease.

In 2010, the Obama administration rolled out a five-year plan for making doctors and hospitals move to electronic health records (EHRs), which are closely related to precision medicine and personalized medicine [19-21]. As of 2013, 78% of office-based doctors used some form of EHR system, up from 18% in the United States in 2001 [22]. The transition to EHRs has augmented the scope of medical record-based information [23,24]. However, quantitative development has not guaranteed qualitative improvement because the quality of the data entered remained unchanged [20]. PHR development and adoption can hasten EHR distribution and upgrade the quality of EHR by providing crucial values to patients, physicians, and health care providers. The goal of these efforts is to provide

patient-centered, timely, and efficient health care. A previous study showed that creating shared health records for patients and their health care professionals can improve patients' ability to become active partners in their own health care [6]. Another study showed that patients wanted to improve the doctor-patient relationship by actively using PHRs [25]. However, thus far, PHRs themselves are facing a huge barrier to continuous development [5,26,27]. There have been many studies conducted to improve PHRs [16,18,28,29], yet only a few studies have been conducted in which patients used the self-administered features of EMR-tethered PHRs, which can enable shared health care and patient-centered practice. If we fail to understand the needs of PHR users, PHRs would inevitably fail to satisfy the users' needs. As a first step to move from rudimentary standalone PHRs to integrated PHRs, EMR-tethered PHRs can offer clues about how we can improve PHRs by implementing patient-centric features in the system.

As the first hospital to attain Healthcare Information and Management System Society Stage 7 status outside of North America, SNUBH introduced a comprehensive EHR to all divisions of the hospital in 2003, launching a connected PHR service in 2013 [30]. Through this study, based on this EHR-friendly circumstance, we have suggested for the first time that users with more chronic diseases tend to use PHR more actively, and regularly utilize the self-administered function. This finding can play a crucial role in developing future functions of PHRs.

Future Directions

First, PHRs must integrate a feature that enhances the accessibility and usability of the self-administered function for older adults. Second, items specific to women's health should be created to overcome the gender differences in PHR usage. Third, PHR functions for each chronic condition should be made to promote PHR usage for patients with chronic diseases. Finally, to maximize mobile device usage of self-administered functions, one solution would be to use a method that

automatically transmits the data measured from a blood pressure monitor, a blood glucose monitor, or a body weight scale to the mobile device via Wi-Fi, without requiring the user to enter the information directly. The incorporation of Wi-Fi capabilities into medical devices could lead to reduced health care costs, while allowing medical teams to obtain patients' health information in real time [31].

Limitations

There are limitations in generalizing the results of this study, due to the fact that the study only involved one university hospital. However, because this study was focused on the use of EMR-tethered PHRs at a large hospital, where the use of EMRs has been in place for more than 10 years, these results will serve as important data for medical institutions that intend to develop the same features, or for national agencies planning to develop integrated PHRs.

This is a cross sectional study, making it difficult to find causal relationships, and the study lacks information on the precise improvement in the health outcomes of PHR users or those who completed Health Notes. This limitation should be offset by further studies. To examine the effects on health outcomes, an analysis is needed regarding the related diseases of those who actively used Health Notes in EMR-tethered PHRs, and the features of PHRs need to be expanded according to the diseases. Hence, this study is relatively significant as it presents the direction of PHR development for the future.

Conclusion

This is the first study that discovered the factors related to the completion of a self-administered function of PHRs tethered to a comprehensive EHR, which can be considered as one of the important determinants of active use of PHRs. The finding that patients with more chronic diseases tended to be active users of PHRs can serve as the basic data for enhancing the features of an EMR-tethered PHR system in the future.

Acknowledgments

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Authors' Contributions

SYJ and KHL designed the study, analyzed the data, and drafted the manuscript as first authors. SY and HB contributed to the discussion of data. JK contributed to the analyses of data. HH supervised the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Univariate analysis of the factors associated with completing Health Notes in Health4U.

[[PDF File \(Adobe PDF File\), 45KB - mhealth_v5i2e19_app1.pdf](#)]

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Abbreviations

EHR: electronic health record

EMR: electronic medical record

PHR: personal health record

SNUBH: Seoul National University Bundang Hospital

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Original Paper

Clinical Evaluation of the Measurement Performance of the Philips Health Watch: A Within-Person Comparative Study

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Abstract

Background: Physical inactivity is an important modifiable risk factor for chronic diseases. A new wrist-worn heart rate and activity monitor has been developed for unobtrusive data collection to aid prevention and management of lifestyle-related chronic diseases by means of behavioral change programs.

Objective: The objective of the study was to evaluate the performance of total energy expenditure and resting heart rate measures of the Philips health watch. Secondary objectives included the assessment of accuracy of other output parameters of the monitor: heart rate, respiration rate at rest, step count, and activity type recognition.

Methods: A within-person comparative study was performed to assess the performance of the health watch against (medical) reference measures. Participants executed a protocol including 15 minutes of rest and various activities of daily life. A two one-sided tests approach was adopted for testing equivalence. In addition, error metrics such as mean error and mean absolute percentage error (MAPE) were calculated.

Results: A total of 29 participants (14 males; mean age 41.2, SD 14.4, years; mean weight 77.2, SD 10.2, kg; mean height 1.8, SD 0.1, m; mean body mass index 25.1, SD 3.1, kg/m²) completed the 81-minute protocol. Their mean resting heart rate in beats per minute (bpm) was 64 (SD 7.3). With a mean error of -10 (SD 38.9) kcal and a MAPE of 10% (SD 8.7%), total energy expenditure estimation of the health watch was found to be within the 15% predefined equivalence margin in reference to a portable indirect calorimeter. Resting heart rate determined during a 15-minute rest protocol was found to be within a 10% equivalence margin in reference to a wearable electrocardiogram (ECG) monitor, with a mean deviation of 0 bpm and a maximum deviation of 3 bpm. Heart rate was within 10 bpm and 10% of the ECG monitor reference for 93% of the duration of the protocol. Step count estimates were on average 21 counts lower than a waist-mounted step counter over all walking activities combined, with a MAPE of 3.5% (SD 2.4%). Resting respiration rate was on average 0.7 (SD 1.1) breaths per minute lower than the reference measurement by the spirometer embedded in the indirect calorimeter during the 15-minute rest, resulting in a MAPE of 8.3% (SD 7.0%). Activity type recognition of walking, running, cycling, or other was overall 90% accurate in reference to the activities performed.

Conclusions: The health watch can serve its medical purpose of measuring resting heart rate and total energy expenditure over time in an unobtrusive manner, thereby providing valuable data for the prevention and management of lifestyle-related chronic diseases.

Trial Registration: Netherlands trial register NTR5552; <http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=5552> (Archived by WebCite at <http://www.webcitation.org/6neYJgysl>)

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KEYWORDS

sedentary lifestyle; monitoring, ambulatory; monitoring, physiologic; accelerometry; actigraphy; photoplethysmography; heart rate; energy metabolism; adult; humans

Introduction

With the increase in passive transportation, spectator-based entertainment, and decreases in energy expenditure through decreased activity during occupational and household work, modern life has evolved to eliminate many forms of physical labor that were prevalent in earlier times [1,2]. Together with the rise in sedentary lifestyles, the incidence of chronic and noncommunicable diseases (NCDs) such as cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes has risen. According to the World Health Organization (WHO), NCDs kill 38 million people each year [3]. Of those NCD deaths, 16 million occur “prematurely” before the age of 70 years. With 17.5 million per year, cardiovascular diseases account for most NCD deaths, followed by cancers (8.2 million), respiratory diseases (4 million), and diabetes (1.5 million). Modifiable behavioral risk factors for NCD development include tobacco and alcohol use, unhealthy diet, and insufficient physical activity [3]. Dietary risk factors and physical inactivity collectively accounted for 10% of global disability-adjusted life years in 2010 [4]. Additionally, approximately 3.2 million deaths annually can be attributed to insufficient physical activity, making this a primary candidate for low-cost interventions aimed at preventing and controlling the impact of NCDs. Guideline and recommendation documents based upon extensive literature reviews from the WHO, European Society of Cardiology, American College of Sports Medicine (ACSM), American Heart Association, American College of Cardiology, American Diabetes Association, and US Preventive Services Task Force all come to the same conclusion regarding physical activity and health: a sufficient level of physical activity is key in primary and secondary prevention of chronic lifestyle-related diseases [5-19]. For adults, at least 150 minutes of moderate to vigorous physical activity in bouts of at least 10 minutes in duration per week is generally recommended by the aforementioned organizations [6,9-14,16,17,20,21].

To help people act on physical activity recommendations, accurate assessment of the intensity, for example, expressed as energy expenditure, and duration of their physical activity is required. Currently, a considerable number of devices are on the market that enable this assessment by their users. These devices predominantly operate using accelerometers to estimate energy expenditure. Recently, technology has advanced, enabling inclusion of a photoplethysmography (PPG) sensor in these devices for the measurement of heart rate. Data from this additional sensor can enable more accurate estimations of energy expenditure because heart rate has been shown to have a linear relationship with oxygen consumption (a measure for energy expenditure) during moderate- and high-intensity activity [22-24]. Using PPG to derive heart rate from the blood volume pulse observed in the microvascular tissue [25], by exploiting the inverse relationship between blood volume and amount of light reflected, has been used for decades in clinical applications such as pulse oximetry and vascular diagnostic tools [26]. The

accuracy of the PPG-derived heart rate estimation compared with electrocardiogram (ECG)-based reference measurements has been validated as highly reliable [26-29]. However, when considering energy expenditure, more variable performance of the multisensor technology devices has been observed [27,30]. For instance, Lee et al [30] observed a mean absolute percentage error (MAPE) of 23.5% for the Basis B1 multisensor device.

Another device exploiting multisensor technology for energy expenditure estimation is the Philips health watch, which makes use of the Philips Cardio and Motion Monitoring Module (CM3-Generation-3), an accelerometer as well as a PPG sensor module developed by the Philips Wearable Sensing Technologies (WeST) division. Its purpose is seamless daily monitoring of heart rate and physical activity and deriving clinically relevant parameters such as total energy expenditure, resting heart rate, step count, and types of activity performed. Tracking these parameters enables self-care and (automated) coaching in health plans complying with aforementioned guidelines, to minimize the risk of developing chronic lifestyle-related diseases and to manage existing morbidity. Monitoring of physical activity as done with the Philips health watch can give users important feedback regarding their daily status on overall activity level, including activity intensity and duration.

Next to heart rate and total energy expenditure, resting heart rate is an important clinical parameter, which the Philips health watch estimates as well. Systematic reviews and meta-analyses indicate that high resting heart rate is an important risk factor for adverse health outcomes, including all-cause mortality, cardiovascular mortality, cardiovascular diseases, and type 2 diabetes [31-35]. In addition to being an informative risk factor, resting heart rate has been demonstrated to be a modifiable treatment outcome [36-47]. Although drug therapy has been shown to result in the largest decline in elevated resting heart rate, exercise therapy has also been shown to reduce resting heart rate [41-44]. Measuring and monitoring resting heart rate, and preventing long-term increases in an individual's resting heart rate by suitable exercise therapy, can therefore support reduction of the risk of adverse health outcomes. In clinical context, resting heart rate is generally measured by asking a person to sit or lie down for 5-15 minutes, during which the heart rate is measured. The heart rate after a short settling period is then considered to be representative of the resting heart rate [48-50]. It should be noted that this resting heart rate measurement is influenced by the duration of the resting period before taking the measurement, posture, and environmental conditions [50,51]. The Philips health watch derives resting heart rate values automatically from continuous heart rate measurements throughout the day, applying automatic selection of periods where a user is in a resting state but not asleep.

The aim of this study was to evaluate performance of total energy expenditure and resting heart rate measures of the health watch. Secondary objectives were to assess the performance of

the Philips health watch with respect to its continuous measurement of heart rate, the estimation of respiration rate at rest and the number of steps a user takes, and the correct classification of activity types: walking, cycling, running, and other.

Methods

Study Design and Compliance

The study was designed as a within-person comparative study where parameters estimated by the Philips health watch (DL8791, Philips, Stamford, CT, USA) were compared with measurements of reference devices. The study was performed in compliance with ISO (International Organization for Standardization) 14155 “Clinical investigation of medical devices for human subjects – Good clinical practice,” the Declaration of Helsinki, and local regulations. An independent medical ethics committee (METC Brabant) approved the study and it was registered in the Netherlands Trial Registry (NTR5552). Before participation all subjects gave written informed consent.

Objectives

The primary objective of this study was to determine, in a clinical study, the accuracy of the Philips health watch regarding the estimation of total energy expenditure and resting heart rate. Secondary objectives included the assessment of accuracy of other output parameters of the monitor: heart rate, step count, activity type, and respiration rate at rest.

Study Population

For this study, adult (≥ 18 years) participants with a body mass index between 19 and 35 kg/m² were recruited from the Dutch general population. Respondents with any of the following criteria were excluded from participation in the study: pregnancy, presence of skin conditions or wounds in the wrist area, presence of a chronic disease for which a physician had contraindicated moderate-intensity exercise without medical supervision, presence of a pacemaker or other implantable electronic device, or presence of a functional or cognitive impairment preventing compliance with the study protocol.

Clinical Procedures

For each participant, the study started with an evaluation of his or her eligibility based on the inclusion and exclusion criteria and, if positive, giving informed consent. Then participants completed the Fitzpatrick skin type questionnaire [52] and received detailed information about the study procedure and the health watch that they received. Subsequently, a participant wore the health watch at home for 3 days during which he or she could carry out his or her normal daily life activities to gather free-living data; participants did not wear reference devices during the free-living period. The participants then performed a laboratory test comprising a variety of daily life

activities, during which data were collected using both the health watch and various reference devices. The purpose of this laboratory test was to assess the accuracy of multiple health watch parameters compared with reference measurements.

The standardized laboratory protocol comprised the following activities: (1) indoor activities including rest (watching television) for 15 minutes and treadmill (4.5 km/h), treadmill uphill 5% (3 km/h), ergometer bike (60 rpm), cross trainer (60 W), household activities (mixture), desk work, lying down, and standing for 3 minutes each and (2) outdoor activities including walking, cycling, and running for 3 minutes each.

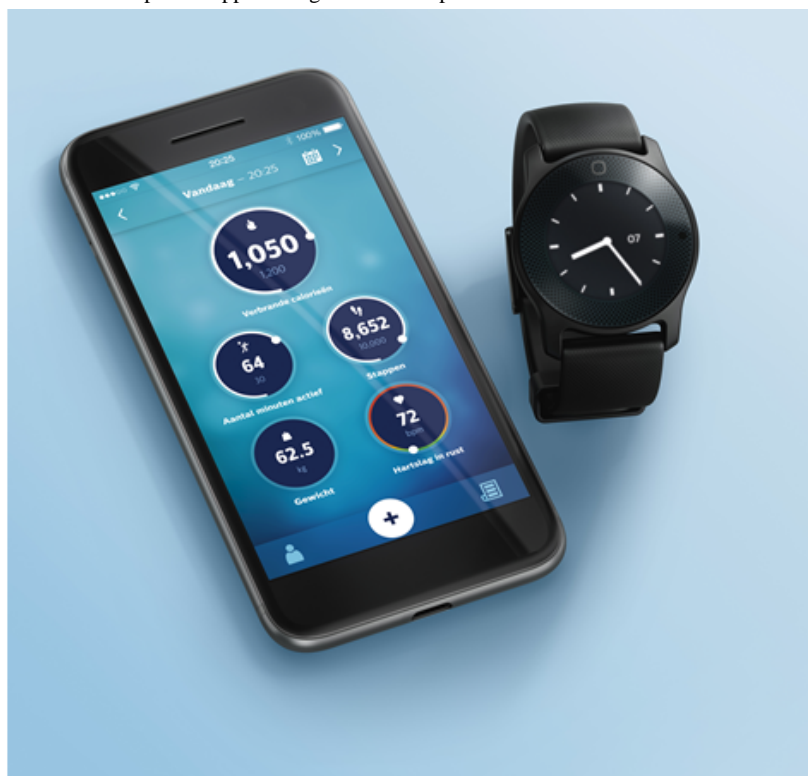
After each activity, there was at least 3 minutes of rest. The 15 minutes of rest at the start of the protocol was included for measuring resting heart rate in the laboratory and respiration rate at rest. The data from this activity were included in the cumulative energy expenditure that was analyzed for the primary objective. During this period, participants were sitting on a chair while watching an emotionally neutral documentary on a television. The mixture of household activities consisted of three 1-minute subactivities: washing dishes, folding towels and handkerchiefs, and vacuum cleaning.

If the outside temperature was less than 10°C (to remain compliant with the K4b² instructions for use) or when it was raining, the outdoor activities were performed indoors. That is, participants walked in the corridors at their own pace, cycled at their own pace on the ergometer bike, and ran on the treadmill at a pace that they set themselves. This occurred for 8 participants. Participants were asked to eat a light breakfast or lunch before the test, to not take caffeine or smoke in the 2 hours before their appointment, and to not carry out intense physical activity in the period before the test.

Investigational Device and Comparators

The investigational device for this study was the Philips health watch, a wrist-worn, PPG-based, heart rate and activity monitor (Figure 1). The watch measures the health parameters at a 1-Hz sampling rate and displays real-time heart rate values and daily cumulative values for steps, active energy expenditure, and total energy expenditure. The 1-minute average values for heart rate, and cumulative steps and energy expenditure over 1 minute, are logged in internal memory and transmitted via Bluetooth to a phone running the companion app for 24/7 monitoring. The companion app displays the parameters over time to provide insights to the user by, for instance, color coding optimal or suboptimal parameter values based on personalized settings that are automatically determined from international standards (i.a. WHO and ACSM) and based on user input and input from the health watch. Additionally, based on a user's personal program for achieving, for instance, a certain daily energy expenditure, coaching cards pushed via the app provide further insight and motivation to promote behavior change toward a healthier lifestyle.

Figure 1. The Philips health watch with companion app running on a mobile phone.



Total Energy Expenditure

For total energy expenditure, the medical reference instrument was a K4b² (COSMED, Rome, Italy). The K4b² is a portable gas analysis system that was designed to be worn during (sports) activities. This instrument has been shown to be valid for the measurement of total energy expenditure [53,54]. For registering heart rate by the K4b² device, participants wore a Polar T34 chest strap (Polar Electro Inc, Lake Success, NY, USA). For assessment of total energy expenditure estimation accuracy of the Philips health watch, cumulative total energy expenditure over the entire laboratory protocol as estimated by the Philips health watch was compared against cumulative total energy expenditure measured by the K4b².

Resting Heart Rate

The Actiwave Cardio (CamNtech, Cambridge, UK) was the reference device for resting heart rate. It is a single-channel ECG waveform recorder that participants wore (only) during the laboratory protocol and it reported heart rate at a frequency of 1 Hz. Following current recommendations [50,51,55], resting heart rate was acquired from the 15-minute rest at the beginning of the laboratory protocol for the Philips health watch as well as the Actiwave Cardio because no reference measurements were taken during the free-living period. Resting heart rate was derived by taking the lowest 5-minute median heart rate value (determined using a sliding-window approach; that is, taking a subset of the data, with a length of 5 minutes, that stepped forward through the data at 1-second increments) during the rest period where participants were watching television for the Actiwave as well as the health watch. The lowest 5-minute median was chosen to derive resting heart rate values that were

minimally influenced by measurement artifacts or disturbances of the resting condition of a participant.

In addition, the free-living heart rate and resting heart rate data were visually evaluated for all participants to verify that the automatic resting heart rate estimation of the health watch did indeed reflect participants' heart rate in resting conditions.

Heart Rate

For assessing the accuracy of heart rate, the health watch heart rate was evaluated over the whole duration of the laboratory protocol. For this purpose, based on the 1-Hz sampled values, mean heart rate values were calculated for 10-second nonoverlapping epochs for the duration of the laboratory protocol for both the reference device (Actiwave Cardio) and the Philips health watch. These data were then compared between devices to determine error values and coverage values, which were defined as the percentage of time the difference between both devices (either absolute in beats per minute, bpm, or relative in percentage compared with the reference) was within specific limits (10 bpm and 10%, respectively).

Resting Respiration Rate

As a reference device for the respiration rate during rest, the K4b² was used, which has been validated for this parameter [56]. The respiration rate was evaluated over the rest part of the laboratory protocol during which the participants were watching television. The mean respiration rate from the K4b² during this activity was compared with the mean respiration rate of the Philips health watch.

Step Counting

The accuracy of the step counting algorithm of the Philips health watch was determined by comparing with a Fitbit One (Fitbit

Inc, San Francisco, CA, USA) device that was clipped onto participants' trouser pockets as per manufacturer's instruction. This waist-mounted step counter has been shown to be highly accurate for step counting during walking [57-59]. As a measure of the accuracy of the step counting algorithm for walking and running activities, the total number of steps for all these activities in the protocol was compared between the Philips health watch and the waist-mounted reference.

Activity Type Recognition

Activity type recognition was compared against the (reference) list of activities from the protocol. The health watch classifies measurement data into 4 different types of activities (walking, running, cycling, and other), where changes between activity types are registered with a corresponding time stamp. Each activity from the laboratory protocol was timed using markers at the beginning and end of each activity that were set by the researcher using a Garmin Forerunner 620 (Garmin International Inc, Olathe, KS, USA). The activity type classifications for the laboratory activities were defined as follows: both treadmill exercises and outdoor walking were defined as walking, stationary cycling and outdoor cycling were defined as cycling, outdoor running was defined as running, and, except for the cross-trainer activity, the remaining activities were defined as other. The cross-trainer activity was not taken into account for determining the accuracy of health watch activity type recognition, as it could be classified as walking or running depending on the intensity at which the participant performed the task. The accuracy of activity type recognition was determined by calculating the average percentage of correct classifications of the consecutive activity type outputs of the

device compared with the reference activity type on a second-by-second basis.

Statistical Analysis

Sample Size Calculation

A 20% margin of equivalence has international consensus for the assessment of equivalence of medicinal products [60,61]. No such guidance exists for medical device comparisons; however, we chose to use more stringent margins in an effort to assess more meaningful equivalence to the reference measures while balancing the sample size of the study. Sample size was calculated for total energy expenditure equivalence compared with mobile metabolic measurements with a K4b² system, based on a 15% margin of equivalence, and for resting heart rate compared with ECG measurements with an Actiwave Cardio device based on a 10% margin of equivalence. As the equivalence margins were expressed as percentages, the statistical hypotheses were expressed in terms of ratios instead of mean differences. Furthermore, data were log-transformed to enable conventional analysis in terms of a difference [62]. Subsequently, the sample size was calculated in Minitab version 17 (Minitab Inc) as the minimal number of participants needed to achieve a significance level of .05 and a power of .8 for the total energy expenditure objective as well as the resting heart rate objective for an equivalence test of paired means. For the sample size calculations, we used data from internal tests (see Table 1) with similar protocols to estimate the expected mean and SD of the (log-transformed) ratio between the health watch and reference measurements for both total energy expenditure and resting heart rate. Factoring in a 10% loss to follow-up, a total of 31 subjects were recruited.

Table 1. Means and standard deviations of the log-transformed ratio between the health watch measurements (x) and the reference measurements (y) based on data from internal tests that were used to determine the sample size for this trial.

Equation	Total energy expenditure	Resting heart rate
$\mu(\log(x) - \log(y))$	0.925	1.032
$\sigma(\log(x) - \log(y))$	0.173	0.055

Analysis of Primary and Secondary Outcomes

For the primary outcomes, total energy expenditure and resting heart rate, equivalence tests of paired means were performed. As explained, log-transformation enabled conventional analysis in terms of a difference [62]. Using this transformation, the primary outcomes were tested using the two one-sided tests (TOST) approach for testing equivalence, applying paired sample *t* tests, at a significance level alpha of .05 and the predefined margins of equivalence [62]. In addition, 95% CIs of the difference of the means were determined, also expressed as ratio and calculated using log-transformation of the ratios.

For the secondary outcomes step count and resting respiration rate, equivalence tests for means were performed, similar to the primary outcomes. For both parameters, equivalence margins were set at $\pm 10\%$ compared with the reference measurement. Additionally, mean errors, mean absolute errors, mean percentage errors, and MAPEs were calculated. For activity type recognition, the accuracy was measured in the form of a

confusion matrix, denoting the probability that the device classifies a certain activity, given a certain activity performed by the participants.

Before data analysis, all data were resampled to a common 1-Hz resolution. Data processing and analyses of primary and secondary outcomes were performed using MATLAB R2014b (The MathWorks, Inc).

Data Exclusion

Because of a history of epilepsy resulting in a safety hazard for laboratory testing in the trial, 2 subjects were excluded from participation. Another 2 participants (P107 and P114) experienced an adverse event that was classified as nonserious and not device-related after assessment by the trial's independent medical monitor. Some data of participants were excluded from specific analyses because data were not correctly logged or, based on objective criteria, were found to be invalid (see Table 2).

These data exclusions led to the following numbers of participants available for each analysis: total energy expenditure, n=26; resting heart rate, n=23; heart rate, n=23; step counting, n=29 (overall); activity type recognition, n=26; resting respiration rate, n=28.

Table 2. Overview of participant data that were excluded entirely or partially from analysis.

Participant	Total energy expenditure	Resting heart rate	Heart rate	Respiration rate at rest	Step count	Activity recognition
P122 ^a	X ^b	X	X	X	X	X
P127 ^a	X	X	X	X	X	X
P107 ^c	X	X	X	X		
P114 ^c	X	X	X	X		
P102 ^d	X			X		
P104 ^{d,e}		X	X		X	X
P106 ^d		X	X			
P128 ^d		X	X			
P126 ^f		X	X			

^aParticipant excluded before data collection.

^bCrosses indicate for which analyses the data of the respective participant were deleted.

^cData excluded owing to possible influence of adverse event.

^dData excluded owing to reference device malfunction.

^eData excluded owing to incorrect execution of treadmill walking.

^fData excluded owing to heart rate being invalid (logged as 0).

Results

Participant Characteristics

A total of 31 participants were recruited, of whom 2 were excluded before data collection. This left 29 participants who

took part in the trial, 14 male and 15 female. We observed the following distribution of the 6 Fitzpatrick skin types (1-6): n=0, 7, 18, 4, 0, 0. Demographics are presented in [Table 3](#).

Table 3. Overview of participants' (averaged) demographic characteristics.

Characteristic	Mean	Minimum	Maximum	SD
Age, years	41.2	18	65	14.4
Weight, kg	77.2	60	102	10.2
Height, m	1.8	1.6	1.9	0.1
BMI ^a , kg/m ²	25.1	20.4	31.5	3.1
RHR ^b , beats per minute	64	49	77	7.3
BMR ^c , kcal/day	1654	1361	2082	216.7

^aBMI: body mass index.

^bRHR: resting heart rate.

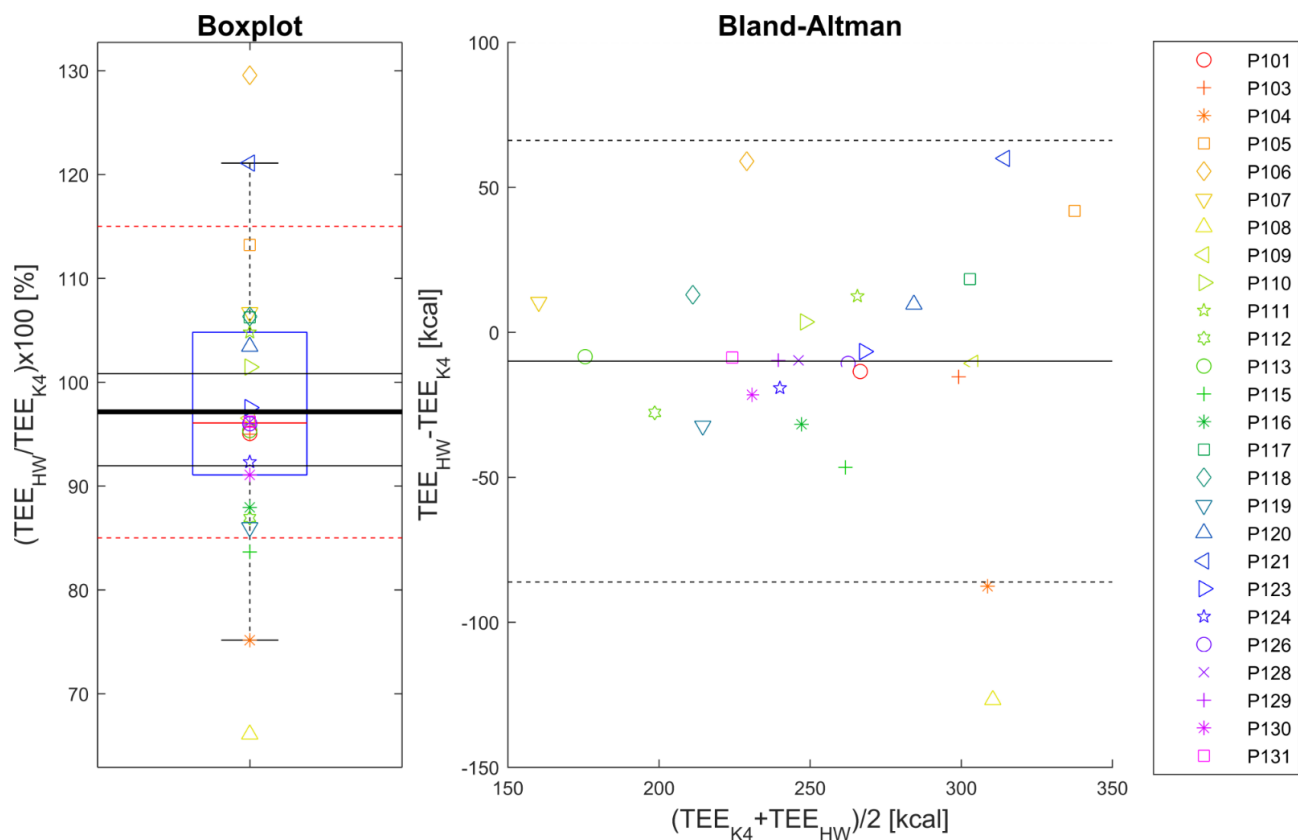
^cBMR: basal metabolic rate.

Total Energy Expenditure

The TOST evaluation was applied at a significance level of .05, for equivalence margins of $\pm 15\%$, leading to rejection of both null hypotheses [62] and therefore the conclusion that cumulative total energy expenditure as measured with the health watch and the K4b² were equivalent. Results of the cumulative total energy expenditure comparison between the Philips health

watch and the COSMED K4b² ambulatory metabolic system are shown in [Figure 2](#). As can be seen in [Figure 2](#), the mean error (97% ratio, 95% CI 92%-101%) in total energy expenditure estimation (indicated by the thick black line) was well within the predefined 15% range of equivalence (indicated by the red dashed lines). There was a mean underestimation of 10.0 kcal, SD 38.9 kcal, which in relative terms was 2.9%, SD 13.1%, of the average reference value. The mean absolute error amounted to 27.5 kcal, SD 28.7 (MAPE 10.0%, SD 8.7%).

Figure 2. Boxplot (left-hand panel) of the ratio of cumulative total energy expenditure (TEE) between the Philips health watch (HW) and the K4b2 (K4) reference. The thick black line indicates the mean of the data, the red dashed lines the predefined $\pm 15\%$ equivalence interval, and the other thin black lines represent the calculated 95% CI of equivalence. Right-hand panel: Bland-Altman plot of the cumulative TEE for the HW and the reference. The solid black line indicates the average bias and the dashed black lines represent the 95% limits of agreement. Symbols represent participants' individual data as indicated in the legend and are the same for both panels.



Resting Heart Rate

The TOST evaluation was applied at a significance level of .05, for equivalence margins of $\pm 10\%$, leading to rejection of both null hypotheses [62] and therefore the conclusion that resting heart rate as derived from the health watch and resting heart rate as derived from the Actiwave ECG during the 15 minutes of rest in the laboratory test were equivalent. Results regarding the comparison are shown in Figure 3. The mean ratio was 100%, and the 95% CI was 99.5%-100.5%. In absolute terms, the mean absolute error was 0.2 bpm as most values were exactly equal to the Actiwave reference, with the maximum deviation being 3 bpm.

Additionally, for each participant separately, we visually assessed whether the resting heart rate from the health watch coincided with the heart rate values at rest during the free-living part of the protocol. Figure 4 shows an example of a heart rate trace measured by the Philips health watch over 3 days of free-living conditions, together with the resting heart rate that was reported over time by the health watch (top), and the total energy expenditure estimation for the same time period (bottom). It can be seen that the resting heart rate corresponds with a low segment of the heart rate trace. In addition, the values sampled for each participant seem to correspond to time periods where subjects were awake and inactive, as can be deduced from the total energy expenditure graph, where sleep can be recognized as periods of low total energy expenditure with relatively low fluctuation.

Figure 3. Boxplot (left-hand panel) of the ratio of resting heart rate (RHR) determined from the Philips health watch (HW) data during the rest protocol in the laboratory to the RHR determined from the Activwave data during the rest protocol in the laboratory. The thick black line indicates the mean of the data, the red dashed lines the predefined equivalence interval, and the other black lines the calculated 95% CI of equivalence. Right-hand panel: Bland-Altman plot of the RHR from the HW and reference. The solid black line indicates the average bias and the dashed black lines represent the 95% limits of agreement. Symbols represent participants as indicated in the legend and are the same for both panels. bpm: beats per minute.

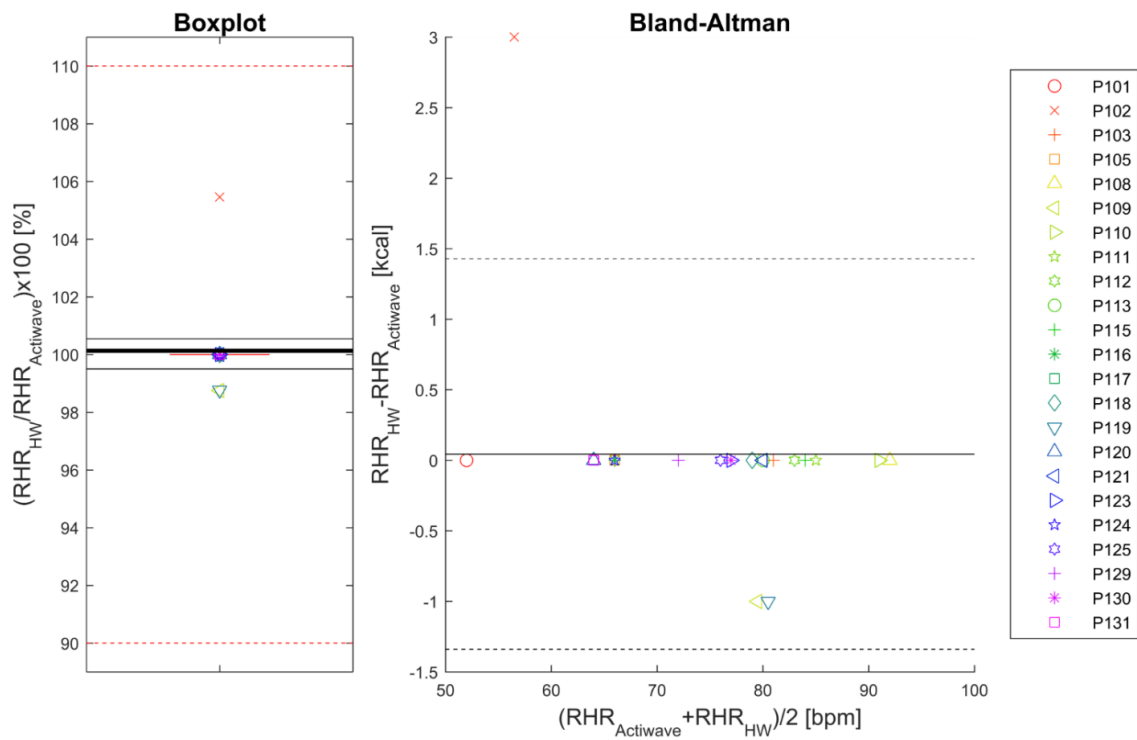
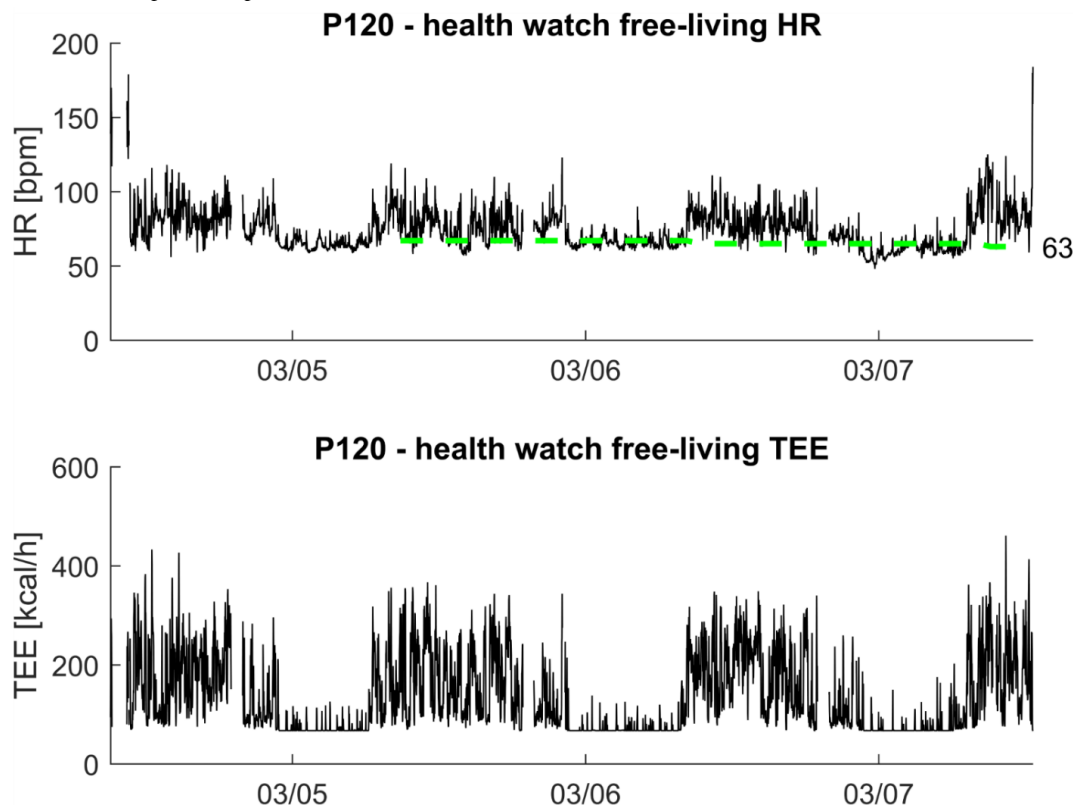


Figure 4. Example of free-living heart rate (HR), resting heart rate, and total energy expenditure (TEE) for participant P120. Top: Philips health watch HR as a function of time for the free-living portion of the trial (black) and the resting heart rate from the health watch (green dashed line; note that resting heart rate requires a 24-hour assessment and therefore day 1 does not have a resting heart rate value). Bottom: TEE as a function of time for the free-living portion of the trial. bpm: beats per minute.



Heart Rate

Table 4 presents the results regarding heart rate measurement accuracy. The mean error was -1.7 bpm and the mean absolute error was 3.1 bpm. This corresponds to a mean percentage error

of -1.3% and a MAPE of 3.1% . Of the available comparative data, the health watch measured heart rate within a difference of 10 bpm with the Actiwave ECG-based reference heart rate 94% of the time and within 10% of the ECG value 93% of the time (see Table 5).

Table 4. Heart rate errors compared with electrocardiogram-based reference that were calculated using 10-second nonoverlapping windows, as means and standard deviations, expressed in beats per minute and percentages.

Activity	Error, bpm ^a		Absolute error, bpm		Percentage error, %		Absolute percentage error, %	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
RHR ^b protocol	0.6	1.8	1.5	1.7	1.0	3.1	2.2	3.0
Treadmill	-4.1	8.3	5.5	7.8	-3.7	7.6	5.2	7.1
Treadmill 5%	-0.3	4.2	3.9	4.2	-0.4	4.0	3.8	3.9
Ergometer bike	0.3	1.1	1.3	0.9	0.3	1.1	1.3	1.0
Cross trainer	-6.1	16.1	8.0	15.3	-4.6	11.9	6.1	11.2
Household	-2.3	5.7	5.7	4.3	-1.7	6.0	6.0	4.4
Desk work	0.9	1.8	1.7	1.7	1.4	3.1	2.4	2.9
Lying down	0.5	0.8	1.1	0.6	0.7	1.2	1.6	1.0
Standing	-0.3	1.4	2.0	1.4	-0.3	1.6	2.3	1.6
Walking	-4.3	9.2	7.1	7.8	-3.8	8.3	6.7	6.8
Cycling	-20.1	26.9	20.7	26.5	-14.5	18.4	15.1	18.0
Running	-6.7	9.7	8.3	8.7	-4.1	6.5	5.5	5.7
Total	-1.7	1.6	3.1	1.4	-1.3	1.5	3.1	1.4

^abpm: beats per minute.

^bRHR: resting heart rate.

Table 5. Heart rate coverage parameters calculated using 10-second nonoverlapping windows for the individual activities as well as for the whole protocol.

Activity	Coverage within 10 bpm ^a , %	Coverage within 10%, %
RHR ^b protocol	98.8	97.8
Treadmill	81.8	81.8
Treadmill 5%	85.2	85.9
Ergometer bike	94.9	94.9
Cross trainer	83.0	84.8
Household	85.4	83.8
Desk work	93.3	92.1
Lying down	90.8	90.3
Standing	93.2	92.9
Walking	64.5	70.7
Cycling	61.7	62.5
Running	72.2	88.7
Total	93.8	93.1

^abpm: beats per minute.

^bRHR: resting heart rate.

Step Counting

Compared with the step count reported by the waist-mounted reference, an overall (average) underestimation of 21 steps was observed corresponding to an overall error of -1.6% (see Table 6). Again, the TOST evaluation was applied at a significance

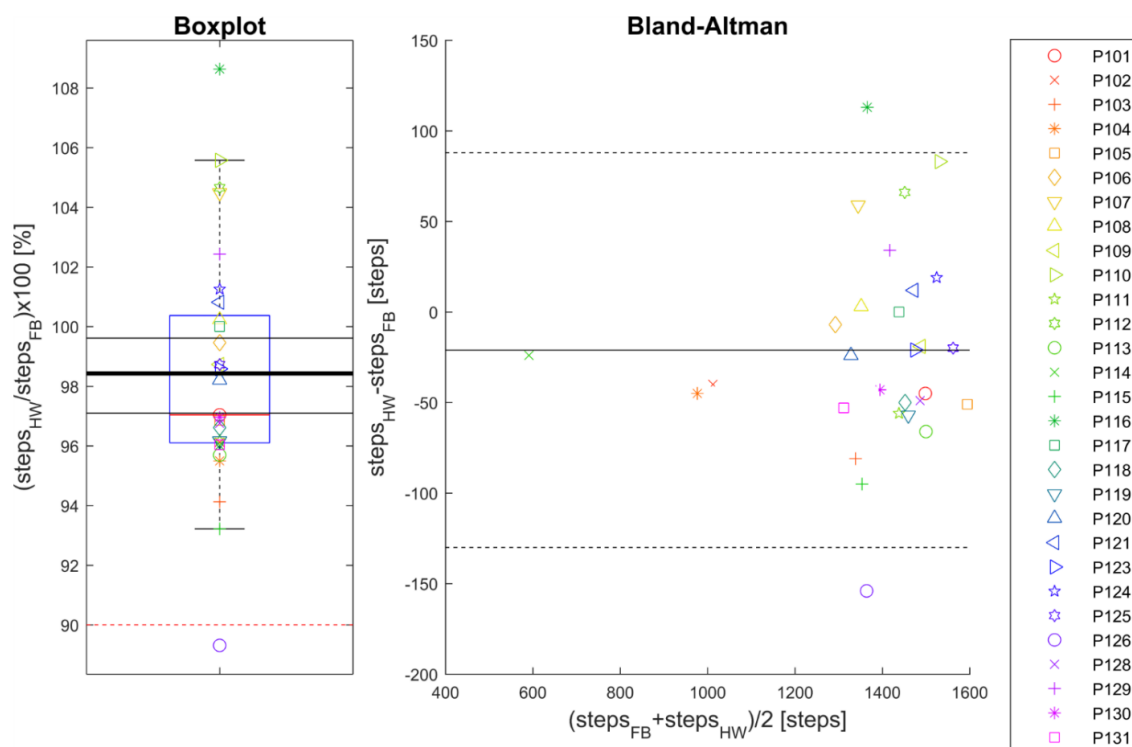
level of .05, for equivalence margins of ±10%, leading to rejection of both null hypotheses and therefore the conclusion that cumulative steps as estimated by the health watch and by the waist-mounted counter were equivalent. The calculated 95% CI boundaries for all walking activities combined were at 97.1% and 99.6% (Figure 5).

Table 6. Errors in step count estimation when compared with the waist-mounted reference, based on the total number of steps for each activity.

Activity	Mean error, steps		Mean absolute error, steps		Mean percentage error, %		Mean absolute percentage error, %	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Treadmill (n=27)	-13.0	11.5	13.4	11.1	-3.7	3.4	3.9	3.2
Treadmill 5% (n=29)	0.0	33.2	19.8	26.3	0.3	12.9	7.3	10.5
Walking (n=28)	-17.6	16.9	18.0	16.4	-6.5	11.0	6.6	10.9
Running (n=29)	8.3	42.2	26.9	33.2	2.4	10.8	6.4	9.0
All walk activities ^a (n=29)	-21.1	55.6	47.9	34.3	-1.6	4.0	3.5	2.4

^aThe last row shows the observed error for the total number of steps of all walking activities.

Figure 5. Boxplot (left-hand panel) of estimated step count as ratio between the health watch (HW) and the waist-worn reference (Fitbit One, FB), for all walk activities combined. The thick black line indicates the mean of the data, the red dashed lines the predefined equivalence interval, and the other black lines the calculated 95% CI of equivalence. Right-hand panel: Bland-Altman plot of the estimated step count of the HW and the reference measurement. The solid black line indicates the average bias and the dashed black lines represent the 95% limits of agreement. Symbols represent participants as indicated in the legend, and the legend is the same for both panels.



Activity Type Recognition

Overall, more than 90% of the time the correct activity type was identified by the Phillips health watch during the annotated laboratory activities (Table 7).

Table 7. A confusion matrix denoting the percentages of correct and incorrect activity type classifications compared with reference annotated activity types.

Annotated activity types	PHW ^a activity type classification, %			
	Other	Walk	Run	Cycle
Other	99.3	0.5	0.0	0.2
Walk	5.5	94.2	0.1	0.3
Run	3.6	6.2	89.9	0.2
Cycle	8.1	0.4	0.0	91.6

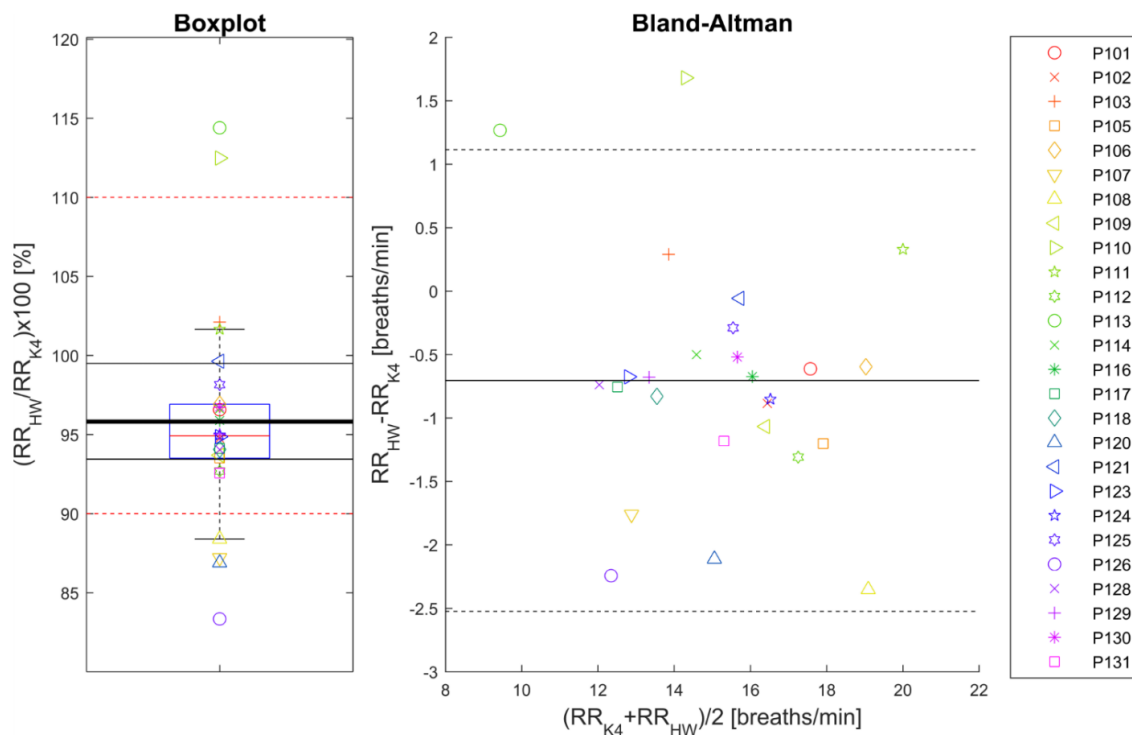
^aPHW: Philips health watch.

Resting Respiration Rate

The TOST evaluation indicated that respiration rate at rest as measured by the health watch and the K4b² were equivalent (.05 significance level, ±10% equivalence margins). Figure 6 shows the boxplot of the ratio between the health watch and the K4b² respiration rate, both averaged over the 15-minute rest

period at the beginning of the laboratory protocol, with the calculated 95% CI boundaries of 93.4% and 99.5%. These data indicate a slight underestimation of respiration rate compared with the reference by -0.7, SD 1.1, breaths per minute. In percentages this amounted to an error of -3.8, SD 8.1, percent. The absolute mean error was 1.2, SD 1.0, breaths per minute (MAPE 8.3%, SD 7.0%).

Figure 6. Boxplot (left-hand panel) of the ratio of estimated respiration rate (RR) from the health watch (HW) and the K4b² (K4) reference, during rest. The thick black line indicates the mean of the data, the red dashed lines the predefined equivalence interval, and the other black lines the calculated 95% CI of equivalence. Right-hand panel: Bland-Altman plot of the estimated RR from the HW and from the reference measurement. The solid black line indicates the average bias and the dashed black lines represent the 95% limits of agreement. Symbols represent participants as indicated in the legend; the legend is the same for both panels.



Discussion

Principal Findings

In this study the measurement accuracy of the Philips health watch, a wrist-worn heart rate and activity monitor, was evaluated against (medical) reference instruments. Resting heart rate was determined on heart rate sampled over a 15-minute resting protocol in sitting position and fell within 3 bpm of the Activwave ECG comparator. During a protocol covering a variety of activities of daily life, the health watch measured total energy

expenditure on average within the predefined 15% accuracy compared with a K4b² mobile metabolic system. These results indicate that the watch can provide valuable information that can help in the prevention and management of lifestyle-related chronic diseases by measuring and tracking resting heart rate and energy expenditure over time and interpreting these data in the context of a user's personalized range of a parameter value or goal based on international standards (i.a. WHO, ACSM). The (automated) coaching that the companion app provides

uses the information to offer further support to making a lifestyle change.

Total Energy Expenditure

Energy expenditure estimation by means of wearable devices is not a new concept. There are many commercially available activity monitors that provide energy expenditure estimates; however, the reported accuracy of consumer-grade devices is highly variable [30,63-66]. Comparison across studies is hampered by differences in the type of reference measure (eg, doubly labeled water, metabolic chambers, or mobile metabolic systems) and differences in the type, intensity, and duration of activities performed during the validation (eg, standardized treadmill walking or free-living evaluation). Similar to our study, Lee et al [30] evaluated several consumer-grade physical activity monitors against a portable metabolic system (Oxycon Mobile) over a 69-minute standardized protocol of various activities. They reported MAPEs of 9.3% (BodyMedia FIT) up to 23.5% (Basis B1 band). Another study that resembled our design was performed by Bai and colleagues [67]. They evaluated activity monitors against an Oxycon Mobile metabolic system over an 80-minute standardized protocol. MAPE values ranged from 15.3% (BodyMedia Core) to 30.4% (Misfit Shine) in this study. Most recently, Nelson et al [68] evaluated several activity monitors over a 65-minute protocol covering 10 minutes of rest and a selection of 11 different activities using a COSMED K4b² as reference. They reported MAPEs ranging from 13% to 35% for energy expenditure prediction over the different activities. In this study, the Philips health watch MAPE for total energy expenditure was 10%, which is highly accurate for this type of device when compared with the performance reported in the aforementioned studies. It is important to realize that the heart rate and acceleration measurements will give an estimation of total energy expenditure, which is less accurate than objective measurement techniques such as doubly labeled water or indirect calorimetry by means of ambulatory metabolic systems. However, these measurement methods are not feasible for long-term 24-hour monitoring of total energy expenditure in daily life and are not readily accessible to consumers [22]. In comparison with self-report questionnaires for physical activity, the Philips health watch provides a more objective measurement of total energy expenditure that is well suited for long-term, noninvasive monitoring. Similar to other validation studies of energy expenditure estimation, our study was limited to an evaluation of participants for a limited time frame at our test facility, as home testing was not practically feasible with regard to obtaining within-person reference measurements [63]. A strength of the study was that the protocol included activities of daily life, such as desk work, household activities, and activities performed outdoors, in addition to more traditional treadmill-based protocols. This will provide a better reflection of daily life performance [69].

Resting Heart Rate

In this study the resting heart rate value determined with the health watch was found to be equivalent to that of the Actiwave reference (Figure 2). With the mean bias centered around 0 and a maximum deviation of 3 bpm, the health watch is suited for inspection of resting heart rate as a risk factor, as dose-response

investigations often report increments in hazards for 5-10 bpm increments of resting heart rate [31,32,34,70]. A limitation of the study was that it was not possible to evaluate the resting heart rate produced by the health watch against a gold standard because there is currently no international consensus on a standardized manner to obtain resting heart rate values. We did, however, follow current recommendations by assessing resting heart rate based on multiple heart rate samples during a 15-minute resting protocol [50,55]. Furthermore, inspection of individual free-living heart rate traces indicated that the resting heart rate estimates of the health watch correspond to low heart rate levels during nonactive, although nonsleep, periods throughout the day. A strength of this method of obtaining resting heart rate by means of continuous heart rate monitoring is that it is much less influenced by circadian or temporary factors such as the "white coat effect," which can confound the measurement [51,71].

Heart Rate

Continuous heart rate logging of the Philips health watch was evaluated against Actiwave measurements over the complete duration of the protocol. Values sampled at 1 Hz were averaged over 10-second nonoverlapping windows. Parak and Korhonen [29] performed a similar comparison over a 50-minute protocol of various activities with a Mio Alpha, a wrist-worn device using a predecessor sensor module to that of the Philips health watch. They found a mean absolute error of 4.43 bpm and MAPE of 5.23% using 5-second nonoverlapping windows. In comparison, the Philips health watch performed better in this study with a mean absolute error of 3.1 bpm and MAPE of 3.1% (Table 4). Additionally, the coverage of the health watch within 10% of the reference device was higher in this study with 93.1% (Table 5) versus 87.5% reported in the study by Parak and Korhonen. For some activities, we observed lower accuracy and coverage presumably owing to the relative short duration of the activities. Our hypothesis was that the short duration of the activities resulted in relatively steep rising and dropping of heart rates, thus negatively affecting the estimation accuracy for only these activities compared with a protocol with longer activity durations resulting in more stable heart rates. Furthermore, during the months of testing (February and March) a temperature shift from the warmer indoor temperature to the lower outside temperature may have caused temporary localized vasoconstriction leading to lower coverage values for the outdoor activities walking and bicycling (Table 5). This phenomenon has been observed in an experimental setup by Maeda and colleagues [72], who demonstrated that the pulsatile AC (alternating current) component of the PPG signal is significantly lower at skin temperatures below 20°C compared with normal skin temperatures. This results in a significantly lower AC/DC (direct current) component ratio and reduces the correlation with ECG-based heart rate measurements. Although the accuracy of the health watch is equivalent to an ECG-based comparator for a high percentage of time, deviations due to, for example, a poor sensor-skin contact or movement artifacts are still possible. Attention to correct wearing of PPG-based devices is therefore important. Furthermore, for the purpose of this device, a 24/7 heart rate and activity monitor, a 93.1% coverage

within 10% can provide a good overall representation of a user's heart rate over the course of a day.

Step Counting

Step counting of the health watch was compared against a waist-worn step counter over walking activities at different speeds, indoors on a treadmill and outdoors. From prior research, it is known that waist-worn devices generally have less error in step counts when compared with observed counts than wrist-worn devices [57-59,73]. Compared with the waist-worn counter, the health watch had a slight average overestimation of 0.3% for treadmill walking at 3 km/h at a 5% inclination and a small underestimation of -3.7% for treadmill walking at 4.5 km/h at 0% inclination (Table 6). These errors were smaller than those reported by Diaz et al [58], who found a mean underestimation of 16.3% and 10.6% when comparing a wrist-worn step counting device with observer counts over comparable slow and moderate speeds.

Activity Type Recognition

Activity type recognition is useful for physical activity monitors as it can give insight to users into the duration of different types of activities that were performed over the course of a day and what amount of energy expenditure was associated with this. Furthermore, activity type classification provides the potential

to enhance energy expenditure estimation [22,74-78]. Overall, more than 90% of the time the correct activity type was identified by the health watch during the annotated laboratory activities. This is a good result when comparing with other studies of automatic activity type recognition, where overall correct classifications range from 42% to 96% depending on the types of activities classified [79-82]. In Table 7 it can be seen that the least accurate activity type was running at 89.9%. Running was classified as walking approximately 6% of the time. One reason that the running recognition was least accurate could be the fact that 2 participants were actually walking during the running part of the protocol.

Conclusions

This study showed that the health watch can estimate total energy expenditure with 85% accuracy during daily life activities and measure resting heart with ± 3 bpm accuracy during rest compared with medical device reference instruments. In addition, the secondary outcome parameters, heart rate, step counts, resting respiration rate, and activity type classification, showed high levels of accuracy. On the basis of these results the health watch can serve its medical purpose of measuring resting heart rate and total energy expenditure over time in an unobtrusive manner, thereby providing valuable data for the prevention and management of lifestyle-related chronic diseases.

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Authors' Contributions

JH, LR, LC, ES, and AG were involved in development of the study. LR, LC, PL, and ES were involved in execution of the study. All authors made a significant contribution to writing, review, and approval of the manuscript.

Conflicts of Interest

JH, LC, PL, ES, and AG are employees of Philips. LR was an employee of Philips during the development and execution of the study.

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Abbreviations

AC: alternating current
ACSM: American College of Sports Medicine
bpm: beats per minute
DC: direct current
ECG: electrocardiogram
ISO: International Organization for Standardization
MAPE: mean absolute percentage error
NCD: noncommunicable disease
PPG: photoplethysmography
TOST: two one-sided tests
WHO: World Health Organization

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Original Paper

Weight Loss Associated With Different Patterns of Self-Monitoring Using the Mobile Phone App My Meal Mate

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Abstract

Background: Obesity is a major global public health issue due to its association with a number of serious chronic illnesses and its high economic burden to health care providers. Self-monitoring of diet has been consistently linked to weight loss. However, there is limited evidence about how frequently individuals need to monitor their diet for optimal weight loss.

Objective: The aim of this paper is to describe app usage frequency and pattern in the mobile phone arm of a previously conducted randomized controlled trial. The relationship between frequency and pattern of electronic dietary self-monitoring and weight loss is also investigated.

Methods: A randomized pilot trial comparing three methods of self-monitoring (mobile phone app, paper diary, Web-based) was previously conducted. Trial duration was 6 months. The mobile phone app My Meal Mate features an electronic food diary and encourages users to self-monitor their dietary intake. All food consumption data were automatically uploaded with a time and date stamp. Post hoc regression analysis of app usage patterns was undertaken in the My Meal Mate group (n=43; female: 77%, 33/43; white: 100%, 43/43; age: mean 41, SD 9 years; body mass index: mean 34, SD 4 kg/m²) to explore the relationship between frequency and pattern of electronic dietary self-monitoring and weight loss. Baseline characteristics of participants were also investigated to identify any potential predictors of dietary self-monitoring.

Results: Regression analysis showed that those in the highest frequency-of-use category (recorded ≥ 129 days on the mobile phone app) had a -6.4 kg (95% CI -10.0 to -2.9) lower follow-up weight (adjusted for baseline weight) than those in the lowest frequency-of-use category (recorded ≤ 42 days; $P < .001$). Long-term intermittent monitoring over 6 months appeared to facilitate greater mean weight loss than other patterns of electronic self-monitoring (ie, monitoring over the short or moderate term and stopping and consistently monitoring over consecutive days). Participant characteristics such as age, baseline weight, sex, ethnicity, conscientiousness, and consideration of future consequences were not statistically associated with extent of self-monitoring.

Conclusions: The results of this post hoc exploratory analysis indicate that duration and frequency of app use is associated with improved weight loss, but further research is required to identify whether there are participant characteristics that would reliably predict those who are most likely to regularly self-monitor their diet.

Clinical Trial: ClinicalTrials.gov NCT01744535; <http://clinicaltrials.gov/ct2/show/NCT01744535> (Archived by WebCite at <http://www.webcitation.org/6FEtc3PVB>)

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KEYWORDS

self-monitoring; mobile phone; obesity; weight loss

Introduction

Obesity is associated with a range of serious and chronic conditions and is estimated by the World Health Organization to be the fifth leading risk for global deaths [1]. In 2008, 1.4 billion adults across the globe were estimated to be overweight and, of these, over 500 million were obese [1]. In the United Kingdom, the economic cost of obesity is immense with an estimated £4.2 billion annual spend by the National Health Service in 2007 [2]. The behavioral approach to obesity has the underlying assumption that dietary and physical activity behaviors are learned and can be modified by changing the preceding event/trigger for the behavior and by manipulating the consequences [3]. A review of behavioral interventions for weight loss showed that lifestyle interventions resulted in average weight loss equivalent to 11% of initial body weight in the short term [4].

Self-monitoring has been ascribed great importance in behavioral approaches to obesity and has been described as the “centerpiece” [5] and “sine qua non” [3] of weight management strategies. Self-monitoring requires a person to deliberately observe and record their behavior. In the self-regulatory model, self-monitoring focuses attention on behavior by raising the persons’ awareness, offering them the opportunity to adjust behavior as necessary to achieve their goal [6]. Traditionally, studies have investigated dietary self-monitoring using paper diaries [7,8], but as technology improves, researchers have also investigated self-monitoring using handheld electronic devices such as portable microcomputers [9-11], personal digital assistants (PDAs) [12,13], PDAs with Subscriber Identity Module (SIM) cards [14,15], or mobile phones [16].

A systematic review of the self-monitoring and weight loss literature found 22 eligible studies published between 1993 and 2009 [5]. Weight loss was found to be consistently statistically significantly associated with self-monitoring of diet. The review highlighted that there is disparity in the way that adherence to self-monitoring is measured in different studies and many are reliant on assessment by self-report leaving a paucity of information about exactly how much self-monitoring is required for weight loss. There is also a lack of generalizability of findings given that studies predominantly consist of white women. It is questionable as to how effective and acceptable self-monitoring interventions are to a more diverse audience.

It is not yet fully understood whether dietary self-monitoring needs to be conducted over the long term to aid weight loss or whether there is a “learning effect” such that self-monitoring needs only to occur for a short time for permanent changes to be implemented. It is also not known whether dietary self-monitoring can be effective if done intermittently or whether it must be done consecutively on a daily basis for optimum effect. Such information would be useful because it could help to guide individuals on how much dietary self-monitoring they need to do to facilitate their weight loss effort. As technology advances, there is exciting potential for more objective assessment of self-monitoring given that electronic records can be time and date stamped.

One study has provided some valuable data in this area by investigating how a PDA was used for dietary self-monitoring in a weight loss trial. The Self-Monitoring and Recording using Technology (SMART) trial conducted by Burke et al [17] compared weight loss in 210 participants over 2 years [17]. Participants were randomized to one of three dietary self-monitoring arms: a paper diary, PDA, and PDA with feedback. Adherence to dietary self-monitoring was defined as the percentage of days with adequate calories recorded and investigated within three categories (<30%, 30%-59%, ≥60%). The trial found that regardless of group, those who were adherent 60% or more of the time lost more weight than those adherent less than 30% of the time ($P<.001$). However, weight loss at 18 months in the two highest categories of adherence to dietary self-monitoring in all groups (30%-59% and ≥60%) was similar. The researchers suggested that in this case lower levels of adherence to dietary self-monitoring were sufficient to produce the same weight change results as higher levels after this duration of self-monitoring. Because PDAs have now largely been superseded by mobile phones and smartphones, the analysis in this paper will build on the prior evidence by investigating how participants used a mobile phone app for weight loss. The findings presented are a post hoc analysis of the data collected in a pilot trial of My Meal Mate a mobile phone app for weight loss [18]. The aim of this paper is to describe app usage frequency and patterns in the My Meal Mate arm of the My Meal Mate pilot randomized controlled trial. The relationship between frequency and pattern of electronic dietary self-monitoring and weight loss has also been investigated. This work is innovative because the researcher-controlled app provides objective time-stamped data, which allows for a unique exploration of electronic dietary self-monitoring by participants in a 6-month weight loss trial. Therefore, this topic is potentially of interest to the health community and also to the wider quantified self-community.

Methods

My Meal Mate is an evidence-based mobile phone app designed to facilitate weight loss and has been investigated in a pilot randomized trial [18]. A detailed description of the My Meal Mate intervention has been discussed elsewhere [19] as have the methods and results of the My Meal Mate pilot trial [18]. Briefly, My Meal Mate features an electronic food diary and users are required to select and log food and drink items from a 23,000-item database [18,20]. My Meal Mate was programmed so that all food consumption data were automatically uploaded with a time and date stamp. This presented an opportunity to capture objective information about how people used the electronic diary to self-monitor their diet. A pilot trial was conducted whereby 128 overweight or obese participants were randomized to one of three different methods of dietary self-monitoring; My Meal Mate mobile phone app (participants received a HTC Desire mobile phone with the app predownloaded), paper diary, and online food diary. Because this was a pilot trial, the key outcomes under consideration were feasibility and acceptability; as such, the trial was not statistically powered to detect a particular change in weight.

Therefore, a formal sample size calculation was not considered appropriate and the final sample size was a pragmatic decision.

Trial volunteers were recruited by email, intranet, and posters from large local employers. The trial had minimal contact in that participants did not receive any dietary advice and were advised to use the self-monitoring intervention for the first week at least and then as often as they pleased. Participants returned for follow-up at 6 weeks and 6 months. Height, weight, and percentage body fat were measured at three time points (baseline, 6 weeks, and 6 months) by fieldworkers blinded to intervention group. A number of self-administered demographic questionnaires were also completed. A 20-item scale was used to measure conscientiousness. Conscientiousness has been described as “a tendency to be organized, strong-willed, persistent, reliable, and a follower of rules and ethical principles” [21]. The scale was taken from the International Personality Item Pool website, which hosts a freely available inventory of personality measures [22,23]. Participants were requested to self-report how much they agreed with each item (eg, “I pay attention to detail”) on a Likert scale of one to five. Conscientiousness is one of five domains that make up the five-factor model of personality (along with extroversion, agreeableness, neuroticism, and openness) [24]. Conscientiousness, in particular, has been identified as being negatively associated with a number of health-related behaviors, such as tobacco use, diet and physical activity, and drug use [25]. Consideration of future consequences (CFC) was also measured using a 12-item scale that measured “the extent to which people consider the potential distant outcomes of their current behaviors and the extent to which they are influenced by these potential outcomes” [26]. Respondents were asked to rate how characteristic of them a particular behavior was on a Likert scale from one to five. The items were statements such as “I only act to satisfy immediate concerns, figuring the future will take care of itself.”

The analysis discussed in this paper is a post hoc analysis focusing specifically on those participants enrolled in the My Meal Mate arm of the trial (n=43). The relationship between dietary self-monitoring (frequency and pattern) and weight loss was investigated.

Ethical Approval

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects/patients were approved by the University of Leeds, Faculty of Medicine and Health Research Ethics Committee (ethics reference number: HSLTLM/10/002). Written informed consent was obtained from all participants.

Statistical Analysis

Analyses were performed using STATA statistical software version 11 (StataCorp, College Station, TX, USA). Descriptive statistics were used to present baseline characteristics of participants in the My Meal Mate arm of the trial. Throughout the analysis, a complete day of dietary self-monitoring was considered to be one with a biologically plausible energy (kilocalorie [kcal]) intake recorded (≥ 500 and ≤ 5000 kcal/ ≥ 2093 and $\leq 20,934$ kilojoules).

Frequency of Dietary Self-Monitoring as a Predictor of Follow-Up Weight at 6 Months

The differences between participants in terms of frequency of dietary self-monitoring were investigated for a number of characteristics measured at baseline. Descriptive statistics are displayed. Statistically significant differences were assessed between the three categories of frequency of monitoring by a one-way ANOVA (where the variable was found to be normally distributed and other assumptions of the test were met) or the nonparametric equivalent Kruskal-Wallis test as appropriate.

The frequency-of-use variable for the My Meal Mate group (number of days using the app for dietary self-monitoring) is a continuous variable; however, its distribution was found to be U-shaped and did not improve after log transformation making it unsuitable to be treated as a continuous variable in a regression analysis. For analysis, the variable was split so that it could be treated as a categorical variable. Due to the distribution of the data, the variable was cut at three points to make categories (low, moderate, and high frequency of use). The variable was cut automatically by STATA at three points, which gave an equal number of participants in each group. This gave a definition of low-frequency use as 42 days or less (n=13), moderate-frequency use as 43 days to 128 days (n=15), and high-frequency use as 129 days or more (n=15) with dietary data recorded (≥ 500 and ≤ 5000 kcal). An intention-to-treat regression analysis that used weight at follow-up (with baseline observation carried forward for any missing data) as the outcome variable and the frequency-of-use category as a predictor variable was conducted. The model was adjusted for baseline weight, but no other adjustments were made given that no variables were found to differ in a statistically significant way between the categories.

Pattern of Dietary Self-Monitoring as a Predictor of Follow-Up Weight at 6 Months

The frequency of My Meal Mate use is an overall count of days with dietary self-monitoring over the course of the trial, but it misses information about the distribution of the days. For example, persons A and B may have both recorded 50 days on the My Meal Mate app, but person A may have monitored consecutively at the beginning of the trial for 50 days and then stopped, whereas person B may have recorded 50 days intermittently over the course of the 6-month period. Therefore, pattern of monitoring in relation to weight loss was investigated. The distribution of data collected on My Meal Mate was visually inspected and used to divide the participants into discrete patterns of self-monitoring. Differences between the patterns of dietary self-monitoring in a number of key variables measured at baseline were investigated using appropriate inferential statistics (one-way ANOVA or Kruskal-Wallis test as appropriate) and a regression analysis conducted with pattern of adherence as a categorical predictor of follow-up weight (adjusted for baseline weight).

Results

Baseline Characteristics of Participants Enrolled in the My Meal Mate Pilot Trial

Table 1 shows the baseline characteristics of all participants enrolled in the My Meal Mate pilot trial. This paper focuses on participants in the My Meal Mate group, but all three groups in the trial are shown for comparison. Table 1 also shows the main

outcomes from the My Meal Mate pilot trial. The results of the trial are reported elsewhere [18], but have been included here to compare My Meal Mate to the other arms in the trial. Of the 43 adults in the My Meal Mate group, more than three-quarters (33/43) were female and all (43/43) were white. The mean age of the My Meal Mate group participants was 41 (SD 9) years and more than half (32/43) were employed in managerial and professional occupations. The mean participant body mass index (BMI) in the My Meal Mate group was 34 (SD 4) kg/m².

Table 1. Baseline characteristics of all participants enrolled in the My Meal Mate pilot trial.

Participant characteristics	Mobile phone (n=43)	Diary (n=43)	Website (n=42)
Age (years), mean (SD) [95% CI]	41.2 (8.5) [38.6-43.9]	42.5 (8.3) [39.9-45.0]	41.9 (10.6) [38.6-45.2]
Weight (kg), mean (SD) [95% CI]	96.4 (16.0) [91.9-101.8]	97.9 (18.7) [92.2-103.6]	96.4 (19.9) [90.2-102.6]
Body mass index (kg/m ²), mean (SD) [95% CI]	33.7 (4.2) [32.4-35.0]	34.5 (5.7) [32.7-36.2]	34.5 (5.6) [32.7-36.2]
Sex (female), n (%)	33 (77)	33 (77)	33 (79)
Race (white), n (%)	43 (100)	35 (83)	39 (93)
Smoking status (current smokers), n (%)	2 (5)	8 (19)	2 (5)
Occupation (managerial professions), ^a n (%)	32 (74)	22 (51)	20 (49)
Has a university degree, n (%)	31 (72)	24 (56)	22 (53)
Owns a mobile phone, n (%)	18 (42)	19 (44)	14 (34)

^aThe occupation variable was dichotomized; it was originally measured as (1) managerial and professional occupations, (2) intermediate occupations, (3) small employers and own account workers, (4) lower supervisory and technical occupation, and (5) semiroutine and routine occupations.

Use of the My Meal Mate App and Total Weight Change

Over the 6-month trial period, participants used the My Meal Mate app for a median 82 (IQR 28-172) days to record their intake. In all, 40 of 43 participants returned to be weighed at 6 months. All participants completed at least one day of dietary self-monitoring and only two participants completed less than 7 days of dietary self-monitoring. Within the My Meal Mate group, using an intention-to-treat analysis (with baseline observation carried forward for the three missing follow-up weights), the mean weight change at 6 months was -4.6 kg (95% CI -6.2 to -3.0). For trial completers only (n=40), the mean weight change was -5.0 kg (95% CI -6.7 to -3.3).

High-, Moderate-, and Low-Frequency Users of My Meal Mate

Table 2 presents differences in key variables measured at baseline between the different categories of frequency of My Meal Mate use. There were no statistically significant differences found between the frequency-of-use categories for

any of these key variables. There was a suggestion of a trend for greater weight loss at 6 weeks with self-monitoring, but this was not statistically significant. Table 3 presents the results of a regression analysis investigating frequency-of-use category as a predictor of follow-up weight at 6 months (adjusted for baseline weight). Those in the highest adherence category (recorded ≥ 129 days on the My Meal Mate app) had a -6.4 kg (95% CI -10.0 to -2.9) lower follow-up weight (adjusted for baseline weight) than those in the lowest adherence category (recorded ≤ 42 days). This difference was found to be statistically significant ($P=.001$). The difference in follow-up weight was not found to be statistically significantly different between those in the moderate category of adherence and those in the low category of adherence (-1.8 kg, 95% CI -5.3 to 1.8, $P=.33$). If the dummy variable was recoded so that the medium adherence category was the reference category (43-128 days), the high adherence category was found to have a -4.7 kg (95% CI -8.2 to -1.1) lower follow-up weight (adjusted for baseline weight) ($P=.01$). However, it is worth noting that the confidence intervals are fairly wide because the sample is very small.

Table 2. Baseline characteristics of different categories of subsequent My Meal Mate use.

Participant characteristic	Category of frequency of My Meal Mate use (days of dietary self-monitoring)		
	Low (≤ 42) n=14	Moderate (≥ 43 to ≤ 128) n=14	High (≥ 129) n=14
Age (years), ^a mean (95% CI)	39.1 (34.4, 43.8)	40.4 (34.9, 45.8)	44.1 (39.7, 48.4)
Baseline weight (kg), ^a mean (95% CI)	96.8 (88.2, 105.3)	100.5 (90.1, 110.9)	93.5 (84.8, 102.1)
Baseline BMI (kg/m^2), ^a mean (95% CI)	33.8 (31.1, 36.4)	34.8 (32.3, 37.2)	32.7 (30.6, 34.9)
Conscientiousness score, ^a mean (95% CI)	76.5 (66.1, 84.8)	76.1 (70.0, 82.2)	81.2 (76.0, 86.5)
Score for CFC, ^{a,b} mean (95% CI)	31.9 (28.2, 35.6)	33.7 (29.4, 38.0)	28.2 (23.8, 32.5)
Weight change 6 weeks, ^a mean (95% CI)	-1.8 (-2.7, -0.8)	-3.4 (-5.0, -1.7)	-3.6 (-5.0, -2.2)
Sex (female), ^c n (%)	11 (79)	10 (71)	12 (80)
Race (white), ^c n (%)	14 (100)	14 (100)	15 (100)
Managerial and professional occupation, ^c n (%)	10 (71)	10 (71)	12 (80)
Has a university degree, ^c n (%)	12 (86)	8 (57)	11 (73)

^aSignificant differences between the three categories of adherence assessed by one-way ANOVA.

^bCFC: consideration of future consequences.

^cSignificant differences assessed by Kruskal-Wallis.

Table 3. Regression analysis of category of My Meal Mate use as a predictor of follow-up weight (adjusted for baseline weight) in the My Meal Mate arm of the pilot trial.

Category of adherence	n	Weight loss coefficient (kg) (95% CI)	P value
Low (≤ 42 days of dietary self-monitoring)	14	Reference	—
Moderate (≥ 43 days to ≤ 128 days of dietary self-monitoring)	14	-1.8 (-5.3, 1.8)	.33
High (≥ 129 days of dietary self-monitoring)	15	-6.4 (-10.0, -2.9)	.001

Pattern of My Meal Mate Use Over the Course of the Trial

Figure 1 shows the distribution of daily dietary recording by each individual over the course of the trial. The distribution of data in Figure 1 has been visually inspected and used to divide the participants into four discrete patterns of self-monitoring. This categorization is based on the following limits, which were true as a result of the observation of Figure 1:

1. Stopped early: last diary entry before 31 days;
2. Moderate-term monitoring: last entry before 92 days (approximately 3 months);
3. Long-term intermittent monitoring: monitored over the long term (3-6 months), but intermittently with breaks (a break is at least 1 day); and
4. Long-term consecutive monitoring: monitored mostly consecutively over the long term (no more than four breaks and breaks never longer than 10 days).

The differences between the patterns of dietary self-monitoring in a number of key variables at baseline are displayed in Table 4. No statistically significant differences were found between the four different patterns of monitoring on a number of variables except for weight change at 6 weeks. A regression analysis was conducted using follow-up weight as the outcome variable and pattern of adherence category as a predictor (adjusting for baseline weight). The regression output can be seen in Table 5.

The results of the regression analysis show that those who monitored intermittently over the long term had a -7.5 kg (95% CI -11.6 to -3.4) lower follow-up weight (adjusted for baseline weight) than those who stopped monitoring completely before 31 days ($P=.001$). The difference in follow-up weight was not found to be statistically significantly different between the other two categories compared to the “early stoppers” reference group. The confidence intervals around the coefficients were wide, which is likely reflective of the small sample size within categories once the variable was split.

Table 4. Investigation of the differences between patterns of My Meal Mate use for key variables measured at baseline in the My Meal Mate group.

Participant characteristic	Pattern of My Meal Mate use ^a			
	Stopped early (n=11)	Stopped before 92 days (n=9)	Intermittent over long term (n=11)	Consecutive over long term (n=12)
Age (years), ^b mean (95% CI)	36.7 (31.6, 41.9)	42.2 (34.2, 50.3)	42.8 (37.7, 48.0)	43.2 (38.1, 48.3)
Baseline weight (kg), ^b mean (95% CI)	96.4 (84.8, 107.9)	94.5 (80.4, 108.6)	96.3 (85.2, 107.5)	99.5 (90.4, 108.6)
Baseline BMI (kg/m ²), ^b mean (95% CI)	33.9 (30.9, 37.0)	31.2 (29.9, 32.6)	33.6 (30.5, 36.7)	35.5 (32.7, 38.2)
Conscientiousness score, ^b mean (95% CI)	75.6 (64.4, 86.8)	78.0 (67.9, 88.1)	79.6 (72.9, 86.4)	78.2 (73.2, 83.2)
Score for CFC, ^{b,c} mean (95% CI)	33.0 (30.4, 35.6)	30.6 (24.3, 36.9)	29.1 (23.6, 34.6)	32.5 (26.9, 38.2)
Weight change 6 weeks ^b mean (95% CI)	-1.4 (-2.9, -0.1)	-2.6 (-3.9, -1.4)	-4.2 (-6.5, -1.9)	-3.4 (-4.4, -2.4)
Sex (female), ^d n (%)	9 (81)	5 (56)	9 (81)	10 (83)
Race (white), ^d n (%)	11 (100)	9 (100)	11 (100)	12 (100)
Managerial and professional occupation, ^d n (%)	8 (73)	9 (100)	10 (91)	5 (42)
Has a university degree, ^d n (%)	7 (64)	7 (78)	9 (82)	8 (67)

^aStopped early: recorded <31 days; consecutive over long term: monitored over the 6-month period with no more than four breaks of no more than 10 days at a time.

^bSignificant differences between the four patterns of use assessed by one-way ANOVA.

^cCFC: consideration of future consequences.

^dSignificant differences assessed by Kruskal-Wallis.

Table 5. Regression analysis of pattern of My Meal Mate use as a predictor of follow-up weight (adjusted for baseline weight) in the My Meal Mate arm of the pilot trial.

Pattern of adherence	n	Weight loss coefficient (kg) (95% CI)	P value
Stopped early	11	Reference	—
Moderate	9	-3.1 (-7.4, 1.2)	.16
Long but intermittent	11	-7.5 (-11.6, -3.4)	.001
Long consecutive	12	-3.2 (-7.2, 0.8)	.12

Figure 1. Distribution of days of dietary recording on My Meal Mate for each participant (n=43) over the course of the 6-month My Meal Mate pilot trial. The x-axis is the My Meal Mate ID number that was automatically assigned to the participant and the y-axis is dietary self-monitoring in days. Each green shaded box is a day with ≥500 and ≤5000 kcal energy recorded on My Meal Mate.

Discussion

A post hoc analysis investigating the relationship between dietary self-monitoring (using a mobile phone app) and weight loss has been presented. High-frequency users of the My Meal Mate app (recorded ≥ 129 days of intake) were found to have a -4.7 kg (95% CI -8.2 to -1.1 , $P=.001$) lower mean follow-up weight (adjusted for baseline) than moderate users (43-128 days) and a -6.4 kg (95% CI -10.0 to -2.9 , $P=.001$) lower mean follow-up weight than low-frequency users (≤ 42 days). The difference in follow-up weight between moderate- and low-frequency users was not found to be statistically significant ($P=.33$). Those who monitored intermittently over the whole course of the trial had a -7.5 kg (95% CI -11.6 to -3.4 , $P=.001$) lower mean follow-up weight (adjusted for baseline) than those who monitored for a short time and stopped early. Those who monitored for a moderate time and then stopped and those who monitored consecutively over the 6 months did not have a statistically significantly greater mean weight loss than those who monitored for a short time and stopped ($P=.16$ and $P=.12$, respectively). These results provide preliminary evidence that continuous self-monitoring may not be necessary for weight loss.

Participant characteristics such as age, sex, conscientiousness, and CFC were not found to predict extent of self-monitoring as reflected by number of days of app use. However, our sample size may have been too small to detect differences. A post hoc power calculation shows that based on the follow-up values from the mobile phone and paper diary group in the My Meal Mate pilot trial, the sample size had 90% power to detect a statistically significant difference of 13 kg in follow-up weight between two groups and 80% power to detect a difference of 11 kg (at the 5% significance level). The sample size in the trial ($n=43$ in each arm) had 10% power to detect the actual difference in follow-up weight found between groups.

The Relationship Between Frequency of Dietary Self-Monitoring and Weight Loss

Dietary self-monitoring is an important outcome because it has been consistently linked to weight loss [5,8,27]. The frequency-of-use findings presented in this paper are supportive of the findings of the SMART trial which analyzed different categories of adherence to a PDA, PDA with feedback, and a paper diary [13,17]. The SMART trial reported that weight loss was greater (across groups) for those in the highest categories of adherence to dietary self-monitoring ($\geq 60\%$ adherent) than those in the lowest categories ($\leq 30\%$ adherent). For example, in the PDA and feedback group ($n=70$), mean percentage weight change at 18 months was -10% (SD 9%) in the highest adherence category ($\geq 60\%$ adherent), -12% (SD 9%) in the medium adherence category (30%-59% adherent), and -3% (SD 7%) in the low adherence category ($<30\%$). Burke et al [17] found that moderate- and high-frequency users had lost roughly equivalent amounts of weight at 18 months, whereas the findings from this trial of My Meal Mate suggest that high-frequency users had lost a statistically significantly greater amount of weight than moderate users. At 6 months in the SMART trial, it appears that the difference in weight loss

between high- and moderate-frequency users was wider. For example, in the PDA plus feedback arm, those in the high adherence category ($\geq 60\%$ adherent) had a -9% (SD 7%) mean weight change compared to a -2% (SD 5%) mean weight change in the medium adherence category (30%-59% adherent). Because the trial of My Meal Mate was only for 6 months, it is not known whether the weight loss seen would continue to be maintained in the long term. Therefore, the findings from the SMART trial are interesting because the optimum amount of electronic dietary self-monitoring for weight loss in the short term may be different from the optimum amount for long-term weight maintenance.

The Relationship Between Pattern of Dietary Self-Monitoring and Weight Loss

A unique aspect of the analysis presented here is that the pattern of dietary self-monitoring was considered in addition to the frequency. This exploratory analysis does suggest that long-term intermittent monitoring was associated with a greater weight loss and that monitoring in the short or moderate term and stopping completely was not enough to imbue the user with the necessary changes to lose weight by 6 months. Surprisingly perhaps, long-term intermittent monitoring was more effective for weight loss than those who used the My Meal Mate app fastidiously with consecutive days of monitoring and few breaks. However, the small numbers within categories do give wide confidence intervals so results must be interpreted with caution.

There is a gap in knowledge about the optimum frequency and pattern of self-monitoring necessary for successful weight loss. These findings suggest that there may be some kind of "learning effect" in the intermittent group that they did not need to use the My Meal Mate app to track calories every single day, but were perhaps self-managing the days when they needed extra help to track over the long term. It could be speculated that the group of individuals who monitored consecutively every day relied on the phone to self-monitor, but were not learning as much about their intake or feeling as confident about having days of nontracking when they were responsible for their own instinctive self-management. Perhaps those that monitored intermittently over the 6 months were still sufficiently invested in the process of self-monitoring to carry it out over the long term, but during this time their awareness of their dietary intake and self-sufficiency had increased so that they could identify when they needed some more support and could use the diet tracking as and when they needed it. At this stage, this interpretation is conjecture and in a definitive trial with larger numbers, an attempt to classify pattern of self-monitoring in this way would be useful to further investigate how much dietary self-monitoring is necessary.

Predictors of Dietary Self-Monitoring

There is little evidence to suggest which individual characteristics may or may not be predictive of successful dietary self-monitoring. A range of baseline characteristics were investigated between categories of frequency of dietary self-monitoring and pattern of self-monitoring (including personality traits such as conscientiousness and CFC), but none were found to be statistically significantly different. It may be the case that these factors are genuinely not predictors of dietary

self-monitoring or it could be that the sample size was too small to detect such differences. It would be interesting to examine potential predictors of successful dietary self-monitoring in a larger trial. If such characteristics were identified as predictors of successful dietary self-monitoring, it may indicate scope to target those most likely to find it useful.

The Need for a Consistent Dietary Self-Monitoring Adherence Outcome

Researchers have taken different approaches to measuring frequency of electronic dietary self-monitoring, so direct comparison of results is difficult. For example, frequency of use or adherence to dietary self-monitoring has been measured in the following way by different studies: total number of days with over 900 kcals recorded using a handheld microcomputer [28], number of weekly submissions of PDA records [12], as a binary variable with adherent behavior categorized as more than 50% of weekly calorie goal met [29], percentage of days with plausible intakes recorded on a PDA, sampled for the first and last week of the study [30], and self-reported number of days per week with dietary self-monitoring using a mobile phone app in addition to a podcast and Twitter intervention [31].

Frequency of dietary self-monitoring has been measured differently in each study; therefore, it is difficult to describe a range of adherence across the studies. In this trial, the number of days with a plausible energy intake was intended to be analyzed as a continuous variable. However, given the U-shaped distribution of the variable it was more appropriate to split it into categories rather than treat it as continuous in a regression analysis. Although the frequency-of-use variable is useful for exploratory analysis, it is still a rather crude measure of adherence to dietary self-monitoring because it does not provide details about weekly patterns of monitoring over time. Adherence has been measured differently by other researchers. Burke et al [29] created a binary variable of adherent or nonadherent, which was based on the person recording $\geq 50\%$ of their weekly calorie goal. This gives a week-by-week pattern of adherence over time. However, this is still quite an arbitrary cut-off given the paucity of evidence about what constitutes successful dietary self-monitoring. The differing approaches to measuring adherence to dietary self-monitoring make comparison between studies difficult and a standard approach is warranted.

Limitations

Generalizability of the results is limited given that the sample is exclusively of white ethnic origin, predominantly female and mostly employed in managerial/professional occupations. My Meal Mate was a prototype app and participants reported that they frequently encountered bugs that caused the app to close. This may have affected participant engagement. As a pilot, the trial was not statistically powered to detect a particular change

in weight and the primary outcomes were feasibility and acceptability measures. Therefore, the results from this post hoc analysis need to be interpreted with caution given the small numbers in the My Meal Mate arm and the multiple testings, which increases the risk of a type 1 statistical error. In addition to the variables measured at baseline, it is acknowledged that there are other potential predictors of dietary self-monitoring which might be investigated when examining frequency of use of a mobile phone app, such as usability, technology acceptance, satisfaction, and ease of use. Usability in particular might be particularly interesting to examine, given that a recent pilot trial found perception of usability to be associated with high adherence to a technology-supported intervention to improve fitness in older adults [32]. Despite these limitations, the results are interesting and are intended to be interpreted as exploratory and hypothesis generating.

Strengths

The automated time- and date-stamped information collected by the My Meal Mate app is a strength because it allows for objective analysis of dietary self-monitoring. The work presented is also unique in considering not only the frequency of self-monitoring, but also the distribution of monitoring days/pattern of monitoring over time. If more is known about how much self-monitoring is effective and whether monitoring needs to be consecutive or whether breaks in monitoring are acceptable, participants in weight loss trials could be given more prescriptive advice about how best to track their diet and be supported in adherence to self-monitoring.

Conclusion

A post hoc analysis of the relationship between dietary self-monitoring (frequency and pattern) and weight loss in participants using a mobile phone app to facilitate weight loss has been presented. In this trial, the optimum use of the My Meal Mate app for weight loss appeared to be 129 days or more and intermittently over the long term (3-6 months). Given the small sample size within the My Meal Mate arm of the trial and the dangers of multiple testing, the results from this analysis, although interesting, must be treated with caution.

The investigations conducted in this paper are important because although dietary self-monitoring is associated with weight loss, there is a paucity of information about what to recommend to overweight/obese individuals about the optimal level of monitoring. Electronic means of dietary self-monitoring, such as online dietary assessment systems, PDAs, and mobile phone apps, provide a unique opportunity to investigate self-monitoring behavior objectively. Future research should continue to seek to establish the "optimum dose" for effective dietary self-monitoring and whether certain personality traits are associated with effectiveness of self-monitoring for weight loss.

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Authors' Contributions

MC was involved with the design and running of the pilot trial, data collection, analysis and interpretation of the data, and wrote the initial draft of the manuscript. JC and VB assisted in designing the study, interpretation of the data, supervision of the project, and preparation of the manuscript.

Conflicts of Interest

The University of Leeds is establishing a spin-out company called Dietary Assessment Limited and JC is a director of the company.

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Abbreviations

BMI: body mass index

CFC: consideration of future consequences

PDA: personal digital assistant

SMART: Self-Monitoring and Recording using Technology

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Original Paper

Latino Adults' Perspectives on Treating Tobacco Use Via Social Media

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Abstract

Background: Latinos are the largest minority group in the United States, and in California they outnumber non-Hispanic whites. Smoking cessation programs tailored for Latino culture, and this population's specific smoking patterns, are needed. Online social networks for smoking cessation have high potential for Latinos, but have not been tested to date.

Objective: Building a research program on social media apps for cancer prevention in diverse populations, this qualitative study assessed acceptability of tobacco treatment that was distributed via social media for Latino smokers.

Methods: We conducted three focus groups with Latino adults who were former and current smokers recruited from Santa Clara County, California in 2015 (N=32). We assessed participants' smoking histories, attempts to quit, social media exposure, and receptivity to a social media-based smoking cessation intervention. Audio transcripts were translated and coded for themes.

Results: Participants reported factors driving their tobacco use and motivations to quit, and emphasized the importance of community and family in influencing their smoking initiation, cravings and triggers, attempts to quit, and abstinence. Participants valued the communal aspect of social media and suggested strategically tailoring groups based on key features (eg, age, gender, language preference). Participants reported preferring visual, educational, and motivational messages that were connected with existing services.

Conclusions: Participants generally voiced acceptability of a social media-delivered intervention to help them quit smoking, viewed the intervention as well-equipped for catering to the strong community orientation of Latinos, and suggested that the platform was able to address variation within the population through strategic group creation. As a group member reflected, "Podemos hacerlo juntos" (We can do it together).

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KEYWORDS

smoking cessation; tobacco; Latino; Hispanic; social media; focus group

Introduction

Tobacco is the leading preventable cause of death, and is linked to a dozen types of cancer, along with heart and lung disease [1]. Traditional smoking cessation programs remain

underutilized, particularly among racial and ethnic minorities such as Latinos [2]. Latinos are the largest racial/ethnic minority in the United States and in some areas, such as California, Latinos outnumber non-Hispanic whites (15.19 million vs 14.88 million) [3]. Latino smokers tend to smoke fewer cigarettes

than non-Hispanic white smokers and are less likely to be daily smokers than smokers of all other racial/ethnic groups; hence, cessation pharmacotherapy may not be indicated [4]. Furthermore, research indicates that light and intermittent Latino smokers are infrequently advised to quit by healthcare professionals [5]. Among Latino smokers surveyed at a community health fair, only 5% reported ever using cessation medications, and less than 6% were aware of smoking quit-lines [6]. However, surveys of light and intermittent Latino smokers have indicated high readiness to quit and interest in smoking cessation programs [7]. Given light and intermittent smoking patterns and low penetrance of existing smoking cessation programs, innovative behavioral or psychological approaches are needed for the large population of Latinos in the United States.

Tailoring of cessation treatment strategies to target audiences has been a strategy for increasing reach and engagement. In the early 1990s, a printed Spanish-language smoking cessation guide was found to support quitting and was distributed as a best practice [8]. A 2003 review of the research literature identified 10 published tobacco treatment studies that were targeted to Latino smokers, some of which included video and audio enhancements [9]. The authors concluded that greater innovations were needed to leverage state-of-the-art practices for treating tobacco addiction in ethnic minorities, with a focus on Latino smokers [9]. A 2011 review identified an additional 5 tobacco treatment studies focused on Latino smokers; added to Spanish language print materials were home visits with lay health advisors, telephone counseling, and group sessions [10]. Findings generally indicated that treatments increased abstinence, at least in the short-term [10]. The need for more research, with a particular focus on Latino smokers, was underscored. Herein, we sought to explore whether cessation treatments could be acceptably delivered via virtual support groups on mobile devices.

Online social media sites allow real-time interactivity and peer-to-peer support, which may build upon cultural norms and values, with potentially low-cost application for disseminating health interventions to diverse groups. Furthermore, communications generated and catalogued on social media sites provide novel information for better understanding transitions in smoking and emerging product use (eg, electronic cigarettes; e-cigarettes). Twitter is the dominant open social media site, with a reported 320 million active monthly users, representing growth of 9.6% over the same period a year prior [11]. As a platform, Twitter has been utilized in over 140 medical and health care applications [12]. When studying the treatment of tobacco use in a randomized controlled trial (N=160), we found self-reported sustained abstinence for 60-days was 40% for a Twitter smoking cessation support group versus 20% for the comparison group ($P=.012$); 81% of the sample was non-Hispanic white [13]. To support broader reach and engagement, evidence of acceptability among Latino smokers is needed.

Social media is likely to be a viable platform for Latino adult smokers, given the widespread use of the Internet, particularly for the dissemination of health information. A 2010 Pew Hispanic Center study reported that 83% of Latinos received

health information from media sources, including 35% online [14]. Furthermore, 64% reported having changed their behavior based on information from online health sources [14]. From 2009 to 2013, Pew data indicated that Latinos in the United States crossed the *digital divide*, exceeding non-Hispanic whites in cellphone ownership (86%), going online from a mobile device (75%), and social networking (68%) [15]. Furthermore, Latino consumers share information via social media fivefold more often than non-Latino users [15]. Among Latinos in the United States who access social media, 60% do so in English, 29% in Spanish, and 11% equally using English and Spanish; by nativity, 86% of Latinos born in the United States use English, while 55% of foreign-born Latinos prefer Spanish [15]. Within a context of low access to health care, high social media use, and differing language preferences, electronic health approaches have been suggested as ideal methods for reaching Latinos [16]. However, the use of online social networks to aid Latino adults with smoking cessation has not been tested.

To inform a social network-based smoking cessation program, we conducted focus groups with Latinos who were current and former smokers to determine if a tobacco cessation treatment distributed via social media would be acceptable. Secondary research aims were: gathering information and feedback about local Latino smoking profiles, attempts to quit, and social media exposure to inform the intervention strategy and community outreach efforts.

Methods

Sample

Participants were recruited via online classified advertisements (Craigslist), in person by community health workers, and through word-of-mouth in Santa Clara County. Inclusion criteria were: age 18 years or older; identifying as Latino/Latina; residing in the Santa Clara County area; and status as a current daily, social, or former smoker.

Procedures

The focus group moderator was fluent in Spanish and English. The groups were semistructured. The moderator guide prompted questions about mobile phone and social media use, smoking, quitting smoking, and treatment preferences. An initial survey assessed participants' demographic and smoking history information. Study procedures were approved by the Stanford Institutional Review Board; all participants provided signed informed consent in Spanish or English, were compensated US \$50 for their time, and received a meal during the focus group session.

Data Reduction and Analysis

Each focus group was audio recorded. A Spanish/English bilingual coder listened to the focus group audio recordings and outlined initial coding themes, which were discussed and refined by the research team. The audio recordings were simultaneously translated and transcribed to a final written transcription in English. Using a detailed codebook, the same bilingual team member then coded the written transcripts for emergent and preidentified themes of interest using Dedoose [17]. A second coder utilized the codebook to review the coding of the written

transcripts. Discrepancies were discussed with the senior author to come to consensus.

Results

Sample Description

A total of 32 individuals (15 men, 17 women) from Santa Clara County, California participated. Participants included 19 current daily smokers, 4 intermittent or nondaily smokers, and 9 former smokers. Daily smokers averaged 8.4 cigarettes per day (standard deviation [SD] 10.4, range 1-40) and nondaily smokers averaged 4.3 cigarettes per week (SD 3.8, range 1-8). Current smokers reported time to first cigarette upon waking within 5 minutes (3/23, 13%), between 6-30 minutes (3/23, 13%), between 31-60 minutes (6/23, 26%), and greater than 60 minutes (11/23, 48%). Factors that kept participants from smoking sooner included children, having to go outside to smoke, TV, and checking Facebook. Participants reported getting their cigarettes from friends (n=15), gas stations (n=13), liquor stores (n=12), and corner stores (n=12).

All participants had made at least one 24-hour attempt to quit smoking (range 1-7). Identified reasons for quitting related to money, work, a home smoking ban, family and friends, cancer fears, sports, and not feeling the urge to smoke. Among the 23 current smokers, 6 (26%) were not intending to quit in the near future (precontemplation), 7 (30%) intended to quit in the next six months (contemplation), and 10 (43%) were planning to quit in the next month (preparation). Three individuals reported assistance for quitting smoking from a medical provider. Only one respondent reported using nicotine replacement. No participants reported using other cessation medications or formal psychosocial supports to quit (eg, group or individual counseling, quit-line).

Most participants owned a smartphone (27/32, 84%), and all but one kept their phone with them every day. The majority of respondents reported having their phone turned on all the time (20/32, 63%), texting on their phone more than once daily (26/32, 81%), and checking their Facebook page at least once daily (22/32, 69%).

Tobacco Use Association and Triggers

At the start of the focus groups, in a word association task (ie, "What word comes to mind when you think of smoking?"), participants connected smoking to negative health and social effects in the following order of frequency: cancer, money, aging skin, and guilt. Participants also identified positive aspects of smoking, including social activity, calming, weight loss, and hobby.

Triggers for smoking were mentioned throughout the focus group conversations. In order of frequency (with counts indicated) participants identified: stress from school, work, family, and traffic (11); negative emotions such as anger and anxiety (6); alcohol use (4); other habitual triggers (4); others smoking (3); work breaks (2); boredom (2); seeking relaxation (2); and smoking for gastrointestinal regularity (1). Notably, social media was not identified as a trigger to smoke.

Motivations for Quitting Smoking

While a minority of participants were former smokers, all had experience with quitting for at least 24-hours. Motivations for quitting centered around family, including children, siblings, partners, and parents:

I would hide my cigarettes, I used perfume so that my son couldn't smell the cigarette, I would wash my hands, but on one occasion he looked at me and he said, "Oh, you're smoking!" I felt like a bucket full of water fell over me, he said, "Do you want to die? If you don't care about me, continue smoking." His words hurt me so much that in 15 days I quit because I thought that a cigarette was not more important than my son. It was very hard, I had terrible headaches, shaking... but the love for my son is what helped me quit smoking."

Life transitions were a common theme, overlapping with family concerns, as pregnancies and new babies were prominent transitions. Two women and a man successfully quit smoking during a family pregnancy. As one woman shared:

I started smoking when I was 13, and I quit smoking when I was 41, because I got pregnant. After 28 years, it was very difficult for me to quit smoking, but it was the promise I made because I got pregnant, and I haven't smoked for 15 years.

Another woman described her shame and concerns around not being able to quit during pregnancy:

My last pregnancy - I did smoke. It caused me a lot of pain, and I have four children with asthma because I smoked when I would breastfeed. My youngest girl also has asthma. I've always had bronchial disease, and my kids would tell me, "I don't want you to die." I knew it was wrong, but I would get mad, or I'd get sad, and I would get out to smoke. Sometimes I get an urge to smoke, but I love my children a lot, and I want to live for them.

Additional influences identified as motivating cessation were religious faith, medical advice, and financial and health concerns. One participant said her sister became a Christian and stopped smoking, while another shared her promise to God to quit smoking. A third participant shared, "I always would ask my God, 'You know what? I can't do this alone, help me to give up this obsession.'"

Social Support and Community

The importance of social support and community were identified as themes. Participants noted that *two heads think better than one* and emphasized a shared belief that humans are social beings. Another explained, "Sometimes we only need support... you can succeed because there's somebody who wants the same for you." The salience of broader community support was particularly relevant in the context of the isolation of immigration. One participant talked about a friend who confided that she only smoked because she was lonely and sad as an immigrant. She shared:

Sometimes people need to be in a group to be able to see how other people are trying hard to quit in order to encourage themselves to quit too. Some people are in this country and they are alone, so I think [support] would help them.

Social Media for Quitting Smoking

Platforms

Participants reported using various social media platforms, including Facebook, Twitter, Instagram, Skype, Yahoo, and Snapchat. The groups stated a strong preference for Facebook and visual messages. The overall sentiment across groups was acceptability of social media as a vehicle for smoking cessation programs. One participant stated, "I think this idea is very good because... we're 100% cybernetic... and [social media] is the right weapon to use." Another asserted, "I think it would be a magnificent idea because... I have people on there [Facebook] that put they feel bad... and we send them a message, and it helps." Furthermore, social media smoking cessation groups were imagined as supportive of quitting, in contrast to existing social networks of smokers who may encourage continued smoking. Participants also liked the idea of knowing that strangers in a group would withhold judgment toward any failed quit attempts.

Not all participants agreed, however, with one participant stating that his family and friends would be better able to support his quitting compared to, "a group of strangers." One participant resisted the idea of spending more time on her phone, noting that as a parent her time at home is already too hectic. Another respondent voiced concern, explaining:

I don't know how comfortable people would be about going into a group... share with someone that they don't know. Being anonymous... especially since Latinos... we tend to be more like, who do I know versus I don't know you. I think that might become an issue.

Group Formation

Participants discussed whether the groups should be matched on salient characteristics. One social smoker wanted to be in a group of nondaily social smokers. Another participant suggested creating groups based on common interests, similar to what is done on "dating sites." A discussion centered on matching participants by age. One young adult participant stated, "If I see a young person trying to stop... we can do it together." Another participant voiced potential benefits of mixed-age groups, stating:

different ages could help. I know that for the young ones, the pressure they have is very difficult, even more if they're in school, they get stressed out, and they want to relax. So having an adult in that group who has more knowledge could be beneficial to them.

Other respondents encouraged the idea of keeping age unknown. One participant, with the perspective that age should not matter, asserted, "Cancer doesn't look at ages, or race." Another participant reflected:

The most convenient thing is to have the ages unknown because maybe the one who is smoking really needs help. If they say, 'Oh, it's a person who is 60,' and they'll say, 'What's this old man or woman going to know?'

Language Preference

Regarding language preference for a Latino-focused smoking cessation intervention on social media, 7 participants preferred a mixed English/Spanish platform, 4 preferred Spanish only, and 1 preferred English only. Three additional participants did not have a preference, and opted for group leaders to choose. The other 17 participants did not voice a preference. All participants, except the one who preferred English only, reported that Spanish was their dominant language.

Messaging

Participants shared advice on the types of smoking messages that would be most effective for individuals trying to quit smoking. There was a preference for nonforceful communication with no demanding messages, such as, "Don't push; we'll do it because we want to do it." Preferred messages were educational and provided motivation and support. One participant emphasized, "It's important that we know why we are making the decision to quit. It's good to help us understand why we made decisions to quit." Participants also recommended linking social media cessation interventions with existing support systems and services, such as the national smokers quit-line (1-800-QUIT-NOW).

The use of visual images was also encouraged, reflected by the quote, "A picture has a bigger impact than a word." One participant shared, "I have a friend and he's a doctor and he continuously post lungs... [and information] about cigarette filters." Two participants stated that it was uncommon to see images or information about smoking on social media, while others noted postings of drinking and smoking at parties rather than encouragement to quit.

Electronic Cigarettes

Despite not being part of the discussion guide, e-cigarettes represented an emergent topic with a variety of expressed opinions. Some participants were positive towards e-cigarettes with assertions that, "They're not as bad as cigarettes", "They're cheaper than tobacco", and not a "bother" to others with a bad smell. Participants reported seeing e-cigarette advertising cessation claims, although no respondent reported successfully quitting smoking using e-cigarettes. Participants reported a willingness to try e-cigarettes, largely out of curiosity instead of a desire to quit smoking.

Discussion

Latino smokers and recent former smokers from the Bay Area of California largely found the concept of a social media tobacco cessation intervention acceptable. Social media was perceived to be well-equipped to meet the social- and community-oriented experiences of Latinos. Participants also noted that social media could allow for further tailoring of support groups based on homophilous characteristics related to age, smoking frequency,

and language preference. A preference was stated for Facebook, due to participant familiarity with the platform and the ability to leverage visual as well as text-based content. Visual communication of health information improves comprehension, and enhances attention, memory, and recall [18]. Our team's recent evaluation of *Tweet2Quit* in a largely non-Hispanic white sample found that participant engagement (ie, tweeting) predicted success in quitting smoking [13]. More visual messages, as attention-attractors, may encourage quitting success via increased engagement.

Focus groups have been used in research to explore the experience of smoking cessation among ethnic minorities and have highlighted the importance of considering levels of acculturation in program tailoring [19]. Although our groups did not expressly discuss acculturation, participants highlighted a desire for social media smoking cessation groups constructed around similar age and language preferences, which are two potential indicators of acculturation.

Family orientation, social support, and community were prevailing themes in the focus group discussions of smoking, attempts to quit, and social media use, providing a basis for why social media may be particularly well-suited for a Latino-focused smoking cessation intervention. Participants noted the opportunities for community-building in social media venues, which have not previously been available through traditional websites or quit-line interventions. The Latino experience of quitting smoking is also conceptualized as a family or group effort, and social media may address previous calls to tailor interventions for racial/ethnic-specific processes for quitting.

As a local qualitative study, the generalizability of our results is limited. The group moderator was fluent in Spanish, and coding was done via listening in Spanish; however, the final analysis of transcripts was conducted in English, which may

have reduced or changed content in unpredictable ways. Despite these limitations, findings with respect to acceptability of social media, importance of family in health behavior change, and preference for visual material are likely broadly relevant.

In conclusion, a social media-delivered intervention to support smoking cessation appears to be acceptable for Latino smokers. Regarding immediate implications, the study findings support efforts to develop novel interventions for treating tobacco use via social media. These interventions may be tested as standalone cessation programs or as adjuncts to existing treatments. For cultural relevance, message themes within the program should attend to family and community ties and influences. For maximum engagement and inclusiveness, flexibility in language use (ie, English, Spanish, both) should be permitted and encouraged. The specific social media platform may be determined by usage rates and fit of the technology for the intervention's approach and privacy concerns. Regardless of platform, community outreach and engagement is essential to treatment impact, and Latino smokers' tobacco purchasing behaviors may inform channel selection. Based on the focus groups, places to promote a social media quit smoking program would include in gas stations, liquor stores, and corner stores, near where cigarettes are displayed, as well as via word-of-mouth referrals from friends.

The use of social media by Latinos is high; however, the use of these media for health behavior change appears to be underdeveloped. As such, our next steps will center on developing and testing a Latino-specific, bilingual, private, support group-based social media intervention for smoking cessation. The examination of homophily in group communications will be of particular interest, to determine whether directed and reciprocated communications align around shared member characteristics (eg, gender, age, daily/nondaily smoking status, language preference).

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Conflicts of Interest

Dr. Prochaska has served as an expert witness in court cases against tobacco companies and has consulted for Pfizer, which makes smoking cessation medications. All other authors have no competing interests to disclose.

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Abbreviations

e-cigarette: electronic cigarette

SD: standard deviation

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Original Paper

Stress Management Apps With Regard to Emotion-Focused Coping and Behavior Change Techniques: A Content Analysis

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Abstract

Background: Chronic stress has been shown to be associated with disease. This link is not only direct but also indirect through harmful health behavior such as smoking or changing eating habits. The recent mHealth trend offers a new and promising approach to support the adoption and maintenance of appropriate stress management techniques. However, only few studies have dealt with the inclusion of evidence-based content within stress management apps for mobile phones.

Objective: The aim of this study was to evaluate stress management apps on the basis of a new taxonomy of effective emotion-focused stress management techniques and an established taxonomy of behavior change techniques.

Methods: Two trained and independent raters evaluated 62 free apps found in Google Play with regard to 26 behavior change and 15 emotion-focused stress management techniques in October 2015.

Results: The apps included an average of 4.3 behavior change techniques (SD 4.2) and 2.8 emotion-focused stress management techniques (SD 2.6). The behavior change technique score and stress management technique score were highly correlated ($r=.82$, $P=.01$).

Conclusions: The broad variation of different stress management strategies found in this sample of apps goes in line with those found in conventional stress management interventions and self-help literature. Moreover, this study provided a first step toward more detailed and standardized taxonomies, which can be used to investigate evidence-based content in stress management interventions and enable greater comparability between different intervention types.

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KEYWORDS

mHealth; mobile health; relaxation

Introduction

Chronic stress has been shown to influence people's physical and mental well-being [1,2]. For example, evidence is growing that stress is related to depression, cardiovascular disease, human immunodeficiency virus or acquired immunodeficiency syndrome, upper respiratory tract infections, asthma, herpes viral infections, autoimmune diseases, wound healing, and tumor

progression [2,3]. Additionally, chronic stress and health are linked indirectly through stress-related behaviors such as smoking, sedentary lifestyle, poor eating habits, alcohol and drug abuse, as well as insufficient therapy adherence [2,4].

Although the effects of stress depend on the timing, duration, and to some extent on the interaction between genes as well as the previous exposure to environmental adversity [5], an individual's well-being depends not only on his or her exposure

to stress, but also on the way he or she copes with this stress. Two broad types of stress management can be distinguished: problem-focused and emotion-focused coping [6]. Problem-focused stress management refers to methods attempting to alter the relationship with the environment, whereas emotion-focused stress management methods aim at reducing, tolerating, or eliminating stress sensations.

Stress management group interventions usually use a multitechnique approach. The variability between studies and technique descriptions does not, however, allow conclusions about which combination of techniques should be used [7]. The same applies to self-help books in this context (see [8] for a bibliography and reading recommendations). Most of them present a broad range of coping techniques. Although it is unclear how many coping techniques should be adopted to achieve a maximum improvement of stress-related symptoms, it has been shown that not all coping techniques work equally well for every individual (eg, the effects of hypnosis are highly dependent of a person's suggestibility [9]). Moreover, certain stress management techniques are especially useful for reducing specific kinds of symptoms [10].

Besides self-help literature, psycho-technology mobile apps have emerged as a useful complementary tool in psychotherapy [11]. The recent mHealth trend offers a new and promising approach to support the adoption and maintenance of appropriate health behavior. As mobile phone users can be reached anytime and anywhere [12], apps can be used as a platform for behavioral interventions [13]. Furthermore, mHealth apps allow the usage of gamification aspects that can potentially increase users' motivation [14]. Following this idea, mobile phone-based stress management interventions could result in savings for the health care system [15], provided that they are effective.

However, little is known about the usage of specific coping strategies in current stress management apps. Although there are first indications that at least some of them might be effective, for example, StressEraser [16-20] or AEON [21], most stress management apps have not been evaluated yet [22,23]. So far, 3 reviews have been published. Lee et al [22] come to the conclusion that current stress management devices show controversial theoretical underpinnings and a lack of systematic evaluation. Plaza et al [23] investigated app objectives within meditation apps and reported that only 56-61% of these apps were in fact devoted to meditation. Coulon et al [24] conducted the first analysis of stress management apps with regard to 7 evidence-based stress management strategies, transparency in app development, and functionality of the app interface in spring 2015. Mindfulness and meditation as well as diaphragmatic breathing and seeking social support were used most frequently in these apps. Visualization and imagery, active coping, problem solving, and cognitive restructuring were less common. Only half of the samples included evidence-based content, as well as acceptable usability and functionality. This study provided a first impression regarding the use of evidence-based content in current stress management apps including a brief list of problem-focused and emotion-focused coping strategies.

However, to the best of our knowledge, there is no established taxonomy with regard to emotion-focused stress management

strategies. Therefore, a corresponding taxonomy including clear definitions for each strategy was developed for this app analysis. In addition to the emotion-focused stress management strategies that have been investigated by Coulon et al [24] (namely breathing exercises [25-27], progressive muscle relaxation [26,28], meditation or mindfulness [29-31], and visualization or guided imagery [26,32]), the following evidence-based strategies were identified during a thorough literature review: autogenic training [33], biofeedback [26], emotional freedom technique or acupressure [26,34], euthymic methods [35], hypnosis or self-hypnosis [36], (self-)massage [37], and physical stress relief techniques such as yoga [38] or tai chi [39]. As stress sensations can also be influenced by some types of music [40,41], sounds of nature [42], nutrition [43], and sport [44], these aspects were also included (see Table 1 for an overview and definitions). By considering a broader range of established methods, this approach interestingly allows for a more extensive investigation on the usage of emotion-focused stress management strategies.

Based on the taxonomy developed by Abraham and Michie [45], additional evidence-based behavior change techniques have been investigated in this review. This taxonomy has already been used in previous health app analyses [46-50], revealing that the usage frequency of evidence-based behavior change techniques varied with mean scores on a low to moderate level. Furthermore, it has been shown that stress management (which is included as a behavior change technique in this taxonomy) is used only rarely [47,51], thereby underpinning that stress management only seems to play a subordinate role in current health apps. More importantly, using the same taxonomy helps to compare the results of this app review with those of other health apps.

Although problem-focused coping is not the main focus of this taxonomy [45], it is interesting to note that some problem-focused coping strategies for stress management are nevertheless addressed, namely planning of social support and social change [52], time management [53], self-monitoring [54], and goal setting [55].

This was the first study to investigate the usage of evidence-based content in current stress management apps based on such detailed taxonomies. Not only this approach reveals problems in current stress management apps, the detailed and standardized taxonomy of emotion-focused stress management strategies can also be used in further stress management research to increase comparability between different intervention types.

Methods

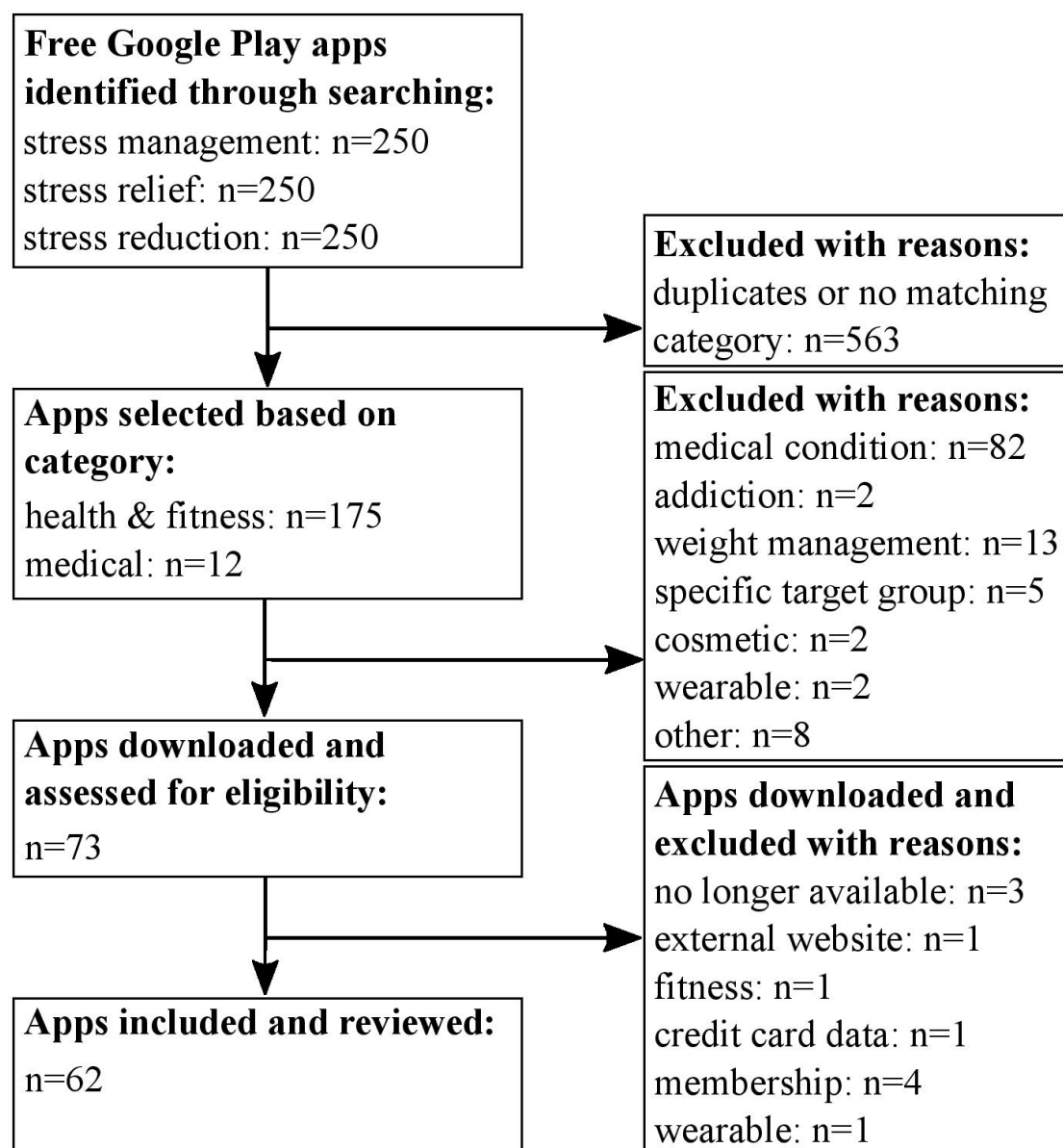
Selecting Apps for Review

As Android has become the most frequently used mobile phone operating system on the global market [56] and systematic reviews for stress management apps from Google Play have not been published yet [24], this review only included apps, which were available through Google Play in October 2015. Apps were identified using the search terms "stress management," "stress reduction," and "stress relief". For each search term, the first 250 free apps were checked regarding the following

inclusion criteria (see [Figure 1](#) for a schematic overview of the selection process): (1) Apps had to be provided in the “Health & Fitness” or “Medical” categories of Google Play to exclude apps that focus on “Entertainment” (eg, mini-game activities), “Beauty,” or “Music & Audio.” In line with this idea based on app descriptions, only apps were chosen that target stress management and well-being; (2) To ensure applicability for a broader range of people, the respective apps should target healthy adults and not specific groups, medical conditions, or weight management; specifically because apps targeting a specific group (eg, children, specific medical conditions) have different requirements compared with stress management apps

for healthy adults; (3) Apps that require membership of a company were excluded for the same reason. Instead the focus was put on free apps, considering the fact that most apps in the categories “Health & Fitness” (90%) and “Medical” (86%) are provided for free in Google Play [57]; (4) Apps that require an additional wearable were also left out, as most wearables are still scarcely accessible to the general public [58]; (5) Finally, this review included only English apps to ensure a broader accessibility. Following this procedure, the only app that had also been investigated in the study of Coulon et al [24] was Breathe2Relax. At the time, about 50% of the apps used in this study were also available for iTunes.

Figure 1. Flowchart for schematic overview of the selection process for stress management apps. The resulting sample comprised 62 apps.



Procedure and Data Analysis

Apps that met all inclusion criteria were downloaded, installed, and tested using the Android Development emulator software of Android Studio version 1.3 (Google Inc) running Android OS 4.4 [59] by both raters in October 2015. At times, this approach was unsuccessful in regards to the presentation of some app content such as playback of audio or video files, download of data, and display of pages. Therefore, apps facing such difficulties were subsequently installed on a Nexus S mobile phone to examine the problematic features.

The 62 apps were downloaded and evaluated by two trained and independent raters (the second author and a graduate student of psychology) regarding two taxonomies: 1 for behavior change techniques and 1 for emotion-focused stress management strategies.

Each app allowed the users to progress at their own speed, allowing both raters to thoroughly check all features of the apps

until it was apparent that no new features were going to be activated. The results of this review are based on content that was provided by the apps themselves. Information and features on websites linked within the apps were not considered.

Evaluation Criteria and Instruments

The evaluation of behavior change techniques was based on an established theory-linked taxonomy. The full list of these techniques including detailed definitions can be found in the study by Abraham and Michie (2008) [45]. Stress management is included as one of those 26 behavior change techniques. Some aspects of problem-focused coping are also included in this taxonomy. However, it does not provide further insight into emotion-focused coping. Thus, a thorough literature review on evidence-based emotional stress reduction methods was conducted in major databases and revealed 15 emotion-focused stress management strategies and definitions (see Table 1).

Table 1. Effective emotion-focused relaxation techniques.

Technique	Definition
Acupressure or emotional freedom technique	Pressure is applied to specific points
Autogenic training	Six standard exercises: heaviness and warmth in the extremities, calm and regular function of the heart, self-regulation of respiration, soothing warmth in the upper abdomen (solar plexus) area, and agreeable cooling of the forehead
Biofeedback	Precise instruments measure physiological activity such as brainwaves, heart function, breathing, muscle activity, and skin temperature. These instruments rapidly and accurately "feedback" information to the user.
Breathing	Manipulation of breath movement or rate
Euthymic methods	Training of sensual behaviors that include positive experiences, such as the sense of smell, hearing, tasting, and feeling. These experiences take place in the real world, not in the imagination.
Food or nutrition	Healthy diet information (eg, which food to eat or which to avoid, how much to eat, drink,...)
Guided imagery or visualization	A facilitated exploration of an image of a safe, comfortable place that can or cannot be specific to the participant is involved including sensory recruitment (visual, auditory, olfactory, tactile, and kinesthetic)
Hypnosis or self-hypnosis	While being in a relaxed state, suggestions are voiced. The suggestion, no matter whether presented by oneself or another, is used to focus the conscious mind upon a single dominant idea.
Meditation or mindfulness	Focus of attention on body and surroundings or thoughts or food in the real world
Music	Strings of sounds, humming, or singing that form a melody
Muscle relaxation	The tensing and relaxing of muscle groups (eg, the legs, abdomen, chest, arms, and face) in a sequential pattern while focusing on the distinction between the feelings of the tension and relaxation
Physical stress relief techniques	Description of yoga, tai chi, stretching, qi gong,... exercises
Self-massage	Massaging or rubbing of a specific body part
Sounds	Single and specific sounds (eg, nature sounds such as waterfalls, river flow, wind, bird song)
Sport	Description of how often and how long a specific sport (such as running, aerobics,...) needs to be performed

The inter-rater reliability was calculated according to Cohen's kappa [60] as commonly used index for inter-rater agreement. To calculate the sum scores, disagreements of the two raters were treated as hits, resulting in a score between 0 and 26 for the behavior change techniques and between 0 and 15 for the stress management strategies.

Results

Inter-rater agreement was acceptable for both, behavior change techniques ($\kappa=.74$) as well as emotion-focused stress management strategies ($\kappa=.73$). The sum scores for each app with regard to the behavior change techniques, the coping relevant behavior change techniques (stress management, prompt self-monitoring behavior, plan social support or social change,

time management, and prompt specific goal setting), and emotion-focused stress management strategies can be found in the [Multimedia Appendix 1](#).

An average of 4.3 behavior change techniques (SD 4.2, range 0-21 out of 26), 1.6 coping-related behavior change techniques (SD 1.29, range 0-5 out of 5), and 2.8 emotion-focused stress management strategies (SD 2.6, range 0-11 out of 15) was found. The highest sum score was found in “Mevii” by Thrive 4-7 with 21 behavior change techniques, 5 coping-specific behavior change techniques, and 9 emotion-focused stress management strategies. With regard to emotion-focused stress management, the highest sum score was found for “Stress Management Guide” by DHMobiApp with 11 different strategies. The behavior change techniques score and the emotion-focused stress management strategies score were highly correlated ($r=.82$, $P=.01$). There was also a correlation between the specific stress management strategies and the coping-relevant behavior change techniques ($r=.69$, $P=.01$).

[Figure 2](#) shows how often each behavior change technique was found in all apps [45]. Coping-relevant behavior change techniques are displayed in black, and the remaining techniques are displayed in gray. “Stress management,” “provide instruction,” and “provide information about consequences” were used most frequently, whereas “motivational interviewing,” “use follow-up prompts,” and “agree to behavioral contract” could not be found in any app.

Regarding the emotion-focused stress management techniques, “sounds,” “breathing,” “meditation or mindfulness,” and “music” were used most frequently. In contrast, recommendations regarding “food or nutrition,” “hypnosis or self-hypnosis,” “guided imagery or visualization,” “sport,” “muscle relaxation,” and “physical stress relief techniques” were used less frequently. Overall, “euthymic methods,”

“acupressure,” “biofeedback,” “autogenic training,” and “(self-) massage” were hardly used (see [Figure 3](#) for details).

The correlation analyses revealed that behavior change techniques and stress management strategies were frequently used in combination. These analyses and the absolute frequencies of each behavior change technique and stress management strategy did, however, not provide insights with regard to which methods were used simultaneously within one app. Therefore, association rules [61] were used to reveal clusters of jointly used methods within the apps. The rules are implications of the form: method X=> method Y, meaning that if method X is used within the app, method Y is used as well. Two indexes are assigned to each rule: support and confidence. Whereas support indicates how frequently the item set appears in the dataset, confidence indicates how often the rule has been found to be true.

The association rules revealed high co-occurrences for several behavior change techniques. For example, “provide instruction,” “plan social support or social change,” “provide information about consequences,” “provide information about behavior health link,” “prompt self-talk,” “prompt barrier identification,” “model or demonstrate behavior,” “prompt self-monitoring behavior,” and “provide general encouragement” were always used in combination with “stress management” (CI=100%). Moreover, “plan social support or social change,” “prompt self-talk,” and “prompt barrier identification” were always used in combination with “provide information about consequences” and “provide instruction” (CI=100%).

Concerning the specific stress management strategies, the analysis revealed that “muscle relaxation,” “autogenic training,” “biofeedback,” “guided imagery or visualization,” “meditation or mindfulness,” and “hypnosis or self-hypnosis” were frequently combined with “breathing” (CI 90-100%).

Figure 2. Behavior change techniques. Absolute frequencies of the 26 behavior change techniques used in the 62 apps, ranked by the most frequently applied techniques. Scoring followed the taxonomy of Abraham and Michie. Coping-relevant techniques are displayed in black and unspecific behavior change techniques are displayed in gray.

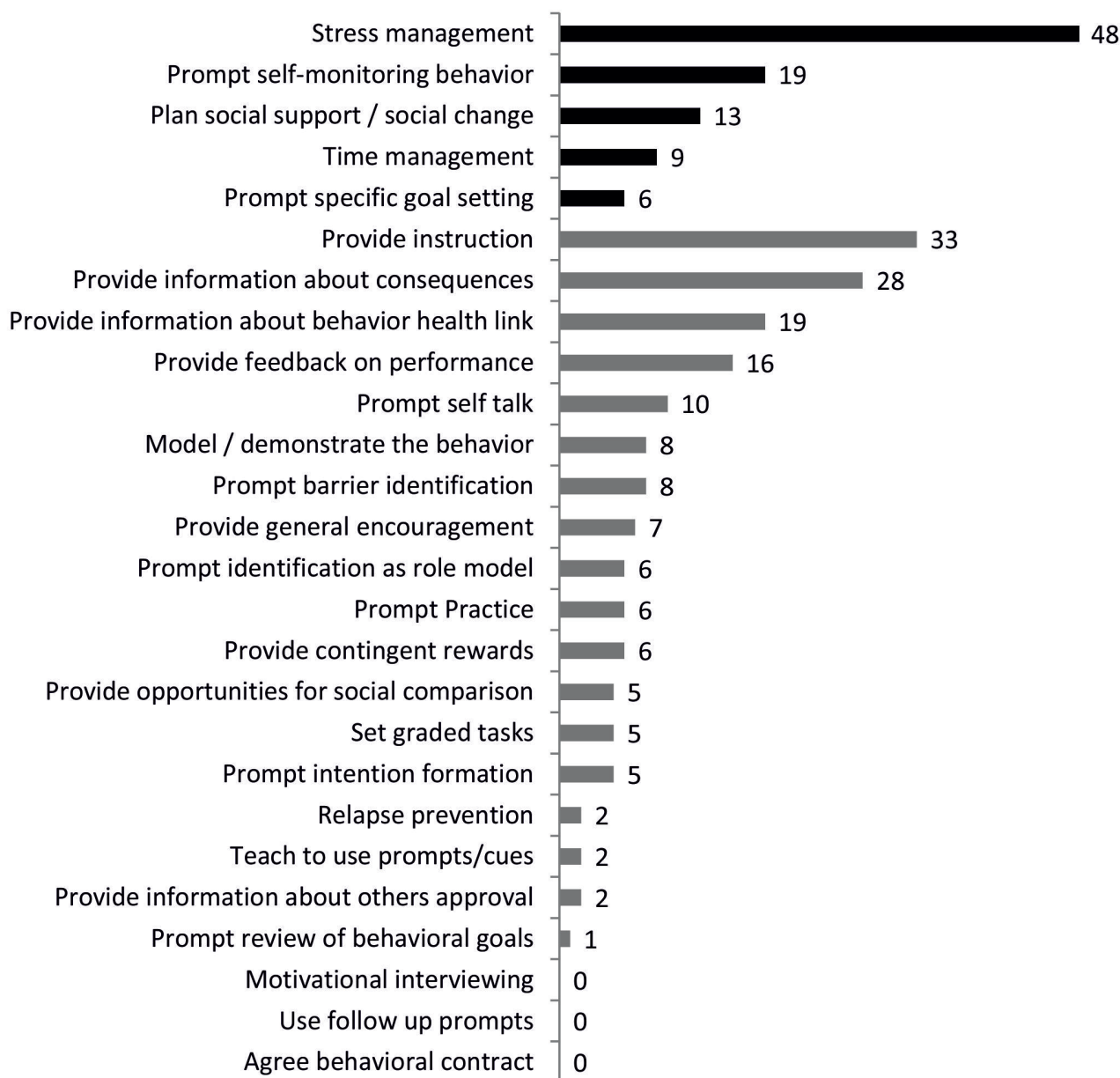
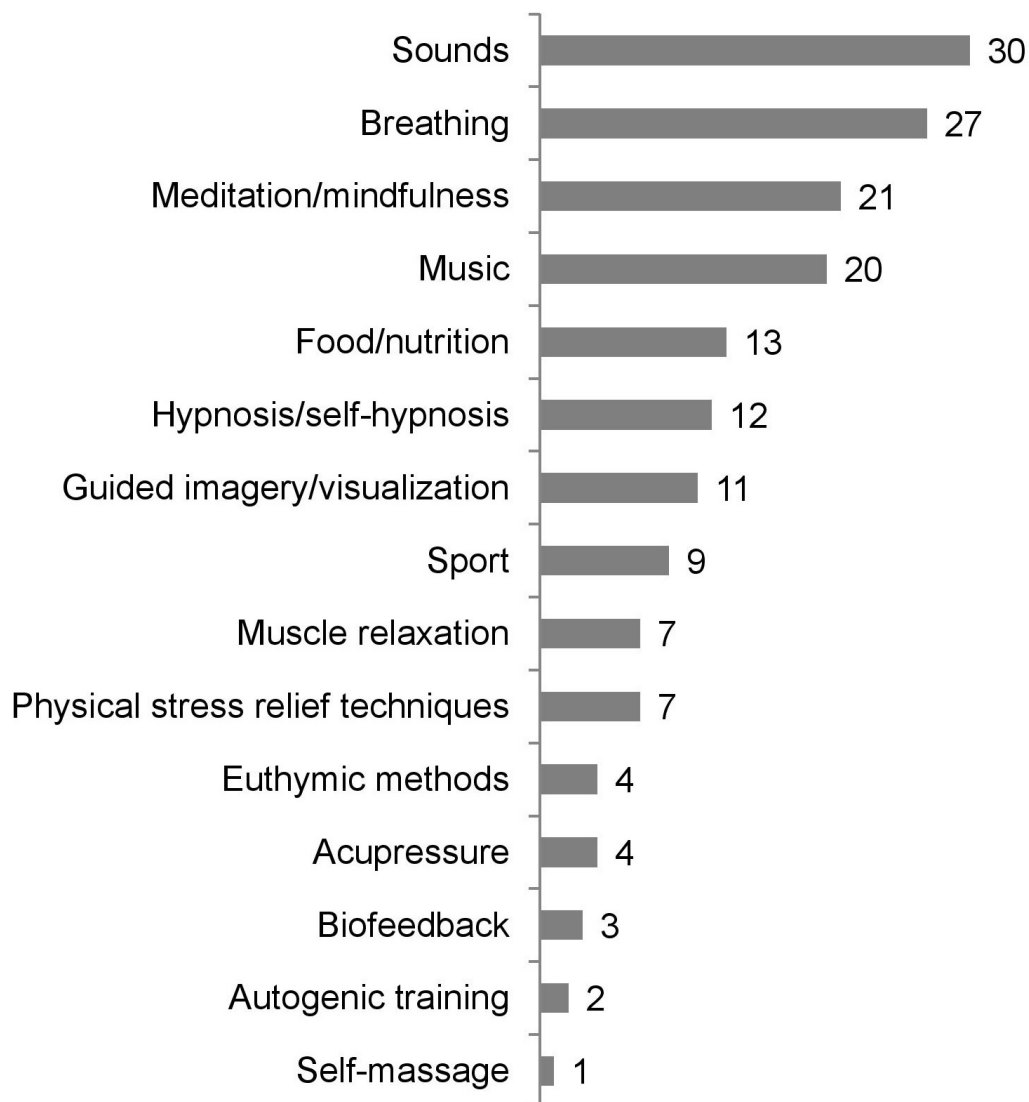


Figure 3. Stress management strategies. Absolute frequencies of the 15 emotion-focused stress management strategies used in the 62 apps, ranked by the most frequently applied techniques. Scoring followed the taxonomy described in Table 1.



Discussion

Principal Findings

The aim of this study was to investigate the use of evidence-based content in free stress management apps in Google Play based on a new taxonomy of emotion-focused stress management strategies as well as an established taxonomy of behavior change techniques [45]. The analysis revealed an average of 2.8 emotion-focused stress management strategies with a high range from 0 to 11. This variability in the usage of different coping techniques goes in line with a review of group intervention studies on stress management in which the number of applied techniques also varies from 1 to more than 10 [7].

As the focus of this analysis was put on stress management apps, it is not surprising that stress management proved to be the most frequent behavior change technique in our sample. It should be mentioned, however, that 23% (14/62) of our sample did not include any emotion-focused stress management strategy at all. Some of these apps only provided information about stress without any further advice on how to cope with it. Others consisted only of playful elements or stress-related quotes. One app was a video with changing colors.

This result corresponds to a recent analysis of stress management apps from the Apple iOS App Store [24] in which no evidence-based strategy was found for one-third of the sample. In the study by Coulon et al [24], “mindfulness or meditation” (48%) and “diaphragmatic breathing” (17%) were found most frequently. In our sample, “mindfulness and meditation” were

found slightly less frequently with 34%, whereas “breathing” exercises were found in nearly half of the sample (44%). Nevertheless, the criterion for breathing exercises was broader in this study, as it also included instructions that aimed at reducing the overall breathing rate. “Visualization and imagery” then again were found only in a small percentage of apps in both studies.

The comparability of results between this study and that of Coulon et al [24] shows that the usage of evidence-based content in apps from iTunes and Google Play apparently does not differ strongly between the two stores. Furthermore, it should be noted that about 50% of the apps that were used in this sample are also available on iTunes; this demonstrates that the choice of store only seems to play a subordinate role for this type of study. There was, however, hardly any overlap between our sample of apps and the one used by Coulon et al [24], as only one app (Breathe2Relax) was investigated in both samples.

Concerning behavior change, the apps in this analysis contained an average of 4.3 techniques. This mean behavior change techniques score was smaller compared with those found in other health app analyses using the same taxonomy but without special focus on stress management. These studies detected an average of 5 [51], 6 [50,62], or even 8 [47,63] behavior change techniques. This variation might be due to differences in app genres. Interestingly, in our sample, stress management and coping-focused behavior change techniques were used more frequently (on average 19 times per technique) than the remaining behavior change techniques (on average 8 times per technique). This indicates that although the absolute number of behavior change techniques was smaller compared with that of other health apps, the designers focused on techniques that were apparently relevant to stress management.

Self-regulation techniques, such as “self-monitoring,” “feedback,” and “goal setting,” have been reported as valued features within focus group discussions [64] and indeed are commonly used in weight management and fitness apps [47,51]. Although “self-monitoring” and “feedback” are considered as backbones of behavior change systems [63], they have only been discovered in a subsample of apps in this study: “Goal setting” was used only in 10% (6/62) of this sample.

From the association rules and the correlation analyses, it can be concluded that apps that use a broad range of emotion-focused stress management strategies also use a wider range of behavior change techniques. Moreover, the association rules revealed that most relaxation methods (90%-100%) in this sample of apps were combined with breathing exercises. This finding strengthens the content validity of the apps, as abdominal breathing exercises are the basic condition for mastery in other relaxation techniques [10].

There is, however, no clear consensus about how many and which behavior change techniques should be used in health behavior change systems [65]. Although 1 meta-analysis from 85 studies of Internet-based interventions based on more than 43,000 participants clearly speaks for an extensive use of different behavior change techniques—the number of techniques was related to greater effect sizes [66]—there was no indication

of greater effect sizes with an increasing number of behavior change techniques in other studies [67,68].

The same applies to specific stress management techniques. Whereas there are recommendations about which techniques might be effective (see the Introduction for further details), there is no consensus about the absolute number and combinations that should be presented.

In general, most self-help books [8] contain a broad range of coping techniques. This might be explained by the fact that some of those techniques are especially useful for reducing specific kinds of symptoms [10]. As symptoms may change over time, it seems practical to provide people with a broad selection of coping strategies from which they can choose the most suitable ones according to their individual situation and specific symptoms. Nevertheless, one should note that although some of the apps in this sample allowed users to rate their symptoms and stress levels, none of those apps used that information to offer content that was specifically focused on the respective pattern of symptoms. Thus, this might be a promising approach for further health app designs.

Besides the obvious lack of evidence-based content in some stress management apps, it should be mentioned that the inadequate realization of behavior change techniques and stress management strategies is one of the largest threats in current stress management apps. One prominent feature is “provide information on behavior-health link.” Some stress management apps of this sample recommended the consumption of alcohol and medicine in order to reduce stress. One app instructed for frenzied and unsystematic breathing, which is related to stress rather than relaxation. These are only two examples of potentially harmful advice. Moreover, there are also first reports that some stress management strategies provided by stress management apps can evoke accompanying symptoms such as dizziness and drowsiness [17]. Besides, there can be disqualifying factors for stress management techniques: One example is autogenic training, which should only be applied under supervision of a physician in cases of diabetes, hypoglycemic conditions, or heart conditions [10]. These restrictions must be pointed out to the user prior to providing further instructions.

Limitations

There are some limitations of this review that should be considered.

It is noteworthy that, although some aspects of problem-focused stress management such as time management, goal setting, and planning social support or social change are included in the behavior change technique taxonomy [45], the main focus of this analysis was put on emotion-focused stress management. Yet, future app analyses might extend the range of problem-focused strategies. The same applies to the taxonomy of behavior change techniques. However, although a more detailed and hierarchical version of the taxonomy is available [69], this study used an early version of the taxonomy [45] to increase comparability with prior health app analyses [46-50].

“Biofeedback” was only found in 3 apps. This might be due the fact that this technique often requires the additional use of a

wearable device. In fact, only few measurements such as heart rate variability can simply be attained via the use of a mobile phone [70]. As most wearables are still scarcely accessible to the general public [58], apps that required additional hardware were not taken into consideration for this study. It might be for this reason that the usage of biofeedback has been underrepresented in this sample.

Finally, the analysis included only free apps. As prior health app analyses found that the use of evidence-based content was associated with the app prices [47,71] it cannot be ruled out that scores might be higher for paid apps.

Conclusions

This study provides an extended overview of the usage of evidence-based content in mobile stress management apps. It depicts the first systematic review of current stress management apps available in the Google Play Store with regard to an established taxonomy of behavior change techniques [45] and

a newly developed taxonomy of emotion-focused stress management strategies. This approach allowed a deeper insight into app content compared with prior app analyses of stress management [24] and mindfulness apps [23,72].

The broad variation of different stress management strategies that was discovered in this sample of apps corresponds to those found in conventional stress management interventions [7] and self-help literature [8]. As there is no consensus about how many and which combinations of techniques should be used, it is difficult to draw conclusions about overall app quality. The analysis, however, revealed a lack of use of evidence-based content in at least a subsample of apps.

This study provides a first step toward more detailed and standardized taxonomies to investigate evidence-based content in, for example, stress management interventions, self-help books, and stress-related mobile technology, enabling greater comparability between different intervention types.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

App scores and relative ranking.

[[PDF File \(Adobe PDF File\), 37KB - mhealth_v5i2e22_app1.pdf](#)]

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Original Paper

Text Messaging to Improve Hypertension Medication Adherence in African Americans From Primary Care and Emergency Department Settings: Results From Two Randomized Feasibility Studies

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Abstract

Background: Hypertension (HTN) is an important problem in the United States, with an estimated 78 million Americans aged 20 years and older suffering from this condition. Health disparities related to HTN are common in the United States, with African Americans suffering from greater prevalence of the condition than whites, as well as greater severity, earlier onset, and more complications. Medication adherence is an important component of HTN management, but adherence is often poor, and simply forgetting to take medications is often cited as a reason. Mobile health (mHealth) strategies have the potential to be a low-cost and effective method for improving medication adherence that also has broad reach.

Objective: Our goal was to determine the feasibility, acceptability, and preliminary clinical effectiveness of BPMED, an intervention designed to improve medication adherence among African Americans with uncontrolled HTN, through fully automated text messaging support.

Methods: We conducted two parallel, unblinded randomized controlled pilot trials with African-American patients who had uncontrolled HTN, recruited from primary care and emergency department (ED) settings. In each trial, participants were randomized to receive either usual care or the BPMED intervention for one month. Data were collected in-person at baseline and one-month follow-up, assessing the effect on medication adherence, systolic and diastolic blood pressure (SBP and DBP), medication adherence self-efficacy, and participant satisfaction. Data for both randomized controlled pilot trials were analyzed separately and combined.

Results: A total of 58 primary care and 65 ED participants were recruited with retention rates of 91% (53/58) and 88% (57/65), respectively. BPMED participants consistently showed numerically greater, yet nonsignificant, improvements in measures of medication adherence (mean change 0.9, SD 2.0 vs mean change 0.5, SD 1.5, $P=.26$), SBP (mean change -12.6 , SD 24.0 vs mean change -11.3 , SD 25.5 mm Hg, $P=.78$), and DBP (mean change -4.9 , SD 13.1 mm Hg vs mean change -3.3 , SD 14.3 mm Hg, $P=.54$). Control and BPMED participants had slight improvements to medication adherence self-efficacy (mean change 0.8, SD 9.8 vs mean change 0.7, SD 7.0) with no significant differences found between groups ($P=.92$). On linear regression analysis, baseline SBP was the only predictor of SBP change; participants with higher SBP at enrollment exhibited significantly greater

improvements at one-month follow-up ($\beta=-0.63$, $P<.001$). In total, 94% (51/54) of BPMED participants agreed/strongly agreed that they were satisfied with the program, regardless of pilot setting.

Conclusions: Use of text message reminders to improve medication adherence is a feasible and acceptable approach among African Americans with uncontrolled HTN. Although differences in actual medication adherence and blood pressure between BPMED and usual care controls were not significant, patterns of improvement in the BPMED condition suggest that text message medication reminders may have an effect and fully powered investigations with longer-term follow-up are warranted.

Trial Registration: Clinicaltrials.gov NCT01465217; <https://clinicaltrials.gov/ct2/show/NCT01465217> (Archived by WebCite at <http://www.webcitation.org/6V0tto0IZ>).

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KEYWORDS

cell phone; text messaging; hypertension; blood pressure; African Americans; medication adherence; telemedicine

Introduction

Hypertension (HTN) is a key risk factor for heart disease and stroke [1], with an estimated 78 million Americans aged 20 years and older suffering from this condition [2]. It is associated with significant health disparities [3], as HTN is more prevalent among non-Hispanic blacks than non-Hispanic whites (42.0% vs 28.8%, respectively [3]), and African Americans suffer from greater disease severity, with earlier onset and more complications than age-matched whites [4].

Adherence to medication regimens is an important component of HTN management [5]; however, only half of all hypertensive patients are considered adherent [6,7]. Forgetting to take medications is one of the most commonly cited reasons for nonadherence [8]. Mobile health (mHealth) strategies, such as text message reminders, could be a low-cost and effective way to improve medication adherence that has broad reach. Cell phone use is widespread, with text messaging even more common. Among American adults, 90% own a cell phone [9] and 81% send text messages [10]. Mobile interventions could be particularly effective among African Americans as studies suggest African-American adults are more likely to own a mobile phone (70% vs 61%) [11] and use it as their primary source of Internet access [11].

The goal of this project was to determine the feasibility and acceptability of BPMED, an automated text messaging system designed to improve medication adherence among African Americans with uncontrolled HTN. We also sought to determine the preliminary effectiveness of this approach compared to usual care controls at one-month follow-up. Our primary outcome measure was medication adherence, with secondary outcome measures of blood pressure (BP) and medication adherence self-efficacy. To account for different ways that African-American patients might interact with the health care system, we conducted two parallel pilot randomized controlled trials (RCTs) with participants recruited from primary care and emergency department (ED) settings.

Methods

We developed BPMED, an automated text message medication reminder system, to assist African Americans with uncontrolled HTN in remembering to take their HTN medications. BPMED's development and study protocol are described in detail

elsewhere [12]; however, key elements are summarized subsequently. The Wayne State University Institutional Review Board (#0410810B3E) approved this study.

Study Design

We simultaneously conducted two unblinded parallel pilot RCTs with participants recruited from primary care and ED settings. Within each pilot RCT, block randomization, with blocks of 10 generated by the study biostatistician, was used to allocate participants equally to receive usual care or BPMED for one month. Blinded group assignments were concealed in an unmarked sealed envelope, which was included with the consent and enrollment packet, and were only opened once a participant was consented. Because many ED participants were not currently taking antihypertensive medications, all ED trial participants were given a 35-day supply of medication.

Recruitment

Primary care participants were recruited from primary care clinics in Detroit and Southfield, MI. Many were affiliated with MetroNet, a practice-based research network in Southeast Michigan. Primary care participants were recruited via provider referral, signs posted in clinic exam rooms, and targeted recruitment letters sent to potentially eligible participants. The ED participants were recruited from a large, urban ED in Detroit, MI, through real-time monitoring of the ED tracking board by research assistants. For the ED pilot RCT, all recruitment, screening, and enrollment were conducted on site and typically occurred immediately after ED discharge. All participants received US \$25 cash for completing each data collection visit (total possible participant incentive=US \$50).

Eligibility Screening and Consent

All potential participants were screened for eligibility, and those eligible were consented, enrolled, and randomized by research staff, followed by baseline data collection.

Inclusion Criteria

Potential participants were required to be African American, aged 18 years or older, have a diagnosis of HTN based on *International Classification of Diseases, Ninth Revision (ICD-9)* codes documented in the medical record, have a cell phone with text messaging, and speak English. Additionally, primary care participants were required to have uncontrolled HTN documented in their medical record on two successive clinic

visits (clinic systolic blood pressure [SBP] >140 mm Hg and diastolic blood pressure [DBP] >90 mm Hg or SBP >130 mm Hg and DBP >80 mm Hg for those with diabetes or kidney disease) and be taking at least one antihypertensive medication. For the ED cohort, presence of an elevated BP (SBP >140 mm Hg) on successive measurements obtained at least one hour apart was required. All BPs were obtained using automated brachial cuff devices, with the participant seated or supine, and the measurement arm supported at the midsternal level.

Exclusion Criteria

Potential participants were excluded if they self-reported any of the following: strict adherence to antihypertensive medication regimens, undergoing hemodialysis, plans to move more than 50 miles away from the recruitment site or to terminate cell phone contract within the next three months, compliance risk as identified by a score ≥ 2 on the CAGE Questionnaire Adapted to Include Drugs (CAGE-AID) for substance/alcohol abuse [13], and/or any other major health problem that would make follow-up difficult. Participants with a documented diagnosis of resistant HTN were also excluded.

BPMED

BPMED is an automated text message system that sends daily medication reminders to users at individually customized times. BPMED also sends two educational messages per week, with content based on HTN management recommendations from the American Heart Association. Topics include smoking cessation, dietary sodium reduction, physical activity, stress, nutrition, weight reduction, and alcohol consumption. BPMED closely aligns with a Health Belief Model [14] framework of behavior change, with medication reminders serving as cues to action. Additional detail on BPMED development has been previously described [12]. Participants who self-reported at baseline that text messaging was not included in their cell phone plan were reimbursed at follow-up US \$0.20 per text message sent/received in the study.

Procedures

Measures

Participant data were collected in-person at baseline and at one-month follow-up. Primary care participant data were collected primarily on the university campus where the research was conducted, whereas ED participant data were collected in the ED or another building on campus. Participants completed self-reported assessments either in paper format or electronically via study-furnished laptops. The primary outcome measure was medication adherence as quantified by the Morisky Medication Adherence Scale (MMAS) [15-17]. The MMAS is a self-reported eight-item instrument (total score range 0-8). Participants with scores less than six points are considered to have low medication adherence. Pill counts were obtained as a second measure of medication adherence; however, they were not analyzed due a high degree of missing data. Secondary

outcome measures included BP and medication adherence self-efficacy, as well as participant satisfaction. For group comparisons, BP was treated as a continuous variable and absolute differences at one-month follow-up, as well as changes over time, were included. Medication adherence self-efficacy was measured using 21 items from the Medication Adherence Self-Efficacy Scale (MASES) [18], a tool that captures self-efficacy for situational medication adherence. Relevant to our study design, MASES was developed and validated in African-American cohorts.

Statistical Analysis

Descriptive statistics for participant characteristics, including demographics, cell phone use, medication adherence, BP, medication adherence self-efficacy, and perceptions of the BPMED intervention were compiled. Missing data from the MMAS was imputed by assigning a zero value for the missing item, which indicated medication nonadherence, so long as no more than two of the eight MMAS items were missing. If more than two items were missing from the scale, the total MMAS score was not computed, and the data were considered missing. Missing data from the MASES was handled through mean imputation of answered items, so long as no more than three of the 21 items were missing. If more than three items were missing, the overall MASES score was not computed and the data were considered missing.

Demographics, baseline medication adherence, BP, and medication adherence self-efficacy, and changes in these measurements from baseline to follow-up, were compared between treatment arms, as well as between primary care and ED settings, using independent samples *t* tests for continuous data and Pearson chi-square for categorical data. We conducted analyses on each of the two pilot RCTs independently and pooled. In the pooled analysis, linear regression was conducted on primary outcome (medication adherence) and secondary outcome measures (SBP, DBP, and medication adherence self-efficacy), including indicators for study setting (primary care vs ED), treatment arm (usual care vs BPMED), baseline SBP, and additional variables that were significantly different between the two pilot studies. Interactions between pilot setting with treatment arm and baseline SBP were also investigated to assess consistent effects on outcomes between studies. All analyses were conducted using Stata 10.0.

Results

Recruitment

We recruited 123 participants for the two pilot RCTs (n=58 for primary care and n=65 for ED) between 2012 and 2014. See [Figure 1](#) for participant flow. The sample was primarily female (55.4%, 67/121) with a mean age of 49.0 (SD 8.3) years. The majority had a cell phone plan that included text messaging (90.8%, 109/120) and most (65.0%, 78/120) reported daily text message use. See [Table 1](#) for participant characteristics.

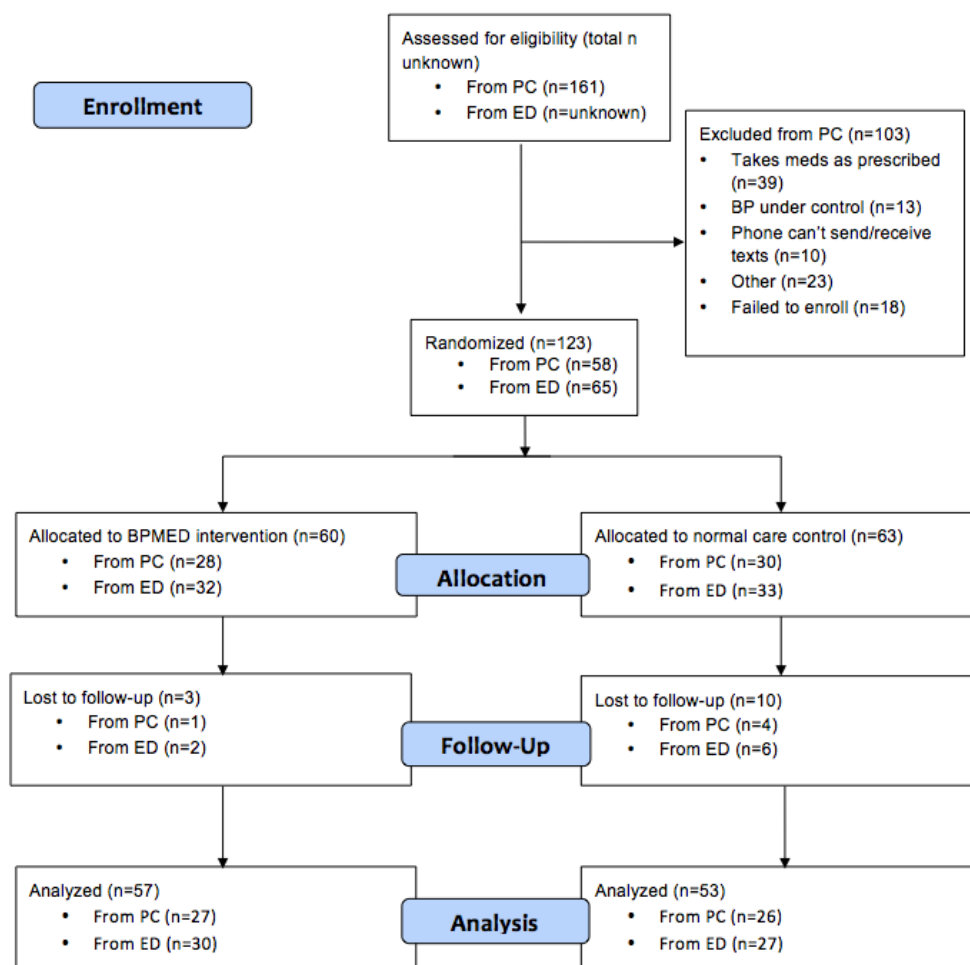
Table 1. Participant demographics.

Characteristic	Primary care	Emergency department	Total
Age (years), ^a mean (SD)	52.2 (7.6)	46.3 (8.0)	49.0 (8.3)
Gender,^a n (%)	n=56	n=65	n=121
Female	37 (66)	30 (46)	67 (55.4)
Male	19 (34)	35 (54)	54 (44.6)
Highest level of education, n (%)	n=55 ^b	n=65	n=120
Some high school	7 (13)	15 (23)	22 (18.3)
High school diploma or GED	16 (29)	21 (32)	37 (30.8)
Some college	16 (29)	22 (34)	38 (31.7)
Associates degree	7 (13)	5 (8)	12 (10.0)
Bachelor's degree or higher	9 (16)	2 (3)	11 (9.2)
Marital status, n (%)	n=56 ^c	n=65	n=121 ^c
Single, never married	27 (48)	42 (65)	69 (57.0)
Married	7 (13)	9 (14)	16 (13.2)
Separated/Divorced	16 (29)	12 (18)	28 (23.1)
Widowed	6 (11)	2 (3)	8 (6.6)
Annual household income (US \$), n (%)	n=55 ^c	n=65	n=120
<10,000	25 (45)	34 (52)	59 (49.2)
10,000-19,999	15 (27)	7 (11)	22 (18.3)
≥20,000	15 (27)	24 (37)	39 (32.5)
Employment status,^a n (%)	n=56	n=65	n=121 ^c
Work part time	5 (9)	12 (18)	17 (14.0)
Work full time	12 (21)	23 (35)	35 (28.9)
Retired	4 (7)	1 (2)	5 (4.1)
On disability	21 (38)	2 (3)	23 (19.0)
Laid off/unemployed	14 (25)	27 (42)	41 (33.9)
Cell phone plan is prepaid (phone cards), n (%)	n=55	n=65	n=120 ^c
Yes	6 (11)	5 (8)	11 (9.2)
No	47 (85)	60 (92)	107 (89.2)
Don't know	2 (4)	0 (0)	2 (1.7)
Length of current cell phone plan ownership, n (%)	n=53	n=64	n=117
≤6 months	9 (17)	8 (13)	17 (14.5)
7-12 months	9 (17)	4 (6)	13 (11.1)
>1 year	35 (66)	52 (81)	87 (74.4)
Frequency of text message use, n (%)	n=55 ^c	n=65	n=120
Never	2 (4)	1 (2)	3 (2.5)
A few times per month	7 (13)	12 (18)	19 (15.8)
A few times per week	11 (20)	9 (14)	20 (16.7)
Daily	35 (64)	43 (66)	78 (65.0)

^a Significant difference between primary care and ED ($P<.05$).

^b Significant difference between arms.

^c Sum total does not equal 100% due to rounding error.

Figure 1. Participant flow through BPMED trials.

Differences Between Primary Care and Emergency Department Samples

On average, ED participants were younger (mean 46.3, SD 8.0 years vs mean 52.2, SD 7.6 years; $P<.001$), less likely to be female (46%, 30/65 vs 66%, 37/56; $P=.03$), and more likely to be employed (employed part/full time: 54%, 35/65 vs 30%, 17/56; $P<.001$). Although patients recruited from both settings had suboptimal BP at baseline, ED participants had significantly higher SBP (mean 165.2, SD 19.2 mm Hg vs mean 136.2, SD 22.2 mm Hg; $P<.001$) and DBP (mean 97.8, SD 12.7 mm Hg vs mean 89.4, SD 11.2 mm Hg; $P<.001$). Additionally, primary

care participants had significantly lower medication adherence self-efficacy than ED participants (MASES: mean 46.7, SD 10.9 vs mean 52.7, SD 8.5; $P=.001$).

Effects of BPMED

A majority of primary care (91%, 53/58) and ED (88%, 57/65) participants completed the one-month follow-up. Although results were analyzed separately for each pilot study, intervention effects were consistent between the two settings, as well as with combined results; therefore, pooled analyses are discussed. Summary data (Table 2) are presented as individual pilot and combined primary and secondary outcome means.

Table 2. Summary of mean primary and secondary outcome measures by study setting and combined.

Measure	Primary care		Emergency department		Pooled	
	Control	BPMED	Control	BPMED	Control	BPMED
MMAS (points)						
Baseline	4.4	4.6	4.8	5.0	4.6	4.8
Follow-up	4.7	5.2	5.7	6.3	5.2	5.8
Change	0.3	0.6	0.7	1.1	0.5	0.9
SBP (mm Hg)						
Baseline	135.4	137.0	164.6	165.9	151.0	152.7
Follow-up	133.4	133.1	147.1	146.5	140.4	140.2
Change	-3.1	-4.6	-18.9	-19.5	-11.3	-12.6
DBP (mm Hg)						
Baseline	88.5	90.3	97.8	97.8	93.5	94.4
Follow-up	86.8	87.5	93.9	92.5	90.4	90.2
Change	-1.7	-3.0	-4.7	-6.5	-3.3	-4.9
MASES (points)						
Baseline	46.8	46.7	51.3	54.1	49.1	51.1
Follow-up	48.1	49.5	52.3	54.0	50.3	52.0
Change	0.2	1.6	1.4	-0.0	0.8	0.7

Medication Adherence, Blood Pressure, and Medication Adherence Self-Efficacy

At follow-up, BPMED participants experienced greater, yet nonsignificant, mean improvements on the MMAS scale compared to usual care (mean change 0.9, SD 2.0 vs mean change 0.5, SD 1.5; $P=.26$). Both control and BPMED participants had improved SBP (mean 140.4, SD 22.0 mm Hg and mean 140.2, SD 21.6 mm Hg, respectively) and DBP (mean 90.4, SD 11.8 mm Hg and mean 90.2, SD 13.6 mm Hg, respectively) at follow-up, but BPMED participants experienced greater, yet nonsignificant, mean improvements in BP compared to usual care (SBP: mean change -12.6, SD 24.0 and mean change -11.3, SD 25.5 mm Hg, $P=.78$; DBP: mean change -4.9, SD 13.1 mm Hg and mean change -3.3, SD 14.3 mm Hg, $P=.54$). However, negligible improvements in medication adherence self-efficacy were noted (MASES: mean change 0.8, SD 9.8 and mean change 0.7, SD 7.0, respectively) with no significant differences found between groups ($P=.92$). Outcomes were similar when analyzed separately by pilot study group.

Predictors of Change in Medication Adherence, Blood Pressure, and Medication Adherence Self-Efficacy

No significant predictors of change in medication adherence, DBP, or medication adherence self-efficacy were found in linear regression (Table 3). Baseline SBP was found to be a significant predictor of overall change in SBP ($\beta=-0.63$, $P<.001$), with higher baseline SBPs associated with greater change. Because ED participants had higher mean baseline SBP, we tested the interaction between study setting and baseline SBP. This interaction was significant and in the same direction for both primary care and ED sites (with different magnitudes), suggesting this effect was not solely due to the presence of ED participants ($\beta=-0.35$, $P=.01$ and $\beta=-0.90$, $P<.001$, respectively). To ease interpretation of setting effects, the interaction was not retained in the model (see Table 3). No other interaction terms were significant for any of the estimated models; hence, they were not included in the final analyses.

Table 3. Regression analyses of treatment arm and pilot study on change in primary and secondary outcome measures.

Outcome variable and independent variable	β (95% CI)	<i>P</i> value
Change medication adherence^a		
Treatment	-0.42 (-1.19, 0.35)	.28
Pilot setting	0.41 (-0.64, 1.45)	.44
Change SBP^a		
Treatment	2.68 (-5.73, 11.10)	.53
Pilot setting	-0.16 (-11.79, 11.47)	.98
Change DBP^a		
Treatment	2.71 (-2.93, 8.35)	.34
Pilot setting	2.12 (-5.67, 9.91)	.59
Change medication adherence self-efficacy^a		
Treatment	-1.40 (-4.46, 1.66)	.37
Pilot setting	1.89 (-2.34, 6.11)	.38

^a Controlling for baseline SBP, age, gender, employment, and baseline medication self-efficacy.

Participant Perceptions

The BPMED participants were overwhelmingly satisfied with the program with no significant differences in satisfaction measures between primary care and ED settings. The vast majority agreed/strongly agreed that BPMED was easy to use (98%, 52/53), were satisfied with BPMED (94%, 51/54), would recommend BPMED to others (94%, 51/54), agreed that BPMED helped them remember to take their medications (89%, 48/54), and believed that BPMED benefited their overall health (87%, 47/54). Overall, most (85%, 46/54) participants agreed/strongly agreed that they would like to keep using BPMED; however, this desire was more common among ED vs primary care participants (97%, 29/30 vs 71%, 17/24, respectively).

Discussion

We sought to document the feasibility, acceptability, and preliminary efficacy of text messages for antihypertensive medication reminders. The BPMED participants were found to be very satisfied with and enthusiastic about the program. This finding is consistent with previous text message medication adherence studies for chronic disease that found moderate to high levels of participant satisfaction [19,20] and general comfort with the technology and message content [21]. Demand for such technology is growing with the existence of a large number of apps (n=193) and websites to send medication reminders and log adherence [22,23]. In 2014, 55% of these medication support apps were tailored toward HTN self-monitoring [22,23].

With expanding interest in mHealth interventions, and increasing emphasis on prevention, there have been calls for large-scale RCTs aimed specifically at chronic conditions such as HTN [24]. Our data support this, showing greater numerical improvements in medication adherence at one-month follow-up among individuals randomized to BPMED. Although this was

not statistically significant, our sample was underpowered to detect modest differences, and intervention effects may be less pronounced over a short-term follow-up period. Existing literature related to text messaging for medication adherence in chronic disease is mixed [24], but a recent meta-analysis of 16 RCTs found a positive overall effect, suggesting a 17.8% increase in medication adherence rates (from an assumed 50% baseline adherence rate to 67.8%, OR 2.11, 95% CI 1.52-2.93, $P < .001$) over a mean follow-up period of 12 weeks (range 4-48 weeks) [20]. Thus, we are encouraged to continue research into the potential benefits of text messaging on medication adherence in this population, and are currently conducting a well-powered RCT of mHealth support to improve BP in a cohort similar to our ED trial, with one-year follow-up (NCT02955537). Our finding of near universal support for continued use of BPMED among ED participants lends further credence to this approach.

Regarding medication adherence self-efficacy (a secondary outcome of interest), only minor, nonsignificant improvements were seen among control and BPMED participants. This finding was unexpected as there is an established connection between medication adherence self-efficacy and medication adherence [25,26]. Our small sample size may have been insufficient to reveal differences in medication adherence self-efficacy. Individuals who received BPMED had numerically greater, yet nonsignificant, improvements in SBP and DBP at follow-up. Although there are few studies of text messaging to improve medication adherence targeting patients with uncontrolled HTN, or evaluating direct effects on BP, this trend is consistent with previous work that has established greater reductions in cholesterol and SBP at six months for patients with heart disease who received a mHealth program compared to controls [27].

These pilots were intended to demonstrate feasibility and acceptability of our approach. As such, we had relatively small sample sizes that contributed to our lack of statistically significant effects of BPMED on our primary and secondary outcomes. As noted, these limitations are consistent with other

work focused on text message reminders for medication adherence in chronic disease. This highlights the need for larger RCTs of text message medication reminders with longer duration follow-up, a need that has been noted in the literature [20]. The measurement of medication adherence utilizing the MMAS was also a limitation. Although its use is well documented [20], the MMAS is a self-reported measure, not an objective assessment, which can suffer from overestimation of medication adherence [28-30]. Future work should incorporate better measures, including instrumented pill bottles/caps [31] and/or biomarkers that may provide better approximations of adherence [32,33]. Because control participants knew they were in a study about medication adherence, a Hawthorne effect may have contributed to the lack of statistically significant between group differences. This may equal out over longer follow-up periods, particularly with less overt measures of medication adherence. Ultimately, BPMED uses a single component approach to improve medication adherence, perhaps the most important limiting factor. Previous work suggests that multicomponent interventions are more effective at improving medication adherence [23]. Interventions that include

bidirectional texting, allowing participants to respond with adherence information, have been found to be significantly more effective than those employing unidirectional text message reminders (relative risk 1.0 vs 1.2, respectively) [34,35]. Moreover, technology-augmented mechanisms, such as instrumented pill bottles, have shown to increase adherence more than text messaging alone [36]. Other similar interventions that utilize pill top monitors and triggered text message reminders when doses are late or skipped found that 87.3% of intervention participants reached 95% or more on-time adherence compared to 61.8% among controls [31]. Future work should take a more robust approach to improving medication adherence, as single component interventions may not be as effective.

Our results demonstrate that text message reminders to improve medication adherence among African Americans with uncontrolled HTN are feasible and acceptable. Our data support the need for more robust trials of mHealth in patients with uncontrolled chronic HTN that are fully powered with longer follow-up periods, more rigorous measures of medication adherence, and multimodal interventions.

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Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
DBP: diastolic blood pressure
ED: emergency department
HTN: hypertension
MASES: Medication Adherence Self-Efficacy Scale
mHealth: mobile health
MMAS: Morisky Medication Adherence Scale
RCT: randomized controlled trial
SBP: systolic blood pressure

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Original Paper

Women's Perceptions of Participation in an Extended Contact Text Message–Based Weight Loss Intervention: An Explorative Study

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Abstract

Background: Extending contact with participants after the end of an initial weight loss intervention has been shown to lead to maintained weight loss and related behavioral change. Mobile phone text messaging (short message service, SMS) offers a low-cost and efficacious method to deliver extended contact. In this rapidly developing area, formative work is required to understand user perspectives of text message technology. An extended contact intervention delivered by text messages following an initial telephone-delivered weight loss intervention in breast cancer survivors provided this opportunity.

Objective: The aim of this study was to qualitatively explore women's perceptions of participation in an extended contact intervention using text messaging to support long-term weight loss, physical activity, and dietary behavioral change.

Methods: Following the end of an initial 6-month randomized controlled trial of a telephone-delivered weight loss intervention (versus usual care), participants received a 6-month extended contact intervention via tailored text messages. Participant perceptions of the different types of text messages, the content, tailoring, timing, and frequency of the text messages, and the length of the intervention were assessed through semistructured interviews conducted after the extended contact intervention. The interviews were transcribed verbatim and analyzed with key themes identified.

Results: Participants (n=27) were a mean age of 56.0 years (SD 7.8) and mean body mass index of 30.4 kg/m² (SD 4.2) and were at a mean of 16.1 months (SD 3.1) postdiagnosis at study baseline. Participants perceived the text messages to be useful behavioral prompts and felt the messages kept them accountable to their behavioral change goals. The individual tailoring of the text message content and schedules was a key to the acceptability of the messages; however, some women preferred the support and real-time discussion via telephone calls (during the initial intervention) compared with the text messages (during the extended contact intervention).

Conclusions: Text message support was perceived as acceptable for the majority of women as a way of extending intervention contact for weight loss and behavioral maintenance. Text messages supported the maintenance of healthy behaviors established in the intervention phase and kept the women accountable to their goals. A combination of telephone calls and text message support was suggested as a more acceptable option for some of the women for an extended contact intervention.

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KEYWORDS

exercise; diet; text messaging; qualitative research; overweight; obesity; weight loss

Introduction

With increasing rates of overweight and obesity worldwide, efforts to promote weight loss and weight loss maintenance have become important aspects of chronic disease prevention and management. Weight loss maintenance is a particular challenge, with weight regains of nearly 50% common in the first year following a weight loss intervention [1]. Research has shown that extending contact beyond an initial weight loss intervention is needed to achieve weight loss maintenance [2-5]. Thus, finding acceptable, efficient, and cost-effective methods to deliver such extended contacts is essential to enable broad population reach [6].

With the development of technology, telephone, text messages (short message service, SMS), email, and Internet have been used to deliver more accessible weight loss interventions [7,8]. These mobile health (mHealth) interventions provide less resource-intensive methods for delivering broad-reach, extended contact for maintaining weight loss.

Text message technology in particular offers a potentially cost-effective method for extending contact [9]. Content and timing of text messages can be tailored to individuals in order to prompt real-time behavior. Participants can give feedback on progress and, in return, receive automated responses.

Recent studies examining the efficacy of text message-delivered, extended contact weight loss maintenance interventions [9-13] are not universally positive. Although the majority of participants find text messaging helpful, with participants generally satisfied with the text messages and the support that they provided [10-14], further intervention development is needed. Qualitative investigation is particularly useful for further intervention refinement, and qualitative data, particularly on extended contact, text message-delivered interventions has been limited to date. Two qualitative investigations have examined the acceptability of extended contact text message interventions following an initial weight loss intervention in an adolescent and a general adult, overweight population [12,14]. Untailored, one-way text messages were used for the study in the adult population [12], whereas in the other, adolescents received semitailored, two-way text messages [14]. The importance of tailoring the content and timing of the text messages to individual needs was a theme that emerged from both studies as an area that could be improved. Both of these extended contact interventions were relatively short (1-3 months) in duration and feedback supported extending the length of extended contact. An in-depth understanding of the acceptability of longer duration (6-month) extended contact, tailored, two-way, text message interventions is warranted.

In a recent study, we examined the feasibility and pre-post efficacy of a 6-month text message-delivered extended contact intervention in promoting the maintenance of weight loss and physical activity and dietary behavioral change in breast cancer survivors who completed an initial 6-month telephone-delivered weight loss intervention [13]. Overall, the results from this pilot study suggested that this highly tailored text message-delivered, extended contact intervention was feasible to deliver and that

it might have helped to attenuate weight regain and promote the maintenance of long-term changes in physical activity. Furthermore, 80% (20/25) of women found the intervention helpful (based on a single satisfaction item). Breast cancer survivors are a subgroup of women where weight management, increasing physical activity, and improving dietary quality are encouraged to improve cancer outcomes as well as overall chronic disease risk [15]. This study reported on the results of qualitative interviews in this sample of breast cancer survivors that sought to explore women's perceptions of the acceptability of text message content, timing and frequency, level of automation, and length of contact. The results will inform further development of extended contact text message interventions.

Methods

Study Design

The aims of this study were addressed in the context of the Living Well after Breast Cancer feasibility trial, a randomized controlled pilot study evaluating a 6-month telephone-delivered weight loss intervention (versus usual care) for breast cancer survivors. Women who completed the 6-month telephone-delivered intervention were invited to take part in a 6-month extended contact intervention delivered via text messages. The methods and results of the initial 6-month randomized controlled trial [16] and the pre-post extended contact text message intervention have been previously reported [13].

Participant Recruitment

Briefly, 90 women diagnosed with stage I-III breast cancer in the previous 9-18 months (age 18-75 years; body mass index 25-40 kg/m²) were recruited from a state-based cancer registry. Following baseline assessment, participants were randomized to either a 6-month telephone-delivered intervention (n=45) or usual care group (n=45). Of the 40 women who completed the 6-month intervention and assessment, 37 owned a mobile phone and 30 consented to participate in the extended contact intervention (81% of those eligible). Of the 7 who did not take up the extended contact intervention, 1 participant did not feel she needed the support, 1 used her mobile phone for emergencies only, 3 did not join for health or family reasons, and 2 were not contactable for consent [13]. The qualitative interview was completed by 27 women (90% of those consenting) after completion of the extended contact intervention.

Intervention

The initial 6-month telephone-delivered intervention included up to 16 calls from an accredited dietitian (coach) and posted printed project materials. The intervention focused on supporting participants to achieve modest weight loss of 5-10% through increasing moderate-to-vigorous physical activity, reducing energy intake (as well as improving dietary quality), and with an emphasis on behavioral change strategies. Participants were also offered text messages at their second call to support and prompt behavioral change in between intervention calls. Over half (57%, 17/30) of the women who participated in the extended contact intervention had received text messages during the initial 6-month intervention.

The extended contact intervention was delivered via individually tailored text messages. The aim was to maintain improvements in physical activity, dietary intake, and body weight that had been established in the initial intervention.

At the start of the extended contact intervention, participants received a telephone call from their coach to gather information to determine individual preferences for the content, timing, and frequency of text messages. A weight loss or weight maintenance goal was set, and two shorter-term goals that focused on either, physical activity and dietary behaviors or both, were established with the coach.

Each participant received a minimum of 21 text messages over the 6-month intervention, including at least twelve to prompt self-monitoring of weight, 3 text messages to reset goals for weight, and 3 text messages to reset goals for each of their

physical activity and dietary behavior targets. In addition, participants could choose to receive text messages to check on goal attainment (maximum $n=24$ for each behavior) and to cue for planned behaviors (maximum $n=48$ for each behavior). Participants were asked to respond “yes” or “no” to the goal checks. An automated response was then sent in reply. In some cases, participants responded to these goal checks in a way that was not recognized by the system as “yes” or “no.” In such cases, the participant reply was reviewed by a member of the research team and an individual text message was sent to the participant. The lag time for researcher-generated (nonautomated) responses varied considerably (median: 57.5 minutes; minimum-maximum: 2 minutes to 3 days, 9 hours), depending on whether participant goal check replies were received during work hours or after hours. Examples of each type of text message are shown in [Table 1](#).

Table 1. Examples of the types of text messages sent during the intervention.

Text message type	Example of text messages
Behavioral prompt	U have already come a long way Karen. Keep it up & walk 3x30mins this week. Amy
Prompt weight self- monitoring	Hi Karen. Have u checked ur weight lately? Make time 2 weigh yourself today. Amy
Goal check	On top of things Karen? Did u eat salad 5x this week? Text me back yes or no & let me know. Amy
Goal check reply to yes	Great work Karen. Be prepared & plan ahead 4 this week so u can achieve ur goal again this week. Put ur plans into action. Amy
Goal check reply to no	Its ok Karen - its natural 2 have a slip every now & again. But remember every day is a new beginning so get back on track - I know u can do it. Amy
Goal reset: weight	If u have a new weight goal 4 the next 6 weeks text it 2 me Karen so I know & can keep supporting u. Amy
Goal reset	Are u focusing on ur portion sizes & making sure u eat breakfast Karen? If u want 2 change ur diet goal text me back & let me know. Amy

After 12 weeks of the extended contact intervention, participants received a telephone call from their coach to check on the relevancy of the text messages and to adjust goals, frequency, and the types of text messages as required.

Data Collection and Outcomes

Interviews were conducted from March to November 2012 by one investigator (LS) not involved in intervention delivery. A semistructured interview guide was used during the interview, and the focus of the questions surrounded women’s likes and dislikes about the language, content, and timing of the text messages, and their suggestions for improving text message support for physical activity and healthy eating ([Multimedia Appendix 1](#)). Interviews were audio-recorded, transcribed verbatim using word processing software, and the transcript accuracy was checked.

Data Analysis

Thematic analysis was conducted by 2 investigators (JJ) and (LS) and a research assistant independently, with initial themes

generated. A fourth investigator (BF) then reviewed the transcripts to ensure appropriate theme formation.

Results

Principal Findings and Baseline Characteristics of Participants

In total, 27 interviews were conducted (mean duration: 9 minutes 40 seconds, range: 1:53-19:56). Participants were all white with a mean age of 56.0 years (SD 12.0) and mean BMI 30.4 kg/m² (SD 4.2) and were at a mean of 16.1 months (SD 3.1) postdiagnosis at study baseline. The majority of women were married or in a de facto relationship (85%, 23/27), employed full or part-time (67%, 18/27), with no dependent children (70%, 19/27) and post-menopausal at breast cancer diagnosis (63%, 17/27). All women had undergone breast cancer surgery, and most had also been treated with chemotherapy (63%, 17/27), radiation therapy (78%, 21/27), and endocrine therapy (74%, 20/27). Participants who completed interviews at 12 months were largely representative of the group of intervention participants at baseline ($n=45$; [Table 2](#)).

Table 2. Baseline characteristics of all intervention participants (n=45) and those who received extended care and were interviewed for the qualitative analysis (n=27).

Baseline characteristics	All intervention participants (n=45)	Participants interviewed (n=27)	Participants not interviewed (n=18) ^a	<i>P</i> ^b
n	45	27	18	
Age (years), mean (SD)	56.4 (9.0)	56.0 (7.8)	56.9 (10.8)	.76
Body mass index (kg/m ²), mean (SD)	30.6 (4.3)	30.4 (4.2)	30.9 (4.5)	.66
White, n (%)	43 (96)	27 (100)	16 (89)	.16
Married or de facto, n (%)	35 (78)	23 (85)	12 (67)	.17
Children (nil <18 years at home), n (%)	35 (78)	19 (70)	16 (81)	.27
Household income, n (%)				
≥AU\$1578 per week ^c	11 (24)	7 (26)	4 (22)	>.99
<AU\$1578 per week or refused or missing or don't know	34 (76)	20 (74)	15 (78)	>.99
Completed education beyond high school, n (%)	33 (73)	20 (74)	13 (72)	>.99
Employed (full-time, part-time, casual), n (%)	28 (62)	18 (67)	10 (56)	.54
Postmenopausal at diagnosis, n (%)	24 (53)	17 (63)	7 (39)	.14
Time since diagnosis (months), mean (SD)	16.1 (3.0)	16.1 (3.1)	16.1 (2.9)	.97
Chemotherapy, n (%)	29 (64)	17 (63)	12 (67)	>.99
Radiation, n (%)	35 (78)	21 (78)	14 (78)	>.99
Endocrine therapy, n (%)	32 (71)	20 (74)	12 (67)	.74

^a Not interviewed: not part of the extended care sample (n=15), unable to contact or declined qualitative interview (n=3).^b *P* value for difference in interviewed versus not interviewed by independent-samples *t* test (continuous) or chi-square test (categories).^c Top 2 quintiles for household income based on the Australian population at the most recent census [17].

Of those who received the text messages and completed the interview, 42% were frequent text message users before the baseline intervention, 12% used texts to “some degree,” and 46% were not text message users.

The 27 women who were interviewed received an average of 7 text messages per fortnight (range 2-11 texts); generally, 1 x weight self-monitoring, 3 x planned behavior prompts, 2 x goal checks, and 1 x tailored goal check reply and 1-2 goal resets each month. There was a 67% response rate to goal checks with participants replying to every 2 in 3 goal check messages and a 20% response rate to goal reset messages.

Overall Perceptions of the Extended Contact Intervention

Women found the extended contact text message intervention highly acceptable. The majority of women found the number and timing of texts suitable, as it was based on their preferences determined through the initial tailoring interview and updated at the 12-week call. Participants generally reported reading all the text messages, although they might not have been read them straight away, and for some, the reading of the text messages tapered toward the end:

I always read the messages...I did take on what you're saying in the beginning. You really read the message,

but in the end...I suppose I slightly less focused on reading the whole thing, just picking up the gist of it.
[6: 47 years]

Participants felt 6 months was a good duration for an extended contact intervention as “you're learning to stand on your own two feet but you're not totally alone. You know that you've got support there....” (12: 49 years) while others felt extending the program longer than 6 months would be beneficial “I would probably go longer” (5: 44 years).

Some commented that they found the texts more convenient than telephone calls and more time efficient. For this group of women, there were rarely issues with the language or abbreviations used in the texts. “I found her abbreviations quite easy to understand” (22: 65 years).

There were no patterns of differences in acceptability between those who had received text messages during the initial intervention and those who did not.

Text Messages Acted as a Prompt for Clients

A common theme from the interviews was that the text messages were a prompt (or reminder) of topics covered, and particularly of specific skills taught during the initial intervention:

I like the ones that said specifically, 'have you remembered to weigh yourself this week'... 'Remember

to record what you eat,' those sort of things cause they're practical things that came straight out of the book, and it brings you back to...a, b, and c [6: 47 years]

The text messages also reminded women of the goals they had set:

I think they were good...To keep one on the straight and narrow. Just a reminder and a good follow up. Yes, to keep me on track [18: 62 years]

It's like...the voice in your head...telling you what to do [14: 51 years]

Text Messages Maintained the Perception of Accountability for Clients

The text messages provided a continuation of the “check-in” that the coach had provided over the telephone during the initial intervention. Participants found the goal check text messages kept them accountable to the program aims. “I’d be more aware of what I’m putting in my mouth, because I haven’t reached my goal yet” (14: 51 years).

Responding to text messages about whether weight, diet, or activity goals had been met meant that the participants had to stop and weigh themselves or think about whether they had reached the goal they had set.

I knew that there'll be one coming in on Sunday afternoon. And I thought, 'I've just got to get that last walk in before so...I can say yes, that I've done the five walks [17: 58 years]

Some women said the interaction and personalized support was important, particularly if their goal was not achieved.

I think for me, the crux of the program was, 'what are your goals?', 'have you met them?', and if you haven't, 'what are you going to do'I think that was probably the most important part [24: 58 years]

Tailoring of Content and Schedules of Text Messages Was Important to Clients

The women were happy with the content, timing, and frequency of the text messages primarily because they had negotiated these with the coach and the text messages were based on their preferences.

There was nothing that I didn't like because it was upfront. How much SMSing do you want? What do you want? You can tell us if you don't like it, or if it's too much or it's too little. So I found what we had settled on originally was fine [3: 61 years]

And yes, because there was an in-depth conversation beforehand. We worked out together about what I would need. So I felt that I had had an input into what I wanted [9: 67 years]

The participants felt the text messages were relevant to their situation and the interaction was useful as “The content of the messages changed...with whether I lost or whether I gained or nothing” (20: 62 years). “It felt very personal” (18: 62 years).

Suggestions From Participants

A few of the women expressed a preference for continued telephone calls instead of text messaging for receiving the extended contact. They felt the text messages were not as personal as the calls and did not provide the emotional support that the telephone calls had provided. These were generally the women who would respond to goal checks with more detail than a “yes” or “no” and required researcher-generated goal check responses rather than the standard automated responses to goal check replies. Some women would have liked a mix of the text message and telephone modalities. It was often women who were not comfortable or familiar with text messaging in general who would have preferred telephone calls.

For me personally, the telephone is good...I'm quite a communicator so I think there's restriction with text messages and sometimes the message can be delivered quite differently to what it's actually meant to be [23: 59 years]

It would be nice, a mix. SMS are fine...most of the time. But there were a couple of times where I wasn't losing weight. It would have been nice to talk to her [3: 61 years]

Some preferred a different modality such as email or telephone, which allowed them to give more feedback and have more of a 2-way conversation. A couple of the participants felt that email would have been useful as an extra modality.

Because sometimes texts are good and they're quick, doing emails, I mean they could be a good thing as well. Because you tend to....say more [21: 44years]

Because you can express yourself a little more than a text message. In a text message you can't convey/focus on everything that you want [7: 65 years]

Discussion

Principal Findings

The number of text message–delivered health interventions is exponentially increasing [18], and qualitative investigation into the user experience is an important part of their evaluation. Our exploratory study provides evidence that an extended contact intervention delivered by text messages to support the maintenance of weight loss and related behaviors is acceptable to breast cancer survivors. In particular the initial and mid-intervention tailoring calls appeared to be a key to the acceptability of the text messages. The tailoring that this allowed ensured that participants received the appropriate type, timing, and number of text messages.

The aims of an extended contact intervention are to support and sustain the behavioral changes and habits developed in the initial, intensive intervention phase [12,19]. In this study, women’s consistent reporting that the text messages acted as a prompt and kept them accountable to their goals suggested the intervention met these aims. However, without the telephone support in the initial phase of the intervention, the acceptability of the text messages might have been very different. The telephone coaching allowed rapport to be established between the participant and the coach and the development of behavioral

change skills, which were a key aspect of the text messages. The text messages leveraged the rapport and skills established in the initial intervention. For some women, continued telephone contact for ongoing emotional support was a preference over the text messages. Rapport and support may be particularly important in this group of women who have been through the diagnosis and intensive treatment involved in breast cancer and all the emotional effects this has incurred.

Responding to participant text messages is time-consuming and the availability of someone to reply to these messages around the clock 7 days a week will increase the cost of such a program. Donaldson et al [10] questioned whether full automation would be impersonal. The feedback in this study suggested that receiving responses from the counsellor was important when replying to goal check text messages and that the automatic responses were generally acceptable. No negative comments arose during the interviews regarding delays for researcher-generated (nonautomated) responses when participant goal check replies were made after researcher working hours. This suggested that participants did not have an expectation for a 24-hour service.

Feedback in relation to the 6-month duration of the intervention was positive. Some women did, however, report that the text message itself rather than the content was more of a prompt toward the end. Extending the duration of text message interventions beyond 6 months may increase the likelihood of participant fatigue with the messages for some women and therefore reduce the influence and cost-effectiveness of such interventions. Developing a fully automated system, which would allow participants to self-tailor the type and frequency of text messages, might be an option for participants wanting longer-term support. Whether full automation would be as acceptable would require further investigation. In the only other study to examine preference for the length of intervention, Shaw reported a preference for the intervention to continue beyond a month [12].

Some research [20] has suggested that text messages may be more acceptable in a younger phone- and tech-savvy population. The women in this study were generally very accepting of the technology and, with the exception of a couple of participants, did not report any difficulties with the technology. Younger people may be more saturated with text messages, whereas for the women in this study, receipt of text messages may be less

frequent and the unique nature may therefore act as more support. Gathering qualitative feedback from different age groups would be beneficial in planning future interventions [18].

Email was suggested by a couple of participants as an alternative support; however, this may not provide a real-time prompt to prevent certain behaviors and encourage others. Many do not access emails as frequently, and emails may be more associated with work and may not be as readily accessible if away from a computer or on holidays [21]. Some of the women preferred the support from telephone calls received in the initial intervention phase, as this enabled an easier two-way conversation. Offering alternate supports such as email and telephone calls will increase the cost of extended contact in comparison to a solely text message intervention; however, it may increase uptake and acceptability and reduce attrition [22].

Limitations

Study participants were a group of breast cancer survivors who volunteered for the study. The high level of acceptance of the text messages may thus reflect this self-selection, with women who did not feel comfortable receiving text messages opting out of study participation. Generalizing findings to the broader adult population and, in particular, males should be done with caution. However, even outside the research context, receipt of text messages will always be an 'opt-in' occurrence, and thus the study results are likely generalizable to those women who would be adopters of such an intervention.

Conclusions

Qualitative evaluation from a group of breast cancer survivors receiving extended contact via text messages suggested that this modality was effective in providing support for maintaining weight loss, physical activity, and dietary behavioral change. Importantly, this modality was seen as acceptable in this group of women. The text messages prompted healthy behaviors for participants and kept them accountable to their goals. Tailoring the number, type, and frequency of text messages was a key to the acceptance of the text messages. Providing semi-automated feedback also improved acceptability. Offering an array of support methods such as telephone support or email as an alternative to text messages may improve participation in extended contact interventions and requires further investigation.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

[PDF File (Adobe PDF File), 40KB - [mhealth_v5i2e21_app1.pdf](#)]

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Original Paper

Features of a Mobile Support App for Patients With Chronic Obstructive Pulmonary Disease: Literature Review and Current Applications

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a serious long-term lung disease in which the airflow from the lungs is progressively reduced. By 2030, COPD will become the third cause of mortality and seventh cause of morbidity worldwide. With advances in technology and mobile communications, significant progress in the mobile health (mHealth) sector has been recently observed. Mobile phones with app capabilities (smartphones) are now considered as potential media for the self-management of certain types of diseases such as asthma, cancer, COPD, or cardiovascular diseases. While many mobile apps for patients with COPD are currently found on the market, there is little published material on the effectiveness of most of them, their features, and their adoption in health care settings.

Objectives: The aim of this study was to search the literature for current systems related to COPD and identify any missing links and studies that were carried out to evaluate the effectiveness of COPD mobile apps. In addition, we reviewed existing mHealth apps from different stores in order to identify features that can be considered in the initial design of a COPD support tool to improve health care services and patient outcomes.

Methods: In total, 206 articles related to COPD management systems were identified from different databases. Irrelevant materials and duplicates were excluded. Of those, 38 articles were reviewed to extract important features. We identified 214 apps from online stores. Following exclusion of irrelevant apps, 48 were selected and 20 of them were downloaded to review some of their common features.

Results: Our review found that out of the 20 apps downloaded, 13 (65%, 13/20) had an education section, 5 (25%, 5/20) consisted of medication and guidelines, 6 (30%, 6/20) included a calendar or diary and other features such as reminders or symptom tracking. There was little published material on the effectiveness of the identified COPD apps. Features such as (1) a social networking tool; (2) personalized education; (3) feedback; (4) e-coaching; and (5) psychological motivation to enhance behavioral change were found to be missing in many of the downloaded apps.

Conclusions: This paper summarizes the features of a COPD patient-support mobile app that can be taken into consideration for the initial design of an integrated care system to encourage the self-management of their condition at home.

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KEYWORDS

mHealth; COPD app; COPD support tool; self-management application; chronic diseases, application design; WELCOME

Introduction

Chronic obstructive pulmonary disease (COPD) is a serious long-term lung disease in which the flow of air out of the lungs is progressively reduced. The deterioration in lung function is caused by airway remodeling and progressive loss of lung tissue and damage to the lung parenchyma caused mainly by cigarette smoking. The burden of COPD is huge and is still growing. A World Health Organization (WHO) report anticipates that by 2030, COPD will become the third cause of mortality and seventh cause of morbidity worldwide [1]. It is also a disease state often associated with several comorbidities such as cardiovascular disease, metabolic syndrome, osteoporosis, mental health diseases, and lung cancer [2]. Research has shown that the early, accurate diagnosis of COPD and lifestyle management of patients with COPD can have a crucial impact on handling the long-term condition [3,4]. The treatment of stable COPD is highly dependent on the patient's symptoms and clinical manifestations.

Today, mobile health (mHealth) is extensively used for health services and patient education. mHealth is a term used to describe the practice of medicine with the support of mobile computing and mobile devices such as tablets, mobile phones, and personal digital assistants (PDAs) for health care. Software apps, specifically designed for and available on mobile devices, have been actively adopted by users of mobile phones and tablets [5]. As of June 2016, according to Apple, 2 million apps were available to download in the Apple Store while the Android Market was offering 2.2 million apps [6]. Mobile apps and bespoke software tools can be used to help people self-manage their health and wellness with convenience while being on the move [7]. Working in the health care system involves extensive mobility of health care professionals as well as communication and collaboration among colleagues and patients. Indeed, the UK Department of Health has recommended that apps be "prescribed" as part of the care for long-term conditions [8]. However, there are few published studies addressing which specific features of mobile health apps offer the greatest potential to benefit patients with COPD in an effective way.

The management of COPD requires a multidisciplinary approach, involving both pharmacological and

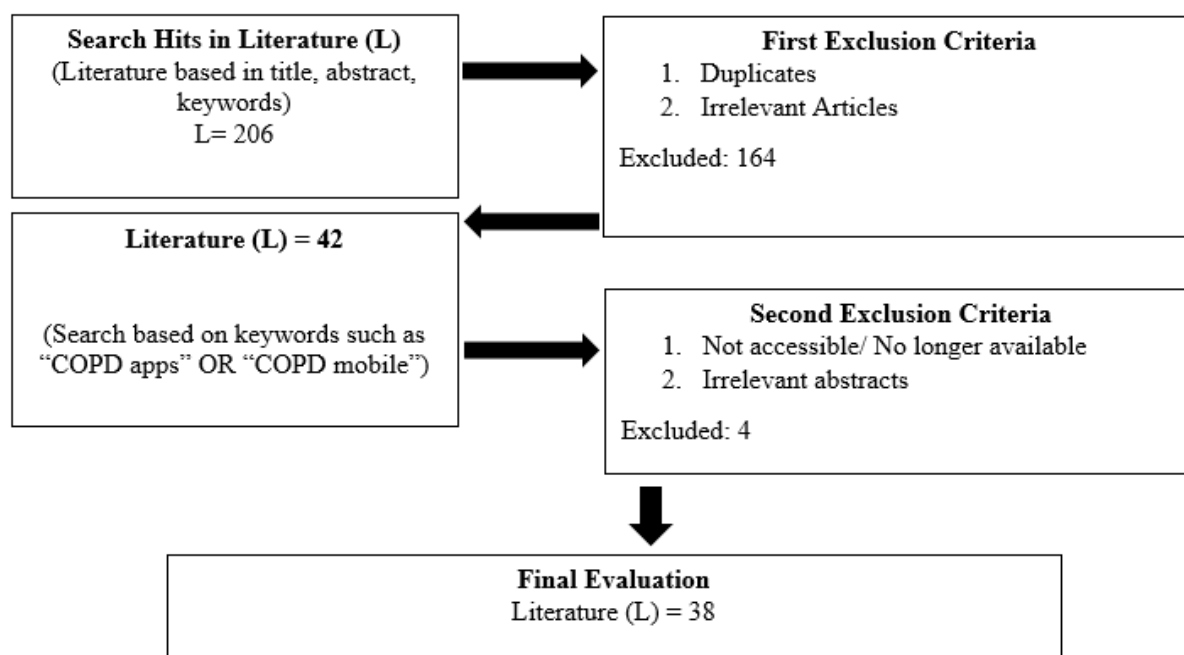
non-pharmacological treatment. Finding the right features to be incorporated in a support tool for patients with COPD seems to be very challenging. However, some studies show that effective management of COPD through integrated care systems, mHealth, and other technologies has the potential to both benefit the patient and reduce hospitalization costs in long-term management of COPD [9,10]. Comorbidities such as heart failure and diabetes add to the disease burden [11,12]. Providing the patient with the right care at the right time is crucial in order to prevent exacerbations, reduce hospitalization, and reduce mortality risks. Other factors, such as adopting a healthy lifestyle (good nutrition and exercise), result in a better quality of life in patients with COPD [13].

The main objective of this study was to review mobile apps, COPD management systems, and the literature in order to identify features for a COPD mobile support app. The features identified from the literature and from the apps can then be considered in the initial design of an integrated care system for the WELCOME European Union project to fill the missing links of a COPD support tool [14]. The main target user of such a support tool will be mainly patients with COPD including those suffering from different comorbidities. The support tool designed for patients can also be used to record important data on a main database to help health care professionals follow-up on their patients' health conditions closely.

Methods

Pilot Studies and Articles

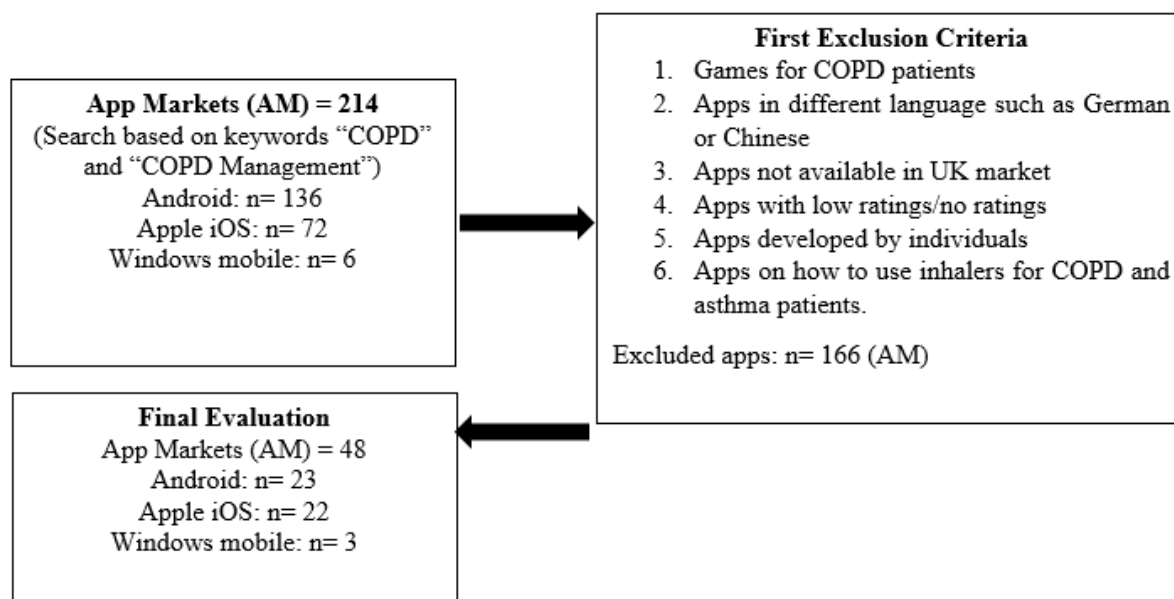
A search was conducted using the term "COPD apps"/"COPD mobile" to retrieve any pilot studies carried out on different health systems or mobile apps for COPD. Many studies retrieved were about prototypes or apps not yet published in any online market. A thorough search was done retrieving data from different databases such as ACM, Science Direct, IEEE Xplore, Medline, Scopus, and Google Scholar from 2009 to 2014. The logical operators "OR" and "AND" were used to identify duplicates. The search was based on the metadata (eg, title, abstract, and keywords). The detailed selection process is shown in Figure 1. A total of 38 articles were downloaded based on the keywords and were reviewed to extract features that could be considered for a COPD support tool.

Figure 1. Selection criteria for published articles.

Mobile Apps

This first step was carried out by searching the COPD-related apps from app stores such as Google Play Store, iTunes, BlackBerry World, Windows Phone, and Nokia's Ovi store. The European Directory of Health Apps and the National Health Service (NHS) App stores automatically have their apps listed in either Google Play or the Apple Store. A total of 214 apps were identified on the various mobile markets using the search term “COPD” and “COPD Management.” The Google Android market had the highest results (63.6%, 136/214), followed by the Apple iOS (33.6%, 72/214) and Windows mobile (2.8%, 6/214) platforms. No results were found on the Blackberry store.

A further evaluation was then performed to select relevant apps for this study. Only English-language mHealth apps available in the UK market were selected following the original systematic search. Several criteria had to be considered while selecting apps from their respective markets. The inclusion and exclusion criteria that were considered for this study are shown in [Figure 2](#). The comprehensiveness and consistency of information were assessed for apps presenting health information about COPD. Company-designed apps rather than individual ones were selected. This is to ensure that the apps have been reviewed and have professional recognition. All identified apps are available on the UK market and contain information written in English.

Figure 2. Breakdown of the online markets search process.

Results

Features Identified in Studies

One important feature for an efficient support tool is the ability to detect any symptom that can lead to a potential exacerbation. An exacerbation is defined as a worsening of a patient's symptoms from his or her usual stable state. The symptoms can then be analyzed by smart algorithms or health care professionals to detect the potential risk of an exacerbation [15]. It is still debatable whether telemonitoring on its own can help reduce hospitalization. Telemonitoring of patients' condition, behavior (ie, physical activity, adherence to medication) and symptoms may be assistive in the early detection and treatment of an exacerbation of COPD, and in turn improve patients' quality of life and reduce the high costs associated with COPD exacerbations. The Telescot program investigated the impact of a telemetric COPD monitoring service. Results did not show any reduction in hospital admissions or improvement in quality of life [12]. However, there have been some tools such as TEXAS and EXACT to quantify and measure exacerbations in patients with COPD patients [15,16]. The validity of TEXAS, an automated telephonic exacerbation assessment system which records symptoms and use of medication, has been assessed. The study was carried out on 86 patients with COPD. The results showed that TEXAS, when compared with other tools such as a paper diary or medical record review, showed the highest detected rates of exacerbations and patients' compliance in providing exacerbation-related information [16]. The EXACT daily diary was designed to standardize the process for assessing acute exacerbations of patients with COPD by providing a direct measure of patient-reported symptoms of exacerbation [15]. It is the first instrument that went through a qualification review by the Food and Drug Administration (FDA). Thus, systems like TEXAS and EXACT, if integrated into existing clinical services, can be helpful in providing the necessary information

to help detect any potential exacerbations in patients with COPD and help improve their condition.

Another important feature for a COPD support tool is the self-management of physical activity. Improvement of physical activity levels could not only result in better physical functioning and less dyspnea, but also in a higher quality of life and lower risks for exacerbation-related hospitalization and mortality. The COPD Self-Management Activation Research Trial (SMART action) was designed for patients with COPD who were unable to attend a pulmonary rehabilitation center. Patients were receiving COPD self-management education by a health coach and weekly telephone calls for monitoring purposes [17]. Having a mHealth system that could be used to follow up patient's physical activities would be beneficial to both health care providers and patients.

A recent manual, Self-Management Program of Activity, Coping and Education (SPACE), was developed in 2012 which included a self-report chronic respiratory questionnaire, an incremental shuttle-walk test, and an endurance shuttle walking test for patients with COPD [18]. Patients were observed during at the 6-week and 6-month follow-ups. The pilot study showed significant improvement for dyspnea management, exercise capacity, and breathlessness. SPACE also showed improvement in quality of life, endurance capacity, and reduced depression. The SPACE manual focused on education and behavior change for successful self-management of COPD. Such a manual could potentially be incorporated in a mHealth system to allow patients to refer to the self-management program remotely.

In the Netherlands, an autonomous mobile system for the management of COPD was piloted with actual patients with COPD to see the effectiveness of such a system in detecting and preventing exacerbations [19]. The main components of the COPD management system include a mobile phone, an intelligent model that works out algorithms based on the

patient's input, and a Web Center that reports the health conditions of patients to physicians. The mobile phone app, known as "AERIAL" has many identified features essential for COPD management, for example, patients have to fill questionnaires regularly for follow-up and send pulse-oximeter and micro-spirometer readings via Bluetooth to a central server to be monitored by health care professionals. The app was developed on the Android platform. To improve the system in terms of performance, error logs, and phone interface, it was evaluated with five patients and the results obtained from the first evaluation of two patients. Patients found the system easy to use but further research has to be carried out to see whether the system is accurate enough to predict exacerbations based on patient's data. Overall the study showed that there is potential in improving the quality of life of patients using similar systems; however, the system did not include an educational program about medication, inhalation techniques, or smoking cessation [19].

Other COPD management systems deployed on mobile apps (ie, Me&MyCOPD and CGI CommunityCare360) are mHealth systems that allow patients to access personalized coaching and real-time information about their disease and treatment. Me&MyCOPD also allows patients to collect, transmit, and access their clinical data [20]. Health care professionals are able to monitor medication adherence and other features such as device tracking, patient training, managing clinic visits, and providing advice on lifestyle management. The mobile app CGI CommunityCare360 Health was developed by the Canadian company CGI Group and makes use of integrated care to connect patients, primary care physicians, case coordinators, work coordinators, extended care teams, mobile care providers, first responders, administrators, and managers [21]. It improves care coordination and patient empowerment. It also supports patients suffering from chronic diseases through questionnaires and a telemonitoring system to communicate with the health care providers directly through email messaging.

Effing et al [22] identified the following components of a self-management program for patients with COPD: (1) smoking cessation advice and support, (2) self-recognition and treatment of exacerbations, (3) exercise and increased physical activities, (4) nutritional advice, and (5) dyspnea management. Self-registration techniques such as diaries or tools to measure variables are other features identified to be useful for patients with COPD [23]. The study emphasized that since patients with COPD are mostly aged above 50 years old, apps developed for them need to include a user-centered design appropriate for use by the elderly.

Another paper showed that there is a need for personalized feedback for chronic disease management systems [24]. The study by Chomutare et al highlighted some of the missing links such as personalized education and core features (eg, a social network) that could have an impact on clinical outcomes.

The M-COPD system was developed by the Australian E-Health Research Centre, CSIRO (AEHRC) to enrich the link between patients and health care professionals. The system consists of a Web portal for clinicians and a mobile app for the self-assessment of symptoms and vital signs such as sputum,

wheezing, cough, heart rate, and body temperature [25]. The main features identified were (1) reports; (2) email and mobile short message service (SMS); (3) monitoring; (4) reminders; and (5) education. The inconvenience for patients in such systems is that they need to use devices on their own at home to record body temperature, heart rate and pulse oximetry, and upload their measured values through the mobile phone.

In a clinical trial at the Royal Perth Hospital in Western Australia, 10 patients with COPD were recruited for a 3-month period to evaluate the M-COPD system [25]. Patients had to manually input observed and measured clinical data via a mobile Web browser. Results showed that the M-COPD system was very useful in terms of delivering patients' data to clinicians in real-time so that the latter can remotely assist patients and deliver the right intervention. M-COPD was also found to be cost-effective as it results in large savings of time and costs compared to traditional nurse-visit programs. Overall, the M-COPD system showed great potential in improving the treatment and diagnosis of exacerbations and could also be used to track other symptoms and alert nurses in case symptoms moved above an assigned threshold.

Leading a healthy lifestyle can enhance the health of patients with COPD and reduce hospitalizations. Beattie et al [13] investigated how technology could be used to support lifestyle through a self-management app called CALS: COPD Lifestyle Support through Self-Management. According to this study, features that are necessary for a lifestyle support tool are (1) a smoking cessation program; (2) medication adherence; (3) healthy diet; (4) exercise; (5) breathing techniques; and (6) education. The study also highlighted that another important feature is the use of behavioral change and self-efficacy through the delivery of educational content, goal setting, related feedback, and monitoring of symptomatic features. By using such psychological factors, it can be determined whether a patient with COPD can perform or should avoid certain activities [26] and how to encourage patients to follow a specific program. Human behavior understanding (HBU) has been applied in various systems to support COPD (eg, monitoring a patient, medication intake, status monitoring, and daily activities) [27]. It must be noted that such behavioral support features were not evident in any of the 20 apps identified in this study.

The health of patients with COPD is related to environmental factors such as (1) temperature; (2) pollution level; (3) humidity; and (4) the chemical composition of air. COPD24 is a system that is based on telemonitoring and tele-treatment for patients with COPD. The COPD24 project takes into account the monitoring of patients' vital signs as well as the surrounding environment, via dedicated sensors deployed within a wearable body area network (BAN) system and other meteorological sensors. Transmission of vital signs is achieved via wireless connections to health care providers and feedback is sent to patients in real-time. Air quality information is provided by the COPD24 service to warn patients about any hazardous areas that could affect their health. This system was evaluated with 30 patients over a 3-months trial period and showed that it is very important to make the patients self-manage their condition by monitoring both their symptoms and environment [28].

Features Identified in Apps

After the first selection process, the 48 apps identified were listed in a spreadsheet and 29 (60%, 29/48) were categorized as medical, 17 (35%, 17/48) as educational, and 2 (4%, 2/48)

as social network apps. Of those, 20 apps were downloaded on Android (70%, 14/20) and iOS (30%, 6/20) mobile devices and studied to identify some common features in those applications (Table 1).

Table 1. List of mobile apps and their features.

Name	Type ^a	Features
Chronic Obstructive Pulmonary Disease (COPD) @Point of Care	Medical	My Treatment, My Lab Results, My Journal, My Exacerbations, My Side Effects, My Medical History, patient education, charts
COPD ^b	Educational	Medical history, spirometry, medical examination, education, calendar
Pulmonology pocket	Educational	Guidance, assessment, monitoring, interactive calculators, index search, medication table
Miniatlas COPD	Medical	Education, communication, images
COPD (Chronic Obstructive Pulmonary Disease) Guide	Educational	Education
COPDexchange	Medical	Education, calculators
COPD Diary Card	Medical	Diary, mailing
Me&MyCOPD	Medical	Goals, status, advice, care plan, education
Calculate by QxMD	Medical/Calculator	Medical Calculators
Daxas – HCP	Educational	Guides, education for health care providers
Pulm- Pulmonology Pocket	Educational	Education, calculators, treatment guidelines, medication table
Pranayama Free	Educational	Breathing techniques (education)
COPD Guide	Educational	Education, guidelines
COPD Guide	Educational	N/A
PulmCCM	Educational	Education, guidelines
MEDGuide Emergency	Medical	Quick reference for emergencies, use of drugs (education)
Breathefree App	Medical	Choosing inhalers (education), calendar, medical news, severity of COPD
CGI CC360 HealthCenter Phone	Medical	Overview, results and goals, diary, questionnaire, calendar, device result, My Medication
ConnectMyCare	Medical	My Nurse, My symptoms, My Journal, My Appointments, My Medications, My Resources, My Providers, My Questions, reminders, calendar
palmEM: Emergency Medicine	Medical	Quick medication reference (education)

^aType includes medical, educational, or social.

^bCOPD: chronic obstructive pulmonary disease.

Many of the downloaded apps showed similar functionalities such as tracking of symptoms, exacerbations, questionnaires, and educational material. Out of the 20 identified COPD apps, 11 (55%, 11/20) were categorized as medical, 9 (45%, 9/20) as educational, and none as social network apps. Medical apps provide contact with health care professionals, lifestyle management applications, symptom tracking, or a list of medication. Educational apps are those which only provide guidance on COPD management to both patients and health care professionals to be used as a reference; they do not take any input from patients. Many such apps enhance the understanding of disease management and provide useful videos and links to other COPD forums. It has been observed that the number of medical COPD apps found across different platforms exceeded the number of educational or social networking apps.

The mobile apps that we downloaded had many features in common. A guide to the treatment and management of COPD and educational resources including videos, forums, and information including therapies and oxygen therapy were found to be the most common. Some apps had assessment scales and lookup tables related to COPD. Tools such as calculators for spirometry, body mass index (BMI), or tobacco consumption were also included in some of the apps to monitor patients' lifestyle factors that could affect their condition. A management tool to enable patients to track and store relevant health information between clinician visits was also a feature in many of the downloaded apps. This included diaries related to (1) food and nutrition; (2) medications; (3) symptoms; (4) measurements; (5) physical activity; and (6) sleep. Other functionalities present were email messaging or any type of communication with health care providers. Finally, a tracking

symptom feature in order to see if there is any improvement or deterioration in patients' health condition was also included in some apps. The most common features and the percentages of

the selected apps containing those features are shown in [Table 2](#).

Table 2. The number of downloaded apps containing the identified common features (N=20).

Feature	n (%)
Education	13 (65)
Medication/ treatment	5 (25)
Guidelines	5 (25)
Look-up tables	3 (15)
Symptom tracking	3 (15)
Diary or calendar	6 (30)
History	2 (10)
Email	6 (30)
Calculators	4 (20)
Others	5 (25)

Discussion

Principal Findings

The findings presented here provide new insights into the potential features that should be considered in designing a mHealth system to assist patients suffering from COPD. They highlight not only the necessary essential tools but also the programs needed to support patients with COPD [13]. When designing systems for self-management of chronic diseases, we must consider other factors such as age, information technology experience, education level [12], and possible comorbidities [12,14]. Moreover, all educational material has to be retrieved from a trustworthy source such as the National Institute for Health and Care Excellence (NICE) or Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines. The platform tool can also be used to boost patient's psychological motivation and help them adhere to medication by using different features like questionnaires or diaries ([Table 2](#)).

Mobile technologies and telehealth have the potential to provide patients with COPD a better quality of life if the vital features are incorporated in an app. An important parameter is that every COPD exacerbation event has a gradual increment phase preceding the peak exacerbation time for up to several days and a potential early detection of such a tendency towards this peak event could prevent its occurrence and lead to a significantly milder clinical presentation. Therefore, the use of a system for the early diagnosis of evolving exacerbations is expected to be very cost-effective and could diminish the cost of severe deteriorations [29]. There may also be reductions in health complications and hospital admissions, but this is still debatable [12,25,30,31]. Although there is little published material on the effectiveness of the identified COPD apps, previous studies identified the desired features for a COPD support app. The features for a support tool for a patient app are summarized in [Figure 3](#). So far, the apps identified on the market are limited in terms of functionalities and very few of them emphasize the needs of patients with COPD with comorbidities.

Other features (ie, social networking tools) can be important as they allow patients to share information about their personal experience, symptoms, treatments, and outcomes. Some apps allow patients suffering from different diseases to share data and discuss their health with health care professionals, thus improving knowledge sharing [32]. Through collaborating and knowledge, patients from diverse clinical backgrounds may feel better and knowledge-based communities can be formed [33]. Missing links such as personalized information, education about COPD, and electronic coaching (e-coaching) features in an app could improve the way patients manage their lifestyle.

Since COPD is a highly symptomatic disease, patients may not recognize small day-to-day variations in their pulmonary symptoms. Lack of symptom awareness and pace of symptom worsening make daily telemonitoring of patients with COPD an attractive and beneficial approach to facilitate an early intervention. Telehealth also has the potential to allow health care professionals to monitor patients remotely for deteriorations or long-term trends and offers opportunities for intervention to improve outcomes. They can view the data of their patients on a constant basis, not only periodically at the outpatient clinics. They are also able to define the current health status of their patients and provide coaching on how to cope with certain adverse symptoms or receive the proper treatment. In addition, they can send motivational messages to patients in order to ensure that they perform their regular exercises, follow the assigned smoking cessation program, and so on. Moreover, telemedicine may be beneficial for obtaining an active lifestyle by increasing patients' awareness through self-monitoring, goal setting, and improving self-efficacy. On the other hand, a recent review reported concerns from health care professionals that telehealth may promote patients' dependency on health care providers and telehealth data, especially in the more severe patients. In addition, health care professionals indicated that the technical type of work brought by telehealth increases burden and undermines aspects of their professional identity [34].

Our study has shown that the majority of the identified apps had an education section, whereas some of them referred to

medication and guidelines, and about one third included a calendar or a diary and many other features such as reminders or symptom tracking. This literature and pilot study describe the different features for which patients with COPD should be

monitored by mobile apps (Figure 3). The common features identified from the downloaded apps and from the literature are shown in Figure 4.

Figure 3. Features, including tools and programs, identified in this study that should be taken into consideration when building a support tool for patients with chronic obstructive pulmonary disease.

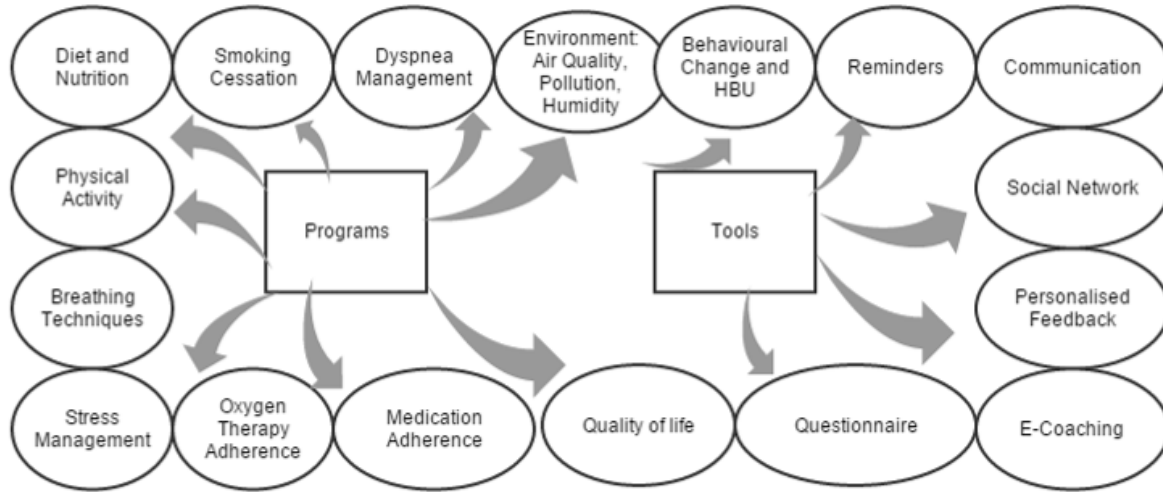
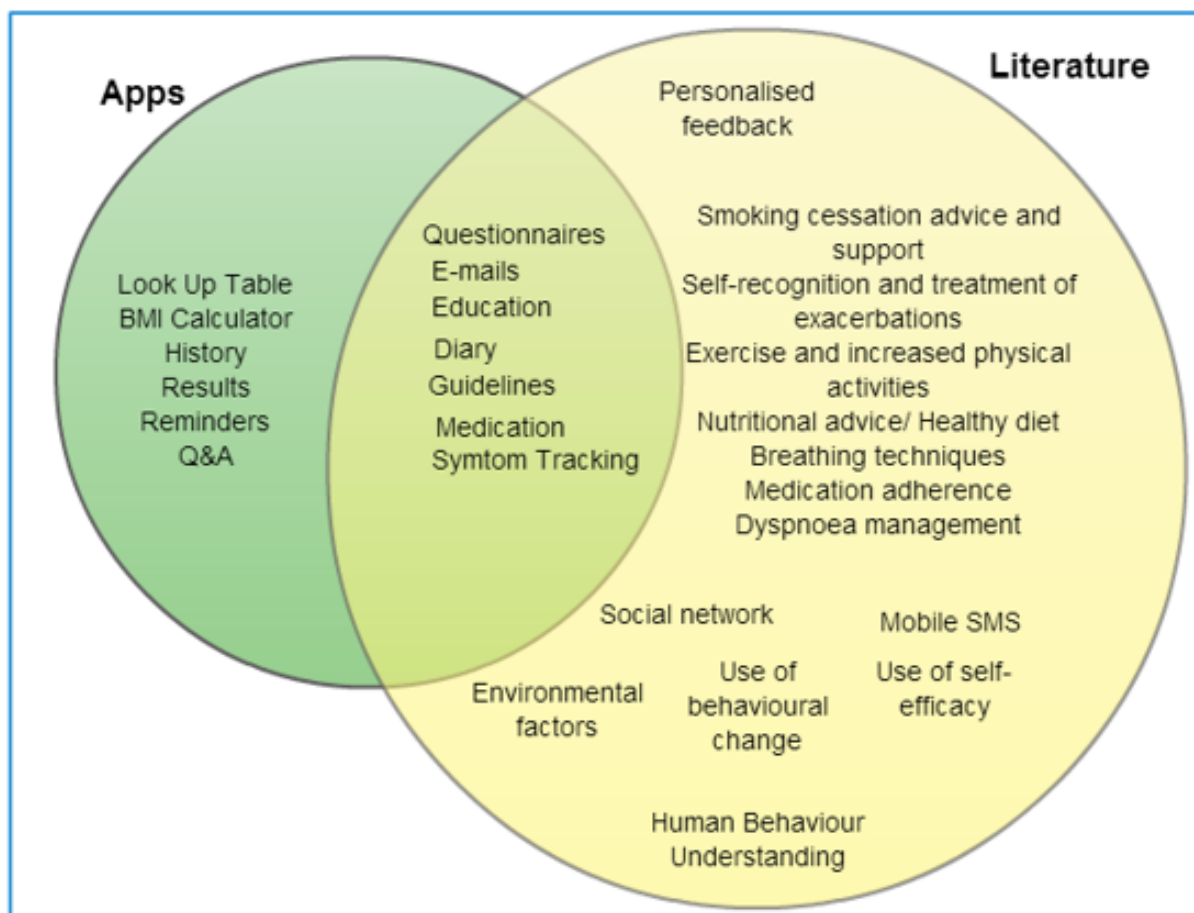


Figure 4. Common features identified in the downloaded apps and in the literature.



Limitations

There are many apps available in the various online markets; after limiting the search results, 214 apps were identified.

However, due to limited resources, only 20 apps were downloaded. More apps could be downloaded to review their features for further research. Moreover, only native mobile apps were searched; no mobile Web-based apps were considered.

Conclusions

The management of COPD requires a multidisciplinary approach involving many different types of treatment; currently the system is very segregated. While many of the features identified such as questionnaires, emails, education, or diary tools were found to be common in this study, others like social networking tools, personalized education, feedback, e-coaching, and psychological motivation to enhance behavioral change have been found to be missing in many studies and apps. This shows that not enough research has been conducted to analyze features for a COPD support tool.

Many features seem to have been considered in the literature but are not implemented in current support apps targeting patients with COPD with different comorbidities. Hence, these features can and should be incorporated in a single app for better monitoring, follow-up by health care professionals, and lifestyle management for patients with COPD. This can lead to a balance between obtaining improved clinical outcomes with minimal inconvenience to the patient. The tool can be mainly designed for elderly patients with a user friendly interface to collect data which will be easily accessible to health care professionals. The design of the proposed app must be followed by an evaluation of such a self-management support tool to study its impact on patients' health outcome as the literature is scarce in this regard.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

COPD: chronic obstructive pulmonary disease

e-coaching: electronic coaching

mHealth: mobile health

SMART: Self-Management Activation Research Trial

SPACE: Self-Management Programme of Activity, Coping and Education

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Original Paper

Mobile Technology Use by People Experiencing Multiple Sclerosis Fatigue: Survey Methodology

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Abstract

Background: Fatigue is one of the most commonly reported symptoms of multiple sclerosis (MS). It has a profound impact on all spheres of life, for people with MS and their relatives. It is one of the key precipitants of early retirement. Individual, group, and Internet cognitive behavioral therapy-based approaches to supporting people with MS to manage their fatigue have been shown to be effective.

Objective: The aim of this project was to (1) survey the types of mobile devices and level of Internet access people with MS use or would consider using for a health intervention and (2) characterize the levels of fatigue severity and their impact experienced by the people in our sample to provide an estimate of fatigue severity of people with MS in New Zealand. The ultimate goal of this work was to support the future development of a mobile intervention for the management of fatigue for people with MS.

Methods: Survey methodology using an online questionnaire was used to assess people with MS. A total of 51 people with MS participated. The average age was 48.5 years, and the large majority of the sample (77%) was female.

Results: Participants reported significant levels of fatigue as measured with the summary score of the Neurological Fatigue Index (mean 31.4 [SD 5.3]). Most (84%) respondents scored on average more than 3 on the fatigue severity questions, reflecting significant fatigue. Mobile phone usage was high with 86% of respondents reporting having a mobile phone; apps were used by 75% of respondents. Most participants (92%) accessed the Internet from home.

Conclusions: New Zealand respondents with MS experienced high levels of both fatigue severity and fatigue impact. The majority of participants have a mobile device and access to the Internet. These findings, along with limited access to face-to-face cognitive behavioral therapy-based interventions, create an opportunity to develop a mobile technology platform for delivering a cognitive behavioral therapy-based intervention to decrease the severity and impact of fatigue in people with MS.

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KEYWORDS

mobile phone technology; multiple sclerosis; app; fatigue; symptoms; cognitive behavioral therapy; intervention

Introduction

New Zealand has a high prevalence of multiple sclerosis (MS). In 2006, the age-standardized prevalence of MS among the general population of New Zealand was 71.9 per 100,000 [1]. In contrast, the age-standardized prevalence of MS in Māori has remained constant at 17.5 per 100,000 [1]. Between 1968 and 2006, the disease frequency for MS in New Zealand has increased by nearly 90%, from 37.8 in 1968 to current level of 71.9 [2]. During the same 38-year period, the gender ratio essentially remained constant.

One of the most commonly reported symptoms of MS is fatigue, affecting more than 80% of patients [3]. Although often identified as a symptom of MS, fatigue is often not treated, perhaps because it typically appears unrelated to the severity of the central disease process [4]. MS fatigue differs from tiredness experienced by healthy people in both severity and impact. MS fatigue has a profound effect on all spheres of life [3,5] for people with MS, their relatives, and the nursing staff [6,7]. Fatigue is one of the key precipitants of early retirement [8,9].

Little is known about levels of fatigue severity and the impact experienced by people with MS fatigue in New Zealand [10]. Self-report measures of fatigue can be an appropriate assessment option given the subjective experience of the symptom. The advantage of self-report measures are that they are generally short, widely available, easy for the patient to understand, and require little training by the assessor [11]. Additionally, self-report measures of fatigue have concurrent validity and are acceptable to people with MS [12]. There is, however, large variation and inconsistency across studies measuring the severity and impact of MS fatigue, which might be partly due to different measures used [13-16].

At present, the range of measurement options means assessors need to be clear about the aspects of fatigue they intend to measure (eg, severity or impact of fatigue), in which population and for what purpose, in order to select the most relevant self-report measure. There is a paucity of research regarding which measure of fatigue is the most appropriate under differing conditions. A more concise definition of fatigue is needed, along with a high-quality measurement instrument. To attempt to address these issues for people with MS, the Neurological Fatigue Index for MS was developed [16]. This scale was designed to conform to the Rasch measurement model [17] and rigorously tested to determine its reproducibility. The scale can be used with people with MS of “any age, sex, and duration (of MS symptoms)” [18]. The minimum clinically important difference for the Neurological Fatigue Index for MS was found to be small (2.49 of a 30-point range), such that changes in the physical, cognitive, summary, and nocturnal sleep scales were aligned with the respondents’ perceived changes in fatigue, and most importantly, the resultant scores showed no change when none was perceived [18].

The 13-item, self-report measure Fatigue Symptom Inventory was originally designed to measure the intensity and duration of fatigue and its interference with quality of life in breast cancer patients [19]. Although the Fatigue Symptom Inventory has not

been validated for MS, Hann et al [19] suggest that the Fatigue Symptom Inventory could be used to evaluate the physical and psychological characteristics of fatigue and quality of life across groups of patients with different diagnoses, and it has been used extensively in research with MS patients.

Along with challenges in measuring severity and impact of MS fatigue and the lack of New Zealand data, there have been challenges in terms of delivering interventions for this group of people. Cognitive behavioral therapy interventions for MS fatigue, delivered in individual, group, or Internet programs, have been found to be effective [20-25]. However, cognitive behavioral therapy interventions delivered face-to-face are not readily available due to the lack of people with this training working in MS-related services and limited health resources [10].

In New Zealand, a recent survey suggests 86% of people use the Internet, of whom 91% have access to broadband [26]. A key limitation of Internet-based cognitive behavioral therapy programs for MS fatigue is that the person needs to be in front of a computer. However, the number of people using smartphones that have access to the Internet is increasing [26], providing a fruitful opportunity for health applications. The key advantages of mobile phone technologies include the ability to provide an individual level of support to change health behaviors and improve disease management, allowing temporal synchronization of the intervention delivery and allowing the intervention to claim people’s attention when it is most relevant or in the best context [27]. There is increasing evidence that text messages and other smartphone technology are effective in drug adherence, improved diabetes self-management [28], and cessation of smoking interventions [29]. However, other than wearable sensors including accelerometers, gyroscopes, and pressure-sensitive textiles [30], there is limited evidence for the use of smartphone technology in people with MS [31-33].

The aim of the current project was to survey people with MS to (1) review the types of mobile devices people with MS use or would consider using for a health intervention, (2) identify the level of Internet access they have, and (3) characterize the levels of fatigue severity and their impact experienced by the people in our sample to provide an estimate of fatigue severity of people with MS in New Zealand. The ultimate goal of this work was to guide the future development of a mobile intervention for the management of fatigue for people with MS.

Methods

Questionnaire

A positivist paradigm theoretical framework and survey methodology using a questionnaire was used. The questionnaire included the following:

1. Collection of basic demographic data to enable the contextualization of the data and duplicate checking
2. Assessment of fatigue severity measured using the Neurological Fatigue Index for MS [16]
3. Assessment of fatigue impact measured with the Fatigue Symptom Inventory, a 13-item self-report measure designed to

assess the severity, frequency, and daily pattern of fatigue, as well as its perceived interference with quality of life [34]

4. Questions on mobile phone and Internet usage derived from the New Zealand World Internet Project [26] (approval for this use was obtained)

Recruitment

People with MS were initially contacted via email by the Multiple Sclerosis Society of New Zealand. The study used Dillman's [35] tailored survey design, which has been shown to result in high response rates. It was not assumed that participants had access to the Internet. A link to a website was provided in the email, where participants could either complete the survey online, request a call from the researcher to carry out the survey by telephone, request a hard copy of the survey that they returned by post, or request an electronic copy of the form by email.

Statistical Analysis

All analysis was undertaken using SPSS Statistics (2015, IBM Corp) software. The questionnaire data were analyzed as follows:

1. Basic demographic data were checked for duplicate form submissions. We planned to exclude any duplicate questionnaires from the analysis.
2. Fatigue severity was calculated by summing relevant items of the Neurological Fatigue Index for MS summary, physical, diurnal sleep, nocturnal sleep, and cognitive scales. The raw ordinal data were converted to interval-level data using the conversion table set out by Mills and colleagues [16]. Descriptive statistics (means, SDs, ranges) were then calculated.

3. Fatigue impact, as measured by the Fatigue Symptom Inventory, was analyzed descriptively (median, interquartile range, range) for the following subscales: most severe fatigue, least severe fatigue, average fatigue, present fatigue, and fatigue interference with daily life activities.

4. Internet and mobile phone usage was analyzed using frequencies and cross-tabulations by key demographic variables (age, gender, area, and ethnicity).

Ethics Approval

Ethics approval for the study was obtained from the Auckland University of Technology Ethics Committee (approval number 15/99).

Results

In total, 51 people with MS took part in the study. We cannot comment on the response rate as recruitment was via social media. The mean age of the participants was 48.5 (SD 12.8) years and ranged from 26 to 71 years. A large majority (39/51, 77%) were female, 16% (8/51) were male, and the majority were New Zealand European. The demographic distribution of the respondents is shown in Table 1. Of the 51 respondents, 38 (75%) lived within an urban environment.

Findings of the levels of fatigue severity and their impact experienced by participants are shown in Table 2. On average, people suffered from significant levels of fatigue as measured with the summary score of the Neurological Fatigue Index (mean 31.4, SD 5.3, range 15-40; maximum possible score is 40). The highest fatigue scores were in the physical subcategory.

The Fatigue Symptom Inventory [24,34] is designed to assess the severity, frequency, and daily pattern of fatigue as well as its perceived interference with quality of life (see Table 3).

Table 1. Demographic characteristics of participants (N=51).

Characteristics	
Age (years), mean (SD)	48.5 (12.8)
Range of cohort (years)	26-71
Gender, n (%)	
Female	39 (77)
Male	8 (16)
Missing data	4 (8)
Ethnicity, n (%)	
New Zealand European	39 (77)
European	7 (14)
Australian	1 (2)
Missing data	4 (4)
Employment, n (%)	
Full-time	14 (28)
Part-time	7 (14)
Not employed	24 (47)
Missing data	6 (12)

Table 2. Descriptive statistics of the Neurological Fatigue Index (n=47).

Subscale	Mean	SD	Minimum	Maximum
Physical	25.8	4.7	10.0	32.0
Cognitive	11.1	2.8	4.0	16.0
Relief by diurnal sleep or rest	16.7	2.7	11.0	23.0
Abnormal sleep and sleepiness	14.6	2.8	9.0	20.0
Summary	31.4	5.3	15.0	40.0

Table 3. Descriptive statistics of the Fatigue Symptom Inventory (n=47).

	Mean (SD)
Fatigue severity in past week	
Maximum fatigue in past week	7.06 (1.87)
Minimum fatigue in past week	3.28 (1.87)
Average fatigue in past week	5.09 (1.90)
Fatigue right now	5.19 (2.48)
Subtotal	5.15 (1.74)
Fatigue interference with activities in past week	
General activity	5.28 (2.65)
Ability to bathe and dress yourself	2.38 (3.00)
Normal work activity	4.72 (2.95)
Ability to concentrate	4.43 (2.88)
Relations with other people	3.81 (2.54)
Enjoyment of life	5.26 (2.62)
Mood	4.72 (3.01)
Subtotal	4.37 (2.29)
Frequency of fatigue in the past week	
Number of days fatigued in past week	5.72 (1.81)
How much of the day were you fatigued	5.45 (2.48)
Subtotal	5.59 (2.14)

Lower scores denote less acute problems with fatigue. The total mean score of fatigue severity in the past week was 5.59 (SD 1.9). In total, 84% (43/51) of respondents scored on average more than 3 on the fatigue severity questions, implying significant fatigue. The total mean score for fatigue interference with activities during the past week was 4.37 (SD 2.3). Fatigue frequency during the past week was 5.45 (SD 2.5). The majority of participants reported their fatigue to be worst in the afternoon (22/51, 43%), but a sizeable group said there was no consistent pattern to their fatigue (14/51, 28%). The majority of participants (37/51, 73%) reported the use of strategies to alleviate fatigue (eg, timing of certain activities, managing stress, pacing and resting).

Mobile phone usage was high, with 86% (44/51) of respondents reporting that they have a mobile phone; 41% (44/51) use an iPhone, 39% (20/51) use an Android phone, 2% (1/51) use a Windows phone, and 4% (2/51) use a Blackberry. In addition, 9% (5/51) have access to 2 phones.

Mobile phone apps were used by 75% (38/51) of respondents. A total of 6% (3/51) stated they didn't know, and 20% (10/51) did not answer the question. Along with mobile phones, people with MS reported using a range of other mobile devices, including laptops (32/51, 63%) and tablets like iPad (25/51, 49%), iPod Touch (6/51, 12%), iPad Mini 4 of 51 (4/51, 8%), and e-book readers (14/51, 28%). Half of respondents (25/51, 49%) had access to 2 mobile devices. Finally, 1 participant could not afford a tablet and 1 person reported having no need for one.

When asked where they were able to access the Internet, 92% (47/51) reported accessing the Internet from home. Other locations where participants accessed the Internet included work, locations outside the home, and other homes (Table 4). Daily Internet usage was commonly reported by participants with an average use of 2 hours, 23 minutes per day. One-quarter (13/51, 26%) of participants did not access the Internet at all.

Table 4. Locations where participants have Internet access.

Location	Percentage
Home	92
Work	33
School	2
Internet café	4
Other homes	16
Library	6

Some participants reported that mobile phone or app use was negatively affected by their symptoms, such as visual problems (6/51, 12%) and weakness (15/51, 29%). Examples of visual problems included trouble focusing, optic neuritis, and blind spots. People also reported other symptoms of MS that could affect their use of such technology, such as eyestrain, general fatigue, numbness in the fingers, numbness of 1 side of the body, excessive tremor in hands and fingers, and 1 person reporting difficulty with voice recognition training problematic because of slurred speech.

Only a small percentage of participants (4/51, 8%) reported the use of special devices to access mobile technology. Such special devices included onscreen virtual keyboards (12/51, 23%), alternative mouse systems (3/51, 6%), voice recognition (3/51, 6%), and a screen magnifier (2/51, 4%).

In summary, New Zealand survey participants with MS reported high levels of both fatigue severity and fatigue impact. Responses also indicated that the large majority of participants have a mobile device, use apps, and have access to the Internet.

Discussion

Principal Findings

This study assessed levels of fatigue severity and their impact experienced by people with MS in New Zealand. Fatigue severity was measured using the Neurological Fatigue Index for MS. Fatigue significantly affected nearly all of those who took part in the study; both physical and cognitive fatigue affected their quality of life. Of the subscale categories surveyed, fatigue predominantly affected motor function and sleep patterns, findings which are in line with the studies of Thomas et al [23] and Carnicka et al [36]. Difficulties with motor function and sleep often lead to anxiety and depression [5,23,36,37]. Disruption of melatonin circadian rhythm production and lower waking cortisol levels have been linked with higher disability and fatigue scores in MS patients [38,39]. The majority of participants in this study experienced more fatigue in the afternoon. This is consistent with subjective reports of increasing cognitive fatigue during the day by MS patients [40].

On the Fatigue Symptom Inventory, the majority (43/51, 84%) of respondents reported this to be severe. Such levels of fatigue interfered significantly with people's day-to-day activities, results that are consistent with those of Mills and Young [41], who also found relationships between fatigue and disability, disease type, and sleep.

Given that both fatigue severity and fatigue impact were reported to be severe and significant, there is an important need for accessible evidence-based interventions for people with MS. The possibility of using mobile technology to deliver such an intervention could be a solution to the current health environment of scarce resources because people with MS appear to be open to smartphone use in health care and have reported many potential benefits [33,42]. This study obtained some useful findings in regard to access and use of mobile technologies by people with MS fatigue. The majority of participants in this survey were open to smartphone use, and only a small number of participants (2/51, 4%) reported MS symptoms that restricted their use of mobile phone apps. Furthermore, most respondents in the study had a mobile phone and access to the Internet at home, suggesting that a sufficient platform exists to develop a mobile app to deliver a cognitive behavioral therapy-based intervention for MS fatigue.

The use of mobile technology in providing an intervention for MS fatigue would need to consider MS disabilities which may limit dexterity, and the design and implementation of eHealth apps should be tailored to the patients' individual needs [43].

There are a number of general benefits associated with mobile technologies [44], which are also relevant to the population of interest. The application of inexpensive wireless technologies such as accelerometers and gyroscopes combined with Internet-based or smartphone apps offers researchers and clinicians a viable method of monitoring patients with MS. Such feedback and biofeedback could improve self-management and home-based rehabilitation [30,45]. Mobile technologies can lower the costs and burden of travel to clinic-based assessments, remove the subjectivity of self-reporting, and improve the capture of data with greater accuracy and precision regarding the daily impairment, disability, and functioning of patients with MS [30,45]. Mobile technology also permits accessing interventions at times of the day when the user is least affected by fatigue [40].

Limitations and Future Directions

With such a small survey (51 respondents) and unknown response rate it is difficult to ascertain conclusively the nature and severity of symptoms of MS fatigue or the use of mobile devices. However, the sample is reflective of the typical epidemiology of people with MS (eg, predominantly female and white). The findings of the study will be used to investigate the benefits of a mobile technology app to deliver a cognitive behavioral therapy-based intervention for the management of MS fatigue.

Conclusion

This survey has demonstrated that New Zealand respondents with MS experienced high levels of both fatigue severity and fatigue impact. The majority of participants have a mobile device and access to the Internet. These factors, along with

limited access to face-to-face cognitive behavioral therapy-based interventions, create an opportunity to develop a mobile technology platform for delivering a cognitive behavioral therapy-based intervention to improve the severity and impact of fatigue in people with MS.

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Authors' Contributions

KvK, PK, and DB led on the study design. Data collection was completed by NR and supervised by KvK, PK, and DB. Data were analyzed by WM-W and PK and the manuscript was drafted by WM-W and reviewed by KvK, PK, and DB. All authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

MS: multiple sclerosis

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Original Paper

Use of a Novel Artificial Intelligence Platform on Mobile Devices to Assess Dosing Compliance in a Phase 2 Clinical Trial in Subjects With Schizophrenia

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Abstract

Background: Accurately monitoring and collecting drug adherence data can allow for better understanding and interpretation of the outcomes of clinical trials. Most clinical trials use a combination of pill counts and self-reported data to measure drug adherence, despite the drawbacks of relying on these types of indirect measures. It is assumed that doses are taken, but the exact timing of these events is often incomplete and imprecise.

Objective: The objective of this pilot study was to evaluate the use of a novel artificial intelligence (AI) platform (AiCure) on mobile devices for measuring medication adherence, compared with modified directly observed therapy (mDOT) in a substudy of a Phase 2 trial of the $\alpha 7$ nicotinic receptor agonist (ABT-126) in subjects with schizophrenia.

Methods: AI platform generated adherence measures were compared with adherence inferred from drug concentration measurements.

Results: The mean cumulative pharmacokinetic adherence over 24 weeks was 89.7% (standard deviation [SD] 24.92) for subjects receiving ABT-126 who were monitored using the AI platform, compared with 71.9% (SD 39.81) for subjects receiving ABT-126 who were monitored by mDOT. The difference was 17.9% (95% CI -2 to 37.7; $P=.08$).

Conclusions: Using drug levels, this substudy demonstrates the potential of AI platforms to increase adherence, rapidly detect nonadherence, and predict future nonadherence. Subjects monitored using the AI platform demonstrated a percentage change in adherence of 25% over the mDOT group. Subjects were able to use the technology successfully for up to 6 months in an ambulatory setting with early termination rates that are comparable to subjects outside of the substudy.

Trial Registration: ClinicalTrials.gov NCT01655680 <https://clinicaltrials.gov/ct2/show/NCT01655680?term=NCT01655680>

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KEYWORDS

medication adherence; artificial intelligence; clinical trials as topic

Introduction

Accurately monitoring and collecting drug adherence data can allow for better understanding and interpretation of the outcomes of clinical trials [1-3]. The advent of electronic monitoring has generated a wealth of published data on the value of analyzing drug adherence and using this information as an explanatory variable in itself [4-6]. In order to understand the dose-response relationship of an investigational drug, or understand factors contributing to intersubject variability in response to a drug, it is imperative to properly capture and understand the dosing history (ie, actual doses taken, missed doses, late doses). To ignore these variations in adherence is a “lost opportunity if not a scientific lapse” [4] in both clinical research and in population health.

Monitoring Methods in Clinical Research

Most clinical trials use a combination of pill counts and self-reported data to measure drug adherence, despite the drawbacks of relying on these types of indirect measures. It is assumed that doses are taken, but the exact timing of these events is often incomplete and imprecise. Pill counts have frequently been shown to underestimate poor adherence and nonadherence [1,7-13].

A recent study questioned the utility of pill count data when compared with pharmacokinetic data [2]. For the 1765 subjects receiving active drug in 8 Phase 2 or later psychiatric trials conducted between 2001 and 2011, the estimated nonadherence rates of 12.8-39.2% from the pharmacokinetic data (with nonadherence defined as >50% of pharmacokinetic samples below the limit of quantification for the study drug in plasma) proved far higher than the nonadherence rates of 0.0-5.1% estimated by pill counts in 5 of the 8 studies [2].

The advent of electronic monitoring packaging (EMP) allowed for more reliable collection of adherence data, giving researchers the ability to collect the date and time stamp of each bottle/package opening (frequently in real time), and providing patients with some reminders and feedback. The short duration of many of the trials that implemented EMP (and the variability in quality of the study designs) in a systematic review of 37 studies using forms of EMP precluded definitive assessment of their effect on adherence [14]. One limitation of EMPs is that they do not verify drug administration. Meticulously removing pills from pill bottles led researchers to prematurely halt a large human immunodeficiency virus (HIV) prevention trial (VOICE) for lack of efficacy, with data suggesting that approximately 70% of the female participants in the study had no measurable tenofovir blood concentrations (the main study drug under

investigation) despite approximately 90% of these patients claiming to be adherent [15,16]. More reliable measures tend to be hardware-based and require changes to the drug manufacturing process itself, incurring high costs and operational challenges [17].

Due to its ability to ensure treatment adherence, directly observed therapy (DOT) has been used for decades, both to measure and maximize adherence for treatment of tuberculosis infections and antiretroviral therapies [18-21], and to ensure ingestion in inpatient settings or in early-phase clinical trials when subjects are dosed in the clinic. However, for trials conducted in outpatient populations, the cost and logistical complexity of administering DOT forces clinical trials to switch to less intensive monitoring, despite the continued and largely unmeasured risk of nonadherence [22].

Artificial Intelligence Platform

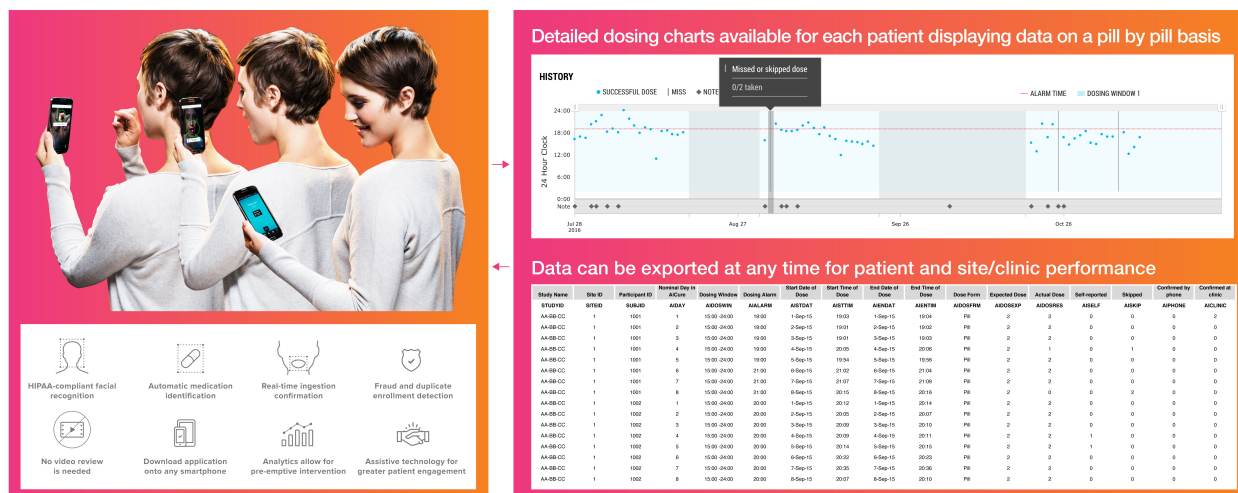
The artificial intelligence (AI) platform AiCure (New York, NY) uses AI to visually confirm medication ingestion (Figure 1) via software that can be downloaded as an app on any mobile device. Using facial recognition and computer vision, software algorithms identify the patient, the drug, and confirm ingestion. Date and time stamps are collected for each individual pill. Adherence data fall into the following 6 categories: (1) visual confirmation of ingestion using the AI platform app, (2) self-reported dose via the *self-report* button in the app (no visual confirmation), (3) self-reported dose over the phone to the study coordinator, (4) missed dose, (5) skipped dose, and (6) dose taken in clinic. Encrypted data for each dosing administration are sent to cloud-based dashboards for real-time monitoring and intervention, with suspicious activity, duplicate enrollment, or incorrect usage triggering alerts. Study subjects were provisioned a smartphone with the AI app predownloaded to monitor study drug compliance. The AI app was installed with Health Insurance Portability and Accountability Act-compliant AI software.

The present report describes medication adherence results from an exploratory pilot substudy, using the AI platform compared with modified DOT (mDOT) 3 times per week during a clinical study (Study M10-855 [ClinicalTrials.gov NCT01655680]) of an investigational adjunctive oral medication (ABT-126) that was evaluated for treatment of cognitive impairment in patients with schizophrenia. The objectives of this exploratory pilot substudy were to evaluate the AI platform as a real-time monitoring method for study drug adherence, and to examine the feasibility of using the platform in a 6-month Phase 2 schizophrenia study.

Figure 1. Artificial intelligence platform.

Computer vision and neural networks confirm medication ingestion

Real-time data are encrypted and transferred to cloud-based dashboards



Methods

Study M10-855 (AbbVie Inc.) was a Phase 2, multicenter, randomized, double-blind, placebo-controlled, dose-ranging, parallel-group, 24-week study of the safety and efficacy of an investigational adjunctive treatment (ABT-126) for the treatment of cognitive deficits in nonsmoking subjects with schizophrenia who were clinically stable. The study was conducted from May 2012 to July 2014 at a total of 31 sites in the United States, 20 sites in Russia, and 7 sites in the United Kingdom. Overall, 431 subjects were randomized to 25, 50, or 75 milligrams (mg) ABT-126 or matching placebo administered as 3 capsules once daily in the morning. All subjects provided informed consent prior to any study procedures.

Adherence was measured by review of returned study drug blister cards. Subjects with less than 70% adherence received intense counseling on the importance of adherence, and could also be withdrawn from the study. In addition, a later amendment of the protocol included an optional adherence program (AI substudy) for US sites. Ten of the 31 US sites agreed to participate. In addition to the blister cards, subjects at these sites were asked to choose between the AI platform and mDOT as a further adherence measure. mDOT required study staff (or a third party) to observe and record study drug adherence at least 3 times per week. Subjects monitored by the AI platform were assigned a device with the AI app downloaded. Adherence data from the AI substudy were not entered into the clinical study database. Sites participating in the AI substudy continued to record adherence based on returned blister cards at each visit.

Pharmacokinetic blood samples for the analysis of ABT-126 plasma concentrations were collected at weeks 2, 4, 6, 10, 12, 16, 18, 22, and 24. At weeks 2 and 4, the pharmacokinetic samples were collected prior to dosing at the site on the week 2 and week 4 visit days. At weeks 6, 12, 18, and 24, the pharmacokinetic samples were collected (when possible) following the cognitive and functional assessments. At weeks

10, 16, and 22, the pharmacokinetic samples were collected at any time during the visit.

The primary exploratory analyses for the AI substudy were performed for all randomized subjects who received the study drug at the 10 designated US sites, and included data through week 24. Daily adherence data captured by the AI platform were summarized by week (7-day intervals). The protocol-planned measure for adherence used pill count data based on the returned blister packs. The main adherence measures for the analyses in this paper were based on scheduled pharmacokinetic sampling results and AI platform-measured parameters. A subject on ABT-126 was said to be adherent for a given week based on pharmacokinetics, if the subject's pharmacokinetic sample taken during that week had measureable study drug concentration (ie, concentration above the lower limit of quantification [LLOQ]). A subject's AI platform adherence rate for a given week was defined as the number of doses captured by the AI platform relative to the number of planned doses for that week. Additionally, each subject had cumulative pharmacokinetic and AI platform adherence rates calculated for each study week, based on data from that week and previous weeks with nonmissing data. No planned sample size or power calculations were performed for these post hoc exploratory analyses. The analyses are exploratory in nature, and the reported results need to be interpreted descriptively to generate future hypotheses.

Results

In the M10-855 study, a total of 431 adult subjects with schizophrenia (placebo, n=144; 25 mg ABT-126, n=66; 50 mg ABT-126, n=151; 75 mg ABT-126, n=70) were randomized and received at least 1 dose of study drug or placebo. Subjects remained on their baseline antipsychotic treatment regimen during the study. Ten of the 31 US sites participated in the AI substudy. A total of 75 subjects were enrolled at these sites (Table 1). Of these 75 subjects, 53 were monitored with the AI platform. Of these 53 subjects, 12 were grandfathered into

the substudy after 6-to-20 weeks of daily administrations of the study drug prior to AI platform monitoring. Among the subjects who used the AI platform, the following completed the study: placebo, 8 of 15 subjects (53%); 25 mg ABT-126, 7 of 8 subjects (88%); 50 mg ABT-126, 12 of 19 subjects (63%); and 75 mg ABT-126, 9 of 11 subjects (82%). All 22 subjects who chose

to be monitored by mDOT 3 times per week (per protocol) completed the study (placebo, n=7; 25 mg ABT-126, n=6; 50 mg ABT-126, n=4; 75 mg ABT-126, n=5). The early discontinuation rate in the AI group (17 of 53 subjects, 32%) was similar to the early discontinuation rate at the 21 US sites not participating in the AI substudy (36 of 135 subjects, 26.7%).

Table 1. Subject disposition (AI substudy). AI: artificial intelligence; mDOT: modified directly observed therapy; mg: milligrams.

Parameter	Dose of ABT-126				Overall
	Placebo	25 mg	50 mg	75 mg	
All subjects participating in the AI substudy, N	22	14	23	16	75
Completed study, n (%)	15 (68%)	13 (93%)	16 (70%)	14 (88%)	58 (77%)
Withdrawn, n (%)	7 (32%)	1 (7%)	7 (30%)	2 (13%)	17 (23%)
Subjects monitored using the AI platform, N	15	8	19	11	53
Completed study, n (%)	8 (53%)	7 (88%)	12 (63%)	9 (82%)	36 (68%)
Withdrawn, n (%)	7 (47%)	1 (13%)	7 (37%)	2 (18%)	17 (32%)
Suspicious, n (%)	6 (40%)	4 (50%)	9 (47%)	0 (0%)	19 (36%)
Grandfathered, n (%)	3 (20%)	2 (25%)	3 (16%)	4 (36%)	12 (23%)
Subjects monitored using mDOT, N	7	6	4	5	22
Completed study, n (%)	7 (100%)	6 (100%)	4 (100%)	5 (100%)	22 (100%)
Withdrawn, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Suspicious subjects were those flagged by the AI platform as having dosing parameters outside of normal activity. Grandfathered subjects were those enrolled in the study before the option to use the AI platform was introduced.

For all subjects in the AI substudy (n=75), the mean age was 45.9 years (standard deviation [SD] 10.86) and 55% (41/75) of the subjects were male (Table 2). Overall, 52% (39/75) of subjects were black, 41% (31/75) were white, 5% (4/75) were

Asian, and 1% (1/75) were Hawaiian. Subject demographics in the AI substudy were similar to those at all US sites (n=210) and mean age was 45.1 years (SD 11.20), 59% of subjects were male, and the majority of subjects were black (57%). In the AI substudy, the treatment groups were reasonably balanced with respect to age, sex, and race, with the exception of a higher percentage of white subjects and lower percentage of black subjects in the 75 mg ABT-126 group compared with the placebo, 25 mg, and 50 mg ABT-126 groups.

Table 2. Demographic characteristics (AI substudy). mg: milligrams.

Variable	Dose of ABT-126				Overall	
	Placebo (N=22)	25 mg (N=14)	50 mg (N=23)	75 mg (N=16)		
Age, years	Mean	47.6	45.6	45.0	45.3	
	Standard deviation	7.87	9.52	11.77	14.40	
	Median	47.5	47.5	49.0	48.5	
	Minimum, Maximum	32, 64	29, 62	21, 63	20, 65	
Sex, n (%)	Female	9 (41%)	8 (57%)	10 (44%)	7 (44%)	34 (45%)
	Male	13 (59%)	6 (43%)	13 (57%)	9 (56%)	41 (55%)
Race, n (%)	Asian	1 (5%)	0 (0%)	2 (9%)	1 (6%)	4 (5%)
	Black	15 (68%)	8 (57%)	12 (52%)	4 (25%)	39 (52%)
	Hawaiian	0 (0%)	1 (7%)	0 (0%)	0 (0%)	1 (1%)
	White	6 (27%)	5 (36%)	9 (39%)	11 (69%)	31 (41%)

Subjects who were monitored by the AI platform, received ABT-126 (25, 50, or 75 mg), and had available pharmacokinetic data had geometric mean ABT-126 drug levels (normalized to the 50 mg dose) that were higher at each time point evaluated through week 24 compared with subjects monitored by mDOT (Figure 2). At week 24, the geometric mean drug level, normalized to the 50 mg dose, was 16.6 nanograms/milliliter (ng/mL; SD 4.42) for subjects using the AI platform compared with 9.6 ng/mL (SD 6.56) for subjects monitored by mDOT. The analysis set consisted of all subjects who received any dose of ABT-126 at the participating US sites and had available pharmacokinetic data. Visits were based on a categorization of collection-day data into weekly windows.

Based on an analysis of subjects who received ABT-126 at the AI substudy sites and had available drug concentration data, cumulative pharmacokinetic adherence was higher from week 2 through week 24 for subjects monitored using the AI platform compared with subjects monitored using mDOT (Figure 3). The mean cumulative pharmacokinetic adherence over 24 weeks was 89.7% (SD 24.9) for subjects receiving ABT-126 and monitored using the AI platform (n=28) compared with 71.9% (SD 39.8) for subjects receiving ABT-126 and monitored by mDOT (n=15). The difference was 17.9% (95% CI -2 to 37.7; $P=.08$). Subjects (n=69) at the 21 US sites not participating in the AI substudy had cumulative pharmacokinetic adherence over 24 weeks of 78.1% (SD 29.7). The analysis set consisted of all subjects who received any dose of ABT-126 at US sites selected to use the AI Platform and who had available pharmacokinetic data. Visits were based on a categorization of collection day data into weekly windows. Pharmacokinetic adherence was defined as ABT-126 levels greater than the LLOQ (0.7 ng/mL). Cumulative results were based on data from current and previous visits with nonmissing data.

A total of 19 subjects (19/53, 35.8%; 13 subjects on active drug [including 4 subjects in the 25 mg ABT-126 group and 9 subjects in the 50 mg ABT-126 group] and 6 subjects on placebo) were flagged as having suspicious drug administration behavior by the AI platform (Table 1). The generation of the

platform used in the study utilized manual review of deidentified video data to identify suspicious behaviors (leaning out of the field of view, tampering with the drug, spitting out the drug, hand to mouth gestures, and turning the device away). Seven of 13 subjects (54%) had at least 1 pharmacokinetic sample showing a drug concentration of zero or below LLOQ, or did not complete the trial. At week 24, mean cumulative pharmacokinetic adherences for suspicious subjects using the AI platform (n=10), for nonsuspicious subjects using the AI platform (n=18), and for subjects monitored using mDOT (n=15) were 78.9% (SD 36.8), 95.7% (SD 12.7), and 71.9% (SD 39.8), respectively. At week 24, mean cumulative pharmacokinetic adherence for subjects grandfathered into the substudy and using the AI platform (n=7) was lower (81.0%, SD 37.8) compared to those who began the study with the AI platform (n=21; 92.6%, SD 19.4).

The average cumulative dose adherence measured by the AI platform through week 24 was 80%. Of note, concordance was not demonstrated between the AI platform and pharmacokinetic cumulative adherence rates, giving a Pearson's correlation of $r=0.33$ (95% CI -0.12 to 0.65). At the AI substudy sites, the mean percentage of subjects with adherence >70%, as measured by review of returned study drug blister cards, was >90% at all study visits evaluated (weeks 2, 4, 6, 10, 12, 16, 18, 22, and 24) for each treatment group (including subjects monitored with the AI platform and those monitored by mDOT).

Subjects received 3 study drug capsules per daily dose, for a total of 21 capsules per week. The mean total capsules per week based on visual confirmation of ingestion by the AI platform ranged from 14.6 to 18 and the total mean missed/skipped capsules per week ranged from 1 to 3 for subjects receiving any dose of study drug (placebo or ABT-126) who were monitored using the AI platform. Overall, the mean time required to take a capsule (placebo or active drug) while being monitored with the AI platform ranged from 40.3 to 70.6 seconds from weeks 1 to 24. The average time taken per dose of study drug (3 capsules; placebo or active drug) throughout the study was 3 minutes.

Figure 2. Geometric mean ABT-126 plasma concentrations, normalized to the 50 milligram dose, for subjects who participated in the adherence substudy stratified by artificial intelligence platform versus modified directly observed therapy use. Error bars indicate mean with standard errors. ng/mL: nanograms/milliliter; mg: milligram.

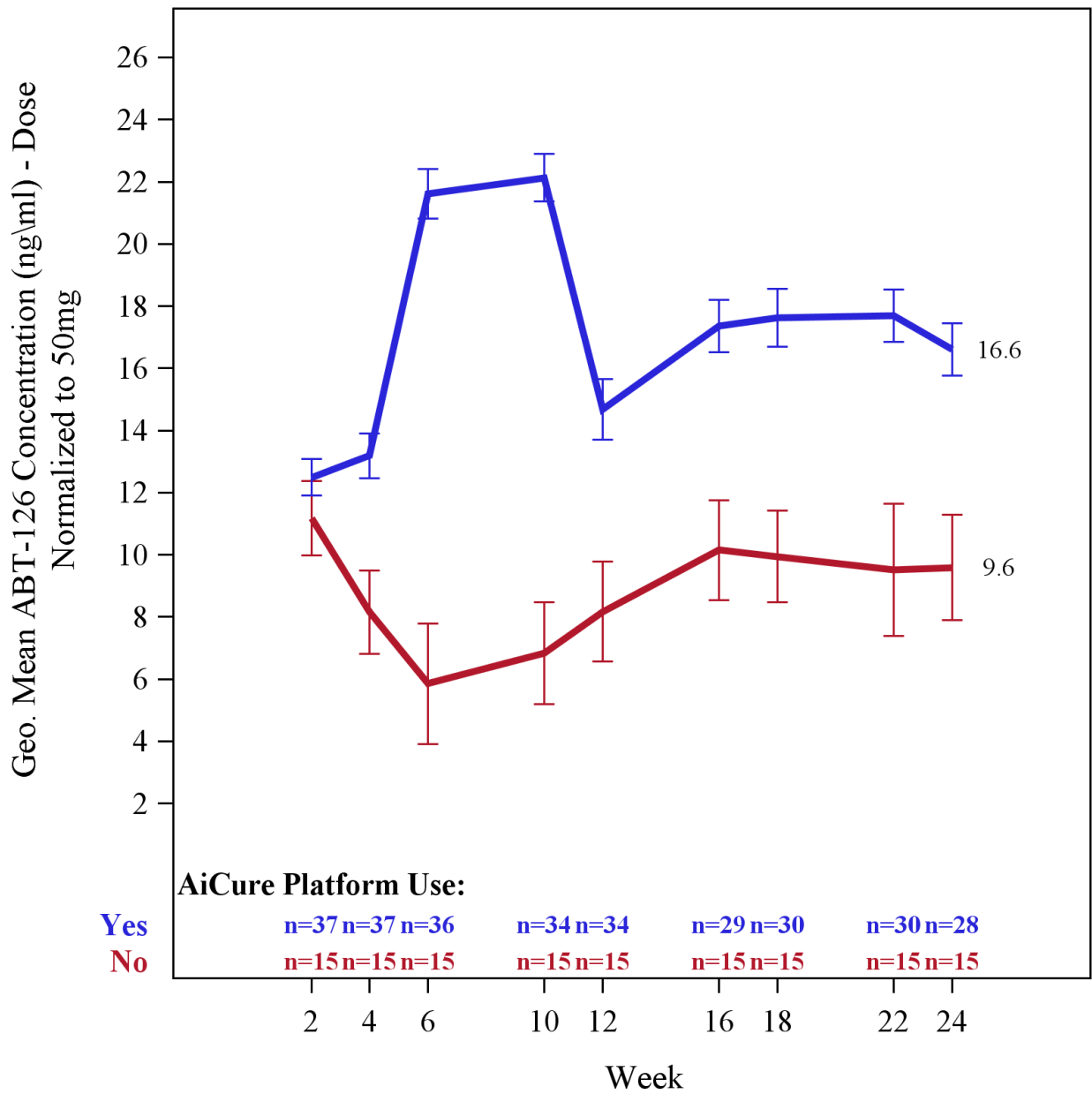
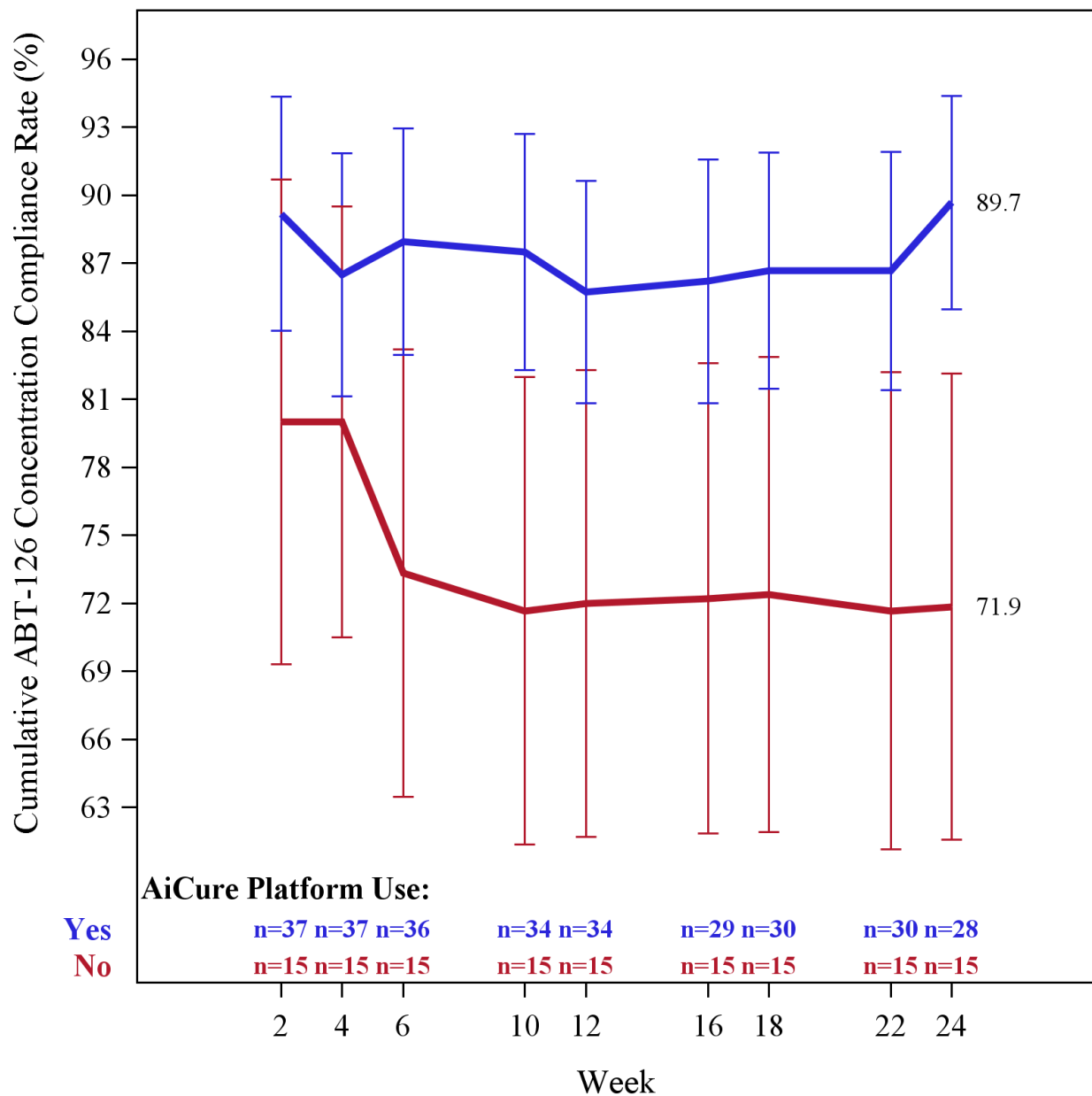


Figure 3. Cumulative adherence based on study drug (ABT-126) concentration.



Discussion

Electronic monitoring of medication adherence [23] has highlighted the value of obtaining real-time dosing data for better informed pharmacokinetic, pharmacodynamic, and efficacy analyses, and for treatments requiring close monitoring [12,24]. Although the accuracy of electronic monitoring has been validated based on observed dosing [25], most studies have not evaluated electronic monitoring using drug levels in the blood; sensitivity and specificity are typically measured against biomarkers such as detected HIV viral load [26-28] or adherence is compared to less reliable measures, such as pill counts or patient self-reports [16].

Other monitoring methods using ingestible sensor technology or breathalyzer monitoring have demonstrated the accuracy of these methods based on adherence markers or plasma drug

concentrations collected during observed dosing [29,30]. However, usability outside of controlled settings has not been robustly assessed [29,30]. Evaluations of new monitoring methods should include effects on adherence, concordance with drug concentration measurements in ambulatory settings, and ease of adoption.

Principal Results

In the present study, the AI platform was introduced into 10 of 31 US study sites participating in a Phase 2 study of ABT-126 in subjects with schizophrenia to augment standard and more intensive adherence assessments (eg, pill counts and mDOT), and to evaluate and test feasibility of the AI platform in this setting. Adherence measures (AI platform vs mDOT) were compared with drug concentration measurements to build a framework for evaluating the effectiveness of the AI platform in measuring drug ingestion and promotion of treatment

adherence. Subjects monitored using the AI platform appeared to be more adherent to study drug dosing compared to subjects receiving mDOT 3 times per week, based on plasma drug levels. The differences detected in study drug concentrations might have been more pronounced had a measure such as mDOT (which helps support optimal adherence [21]) not been the comparator in this study, or had a drug with a shorter half-life than ABT-126 been evaluated (the plasma concentrations of which would have been more sensitive to missed doses).

Lack of concordance between the AI platform and pharmacokinetic cumulative adherence rates, giving a Pearson's correlation of $r=0.33$ (95%CI -0.12 to 0.65), may be explained by the following three considerations: (1) 9 patients receiving active study drug were grandfathered into the substudy, each of whom had pharmacokinetic samples with no corresponding AI platform adherence data; (2) the AI platform dataset contained a maximum of 540 data points for each subject, compared to a maximum of 9 data points for each subject in the pharmacokinetic dataset; and (3) the AI platform dataset included doses that were missed, skipped, or self-reported, highlighting suboptimal adherence that may not have been captured in the pharmacokinetic dataset.

Cumulative adherence, measured by study drug concentrations above the LLOQ, appeared to be higher through 24 weeks for subjects monitored using the AI platform (89.7%) compared with subjects monitored using mDOT (71.9%). The difference was 17.9% (95% CI -2 to 37.7; $P=.08$).

Subjects monitored using the AI platform demonstrated a percentage change in adherence of 25% over the mDOT group. The study drug concentration among the mDOT group (71.9%) is consistent with the McCann et al study, which showed nonadherence rates of 12.8-39.2% [2]. Deceptively removing pills to feign higher adherence leads to the low rates of nonadherence typically measured by pill count, as seen in the aforementioned study (0.0-5.1% [2]) and in the present study (0-3%). The discrepancy between the adherence rates reported by pill count and those measured through pharmacokinetic sampling is substantial. Within the AI group, subjects who were identified as suspicious had lower cumulative pharmacokinetic adherence at week 24 compared to subjects who were not identified as suspicious (78.9% vs 95.7%). Subjects who were grandfathered into the substudy had lower cumulative pharmacokinetic adherence at week 24 compared to subjects who were not grandfathered into the substudy (81.0% vs 92.6%). Excluding these first 2 groups might have led to higher cumulative adherence in the AI group.

The AI platform was successfully utilized in this multicenter study among cognitively impaired subjects with schizophrenia. Subjects were able to use the technology successfully for up to 6 months in an ambulatory setting. Acceptance of mobile

technology has received little attention in this patient population and has primarily relied on the use of mobile devices for patient self-assessment, and as psychoeducational tools [31,32].

Limitations

The principal limitation of this substudy was the lack of randomization; subjects were allowed to choose between the AI platform and mDOT. Of the 75 subjects at the 10 sites, 22 self-selected mDOT, possibly adding bias to the study results. However, it is worth noting that 17 of the 22 subjects had already started the study prior to the introduction of the AI platform, or were already receiving DOT at board and care facilities. A second limitation was the small sample size of subjects randomized to active drug (AI platform, $n=38$; mDOT, $n=15$). A third limitation was the inconsistent use of mDOT. Although mDOT usage was suggested at all US sites, not all subjects received direct observation 3 times per week. A fourth limitation was the use of the plasma concentrations in the analyses without regard to the collection time relative to the recorded last dose. The impact of this variable on the conclusions is believed to be negligible since the threshold for declaring lack of adherence was a concentration below the LLOQ, which is a conservative criterion that should not be very sensitive to collection time relative to dosing time variations.

Conclusions

Extensive evidence of nonadherence in clinical trials, which includes behaviors such as removing pills from blister cards or bottles while reporting high adherence, can undermine trial results by providing false data and preclude true assessments of efficacy and safety [3]. AI platforms have the potential to increase adherence, identify poor-performing subjects, and improve data quality. Detailed dosing patterns based on confirmed ingestions allow for real-time intervention to further improve adherence rates and subject retention. In clinical practice, where poor adherence to antipsychotic treatment is linked to increased hospitalization rates, the availability of real-time data could allow for quicker and more effective interventions, potentially improving outcomes and reducing relapses [33]. In clinical research, this technology might be useful to predict future behavior during placebo lead-in periods in clinical studies by allowing for early detection and intervention [3,34]. Such technology can also help researchers understand the response patterns among patients in trials and terminate the development of ineffective drugs with confidence, leading to improved decision-making and accelerated clinical trial results. The use of AI to visually confirm medication ingestion is a valid contribution to the armamentarium of tools that could help reduce uncertainties and costs associated with high rates of nonadherence in clinical trials and real-world settings.

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Conflicts of Interest

Laura Shafner and Adam Hanina are employees of AiCure (New York, NY, USA) and consultants to AbbVie. Adam Hanina is a shareholder of AiCure (New York, NY, USA). David Walling is a consultant to Otsuka, Eli Lilly, Janssen, and Acadia. John E. Hinkle, PhD, has active consulting agreements with AiCure and several drug discovery, pharmaceutical, medical food, and contract research organizations. Christy Chuang-Stein, PhD, reports consulting agreements with AiCure, AstraZeneca, AbbVie, TEVA, Amgen, and Merck Serono. Earle Bain, MD, and Ahmed A. Othman, PhD are employees and shareholders of AbbVie.

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Abbreviations

- AI:** artificial intelligence
- DOT:** directly observed therapy
- EMP:** electronic monitoring packaging
- HIV:** human immunodeficiency virus
- LLOQ:** lower limit of quantification
- mDOT:** modified directly observed therapy
- mg:** milligram
- mL:** milliliter
- ng:** nanogram
- SD:** standard deviation

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Original Paper

Accuracy and Adoption of Wearable Technology Used by Active Citizens: A Marathon Event Field Study

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Abstract

Background: Today, runners use wearable technology such as global positioning system (GPS)-enabled sport watches to track and optimize their training activities, for example, when participating in a road race event. For this purpose, an increasing amount of low-priced, consumer-oriented wearable devices are available. However, the variety of such devices is overwhelming. It is unclear which devices are used by active, healthy citizens and whether they can provide accurate tracking results in a diverse study population. No published literature has yet assessed the dissemination of wearable technology in such a cohort and related influencing factors.

Objective: The aim of this study was 2-fold: (1) to determine the adoption of wearable technology by runners, especially “smart” devices and (2) to investigate on the accuracy of tracked distances as recorded by such devices.

Methods: A pre-race survey was applied to assess which wearable technology was predominantly used by runners of different age, sex, and fitness level. A post-race survey was conducted to determine the accuracy of the devices that tracked the running course. Logistic regression analysis was used to investigate whether age, sex, fitness level, or track distance were influencing factors. Recorded distances of different device categories were tested with a 2-sample *t* test against each other.

Results: A total of 898 pre-race and 262 post-race surveys were completed. Most of the participants (approximately 75%) used wearable technology for training optimization and distance recording. Females ($P=.02$) and runners in higher age groups (50-59 years: $P=.03$; 60-69 years: $P<.001$; 70-79 year: $P=.004$) were less likely to use wearables. The mean of the track distances recorded by mobile phones with combined app (mean absolute error, MAE=0.35 km) and GPS-enabled sport watches (MAE=0.12 km) was significantly different ($P=.002$) for the half-marathon event.

Conclusions: A great variety of vendors ($n=36$) and devices ($n=156$) were identified. Under real-world conditions, GPS-enabled devices, especially sport watches and mobile phones, were found to be accurate in terms of recorded course distances.

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KEYWORDS

athlete; wearables; mobile phones; physical activity; activity monitoring

Introduction

Overview

Wearable technology such as global positioning system (GPS)-enabled sport watches, activity trackers, heart rate monitors, or even smart clothing is considered the number 1 trend in 2016 and 2017 according to the world-wide survey of fitness trends [1,2]. Mobile phones and related exercise apps are likewise ranked in the top 20 of this survey. Due to the ubiquitous nature of wearables and mobile phones, app features such as distance recording, optimization of training sessions, and the information on burned calories are no longer merely available for professional athletes. However, the variety of wearable devices for activity monitoring is overwhelming. The systematic research in terms of device or app accuracy in nonlaboratory settings in the context of long-distance running seems to be underrepresented in the literature [3].

Related Work

According to Düking et al [4], wearables “are lightweight, sensor-based devices that are worn close to or on the surface of the skin, where they detect, analyze, and transmit information concerning several internal and external variables to an external device (...),” (p. 2). In particular, GPS-enabled devices can be considered reliable tracking devices, which holds true even for inexpensive systems.

As a study conducted by Pugliese et al suggests, the increasing use of wearables among consumers has implications for public health. Monitoring an individual’s personal activity level, for example, steps taken in one day, can result in an increased overall physical activity [5]. A moderate level of physical activity can prevent widespread diseases such as diabetes or hypertension [6-8] and thus result in decreasing costs for public health care systems in the long term [9,10].

Yet, in the context of the quantified-self movement, a high accuracy of these consumer-centric devices is desirable. In theory, the measurements obtained by different vendors and device categories (ie, GPS-enabled system vs accelerometer-based) should be comparable with each other [11].

Noah et al studied the reliability and validity of 2 Fitbit (Fitbit, San Francisco, CA) activity trackers with 23 participants. There seems to be evidence that these particular devices produce results “valid for activity monitoring” [12].

A study by Ferguson et al evaluated several consumer-level activity monitors [13]. The findings suggested the validity of fitness trackers with respect to measurement of steps; however, their study population was limited to 21 young adults.

At present, and to the best of our knowledge, no study exists that examines the adoption of consumer-level devices in a broad and diverse population. This is supported by the meta-analysis by Evenson et al: “Exploring the measurement properties of the trackers in a wide variety of populations would also be important in both laboratory and field settings.” We conclude that “more field-based studies are needed” (p. 20) [3]. In particular, this

should include all age groups, different fitness levels, and a great variety of related devices.

Aims of the Study

This study addressed the need for more real-life field evaluations of wearable devices [3]. This is especially important for researchers as well as for providers of health care programs. For instance, insurance companies offering reduced payments to their customers can thereby analyze the distribution of smart wearable devices and their respective accuracy. This allows for adjustments in health intervention programs. Moreover, the study provided a first baseline for researchers that want to validate their own findings in this field.

In this context, the aim of the study was 2-fold: (1) to determine the adoption of wearable technology, especially “smart” devices and (2) to investigate on the accuracy of tracked distances as recorded by such devices. The study cohort comprises participants from a public “Sport for All” road running event, that is, primarily physically active and healthy citizens across all age groups.

Methods

Road Running Event

The Trollinger-Marathon is an annual running event located in Heilbronn, a city in southern Germany [14,15]. In 2016, runners could choose between 4 different course distances: (1) full marathon, 42.195 km; (2) half-marathon, 21.0975 km; (3) walking or nordic walking course, 14.4 km; and (4) a marathon relay, approximately 3×14 km. The event itself took place on May 8, 2016. According to the organizer, a total of 6894 adult runners had registered for the event. Of the registered runners, 6481 actually lined up for the race of which finally 6331 completed the course [15]. The event organizer was a member of the German Road Races Society, and both the full marathon and half-marathon courses were measured according to Association of International Marathons and Road Races (AIMS) and International Association of Athletics Federation (IAAF) regulations. Both event categories were precisely measured by an accredited AIMS and IAAF Grade A or B measurer and therefore considered a valid baseline for the intended distance comparison.

At city marathon events, for example, New York or Berlin, GPS signal strength can be influenced by narrow streets and house constructions [16]. As the Trollinger-Marathon course is mainly characterized by an open landscape, no building-associated limitations exist at the event location. Thus, a good overall GPS coverage can be assumed.

Questionnaire

Two questionnaires were designed: (1) a pre-race questionnaire, Q₁, to determine which kind of performance monitoring technology was predominantly used by runners of different age, sex, and fitness level and (2) a post-race questionnaire, Q₂, to determine the accuracy of the devices that tracked the running course.

Q₁ consisted of 6 items by which quantitative and qualitative data were obtained (see [Multimedia Appendix 1](#) for questions and response options). The primary aim of Q₁ was the collection of cohort-specific data, that is, (1) age, (2) sex, (3) the devices used for exercises and during races, (4) its vendor, (5) the average running activity per week or per month, and (6) the number of running events in the last 12 months. The number of exercises and attended events was assumed as surrogate criterion to determine whether a participant was an amateur or (semi-)professional runner.

Q₂ consisted of 5 items: (1) the tracked distance of (2) one or multiple devices, (3) sex, (4) course category, and (5) the starting block as given by the event organizer (see [Multimedia Appendix 2](#) for questions and response options). Different starting blocks were used to determine whether a runner classified himself or herself as fast or slow.

Runners participated on a voluntary basis in the surveys. Neither personal data nor contact details were collected. Therefore, the resulting records were considered an anonymous dataset that did not conflict with the legislation of national or federal data privacy laws in Germany.

Runners could fill out the paper-based Q₁ on their own. However, most of them preferred to be guided by our survey staff, which consisted of the authors and a group of 9 selected and well-briefed students. The interviewer staff checked whether potential survey candidates had already been asked to participate. Thus, the number of duplicate data entries could be kept very low. In case a participant actively declined an interview, no data at all were noted down.

For the post-race survey, randomly selected race finishers were interviewed. In order to prevent device misreadings caused by physical exhaustion, athletes were not allowed to fill out questionnaires on their own. Instead, their answers were put directly into the corresponding questionnaire by the survey staff.

Recruitment

Only runners of more than the minimum participation age (≥ 16 years) were included in the Trollinger-Marathon cohort. Persons who took part in the marathon relay were excluded from the post-race survey, as no precise information about the relay course sections was made available by the organizers.

For the pre-race survey, the interviews were conducted on May 7 (11:30 AM till 6:30 PM) and May 8 (6:30 AM till 10:00 AM), 2016, while the runners picked up their number bibs, timing chips, and event information. The post-race survey was carried out on May 8 (11:45 AM till 2:15 PM), 2016, at the finish area located in the Heilbronn Frankenstadion.

Data Exclusion

In case of inconclusive device or vendor information and illegible handwriting, questionnaires were strictly excluded, as well as questionnaires with missing information on tracked distances. Thus, for Q₁ and Q₂, the number of related dropouts were 2.7% (25/923) and 21.8% (73/335), respectively.

Statistical Analysis

For further analyses, the remaining, valid questionnaires were transcribed into a relational database setup for this purpose; 1 person read the values as noted in Q₁ and Q₂, whereas another person entered the data into a corresponding data entry mask. Next, the transcribed data were analyzed with the statistics software R version 3.1.2 (R Foundation for Statistical Computing, Vienna, Austria) [17].

Age and sex distributions of the study cohort were compared with the official event starter list—as provided by the organizer—to ensure a satisfying level of representativeness. Logistic regression analysis was applied to examine influencing factors such as sex, age, and exercise frequency on the prevalence of smart devices in the respective subcohorts.

Analysis on Recorded Distance

In theory, the recorded distances should be comparable with each other, as both, the full and the half-marathon, were AIMS-certified for road races.

However, it is unlikely that the exact distance of 42.195 km and 21.0975 km is being recorded, as not every runner can follow the perfect racing line. Moreover, runners may change the road side, resulting in slightly longer distances. For this reason, it is not valid to compare the absolute deviations between the recorded distance and the official track distance (each in kilometers) as true value of the mean. Therefore, it is necessary to compare measured distances with each other via a 2-sided, 2-sample *t* test (significance level $\alpha = .05$). The *t* test was applied to analyze differences among identified device categories, as presented in the following sections.

Results

Principal Findings

A total of 898 valid Q₁ and 262 valid Q₂ were collected and subsequently transcribed into the study database.

Study Cohort

The cohort of the pre-race survey comprised 78.7% (133/169) male and 21.3% (36/169) female full marathon runners. For the half-marathon, 61.9% (396/635) males and 37.3% (239/635) females were recorded. According to the organizer's starting list, 82.4% (593/720) of the marathon runners were males and 17.6% (127/720) female.

For the half-marathon course, a higher percentage of female runners (27.01%, 1492/5524) had themselves registered (male: 72.99%, 4032/5524). [Table 1](#) shows the distribution of sex and age for the full and half-marathon.

For the walking or nordic walking course and the marathon relay event, 32 and 18 questionnaires were collected, respectively. For both subcohorts, no further breakdown for sex or age was conducted.

A total of 39 runners did not fill in the actual event type they took part in and were thus excluded from the cohort analysis.

Table 1. Distribution of sex and age groups among runners for the full and half-marathon (Q₁).

Event	Age group (years)	Male	Pr _{survey} (%)	Pr _{official} ^a (%)	Female	Pr _{survey} (%)	Pr _{official} ^a (%)
Marathon							
	16-29	19	14.3	11	6	16.7	16
	39-39	23	17.3	21	10	27.8	27
	40-49	45	33.8	33	9	25.0	33
	50-59	36	27.1	28	11	30.6	23
	60-69	8	6.0	7	0	0.00	2
	70-79	2	1.5	1	0	0.00	0
	80+	0	0	0	0	0.00	0
	Unknown	0	0	0	0	0.00	0
	Total	133			36		
Half-marathon							
	16-29	94	23.7	22	66	27.6	30
	39-39	84	21.2	28	48	20.1	28
	40-49	93	23.5	25	68	28.5	23
	50-59	97	24.5	20	48	20.1	15
	60-69	24	6.1	5	9	3.8	3
	70-79	4	1.0	1	0	0	0
	80+	0	0	0	0	0	0
	Unknown	0	0	0.2	0	0	0.1
Total		396			239		

^aValues in curved brackets (Pr_{official}) denote the proportion as given in the official starter list for the respective subcohort.

During the post-race survey, questionnaires of 88% (38/43) male and 12% (5/43) female marathon runners and 82.5% (175/212) male and 17.5% (37/212) female half-marathon runners were collected; 2 runners did not state their sex. For the walking or nordic walking course, 5 questionnaires were collected.

Device Category

According to the qualitative data on device names and respective vendor information collected via Q₁ and Q₂, the authors identified 6 major categories of devices: (D₁) mobile phones with related app, (D₂) GPS-enabled sport watches, (D₃) heart rate monitors, (D₄) smart watches, (D₅) wristband activity trackers, and (D₆) other devices.

However, technical differentiation among these categories is a difficult task. As of today some GPS-enabled sport watches can be paired with mobile phones and receive text messages or push notifications. In case the primary purpose of a device was the support of physical activities, it was classified into D₁ rather than D₄. For instance, the Apple Watch was classified in D₄, as it was primarily a lifestyle device. A device was classified as wristband activity tracker if its general shape resembled a bracelet, for example, the Garmin vivofit or Polar Loop. Other Devices (D₆) included simplistic GPS receivers, chest harnesses, GPS-enabled devices for golf court navigation, or even simple analog or digital watches. Device names and the number of occurrences are presented in Table 2. For reasons of clarity and comprehensibility, only devices that occurred 5 or more times in the dataset are listed (for a detailed table with all occurrences, see Multimedia Appendix 3).

Table 2. Device categories, vendors, models, and apps used by runners. Only vendors, devices, and apps with ≥ 5 occurrences collected with Q₁ are listed. Values in curved brackets represent the number of mentions for the respective category, vendor, device, or app.

Category	Vendors	Devices
D ₁ : Mobile phone and app (181)	Apple (80), Samsung (65), Sony (11)	iPhone 6 (22), iPhone 5s (19), iPhone 5 (12), iPhone (11), Galaxy S5 (11), Galaxy S4 (10), iPhone 6s (9), Galaxy S4 mini (8), Galaxy S3 (7), Samsung: other (7) Apps: Runtastic (126), Runkeeper (10), Nike+ Running (9), Endomondo (7), Sports Tracker (6), Strava (6)
D ₂ : GPS sport watch (437)	Garmin (193), Polar (165), TomTom (38), Suunto (18)	M400 (60), Garmin: other (41), V800 (31), Polar: other (31), Forerunner 305 (22), Forerunner 310XT (19), TomTom: other (16), Forerunner 920XT (13), Forerunner 610 (12), Runner Cardio (11), RS300X (10), Ambit 3 Peak (10), Fenix 3 (10), Forerunner 210 HR (9), RC3 (9), RS800CX (9), RCX5 (8), Garmin: other Forerunners (8), RCX3 (7), Forerunner 910XT HR (7), Forerunner 235 WHR (7), Forerunner 205 (6), Forerunner 220 (6), vivoactive (6), Forerunner 110 HR (5), other GPS-enabled sport watch (5)
D ₃ : Heart rate monitor (37)	Polar (27)	Polar heart rate monitor: other (8), heart rate monitor: other (7), A300 (6)
D ₄ : Smart watch (14)	Apple (12)	Apple Watch (12)
D ₅ : Wristband activity tracker (27)	Garmin (11), Polar (8)	Loop (6), vivofit (5), vivosmart HR (5)
D ₆ : Other devices (47)	No specific vendor (36)	Stopwatch (25), watch (6)

As given in [Table 2](#), mobile phones sold by Apple and Samsung were predominant in the study cohort. The majority of the interviewed participants in the D₁ category preferred Runtastic as an accompanying app (69.6%, 126/181), followed by other running apps such as Runkeeper or Nike+ Running. The GPS-enabled sport watch segment (D₂) was also dominated by 2 vendors in particular: Garmin 44.2% (193/437) and Polar 37.6% (165/437). The most popular device was the Polar M400 13.7% (60/437). Devices in the category D₄ (1.9%, 14/743) and D₅ (3.6%, 27/743) seemed to be underrepresented among runners.

Adoption of Wearable Technology

Results of the pre-race survey obtained by Q₁ showed that 26.1% (234/898) of the runners did not use any device for their

exercises or during a running event. In contrast, 8.8% (79/898) of the athletes stated that they used more than 1 device.

Given a total of 977 recorded devices 44.7% (437/977) represented GPS-enabled sport watches, and 18.5% (181/977) were mobile phones with a combined app to track the running performance. The proportion of heart rate monitors (3.8%, 37/977), smart watches (1.4%, 14/977), and wristband activity trackers (2.8%, 27/977) was quite low.

Regression analysis showed that the relation between females and higher age groups and no usage of additional devices for exercise was statistically significant ([Table 3](#)). The subcohort of runners with a higher exercise frequency seemed to be associated with the use of wearable devices for training optimization (odds ratio 2.627). However, this finding was not statistically significant.

Table 3. Features associated with wearable devices and training optimization or distance tracking (n=977).

Feature (n=977 ^a)	Odds ratio	95% CI	P value
Exercise			
Once a month (Ref ^b)	1.0		
Once a week	0.629	0.028-7.040	.71
Twice a week	1.590	0.072-17.274	.71
Three times or more a week	2.627	0.119-28.466	.44
No exercise	0.299	0.012-4.034	.38
Sex			
Male (Ref ^b)	1.0		
Female	0.673	0.486-0.933	.02
Unknown	0.700	0.200-3.266	.61
Age, years			
16-29 (Ref ^b)	1.0		
30-39	1.127	0.693-1.838	.63
40-49	1.009	0.641-1.584	.97
50-59	0.607	0.385-0.949	.03
60-69	0.312	0.159-0.617	<.001
70-79	0.079	0.011-0.400	.004
Event			
Half-marathon (Ref ^b)	1.0		
Marathon	1.017	0.667-1.578	.94
Marathon relay	1.891	0.596-8.430	.33
Walking or nordic walking	0.781	0.372-1.690	.52
Unknown	1.734	0.767-4.487	.22

^aAn extra of 79 data points is included due to multiple answers.

^bReference group in the regression model.

An analysis of device records for the full and half-marathon participants revealed that, in both groups, the majority of runners preferred GPS-enabled sport watches (full: 57.5%, 104/181; half: 42.6%, 297/698). Interestingly, the usage of mobile phones in combination with running apps was more prevalent for half-marathon participants (full: 12.2%, 22/181; half: 19.5%, 136/698).

Accuracy of Tracking Devices

In total, 270 track distances were collected in the post-race survey. Some devices recorded both the number of tracked kilometers and the number of footsteps. The majority of measurements was given in kilometers (97.0%, 262/270). The average number of kilometers for the full marathon and half-marathon courses was 42.385 and 21.154 km, respectively. [Table 4](#) shows the mean recorded distances for each device category, in case the devices were equipped with sensors to track distances.

Table 4. Mean, median, and I and II quartiles of the recorded distances for the full and half-marathon. Median and quartiles are not reported for categories that had <10 data points.

Marathon ^a	n	Mean (km)	Median (km)	Quartile I (km)	Quartile II (km)
D ₁ : Mobile phone and app	4	42.88	–	–	–
D ₂ : GPS sport watch	39	42.33	42.29	42.20	42.38
Half-marathon ^a					
D ₁ : Mobile phone and app	30	21.40	21.41	21.13	21.55
D ₂ : GPS sport watch	179	21.18	21.17	21.09	21.23
D ₄ : Smart watch	2	21.2	–	–	–
D ₅ : Wristband activity tracker	3	20.38	–	–	–

^aD₃ and D₆ devices were technically not equipped with tracking sensor technology.

The longest recorded distances were 43.7 km (full) and 22.55 km (half) and the shortest 41.48 km (full) and 20.00 km (half), respectively; that is, the maximal deviations were 1.5 km for the full marathon and 1.45 km for the half-marathon course. The minimal deviations for both courses were found for the GPS-enabled sport watches. With a mean absolute error (MAE) of 0.35 km (1.7%), mobile phones (D₁) slightly overestimated the half-marathon course. In contrast, measurements obtained by GPS-enabled sport watches (D₂) showed a smaller MAE of 0.12 km (0.6%).

As outlined in Table 4, the number of collected samples for D₄ and D₅ as well as the number of full marathon samples (n=43) was too small. For this reason, only the remaining 2 groups (D₁ and D₂) could be tested in the half-marathon group. In terms of difference in mean, half-marathon measurements collected for mobile phones (D₁) and sport watches (D₂) were not equal to each other ($P=.002$).

For further analysis of half-marathon data, the aforementioned categories, vendors, and devices were compared against each other, visualized via 3 box-and-whisker plots, as depicted in Figures 1-3.

Measurements for devices in D₁ showed a higher variance as devices in D₂, which corresponded to the result of the *t* test and findings in Table 4.

Figures 2 and 3 give a more detailed breakdown for different vendors and frequently used devices at the Trollinger-Marathon. The interquartile ranges (IQRs) by Garmin and Polar devices are comparable. However, data generated by Polar devices show a higher number of statistical outliers. The IQR of TomTom and Suunto devices was found to be the lowest, yet it must be noted that only 16 and 7 data points were available. As depicted in Figure 3, the Garmin devices seem to be the most accurate against the reference distance of the half-marathon course. In contrast, measurements of mobile phones (here: Apple iPhone) show the highest IQR and noticeably deviate from the reference distance (indicated by a dashed line).

Figure 1. Box-and-whisker plot of recorded distances (half-marathon) by device category D1 (n=30) and D2 (n=179). The dashed line indicates the reference distance of 21.0975 km.

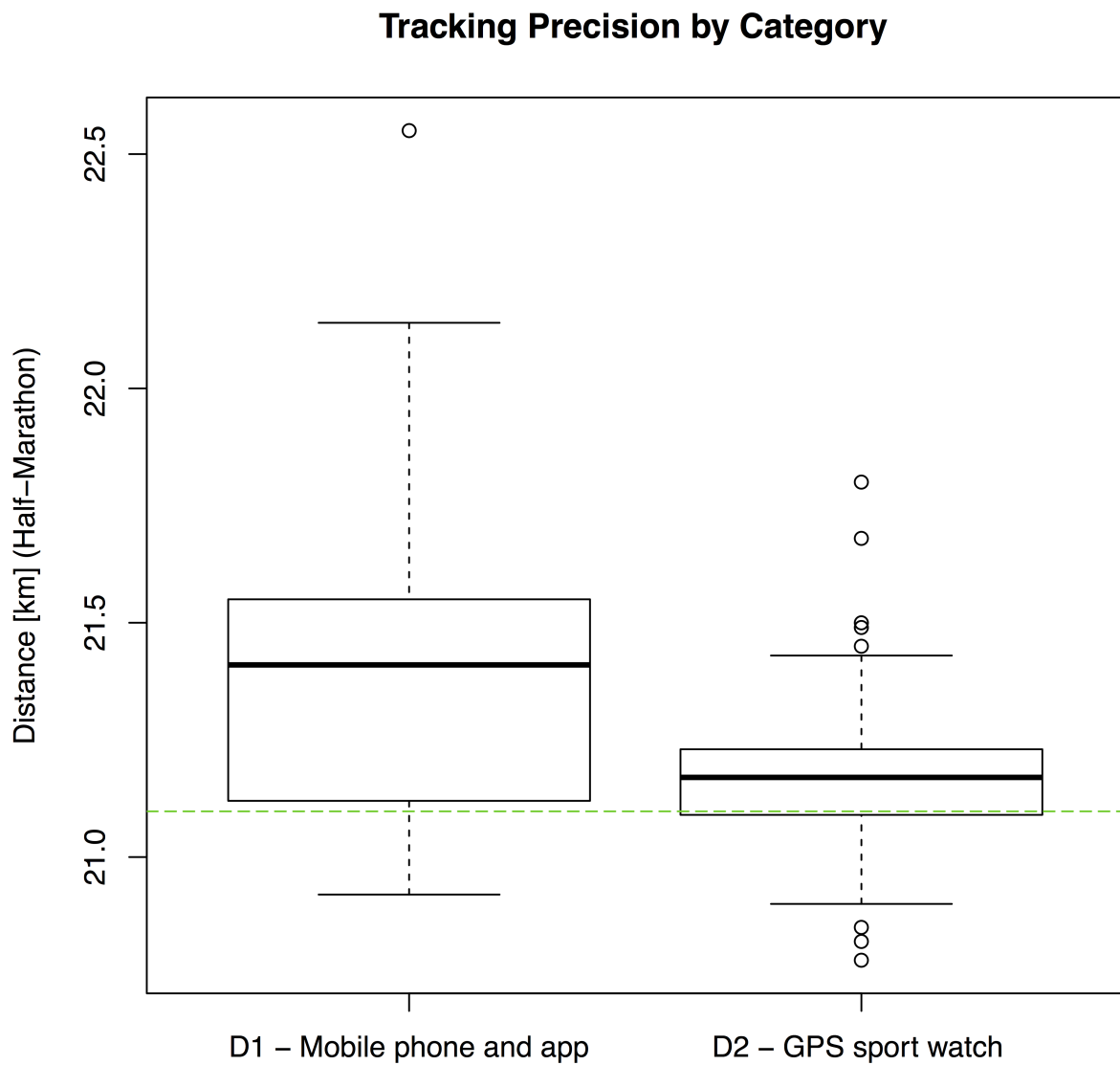


Figure 2. Box-and-whisker plot of recorded distances (half-marathon) by vendor: Garmin (n=77), Polar (n=72), Apple (n=20), TomTom (n=16), and Suunto (n=7). Vendors with less than 7 measurements were omitted. The dashed line indicates the reference distance of 21.0975 km.

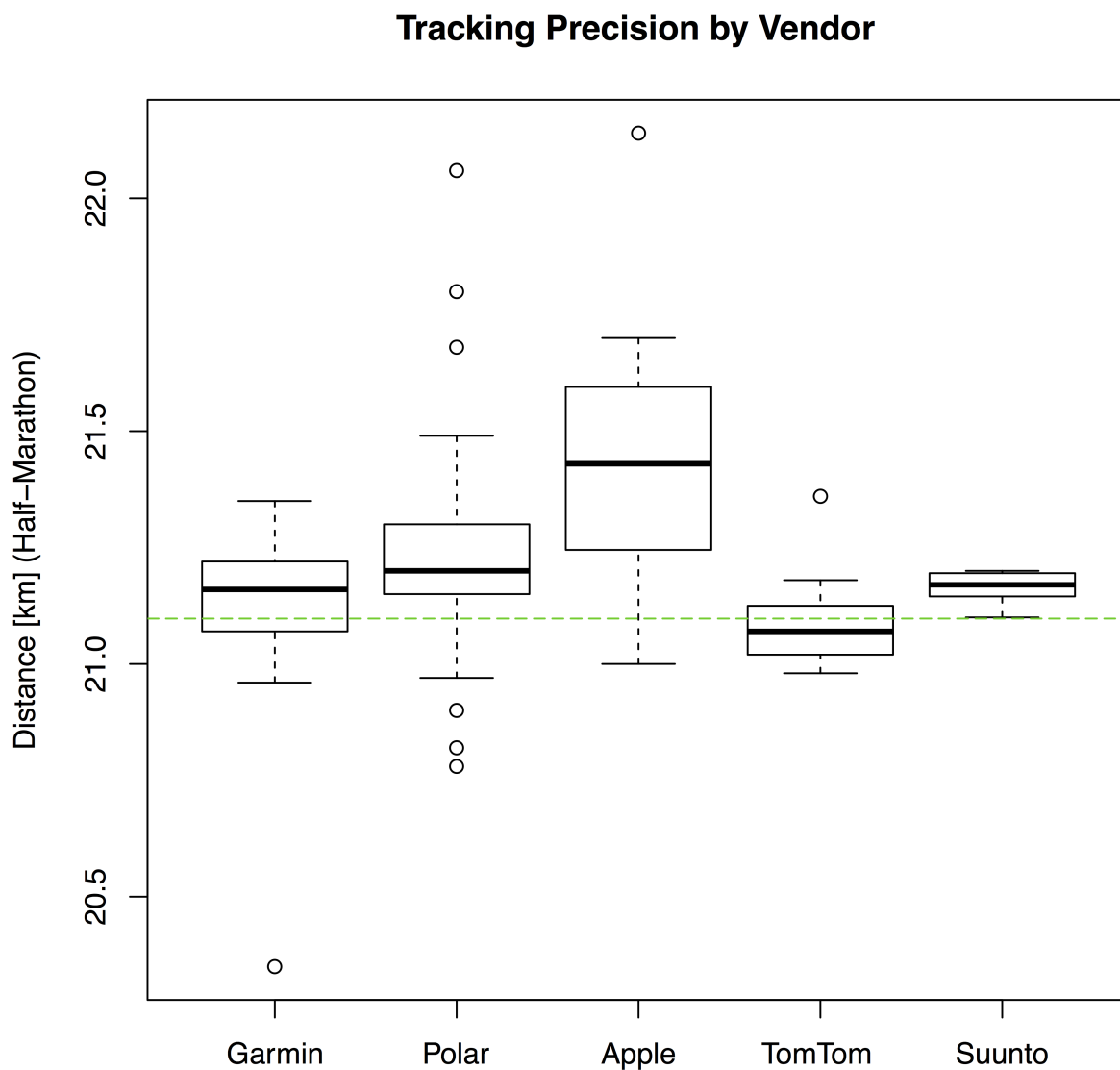
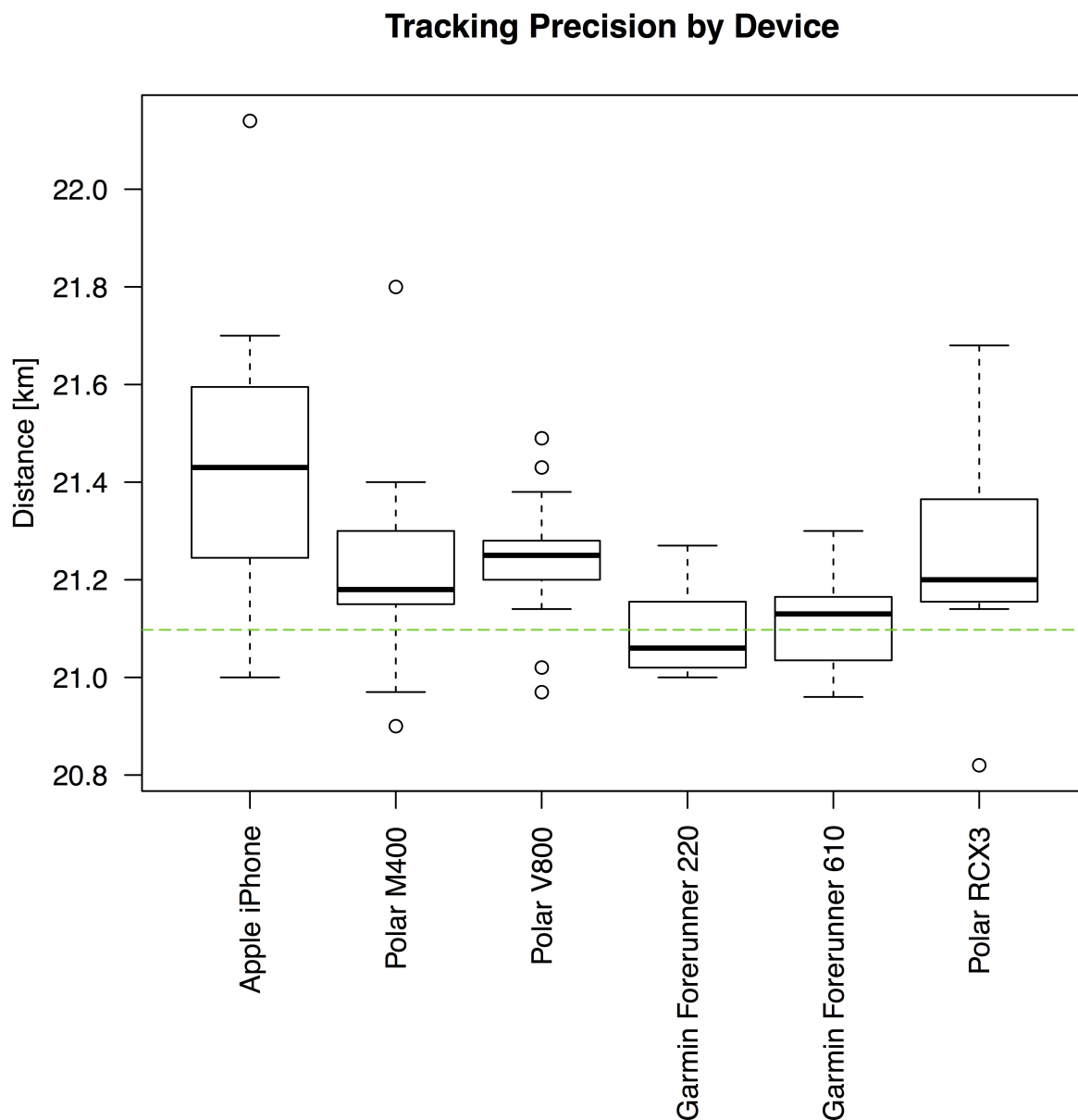


Figure 3. Box-and-whisker plot of recorded distances (half-marathon) by device: Apple iPhone (n=20), Polar M400 (n=36), Polar V800 (n=21), Garmin Forerunner 220 (n=7), Garmin Forerunner 610 (n=7), and Polar RCX3 (n=7). Devices with less than 7 measurements were omitted. The dashed line indicates the reference distance of 21.0975 km.



Discussion

Principal Findings

There is evidence that “smart” devices such as smart watches and activity trackers are not as prevalent in the runners’ community as one might assume according to recent trend surveys regarding wearable usage [1,2].

Our results indicated that conventional GPS-enabled sport watches were predominant for a diverse population of active runners of different fitness levels.

A corresponding logistic regression analysis suggested that supportive technology was not associated with female persons

and persons of higher age groups (60+ years). These findings corresponded with studies on mobile phone ownership, indicating that persons of younger age groups (18-49 years) are more likely to own a mobile phone [18].

The recorded data of GPS-enabled sport watches (D_2) showed the highest accuracy with an average of 42.33 km (full marathon) and 21.18 km (half-marathon). The data captured with mobile phones in combination with an app (D_1) were also quite accurate (average of 42.88 km and 21.40 km). All other relevant device categories D_4 and D_5 , that is, smart watches and wristband activity trackers, were not tested due to a limited sample size.

Overall, the IQR was smaller for GPS-enabled sport watches (D_2) than for mobile phones with combined app (D_1). Measurements of mobile phones showed the highest IQR and noticeably deviated from the reference track distance.

The collected pre-race questionnaires for the full and half-marathon events were a representative sample for the persons that registered for the Trollinger-Marathon Event 2016. The distribution of age groups and sex in the sample was very similar to the proportions reported in the official starter lists.

Limitations

This study suffered from several limitations. As the Trollinger-Marathon 2016 was a regional road race event, only runners from southern Germany were represented in the data of the two survey parts. Yet, no studies exist that show a regional difference in terms of technology affinity in Germany. Therefore, the authors are confident that the results of the survey could be applied to other German regions or road race events as well. However, the results of the Trollinger-Marathon study should be reproduced in other regions and countries to confirm the results. Moreover, as external parameters such as temperature and relative humidity were influencing factors to runners [19,20] and potentially their motivation to participate, it could not be ruled out that the cohort population might be different in another environmental setting, for example, during another season or climate zone.

Furthermore, no explicit checks for duplicate data acquisition were conducted by the interviewer team during the survey. This originated from the fact that most of the event participants were only available for less than a minute when fetching their number bibs and event information. Additionally, due to data privacy aspects, no names or contact information was written down. Thus, a check for duplicates was not possible for obvious reasons. The authors were confident that only a very low number of duplicate data entries occurred.

Participants quickly left the finish area after the event, resulting in a narrow time frame for the interviewers. Therefore, the study suffered from a comparatively small sample size for the post-race questionnaires. Moreover, a higher amount of runners declined to take part in the survey, as most of them were exhausted. As a consequence, the accuracy analysis could not be conducted for the categories D_4 and D_5 due to a small sample size for these particular devices. This experience indicates that the amount of time spent for interviews during a running event should be kept as minimal as possible. However, this restricts the possibilities for qualitative approaches.

In the pre-race phase only, 32 questionnaires for the (nordic) walking event could be collected. A reason for this low response rate was that a major fraction (according to the starter list: 56.5%, 345/611) of the registered walkers or nordic walkers were employees of the main sponsors of the event and the handout of number bibs and event information was conducted at a different on-site location for these participants, which was not accessible for the interview staff.

Comparison With Prior Work

Several studies on the validity and accuracy of consumer-level devices, wearables, or mobile phones, especially pedometers or accelerometer-based technology, exist [10,20-25]. These studies are mostly laboratory based and do not collect data from participants of a running event. Instead, study subjects are equipped with (several) tracking devices, strictly following a study protocol for different types of exercises, for example, treadmill exercises.

In 2014, a meta-review by Bort-Roig et al analyzed whether mobile phone technology was suited for physical activity monitoring. The authors found only a “few studies” that reported on the validity of mobile phone-based assessment. However, “those that did report on measurement properties found average-to-excellent levels of accuracy for different behaviors” [26].

A study on mobile phone pedometers by Leong et al investigated on the reliability of free pedometer Android-based apps (Runtastic, Pacer Works, and Tayutau). They tested whether pedometer-apps were as accurate as a reference pedometer in a free-living environment for 7 days. The authors concluded that “none of the pedometer apps counted steps accurately compared to the reference pedometer,” (p.6) [25].

The studies by Tucker et al [27] and Hendelman et al [20] focused on the validity of step counts and the evaluation of estimated energy expenditure. In contrast, the evaluation of energy consumption was not part of the Trollinger-Marathon study.

In the late 1990s, Schutz et al [28] assessed GPS-based distance recording and found “the GPS technique (...) very promising.” Later research by Maddison et al [29], Cummins et al [30], and Larsson [31] confirmed these findings. For sport-specific field testing, the differential global positioning system (dGPS) was found to have an “acceptable precision” [32]. This was confirmed with the tracking data of GPS-enabled devices observed in the Trollinger-Marathon cohort. All aforementioned studies recruited only around 10-44 participants in their respective study cohort, whereas this study relied on 262 distance data points. In addition, our work referred to a long, precisely measured running course and might therefore be considered a real-world wearable technology evaluation. The general user acceptance and related use pattern was investigated by Shih et al, yet “research focuses mostly on the technical- or device-related challenges” and “less research has focused on individual-related use and adoption challenges” (p.4) [32].

Work by Mauriello et al [33] evaluated a wearable e-textile display with various runners ($n=52$). The authors reported that their cohort also favored wearable devices by Garmin. Moreover, they found a similar proportion of runners who used no supportive “smart” technology during training sessions: “11 participants (21%) reported using pen and paper” compared with 26.1% in our cohort.

To the best knowledge of the authors, no work on the adoption of wearable technology for long-distance running activities exists in the literature. This study adds first answers to the question which devices are being used by healthy and active

citizens of different sex, age, and fitness level participating in half-marathon and marathon events (including nordic walking and walking).

Conclusions

Most of the runners (approximately 75%) who attended an official road running event in southern Germany used wearable technology for training optimization and distance recording. However, the findings of the study indicate that female runners and runners of higher age groups (60+ years) are less likely to use tracking devices for personal running activities.

With 156 identified distinct devices, 25 running apps, and 36 different vendors, the survey revealed that a great variety of wearable or smart technology was actively used by the cohort.

Sport watches represented more than 65.4% of all devices of the study. GPS-enabled devices (sport watches and mobile phones) were found to be accurate in terms of recorded course distances. Yet, the mean of recorded distances between sport watches and mobile phones in combination with apps was significantly different for the half-marathon course ($P=.002$). However, given a long-distance running event, an MAE of 0.12 km (sport watch) versus 0.35 km (mobile phone and app) seems negligible, as this corresponds to approximately 0.6%-1.7% of the total course distance.

To validate our findings, we intend to repeat the study at the next edition of the Trollinger-Marathon (in 2017). Such a follow-up study might confirm adoption rates in 2016 or discover a shift of wearable technology use by runners.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questions and response options of the pre-race questionnaire. This is a translation of the original questionnaire in German language.

[[PDF File \(Adobe PDF File\), 34KB - mhealth_v5i2e24_app1.pdf](#)]

Multimedia Appendix 2

Questions and response options of the post-race questionnaire. This is a translation of the original questionnaire in German language.

[[PDF File \(Adobe PDF File\), 32KB - mhealth_v5i2e24_app2.pdf](#)]

Multimedia Appendix 3

Device categories, vendors, models and apps used by runners as found in the pre-race survey. Values in curved brackets represent the number of occurrences for the respective category, vendor, device or app.

[[PDF File \(Adobe PDF File\), 55KB - mhealth_v5i2e24_app3.pdf](#)]

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Abbreviations

AIMS: Association of International Marathons and Road Races

dGPS: differential global positioning system

GPS: global positioning system

IAAF: International Association of Athletics Federation

IQR: interquartile range

MAE: mean absolute error

OR: odds ratio

Q1: pre-race questionnaire

Q2: post-race questionnaire

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Letter to the Editor

Critique of: “Physical Activity Assessment Between Consumer- and Research-Grade Accelerometers: A Comparative Study in Free-Living Conditions”

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KEYWORDS

Fitbit; activity tracker; actigraphy; physical activity; aerobic exercise; validity

In a recent issue in this Journal, Dominick et al., compared the outcome of a consumer-grade accelerometer against a research-grade accelerometer [1]. More specifically, they compared the Fitbit Flex (Charge and Surge) placed on the wrist against the GT3X (ActiGraph, Pensacola, USA, FL) placed on the hip. The authors observed large differences between methods, i.e. “Fitbit significantly overestimated METs for average daily activity, for overall minutes of reported exercise bouts, and for walking and run or sports exercises (all *P*-values <.001); and for average daily activity, Fitbit significantly underestimated the proportion of time in sedentary and light intensity by 20% and 34%, respectively, and overestimated time by 3% in both moderate and vigorous intensity (all *P*-values <.001)”.

We find a major problem in the design of the present study, with potential to largely affect its results and interpretation. The authors aimed to compare activity measured by two different devices. However, these two devices were attached to two completely different locations, i.e. wrist (Fitbit) vs. hip

(GT3X). As a consequence, the differences observed in this study could actually be due to the different locations rather than the real differences between devices. It is well known that the same accelerometer when attached to the wrist register markedly more accelerations than when attached to the hip [2–4]. As expected, the authors observed a higher level of activity in the wrist-accelerometer than in the hip-accelerometer. If the authors wanted to compare a consumer-accelerometer with a research-accelerometer, which is a very interesting research question, they should have placed both devices (Fitbit and GT3X) on the same wrist. Large-scale studies such as the National Health Examination Survey, NHANES, are placing the GT3X accelerometer on the wrist. There are now available cut-points to classify accelerations from GT3X attached to the wrist into time spent in different intensities of physical activity [2,3], so it would have been fully correct methodologically to attach both devices to the wrist. The authors acknowledge as a limitation that accelerometers were placed in different locations. However, there is no explanation as to why they did so.

Unfortunately, we will only be able to know how comparable of them on the same location. these two accelerometers are when a future study places both

Conflicts of Interest

None declared.

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Letter to the Editor

Authors' Reply to: Critique of "Physical Activity Assessment Between Consumer- and Research-Grade Accelerometers: A Comparative Study in Free-Living Conditions" – Does Location of the Device Matter?

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KEYWORDS

Fitbit; activity tracker; actigraphy; physical activity; aerobic exercise; validity

My co-authors and I thank Dr. Migueles and colleagues for their letter to the editor [1] regarding our recent *JMIR mHealth and UHealth* manuscript [2]. We welcome the opportunity to address the matters raised.

In regard to the core critique that divergent placement of the ActiGraph and Fitbit devices (hip and wrist, respectively) confounds data interpretation in our investigation is limited, given that the methods and subsequent data interpretation were informed by the literature available at the time the study was conducted in 2014. Whereas the ActiGraph GT3X device can be worn on the wrist, the algorithms and cut-point thresholds currently available in the ActiLife software are valid only when the device is worn at the hip. Our study examined the measurement congruence between the first-available, wrist-worn Fitbit device (Flex) and the "gold standard," waist-worn ActiGraph GT3X, in which we employed a longer assessment period (14 days) within free-living conditions that included average day- and minute-level activity, and which also

comprised a range of self-reported bouts of exercise. Because our study used ActiGraph as the criterion measure for device comparison, it would have been methodologically inappropriate to place the device on the wrist.

Both ActiGraph and Fitbit provide a proxy for the actual movements and activities of the subject as they occur in the natural environment. Given that the hip-worn ActiGraph algorithms and cut points are benchmarked against direct clinical observations, [3,4] our study examined the ability of the wrist-worn Fitbit Flex to assess physical activity as compared to the validated estimates provided by ActiGraph within free-living conditions. Hence, this line of research continues to be tethered to evaluations that are akin to comparing "apples to oranges" in the generalized case.

Indeed, research has recently begun to utilize raw acceleration signals for developing improved algorithms for hip and wrist-worn accelerometers [5-7] that also include ActiGraph

devices [8,9]. Case in point, population-based health surveillance systems such as the National Health Examination Survey (NHANES) are using raw acceleration signals to process activity data [10]. However, to date there is no consensus, regarding the use of raw acceleration signals to quantify activity or how to explicitly process data from raw signals [9]. Furthermore, it is not currently possible to access raw acceleration data from the Fitbit device; researchers must rely on activity counts determined by the proprietary algorithms used by Fitbit. Thus, the comparison of apples to oranges remains unavoidable at this point in time and as such there is robust empirical precedent for our study design [11-14].

Our study utilized a collective methodological approach founded on end-user practicality, but evolving toward a more scientifically appropriate means of comparison within truly free-living conditions. With this understanding, and more recent evidence supporting the use of raw acceleration signals [6,8-10], we were forthcoming in the manuscript when we highlighted the limitations of our study. Accordingly, we recommended that future studies use accelerometers that are placed on a common location. Yet, this will ultimately require some

standardized process for determining what wrist-worn accelerometer algorithms to use as well as, identifying approaches to access raw acceleration signals from Fitbit. Other approaches currently being examined by our group include modeling the physical activity measures of the ActiGraph GT3X using Fitbit-derived measures of intensity, steps, and calories, and analyzing the implications of how modeling impacts bout assessment differences between the devices.

To summarize the discussion points, off-the-shelf- and research-grade physical activity monitor use continues to evolve. Our original study design, at the heart of the current discussion, was congruent with then modern scientific methods balanced with end user practicality. As such, our study serves as a research foundation to inform future research directions rather than maintain the status-quo. Our group, and presumably Migueles et al are, are part of a research collective working to better understand and quantify physical activity in a self-correcting fashion that emergent science has always followed and we value the perspective of those who share this vision. By having these discussions, we will collectively move this science forward.

Conflicts of Interest

None declared.

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