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## Contents

### Original Papers

Original Paper

# Improving Adherence to Web-Based and Mobile Technologies for People With Psychosis: Systematic Review of New Potential Predictors of Adherence

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## Abstract

**Background:** Despite the boom in new technologically based interventions for people with psychosis, recent studies suggest medium to low rates of adherence to these types of interventions. The benefits will be limited if only a minority of service users adhere and engage; if specific predictors of adherence can be identified then technologies can be adapted to increase the service user benefits.

**Objective:** The study aimed to present a systematic review of rates of adherence, dropout, and approaches to analyzing adherence to newly developed mobile and Web-based interventions for people with psychosis. Specific predictors of adherence were also explored.

**Methods:** Using keywords (Internet or online or Web-based or website or mobile) AND (bipolar disorder or manic depression or manic depressive illness or manic-depressive psychosis or psychosis or schizophr* or psychotic), the following databases were searched: OVID including MedLine, EMBASE and PsychInfo, Pubmed and Web of Science. The objectives and inclusion criteria for suitable studies were defined following PICOS (population: people with psychosis; intervention: mobile or Internet-based technology; comparison group: no comparison group specified; outcomes: measures of adherence; study design: randomized controlled trials (RCT), feasibility studies, and observational studies) criteria. In addition to measurement and analysis of adherence, two theoretically proposed predictors of adherence were examined: (1) level of support from a clinician or researcher throughout the study, and (2) level of service user involvement in the app or intervention development. We provide a narrative synthesis of the findings and followed the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines for reporting systematic reviews.

**Results:** Of the 20 studies that reported a measure of adherence and a rate of dropout, 5 of these conducted statistical analyses to determine predictors of dropout, 6 analyzed the effects of specific adherence predictors (eg, symptom severity or type of technological interface) on the effects of the intervention, 4 administered poststudy feedback questionnaires to assess continued use of the intervention, and 2 studies evaluated the effects of different types of interventions on adherence. Overall, the percentage of participants adhering to interventions ranged from 28-100% with a mean of 83%. Adherence was greater in studies with higher levels of social support and service user involvement in the development of the intervention. Studies of shorter duration also had higher rates of adherence.

**Conclusions:** Adherence to mobile and Web-based interventions was robust across most studies. Although 2 studies found specific predictors of nonadherence (male gender and younger age), most did not specifically analyze predictors. The duration

of the study may be an important predictor of adherence. Future studies should consider reporting a universal measure of adherence and aim to conduct complex analyses on predictors of adherence such as level of social presence and service user involvement.

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**KEYWORDS**

patient compliance; schizophrenia spectrum and other psychotic disorders; mobile phone; mHealth

## Introduction

E-mental health interventions, defined as "the use of information and communication technology to support or improve mental health care" [1,2], have been proposed as promising alternatives to traditional interventions. Proposed benefits include ease of use, accessibility, and the potential to be less stigmatizing [3-5]. This may be particularly appealing for service users with psychosis who tend to have high relapse rates yet limited access to psychological therapies [4,6]. Psychosis is a debilitating mental health disorder that includes symptoms such as hallucinations, delusions, disorganized thoughts, and speech, as well as diminished emotional expression and lack of volition [7]. Dropout and nonadherence rates for traditional psychological and psychopharmacological interventions are high for people with psychosis. "Dropout" is defined as noncompletion of the study protocol or the study assessments, and "adherence" is defined as the extent to which a participant experiences or engages with a mobile or Internet-based intervention [8]. Dropout rates of 25% for people with psychosis [9-11] and 30-57% for people with first episode psychosis (FEP) are commonly found [12]. Some have suggested that e-mental health technologies may provide a more acceptable therapy format than traditional face-to-face therapy [13]. Rates of adherence across different types of e-mental health interventions for people with psychosis have not been systematically examined.

A recent review of 12 studies highlighted that a specific examination of adherence, the extent to which a participant engages with an intervention, would be helpful for the field of e-mental health [14]. The study demonstrated that service users with psychosis varied in their engagement with the technological interventions; some showed regular or intermittent use and approximately 25-30% of participants did not engage or dropped out [14]. We seek to update this 2013 review for two main reasons. First, since 2013, there has been a dramatic increase in peer-reviewed publications examining Web-based or mobile technologies for a variety of mental health conditions. When reviewing the publication rate of e-mental health papers over the past 20 years, 57% were published in the last 5 years and the number of publications tripled between 2009-2014 [15]. Higgins and Green (2011) recommend that review updates should be carried out every 2 years, especially in a rapidly growing field [24]. Second, examining use and adherence to these new technologies is increasingly important as the benefits are limited if service users do not use them.

In order to obtain an overview of the rates of adherence, two types of adherence rates were collected: (1) mean percentage of the intervention completed and (2) percent of participants that complete the intervention [16]. Previous systematic reviews have developed four main approaches to examining adherence to mobile or Web-based interventions for treatment of depression and anxiety [8,16] (see Table 1 for an overview). The first is to examine factors that contribute to dropout from a study; for example, a comparison of baseline symptomology or demographic factors in participants who stay in the study and those who drop out. The second is to conduct statistical analyses, including correlational or regression analyses within a study to identify potential predictors of adherence. Specific service user factors (eg, demographics and clinical severity) and intervention factors (eg, week 1 vs week 2 of intervention) are most commonly explored. The third is to use questionnaires to retrospectively examine participants' experiences of adherence and perspectives on continued use. The fourth approach is to experimentally manipulate factors within a study to impact upon adherence; for example, to compare different technological interfaces, frequency of use, or behavioral interventions.

**Table 1.** Four approaches to studying adherence.

| Approach | Type of adherence data expected |
|---|---|
| Analysis of dropout data | Comparison of adherent and nonadherent service-user data including demographic, symptom, cognitive or other data; baseline assessment of between group differences |
| Within studies analyses to establish relationship between adherence and various factors | Within study correlational, regression or other analysis of service-user specific factors or intervention specific factors that may impact on the level of adherence to intervention or technology |
| Poststudy questionnaire on participants' experience | Questionnaire data; qualitative or quantitative feedback on satisfaction, acceptability of study or intervention with specific questions on usability, helpfulness, and continued use |
| Experimental manipulation of factors impacting adherence | Comparison of interventions or interfaces that are specifically designed to impact on adherence |

In addition to these four approaches to studying adherence, we evaluated two theoretically proposed predictors of adherence: (1) level of social presence or contact with a researcher, clinician or peer, and (2) servicer user involvement in the development of the intervention or app. The level of social presence or contact refers to the frequency and quality of clinician, researcher, or peer presence or contact throughout the intervention [14]. Several studies have identified that contact and support from clinicians or peers in the form of telephone, email, Web-based forums, or e-chats can help improve adherence to mobile and Internet-based interventions; people with psychosis may particularly benefit from this support [17,18]. Mohr et al [19] outline a "supportive accountability model" whereby a supportive social presence may positively influence accountability, expectations, and bond during a mobile or Web-based intervention. This predictor has some credibility as Day et al [20] found that for acute inpatients with psychosis, a positive relationship with a clinician was related to adherence to medication and a positive attitude toward treatment. In addition, LeClerc et al [11] established that a good therapeutic alliance improved adherence to psychosocial treatment. This review conducted a preliminary examination of the level of social presence and support that is offered in each intervention.

The second potential predictor of adherence is the level of service user involvement in the development of the intervention. This has been highlighted as vital for effectiveness and adherence to interventions [21]. The sense of involvement in the project may promote self-efficacy and therefore accountability to the intervention [19]. Recently, Wykes and Brown [21] emphasized the importance of providing service users with choice, for example, the choice of digital or face-to-face interventions, or a combination of the modalities [22]. Choice leads to a greater feeling of control; this may tap into intrinsic motivation that is important for adherence to interventions [19]. This review highlights any studies that involve service users in the development and improvement of the interventions and the potential impact on adherence. This review updates Alvarez-Jimenz et al's [14] findings; we examined rates of adherence to mobile or Internet-based interventions, trials, or observational studies for people with psychosis.

## Methods

This systematic review was conducted following the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines and recommendations for conducting and reporting systematic reviews (see Multimedia Appendix 1) [23].

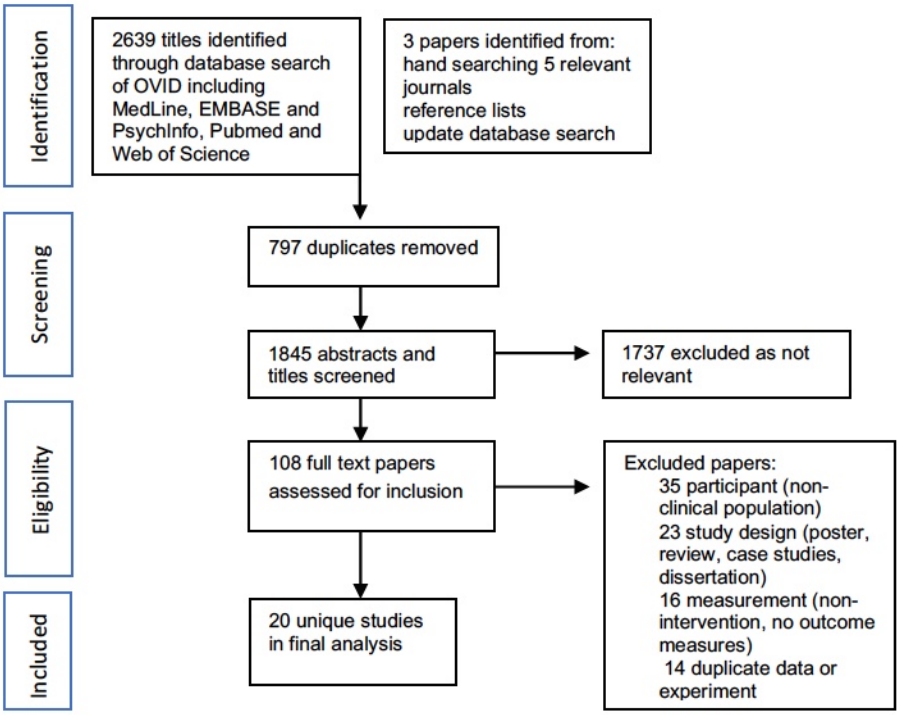
### Eligibility Criteria

The following PICOS criteria [24] were adopted for study inclusion: (1) population: adults (18-65 years); at least 75% of participants have a diagnosis of schizophrenia spectrum disorder according to diagnostic and statistical manual of mental disorders (DSM)-IV or the international classification of diseases (ICD)-10; (2) interventions, trials, or observational studies involving Web-based, mobile, e-technology or Web-based interfaces enabling peer-to-peer contact, patient-to-expert communication, or interactive psycho education or therapy; flexible, accessible monitoring, self-help, and symptom management; (3) comparison group: none were specified; (4) outcomes: at least one measure of adherence or dropout; and (5) study design: as this study aimed to provide an overview of the current state of the field, generous inclusion criteria were adopted. Types of studies included all primary group studies including RTCs; cross-sectional, longitudinal, and comparison studies with and without a control group; cross-over trials, case controls or cohort studies; observational studies with experience sampling components (ESM); and feasibility or acceptability studies. The following exclusion criteria were included: (1) publications written in a language other than English, (2) conference abstracts and theses not published in a peer-reviewed journal, and (3) book chapters.

### Information Sources and Search Strategy

The following databases were systematically searched from August 2013 to November 2016: OVID including MedLine, EMBASE and PsychInfo, Pubmed and Web of Science. The following terms were used in the keyword search of abstracts and titles: (Internet or online or Web-based or website or mobile) AND (bipolar disorder or manic depression or manic depressive illness or manic-depressive psychosis or psychosis or schizophr* or psychotic). Additionally, hand-searching was performed on 5 key journals (Schizophrenia Bulletin, Schizophrenia Research, Journal of Medical Internet Research, Telemedicine and E-health, and Psychiatric Services) along with the reference lists of included primary studies. The term "adherence" was purposely not included in the search terms as most studies do not include references to reported adherence in the title or abstract [16].

**Figure 1.** Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flowchart.




### Study Selection

Titles and abstracts of articles were scanned independently by 2 researchers (CK and ZH). Articles deemed potentially eligible were retrieved in full and independently reviewed (CK and ZH). Disagreement between researchers was dealt with by consensus with a senior member of the research team (TW).

### Data Collection Process

A standard form was used to extract data from selected studies to create 7 results tables. Tables 2-7 comprise: (1) randomized intervention studies, (2) feasibility or acceptability studies, and (3) observational studies. Tables 2-4 include the following study characteristics: study source, sample size, gender, age, diagnosis, study design, purpose of intervention, and control group. Tables 5-7 include characteristics of interventions: levels of adherence, dropout, type of social presence, service user involvement, and measurement of participant feedback.

### Assessment of Methodological Quality and Procedures

The study quality was assessed separately for RCTs, feasibility studies, and observational studies (nonrandomized studies). The RCTs and feasibility studies were separately assessed using the clinical trials assessment measure (CTAM) [25]. The CTAM was designed to assess trial quality specifically in trials of psychological interventions for mental health. It contains 15 items grouped into six areas that are important for assessing bias in psychological interventions that include sample size, recruitment method, allocation to treatment, assessment of outcome, control groups, and description of treatments and analysis. Each study is rated out of a total of 100. This scale has good interrater reliability (.96) and high concurrent validity (.97) [26]. Observational studies were assessed using the Downs and Black scale [27]. This scale comprises 27 questions assessing key areas of methodological quality for nonrandomized studies for systematic reviews. It includes questions on reporting, external validity, bias, confounding, and power. This scale was modified slightly for this study. The question on power (see question 27 of the scale) was simplified to a rating of 1 or 0 following the practice in other reviews [2,28]. Each study is rated out of a total of 28 points. Scores are classified in the following ranges: excellent 26-28, good 20-25, fair 15-19, and poor less than 15. Two reviewers (CK and ZH) independently assessed the quality for all of the included studies. All of the first authors of the included articles were contacted to approve their CTAM or Downs and Black rating and if necessary provide further information to ensure that the quality of the study was not confused with the quality of the reporting.

## Results

### Study Selection

The search strategy returned 2639 titles and abstracts. After removal of 797 duplicates, 1842 titles and abstracts were screened and 108 full text papers were assessed for inclusion. In total, 20 studies met the inclusion criteria (see summary in Figure 1; PRISMA flowchart).

### Study Characteristics

Study characteristics are summarized in Tables 2-4. Six were randomized controlled interventions; 7 were feasibility, acceptability studies; and 7 were observational studies. In total, 656 participants with a diagnosis of schizophrenia spectrum disorders and a mean age ranging from 20-48 years participated. Sixteen studies included individuals with schizophrenia or schizo-affective disorder, 1 study included people with first episode psychosis, 1 included individuals with a dual diagnosis of schizophrenia and substance misuse, and 2 included people with nonaffective psychosis.

**Table 2.** Study characteristics: randomized controlled trials with pre and post outcomes and control group.

| First author and year | Study source (country) | n (%) (male) | Age Mean (SD) | Specific diagnosis (eg, FEP[a], chronic) | Study design | Description of study and type of technology | Control group | Outcome measures |
|---|---|---|---|---|---|---|---|---|
| Palmier-Claus 2013 [29] (also reported in Ainsworth et al, 2013) [30] | United Kingdom | 24 (19) | 33.04 (9.5) | Nonaffective psychosis | Randomized repeated measure cross-over design | Use of mobile phone or text messaging for real time assessment of symptoms | Cross-over control group | Qualitative interviews to assess perceptions and experiences of devices, PANSS, quantitative feedback questionnaire |
| Van der Krieke 2013 [31] | Netherlands | 73 (39) | Intervention: 37 (12.35), control: 40 (13.47) | Nonaffective psychosis, DSM[c] criteria | Randomized controlled trial | Web-based information and decision tool to help patients identify needs and treatment options | TAU[d] | Patient-rated COMRADE[e] CSQ[f] |
| Kurtz 2015 [32] | United States | 56 (41) | COG REM[g] group: 36.1 (12.8), control: 37.1 (12.1) | Schizophrenia or schizoaffective disorder | Randomized treatment trial, quasi experimental design, blinded raters | Social skills training combined with Web-based cognitive training (COG REM) to improve memory and attention | TAU and social skills training combined with computer skills training instead of COG REM training | Neurocognitive assessment, WAIS[h], and others, social skills performance assessment, and quality of life scale |
| Smith 2015 [33] | United States | 32 (17) | Intervention: 40.8 (12.2) Control: 39.1 (10.6) | Schizophrenia and schizoaffective disorder | Randomized control study, blinded raters | Efficacy of virtual reality job interview training on job outcomes and confidence | Waitlist controls | Posttest video role plays of interviews scored by blinded raters, self-report interviewing confidence, 6-month follow-up data on employment outcome |
| Beebe 2014 [34] | United States | 30 (11) | 48.7 (11.6) | Schizophrenia spectrum disorders | Small randomized control study | Comparing the effect of telephone calls only, text message only, and telephone calls and text messages on symptoms and medication adherence | Cross-over groups | Symptoms: BPRS[i], medication adherence scores |
| Moritz 2016 [35] | Germany and United Kindom | 58 (27) | Intervention: 38.9 (11.78), Waitlist controls: 43.41 (8.42) | Schizophrenia | Small randomized control study | Examined whether a Web-based intervention for depression can ameliorate depressive symptoms in schizophrenia | Waitlist controls | CES-D[j] depression scale, PHQ-9[k], paranoia checklist, PANSS |

[a]FEP: first episode psychosis.

[b]PANSS: positive and negative syndrome scale.

[c]DSM: diagnostic and statistical manual of mental disorders.

[d]TAU: treatments as usual.

[e]COMRADE: combined outcome measure for risk communication and treatment decision making effectiveness.

[f]CSQ: client satisfaction questionnaire.

[g]COG REM: cognitive remediation.

[h]WAIS: Wechsler adult intelligence scale.

[i]BPRS: brief psychiatric rating scale.

[j]CES-D: Center for Epidemiologic Studies Depression.

[k]PHQ-9: patient health questionnaire- 9.

**Table 3.** Study characteristics: feasibility studies.

| First author and year | Study source (country) | n (%) (male) | Age | Specific diagnosis (eg, FEP[a], chronic) | Study design | Description of study and type of technology | Control group | Outcome measures |
|---|---|---|---|---|---|---|---|---|
| Nahum 2014, [36] | United States | 34 (25) | Schizophrenia: 23.8 (3.2), control: 23.6 (3.6) | Schizophrenia spectrum disorder | Case-control study | Feasibility of use and efficacy of a novel neuroplasticity based Web-based training program (SocialVille) | Yes, matched healthy controls | Measures of attrition, compliance, and social cognition; facial memory, emotional prosody identification, emotion, and social perception, Functioning, QoL[b], social and role scales |
| Gleeson 2014 (update of Alvarez-Jimenez, 2013) [37] | Australia | 20 (10) | Mean 20.3 | FEP | Single group design | Safety of HORYZONS Web-based psychosocial Internet-based intervention, including peer-to-peer networking, psychoeducation, Web-based psychosocial intervention modules | No | SCID[c], BPRS[d], CDSS[e], BAI[f], Feasibility; usage of Web-based system, User experience questionnaire, safety |
| Ben-Zeev 2014 [3] | United States | 17 (10) | Mean 40.47 | Dual diagnosis schizophrenia and schizoaffective disorder and substance misuse | Single group design | Feasibility study, clinical social worker sent daily text messages to assess medication and clinical status | No | Usability and satisfaction questionnaire, working alliance inventory |
| Ben-Zeev 2014, [38] | United States | 33 (20) | 45.9 (8.78) | Schizophrenia or schizoaffective disorder | Single group design | Feasibility of mobile app resources to facilitate real time illness self-management; mood regulation, medication management, social functioning, sleep, participants asked to complete assessment then intervention if required 3x daily | No | PANSS[g], BDI[h], BMQ[i], acceptability or usability measure, correlation between symptoms and use of phone |
| Palmier-Claus 2013 (see Palmier-Claus et al, 2012 for main study), [39] | United Kingdom | 44 (28) | Acute: 36.8 (10), remitted: 35.5 (8), and UHR: 22 (4.4) | Acute schizophrenia and remitted, UHR | 3 groups of patients with different levels of psychosis | Feasibility of a mobile phone based momentary assessment in individuals with psychosis for clinical management and research purposes | none | Calgary depression scale, momentary assessment scales, PANSS |
| Ventura 2013 [5] | United States | 9 | Not applicable | Schizophrenia, clinically stable | Pilot single group design | Acceptability of PositScience's Internet-based brain fitness program using auditory discrimination tasks | None | MATRICS neuro-cognition, clinical global impression of cognition in Schizophrenia, brief questionnaire on knowledge of cognition, outcome rating scale |
| Schlosser 2016 [40] | United States | 20 (17) | Stage 1: 23.40 (2.6), stage 2: 23.3 (3.7) | Schizophrenia spectrum disorders | Pilot single group design | Feasibility and acceptability of implementing PRIME[j], a mobile app intervention | None | Feasibility measures, adherence measures, satisfaction questionnaires |

[a]FEP: first episode psychosis.

[b]QoL: quality of life.

[c]SCID: structured clinical interview for DSM disorders.

[d]BPRS: brief psychiatric rating scale.

[e]CDSS: Center for Doctoral Studies in social and behavioral sciences.

[f]BAI: Beck Anxiety Inventory

[g]PANSS: positive and negative syndrome scale.

[h]BDI: Beck depression inventory.

[i]BMQ: beliefs about medicines questionnaire.

[j]PRIME: personalized real-time intervention for motivation enhancement.

**Table 4.** Study characteristics: observational and experience sampling method studies.

| First author and year | Study source (country) | n (%) (male) | Age Mean (SD[a]) | Specific diagnosis (eg, FEP[b], chronic) | Study design | Description of study and type of technology | Control group | Outcome measures |
|---|---|---|---|---|---|---|---|---|
| Brenner 2014 [22] | United States | 24 (17) | 44.88 (9.27) years | Schizophrenia or schizoaffective disorder | Single group design | Hand-held device to prompt in the moment ratings of positive and negative affect | No | Comparison of baseline scores and momentary affective forecasting throughout the week |
| Kimhy 2014 [17] | United States | 104 (55) | Schizophrenia: 32.15 (9.19) years, control: 23.95 (5.01) | Schizophrenia spectrum disorder | Case-control study | Rating of momentary emotions (sadness, anxiety, anger, and happiness) using mobile electronic devices | Yes, healthy controls | Measures of emotional granularity from ESM[c]responses and social functioning: PSRS[d], interview, ability task (MSCEIT[e]) Toronto Alexithymia scale, or difficulty identifying feelings or test of reading ability; WTAR[f], BAI[g], BDI[h], symptoms; SAPS[i], Neurcog; MATRICS |
| Hartley 2014 [41] | United Kingdom | 32 ( 22) | 33 (10.7) years | Schizophrenia spectrum disorders, 3+ on the PANSS[j]for hallucinations | Single group design | ESM using a palm computer to capture whether worry and rumination are associated with persecutory delusions and hallucinations | None | Metacognitions around worry; Negative beliefs about ruminations scale, meta-worry questionnaire, |
| Kimhy 2014 [9] | United States | 33 (18) | 27.8 (6.3) years | Schizophrenia spectrum disorders, in patient setting | Single group design | The use of mobile devices to monitor symptoms in in-patient environments | None | Self-report rating of mood and symptoms |
| So 2013 [42] | China and the United Kingdom | 26 (13) | 36.12 (range 20-63) years | In-patients with acute delusions scoring 4+ on the PANSS, schizophrenia spectrum disorder | Single group design | The use of mobile devices (PDA) to monitor symptoms in inpatient environments after the introduction or reintroduction of antipsychotic medication | None | Symptoms: SAPS, PANSS, PSYRATS[k] |
| Sanchez 2014 [43] | United States | 88 (61) | Schizophrenia: 39.55 (13.95), control: 36.83 (14.89) | Schizophrenia and Schizoaffective disorder | Case-control study | Ecological momentary sampling to examine the relationship between emotion, experience, and environment | Healthy control group | PANSS, MATRICS neurocognitive battery |
| Ben-Zeev 2016 [6] | United States | 20 (16) | 39 (12) | Schizophrenia spectrum disorders | Pilot single group design | Acceptability of mobile behavioral sensing | None | Usability and acceptability measures |

[a]SD: standard deviation.

[b]FEP: first episode psychosis.

[c]ESM: experience sampling method.

[d]PSRS: positive symptom rating scale.

[e]MSCEIT: Mayer-Salovey-Caruso emotional intelligence test.

[f]WTAR: Wechsler test of adult reading.

[g]BAI: Beck Anxiety Inventory

[j]BDi: Beck depression inventory.

[i]SAPS: scale for the assessment for positive symptoms.

[j]PANSS: positive and negative syndrome scale.

[k]PSYRATS: psychotic symptom rating scales.

**Table 5.** Characteristics of interventions and rates of adherence: randomized controlled trials with pre and post outcomes and control group.

| First author and year | Length of study | Adherence measure and rate | Dropout rate (%) | Type of social presence | Frequency of social presence | Service user involvement in development | Measure of participant feedback and rating of acceptability |
|---|---|---|---|---|---|---|---|
| Palmier-Claus 2013 (also reported in Ainsworth et al, 2013) [29,30] | 4x a day for 6 days | % of participants completing the intervention: 88, (across all participants) | 1 asked to have SMS[a]stopped 2 days early due to rumination (4.1%) | Once or twice per week based on participants preference | Once or twice per week based on participants preference | Participants were interviewed about their experience | Qualitative interviews with range of perspectives on usability, all participants completed the feedback assessments |
| Van der Krieke 2013 [31] | 6 weeks, self-directed use of website | % of participants completing the intervention: 71% used full functionality of the website | 40(55%) | Assist was available to answer questions over the phone anytime | 3 days a week | Open interviews with 15 patients to evaluate the intervention | 30 used the Web program |
| Kurtz 2015 [32] | COG REM[b]treatment: 50 min/day 3 days/week for 23 weeks<br>SST[c]: 50 min/day, two days/week, for 23 weeks<br>Computer skills:<br>Target 50 hours over 23 weeks | % of participants completing the intervention: 100%, (min criteria for inclusion; all individuals received at least one session) | 8(14.28%) | Interaction with clinician for both COG REM and computer Skills training groups<br>SST group: 2x per week for 50 min, led by researchers | Not applicable | Not applicable | SST Mean number of sessions=32.3<br>COG REM Mean number of sessions=31.9<br>Computer skills=Mean number of sessions=32.2 |
| Smith 2015 [33] | Up to 10 hours of virtual interviews over the course of 5 visits | Mean % of entries completed: 90% of sessions attended and completed | 2(6%) | Basic contact during computer intervention | During intervention only briefly | None reported | 90% attendance rates of sessions |
| Beebe 2014 [34] | 3 months | Mean % of entries completed: 81.60 (across all participants) | 2(6.6%) | Various: weekly telephone calls, daily text messages, both | Various | None reported | Phone calls plus text message group higher adherence by a mean of 5.3% |
| Mortiz 2016 [35] | 3 months | % of participants completing the intervention; 28% used it once a week | 9(15%) | None- unguided | None | None reported | Feedback on use of the program, 72% rated the quality of the program as good to excellent |

[a]SMS: short message service.

[b]COG REM: cognitive remediation.

[c]SST: social skills training.

**Table 6.** Characteristics of interventions and rates of adherence: feasibility studies.

| First author and year | Length of intervention | Adherence measure and rate | Dropout rate (%) | Type of social presence | Frequency of social presence | Service user involvement in development | Measure of participant feedback and rating of acceptability |
|---|---|---|---|---|---|---|---|
| Nahum 2014 [36] | Total of 24 h of Web-based training, 1-2 h per day for 6-12 weeks | % of participants completing the intervention: 78 (completed 24 h of the intervention across all participants) | 8(22-23% attrition rate) | None reported | None reported | Subjects rated their satisfaction in the training program | Subjects took 8.1 weeks (mean) to complete the 24 h of training |
| Gleeson 2014 (update of Alvarez-Jimenez, 2013) [37] | 1 month | % of participants completing the intervention: 60 (completed at least three modules, eg, 33%) | None: all accessed modules | Peer-to-peer Web-based social networking Coaches (expert moderator) | Coaches moderated Web-based activity 2 hours/day weekdays, 1h/day weekend | Developed with service user group | 70% completed 30 weeks, 60% completed >3 Web-based therapy modules, and 75% reported a positive experience |
| Ben-Zeev 2014 [3] | 12 weeks | Mean % of entries completed: 87.00 (mean response rate to text messages for all participants) | 5 (11%) | Mobile interventionist: clinical social worker | Daily, up to 3 text messages a day | None described | Participants responded to 87% (mean) of messages and 90% rated the intervention easy to use, useful, and fun |
| Ben-Zeev 2014 [38] | 1 month | Mean % of entries completed: 86.5 (rate of access to the system for all participants) | 1(3%) | Researcher called participant to check in and assist with technical difficulties | 1x/week | Developed through service user feedback | 90% rated the intervention as highly acceptable, 12% reported it was a complicated intervention, reductions in symptoms PANSS[a]and BDI[b] |
| Palmier-Claus 2013 [39] | 6x a day for 7 days | Mean % of entries completed:72 for those who were compliant with the intervention (eg, completed 33% of data) | 8(18%) | Researcher telephoned participant at least once per week to offer advice and encouragement | Once or twice per week based on participants preference | None described | 82% of participants met compliance criteria of completing at least 33% of the entries |
| Ventura 2013 [5] | 6 weeks, 2 hours/week | Mean % of entries completed: 75 (response rate across all participants) | 1(11%) | Regular phone contact with the study team | Not applicable | None reported | 5 participants completed 12 or more sessions (75% of patients reached adherence criteria) |
| Schlosser 2016 [40] | At least once per week for 12 weeks | Mean % of entries completed (challenges completed) | 0 | Ranged from once a week in stage 1, to 5x a week in stage 2 | Once a day, modified to the service users preference | User-centered design model where participants gave feedback on the iterative development of PRIME[c]in two stages | Mean overall satisfaction with PRIME 8/ 10 |

[a]PANSS: positive and negative syndrome scale.

[b]BDI: Beck depression inventory.

[c]PRIME: personalized real-time intervention for motivation enhancement.

**Table 7.** Characteristics of interventions and rates of adherence: observational or experience sampling method studies.

| First author and year | Length of intervention | Adherence measure and rate | Dropout rate (%) | Type of social presence | Frequency of social presence | Service user involvement in development | Measure of participant feedback and rating of acceptability |
|---|---|---|---|---|---|---|---|
| Brenner 2014 [22] | 6x a day for 7 days | Mean % of entries completed: 98.10 (response rate across all participants) | None | Researcher called participant to check in and assist with technical difficulties | 2x/week | None described | Response rate 98.1% |
| Kimhy 2014 [17] | 10x a day for 2 days | Mean % of entries completed: 79.15 (response rate across all participants) | 35(37%) | None reported | None | None described | Not reported |
| Hartley 2014 [41] | 10x a day for 6 days | Mean % of entries completed: 59 (response rate for completers; completion of the schedule defined as completing at least half of the entries (n=27)) | 5 (15 %) | During the first day, patients contacted to ensure functional equipment | Once in a week, but if needed additional phone contacts were arranged | Feedback questionnaire about involvement | |
| Kimhy 2014 [9] | 10x a day for 1 days | Mean % of entries completed: 81 (response rate for all participants) | 1(3%) | Introduction session for 20 min on first day | None reported | None reported | 81% response rate |
| So 2013 [42] | 14 days 7x a day, randomly | Mean % of entries completed:70.7 (response rate in participants who completed at least 1/3 of entries) | 5 (19%) | Contacted by researcher at least 2x during first week, to offer support and remind to change battery | Participants were encouraged to contact researcher by phone if problems | None reported | 16 participants met criteria for minimum compliance, completing 30 or more diary entries |
| Sanchez 2014 [43] | Phone call 4x a day for 7 days | Mean % of entries completed: 80.16 (response rate for all participants with schizophrenia) | 4 (4%) | Participants were called 4x a day | 4x a day, each patient was interviewed about their environment, goals, and activities | None reported | Response rate to calls was 80.6% in patients and 81.3% in controls |
| Ben-Zeev 2016 [6] | Outpatients 2 weeks 12 hours a day, inpatients 1 week 12 hours a day | % of participants completing the study: 95% (one participant did not charge the phone regularly) | 0 | Once at the beginning to set up phone | Once | Post tudy usability and acceptability questionnaires | 95% felt comfortable using the mobile phone sensing system, and 70% understood how it worked and did not have difficulty keeping the device with them |

## Quality Assessment

Trial quality assessment scores are summarized in Tables 8 and 9. The mean study quality score for the RCTs on the CTAM was 77.3 (range 62-88). Five [31-35] of the RCT studies were deemed to be of adequate trial quality (rating of 65+), except for Palmier-Claus et al [29], which received ratings of 62. As expected due to the lack of randomization, feasibility studies (n=7) had a lower mean score (44.7). The mean quality rating for the observational studies, was 20 and ranged from 17- 24. Three studies fell into the “good” classification range and 4 were “fair.”

**Table 8.** Clinical trials assessment measure (2004), assessment for randomized controlled trials, and feasibility studies.

| Author and year | Total CTAM[a](max 100) | Sample (Q1,Q2) (max 10) | Allocation (Q3,Q4,Q5) (max 16) | Assessment (Q6,Q7,Q8,Q9,Q10) (max 32) | Control (Q11) (max 16) | Analysis (Q12,Q13) (max 15) | Treatment description (Q14,Q15) (max 11) |
|---|---|---|---|---|---|---|---|
| Gleeson et al, 2014[b][37] | 44 | 2,0= 2 | 0 | 10,6,0,0,0= 16 | 0 | 5,6,4= 15 | 3,3,5= 11 |
| Ben-Zeev et al, 2014[b][3] | 36 | 2,0=2 | 0 | 10,6,0,0,0= 16 | 0 | 5,6,4= 15 | 3,0,0,= 3 |
| Ben-Zeev et al, 2014[b][38] | 44 | 2,5=7 | 0 | 10,6,0,0,0= 16 | 0 | 5,6,4= 15 | 3,3,0= 6 |
| Nahum et al, 2014[b][36] | 44 | 2,0= 2 | 0 | 10,6,0,0,0=16 | 0 | 5,6,4=15 | 3,3,5=11 |
| Palmier-Claus et al, 2013[b][39] | 39 | 2,0=2 | 0 | 10,6,0,0,0,=16 | 0 | 5,6,4=15 | 3,3,0=6 |
| Palmier-Claus et al, 2013 [29] | 62 | 2,0=2 | 10,3,0=13 | 10,6,0,0,0=16 | 10 | 5,6,4=15 | 3,0,3=6 |
| Van der Krieke et al, 2013 [31] | 78 | 2,5=7 | 10,3,0=13 | 10,6,10,0,0=26 | 6 | 5,6,4=15 | 3,3,5=11 |
| Ventura et al, 2013[b][5] | 44 | 2,0=2 | 0 | 10,6,0,0,0=16 | 0 | 5,6,4=15 | 3,3,5=11 |
| Kurtz et al, 2015 [32] | 88 | 2,5=7 | 10,0,3=13 | 10,6,10,3,3=32 | 10 | 5,6,4=15 | 3,3,5=11 |
| Smith et al, 2015 [33] | 79 | 2,0=2 | 10,3,0=13 | 10,6,10,3,3=32 | 6 | 5,6,4=15 | 3,3,5=11 |
| Beebe et al, 2014 [34] | 75 | 2,0=2 | 10,3,0=13 | 10,6,10,3,0=29 | 10 | 5,6,4=15 | 3,3,0=6 |
| Mortiz et al, 2016 [35] | 82 | 5,5=10 | 10,3,3=16 | 10,6,10,3,0=29 | 6 | 5,6,4=15 | 3,3,0=6 |
| Schlosser et al, 2016[b][40] | 62 | 2,0=2 | 10,0,0=10 | 10,3,10,0,0=23 | 6 | 5,6,4=15 | 3,3,0=6 |

[a]CTAM: clinical trials assessment measure.

[b]The study is designed as a feasibility or acceptability trial. For ratings of treatment description: Q14 score 3 if website or mobile interface adequately described; for ratings of handling of dropouts, if dropouts described and reasonably analyzed score of 4 given.

**Table 9.** Trial quality characteristics for nonrandomized controlled trials: Downs and Black (1998) ratings.

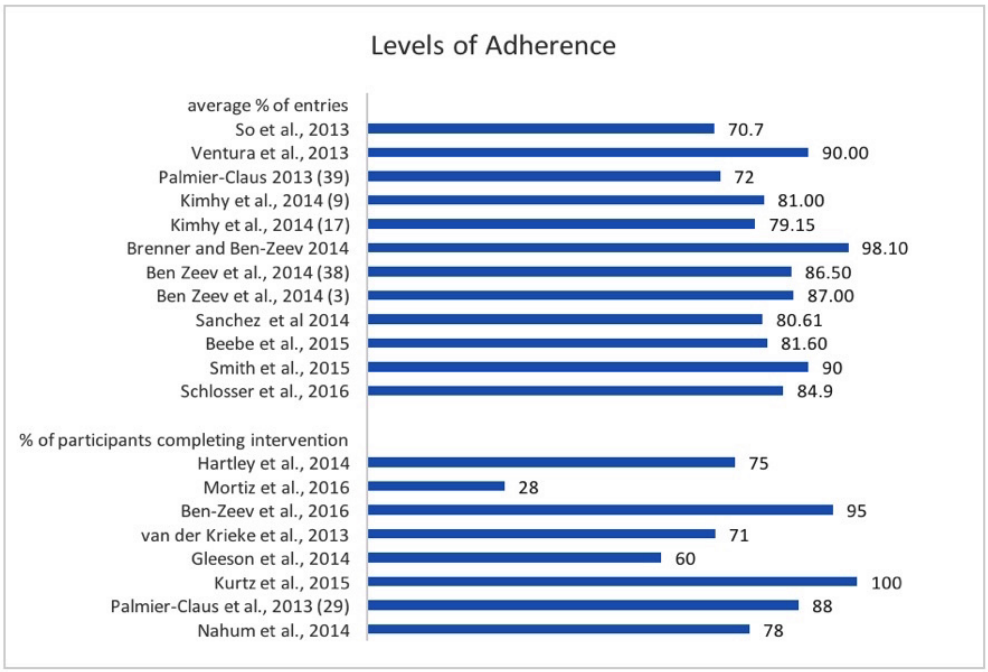
| Checklist Question | Brenner and Ben-Zeev 2014 [22] | Kimhy 2014 [17] | Kimhy 2014 [9] | Hartely 2014 [41] | So 2013 [42] | Sanchez 2014 [43] | Ben-Zeev 2016 [6] |
|---|---|---|---|---|---|---|---|
| Question 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 2 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 3 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 4 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 5 | 2 | 2 | 2 | 2 | 2 | 1 | 1 |
| Question 6 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 7 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 8 | 1 | 1 | 1 | 1 | 1 | 0 | 1 |
| Question 9 | 1 | 0 | 1 | 0 | 1 | 0 | 1 |
| Question 10 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 11 | 0 | UTD[a] | UTD | 0 | 1 | 1 | 1 |
| Question 12 | 0 | UTD | 1 | 1 | 1 | 0 | 1 |
| Question 13 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Question 15 | 0 | UTD | UTD | UTD | 0 | UTD | UTD |
| Question 16 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 17 | 1 | 1 | 1 | 1 | 1 | 1 | UTD |
| Question 18 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 19 | 1 | 1 | 1 | 1 | 1 | 1 | UTD |
| Question 20 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 21 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Question 22 | 1 | 1 | 1 | 1 | 1 | UTD | UTD |
| Question 23 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Question 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Question 25 | 0 | 1 | 1 | 1 | 1 | 1 | UTD |
| Question 26 | 1 | UTD | UTD | 1 | 1 | 0 | 1 |
| Question 27 | 0 | 0 | UTD | 1 | 1 | 0 | 0 |
| Total | 19 | 19 | 21 | 22 | 24 | 17 | 18 |

[a]UTD: unable to determine.

## Adherence: Types of Measurement Across Studies

The most common measures of adherence were percent of intervention completed by participants and percentage of participants completing the intervention. Figure 2 displays the types of adherence measure used and the level of adherence for each study. For the 12 studies reporting mean % of the intervention completed by participants, adherence ranged from 70.7-98.0% with a mean of 83.4%. For the 8 studies reporting the percentage of participants completing the intervention, adherence ranged from 28- 100% with a mean of 74.3%. All of the studies also listed the number of participants that dropped out of the study. This ranged from 0-55% with a mean of 12.3% dropout across both observational and intervention studies.

**Figure 2.** Adherence across all studies: mean percent of entries completed in each study followed by percentage of participants completing the intervention.




### *Approach 1: Analysis of Dropout*

See Tables 5-7 for details of rates of dropout. Five studies analyzed the relationship between specific variables and dropout. In terms of the variables of age or gender and dropout, most of the studies found no relationship [29,41,42]; however, Van der Krieke et al [31] found that the dropouts tended to be younger and male. Hartley et al [41] and So et al [42] did not find a relationship between symptom severity and dropout; however, Palmier-Claus et al [29] (also reported in the original study [30]) found that higher severity on the positive and negative syndrome scale' (PANSS) positive symptom subscale predicted dropout. Finally, Sanchez et al., [43] found that the level of cognitive functioning did not predict completion of the study. See Table 10 for a summary.

**Table 10.** Summary of findings for predictors of dropout and adherence.

| Study | Chronicity or duration of symptoms | Cognitive functioning | Severity of symptoms | Age | Gender |
|---|---|---|---|---|---|
| Van der Krieke et al, (2013) [31] | Yes[a] | | | Yes | Yes |
| Ben Zeev et al, (2014) [38] | | No[b] | No | | |
| Palmier-Claus et al, (2013) [39] | No | | Yes | No | No |
| Schlosser et al, 2016 [40] | No | | No | No | No |
| Kimhy et al, (2014) [17] | | | No | | |
| Hartley et al, (2014) [41] | | | No | No | No |
| So et al, (2013) [42] | | | No | No | No |
| Sanchez et al, (2014) [43] | | No | | | |
| | Duration of the study | Time to complete an entry | | | |
| Palmier-Claus et al, (2013b) [29] | Yes | No | | | |

[a]"Yes" indicates that the variable was found to significantly predict nonadherence or drop out.

[b]"No" indicates that no relationship was found.

### *Approach 2: Analysis of Within Study Predictors of Adherence*

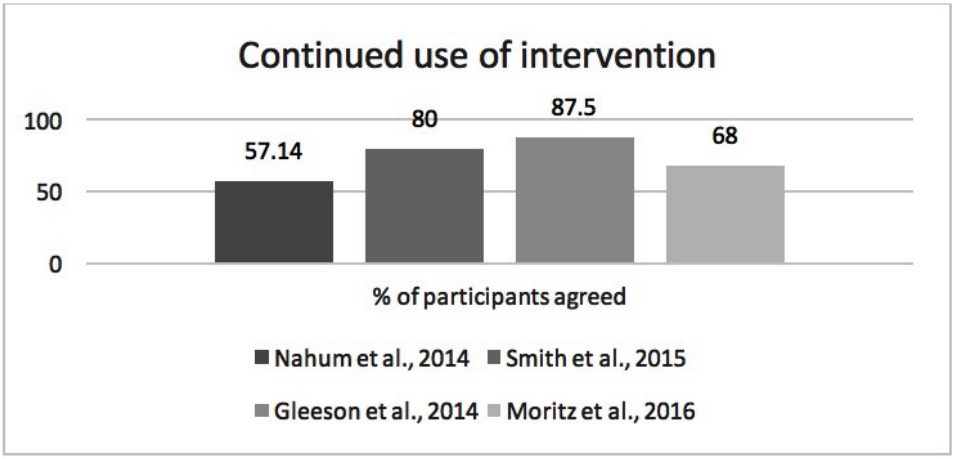
Six studies conducted within-study analyses to examine adherence predictors and found few significant predictors of adherence. Van der Krieke et al [31] analyzed the chronicity of symptoms and reported that service users with first episode psychosis used a Web-based decision aid autonomously more often than service users with chronic psychosis. For those who required assistance from the research team to complete the intervention, 56% were service users in long-term care. However, the report does not provide specific statistical data.

In terms of intervention specific factors, Palmier-Claus et al [29,30] found no relationship between the length of time taken to complete an entry and the number of entries completed by an individual. They also examined number of entries completed across the number of weeks of the study. They found that more entries were completed in the first week than the second week of the intervention and participants rated more highly the question, "were there times when you felt like not answering?" during the second week.

### *Approach 3: Poststudy Questionnaires on Participants' Perspectives on Adherence*

11 studies retrospectively asked participants to provide questionnaire-based qualitative or quantitative feedback about their experience of the study or intervention. All the studies used different rating scales (eg, Treatment Experience Questionnaire in Smith et al [33], idiosyncratic quantitative feedback questionnaire in Palmier-Claus et al [29], and idiosyncratic SocialVille program rating in Nahum et al [36]) and therefore it is difficult to draw comparisons across studies. Four studies specifically asked whether participants would continue to use the intervention [33,35-37]; see Figure 3). For 4 studies, the mean percent of participants who agreed to continue to use the intervention was 73.1%.

**Figure 3.** Percent of participants agreed to continued use of intervention.




### *Approach 4: Analysis of Specific Intervention Manipulations and Effect on Adherence*

Two studies were designed to manipulate conditions that may have an impact on adherence. Palmier-Claus et al [29,30] compared two different types of interventions: SMS text-only (short message service, SMS) interface or a mobile phone–based graphical app. They assessed the acceptability and feasibility of each device and found that participants completed more data points when using the mobile phone interface (mean entries=16.5) compared with the SMS text-only interface (mean entries=13.5; *P*=.002). Schlosser et al [40] increased the frequency and intensity of contact from a research coach from once a week to 5 times a week. This led to improved rates of adherence, for example, number of logins increased from 3.51 days/week to 4.69 days/week.

Interestingly two interventions found that adherence significantly affected the intervention efficacy. Smith et al [33] found that completing more training trials of a virtual reality job interview training correlated with fewer weeks searching before securing a job (*P*<.001) and greater self-confidence (*P*=.03).

Ben-Zeev et al [38] analyzed symptom change throughout the intervention and any related association to adherence and found that change in participants' Beck Depression Inventory (BDI) scores were significantly correlated with use of mobile intervention; less frequent use of the FOCUS mobile intervention was associated with a the greater the reduction in depression score. Change in PANSS scores was not associated with use of the FOCUS app.

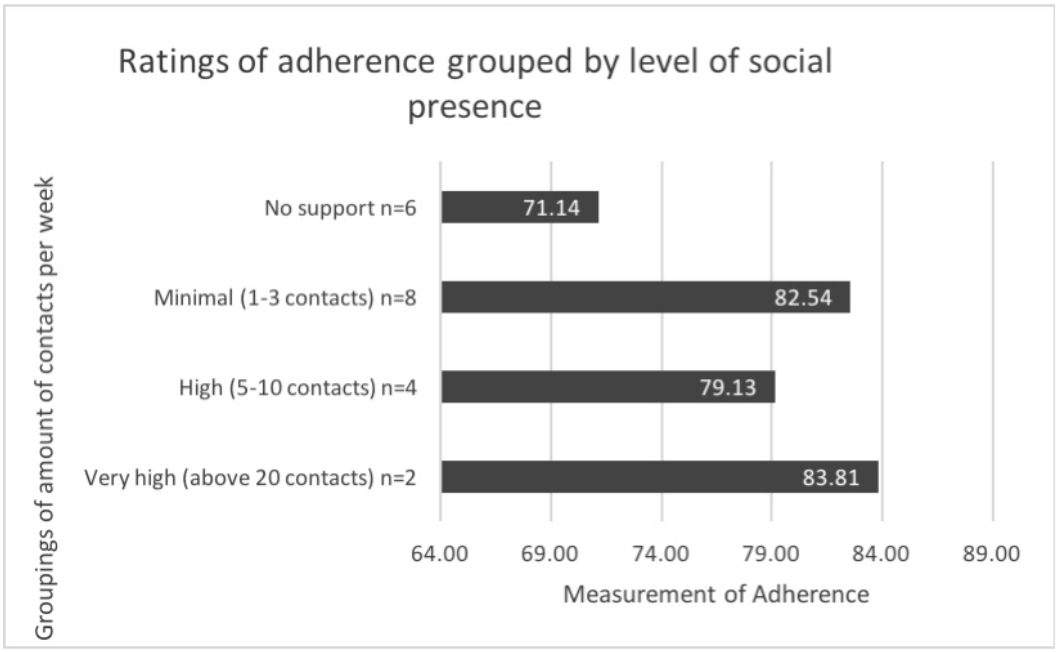
## New Potential Predictors of Adherence

### *Potential Predictor: Social Presence Analysis*

To assess Mohr et al's [19] "supportive accountability" model (social presence leads to better adherence), we examined the amount of contact for each study and the level of adherence to the intervention. As there is heterogeneity across the studies, we provide a narrative synthesis. Across all 20 studies the mean number of contacts per week from a researcher or clinician was 4.4 and it ranged from 0-28 contacts per week. This included face-to-face, mobile, Web-based or telephone-based contacts.

As presented in Figure 4, regardless of level of support there is still a moderate to high rate of adherence across all 20 studies. Interestingly, it appears that studies with very high contact have almost 10% higher rates of adherence (83.8%) than those with no support (71.1%), but studies with minimal contact also had high adherence ratings (82.5%). Anecdotally, the importance of social presence is confirmed from participant reports. Gleeson et al [37] found that 90% of participants cited the use of a Web-based facilitator contributed to their sense of safety when using the Web-based program. All participants either agreed or strongly agreed with statements such as they always felt supported by the Web-based facilitator and 60% reported an increase in feelings of social connectedness. Recently, Schlosser et al [40] found that increasing the frequency of contact with a research coach increased use of the mobile app PRIME significantly. They found that when service users were able to tailor the amount of social support they received, they engaged more with the app.

**Figure 4.** Relationship between social presence and adherence, adherence rates are grouped by frequency of social contact per week from "very high" (20 or more contacts per week), "high" (5 to 10 contacts per week), "minimal" (1 to 3 contacts per week), or "no support" (no contact).




### *Potential Predictor: Service User Involvement*

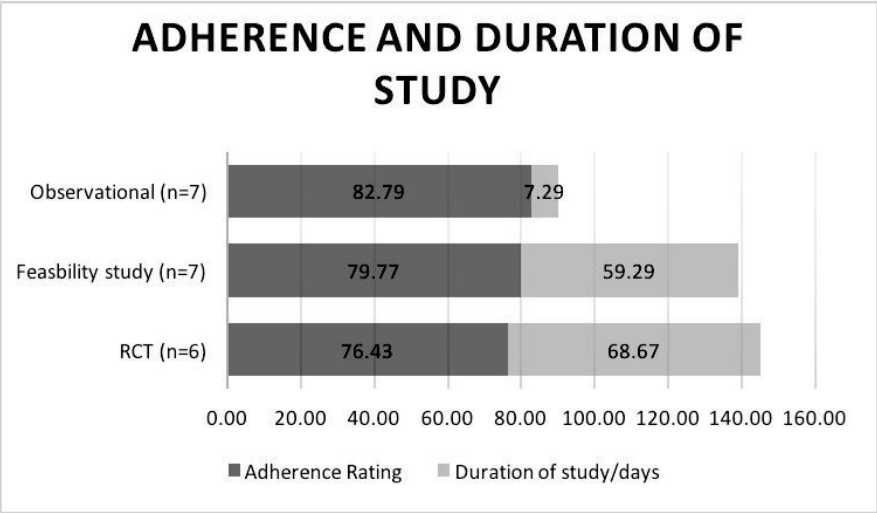
Of the 20 studies included, only 3 described service user involvement in terms of the development or initial piloting of the intervention.

Coproduction, meaning the collaboration of service users and researchers, in the beginning phases of intervention development has a potential influence on participants' perception and adherence to the intervention. Ben-Zeev et al [38] used feedback and recommendations from a pilot with service users to develop a mobile intervention, FOCUS, to facilitate real-time mobile illness self-management. They found that participants rated the intervention highly with 90% acceptability and the mean percent of entries completed was 86.5%. Gleeson et al's [37] HORYZONs program was developed with a service user focus group. It was found that 95% of participants used the social media component, 60% completed the therapy modules, and 75% reported a positive experience with the program. Schlosser et al [40] used an iterative service user feedback process called user centered design (UCD) process. After using the mobile app for 1 week, service users were consulted by means of in-depth interviews about their experience and identified key areas for improvement. The recommended changes were incorporated into the design of the device and this led to a 2 to 3-fold increase in use of the app in week 2. Service users also rated the app at 8 out of 10 in terms of satisfaction. In this case, service users were directly involved in the design, development, and implementation of the new device. When compared with adherence ratings (mean rate of adherence across studies that used different types of adherence ratings) to feasibility studies or RCTs that did not involve service users (mean adherence rate of 78%), service user involvement was associated with higher adherence (mean of 89%), though this is a small number of studies (n=3).

### *Additional Potential Predictor: Duration of Study*

Interestingly, a comparison of the duration of the study (number of days participants are expected to be active in the study) and levels of adherence (averaged across both types of adherence ratings) revealed that the studies with the shortest duration had the highest mean rates of adherence (see Figure 5). The duration of the ESM-based studies ranged from 1 day to 14 days and the mean rate of adherence for these studies was 82.7%. Conversely, the duration of the RCT studies ranged from 6-161 days with a mean adherence rating of 76.4%; the duration of feasibility studies ranged from 7 -84 days with a mean adherence rating of 79.7%.

**Figure 5.** Adherence ratings and the mean duration of the study (number of days) grouped by study type.




## Discussion

### Principal Findings

This is the first review to document rates of adherence and to explore predictors of adherence to mobile and Web-based interventions for people with psychosis. Overall, from the examination of the four approaches to studying adherence across these diverse studies, we conclude that adherence to mobile and Web-based interventions is not necessarily predicted by service user specific factors such as age, symptoms, or gender. However, people with FEP may prefer an intervention that they can independently access [31]. Additionally, adherence is moderate to high across specific intervention factors such as amount of time to complete an entry and across different study designs. However, service users may prefer the mobile phone interface and may adhere more in the first week of an intervention [29]. This review has important implications for the acceptability and use of current interventions and the development of new ones. For example, offering service users choice in terms of the duration of the intervention and also the mode of delivery may have an important influence on adherence. Some service users may prefer a mobile app whereas others prefer a Web-based platform. Two potential new predictors of adherence were explored: (1) more frequent social support and (2) service user involvement in the intervention development. Providing service users with more input and control may add to the value and use of these interventions.

### The Measurement of Adherence

Overall, adherence rates (whether measuring mean percentage of the intervention completed or percent of participants that complete the intervention) to mobile and Web-based interventions for people with psychosis are in line with adherence rates for similar technology-based interventions for other mental health disorders. Rates of adherence to interventions for depression and anxiety are approximately 66% for self-care interventions [16], and a median 56% for a computerized cognitive behavioral therapy (CBT) intervention [44]. Rates for completion of a Web-based site for personality disorder ranged from 80-100% completion; social phobia reported 70-90% completion and the only post-traumatic stress disorder (PTSD) intervention reported completing rate of 64%. In terms of adherence across different types of interventions (eg, face-to-face; medication-based interventions), completion rates of a one-to-one CBT intervention for psychosis was 55% [45] and 68.3% for a one-to-one CBT intervention for FEP [46]. Overall, the current review found moderate to high levels of adherence to Web-based or mobile interventions for psychosis with a range of 60-100% and a mean of 83%.

In terms of the four approaches to studying adherence, the studies in this review varied in terms of the within-study predictors that are associated with adherence, questionnaires used to assess participants' perspectives on factors impacting adherence, and whether or not they conducted any experimental manipulations to impact on adherence.

### Predictors of Adherence and Dropout

Only 2 studies found specific predictors of adherence: less chronic symptoms [31] and a higher rate of adherence was found in the first intervention week than the second [29,30]. Although other predictors of adherence were examined (age, gender, cognition, negative symptoms, and persecutory delusions), none were found to have a significant effect. Two studies also found significant predictors of dropout: severity of symptoms [39], younger age, and male gender [31].

Complex analyses, such as the multiple regression analysis performed by Palmier-Claus et al [39] of specific predictors such as service-user factors (symptoms, socioeconomic factors, interpersonal factors, and cognitive factors) along with e-mental health intervention factors (complexity of the interface, cost, and access) should be a priority for future studies. This will

inform which service-user group may adhere to different type of interventions.

One interesting area of future research would be to examine the duration, frequency, and intensity of the intervention and the effect that this may have on adherence. Studies that last for several months may have more variable adherence than those that last only 1 week. Additionally, longer adherence is not always synonymous with better outcomes. Palmier-Claus et al [29] found that the longer participants used the app, the greater the increase in their depression symptoms. This has important implications for future research; it could be that people will stop using the app as they improve and should therefore be given the opportunity to stop using the app when they have exceeded the benefit. Ultimately, it may be most effective to allow service users choice of the duration, frequency, or intensity of interventions. With supportive guidance, service users may best be able to decide whether or not a technology is helpful and supportive in their recovery.

### Poststudy Questionnaires

Several studies used participant feedback questionnaires, however, they were all different; some were previously published but most were idiosyncratic and this variability also hindered comparison. A standard questionnaire specifically for Web-based and mobile interventions could provide detailed and comparable information on the service user perspective and experience. Additionally, more independent data collection, perhaps from service user researchers not associated with the study, may provide a more unbiased and critical view of the interventions (eg, [47]). The use of posttrial feedback should be a priority for future research studies.

### Experimental Manipulation

Only 2 studies specifically manipulated variables in an attempt to influence adherence or use of the intervention. Both successfully improved adherence to the intervention (eg, mobile phone rather than text message based delivery; higher frequency supportive contact). Experimental manipulation of variables is vital particularly in terms of the types of technologies service users would prefer, the content of interventions and the level of independence, or clinician involvement in use of the intervention.

### New Predictors of Adherence

"Support" in this review was defined liberally as any type of contact with a clinician or researcher involved in the study. Of the 20 studies, 14 reported some level of clinician or researcher contact. This ranged from very limited initial interaction with a researcher to multiple daily support calls from a dedicated mobile interventionist. It should be noted that 7 of the studies were designed as observation studies with ESM components. In this case, researcher or clinician contact may only occur if service users stop filling in the data. Additionally, ESM studies are usually very short so there is less time for absolute dropout. As evidenced by our comparison with adherence ratings grouped by the duration of the study, ESM studies tended to be the shortest studies with the highest adherence ratings.

At present, it is difficult to draw clear conclusions about the importance of support, as only 2 studies specifically reported data on the effect of the Web-based interventionists [37]. However, as demonstrated by Schlosser et al [40], when the amount of coaching support was increased during the second half of the intervention, it led to increased engagement. In the future, it would be interesting for studies to experimentally manipulate the level of support and then measure the impact on adherence, or correlate the ratings of therapeutic alliance in the intervention and the level of adherence. This will clarify the impact of social presence.

Alvarez-Jimenez et al [14] and Wykes and Brown [21] recommend that service user involvement in intervention development might be an important predictor of adherence. However, in the current dataset, only 3 studies included service users in the development of the intervention, so it is difficult to draw conclusions about the impact on adherence. However, adherence to these interventions was very high (84.9%, 86.5%, and 95%). This is an important area requiring future study.

### Quality of Studies

As expected, the RCT studies were rated more highly (77.3%) than feasibility studies (44.7%). All of the studies had interventions carried out by independent assessors and had adequate handling and assessment of dropouts. Only 4 studies had outcome assessments conducted by assessors blind to group allocation. In terms of observational studies, these studies were classified as either fair or good in terms of the quality. Few studies (n=4) used a method of blind rating of outcomes. This is particularly important when assessing service user satisfaction with the intervention, as researcher involvement may unintentionally bias the ratings. Finally, it is difficult to compare study quality across feasibility, RCT, and observational studies. Currently there is no measure to assess the quality of feasibility studies. The CTAM and Downs and Black scales provide a useful reference point; however, direct comparisons are not possible. In the future, RCTs should be developed from the feasibility studies discussed here, to provide further, high quality support for these initial findings.

### Strengths and Limitations of the Review and Recommendations

One of the main limitations of this study is the difficulty of comparing rates of adherence across studies with different interventions and different outcomes. Although most studies provided data either as percent of individuals completing an intervention or the mean percentage of an intervention completed, these two measures may not provide as accurate information when directly combined. A universal measure of adherence should be adopted in addition to more detailed information on the quantity or quality of adherence. For example, Simco et al [16] recommended including not just the percentage of an intervention completed but the number of exercises per week or log-ins per week to get a more qualitative perspective on use. Along these lines, it will be important for future reviews to separate and compare the modes of delivery in their analysis of baseline adherence levels. For example, the baseline rate of adherence to a mobile phone intervention may be different than for a Web-based intervention; comparisons

across and within modes of delivery may provide insight into the types of technologies that are preferred. Finally, it will be important for future reviews to carefully document and unpick any potential risks of harm that service users may experience when using these remote technologies. Reviews should provide an unbiased account of both the benefits and disadvantages of remote interventions, for example, as highlighted by the finding by Ben-Zeev et al (2014b) that participants' BDI scores were significantly correlated with use of mobile intervention; less frequent use of the FOCUS mobile intervention was associated with a greater reduction in depression score. This is an important finding that should guide further use of this intervention (eg, Ben-Zeev et al, 2016). Any potential negative effects should be carefully explored and documented.

The review provides a comprehensive, up-to-date review of adherence across a variety of intervention types and platforms. The strengths include assessing a broad range of different novel technological interventions from text message-based to Web-based to virtual reality-based programs. This allowed us to demonstrate that adherence across different types of studies and a diverse range of interventions is moderate to high. Although the choice between face-to-face and remote intervention was not examined, this result at least demonstrates potential clinical utility. This review is timely as we included up-to-date literature from the past 3 years to ensure that the reader is informed of the most recent developments. The review also provides an innovative exploration of theoretically proposed predictors of adherence. This is the first review of its kind to explore the importance of service user involvement and support in facilitating adherence.

We conclude that specific service user factors such as age or symptom severity may not have a significant influence on adherence; however, the experience of the service user in terms of the development of these technologies and interventions may be an important factor that requires care and consideration.

## Acknowledgments

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

PRISMA checklist.

[PDF File (Adobe PDF File), 62KB - mhealth_v5i7e94_app1.pdf ]

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## Abbreviations

**CBT:** cognitive behavioral therapy
**CTAM:** clinical trials assessment measure
**DSM-5:** Diagnostic and Statistical Manual of Mental Disorders
**ESM:** experiential sampling method
**FEP:** first episode psychosis
**ICD-10:** International Classification of Diseases
**PRISMA:** preferred reporting items for systematic reviews and meta-analyses
**RCT:** randomized controlled trial

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Original Paper

# Development and Testing of an Intelligent Pain Management System (IPMS) on Mobile Phones Through a Randomized Trial Among Chinese Cancer Patients: A New Approach in Cancer Pain Management

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## Abstract

**Background:** Cancer has become increasingly prevalent in China over the past few decades. Among the factors that determine the quality of life of cancer patients, pain has commonly been recognized as a most critical one; it could also lead to the ineffective treatment of the cancer. Driven by the need for better pain management for cancer patients, our research team developed a mobile-based Intelligent Pain Management System (IPMS).

**Objective:** Our objective was to design, develop, and test the IPMS to facilitate real-time pain recording and timely intervention among cancer patients with pain. The system's usability, feasibility, compliance, and satisfaction were also assessed.

**Methods:** A sample of 46 patients with cancer pain symptoms were recruited at the Oncology Center of Xinhua Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Chongming Branch (hereinafter referred to as "the Oncology Center"). In a pretest, participants completed a pain management knowledge questionnaire and were evaluated using the baseline cancer pain assessment and Karnofsky Performance Status (KPS) evaluation. The participants were then randomly assigned into two groups (the trial group and the control group). After a 14-day trial period, another round of cancer pain assessment, KPS evaluation and pain management knowledge assessment were repeated. In the trial group, the data were fully automatically collected by the IPMS. In the control group, the data were collected using conventional methods, such as phone interviews or door-to-door visits by physicians. The participants were also asked to complete a satisfaction questionnaire on the use of the IPMS.

**Results:** All participants successfully completed the trial. First, the feasibility of IPMS by observing the number of daily pain assessments recorded among patients was assessed. Second, the users' satisfaction, effectiveness of pain management, and changes in the quality of their lives were evaluated. All the participants gave high satisfaction score after they used IMPS. Both groups reported similar pain scores and KPS scores at the baseline. At the end of the trial, the mean pain score of the trial group was significantly lower than of the control group ($P$<.001). The ending KPS score of the trial group was significantly higher than of the control group ($P$<.001). The improvement of pain management knowledge score in the trial group was more pronounced than that in the control group ($P$<.001).

**Conclusions:** This study provided preliminary data to support the potentials of using IPMS in cancer pain communication between patients and doctors and to provide real-time supportive intervention on a convenient basis at a low cost. Overall, the

IPMS can serve as a reliable and effective approach to control cancer pain and improve quality of life for patients with cancer pain.

**Trial Registration:** Clinicaltrials.gov NCT02765269; http://clinicaltrials.gov/ct2/show/NCT02765269 (Archived by WebCite at http://www.webcitation.org/6rnwsgDgv)

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**KEYWORDS**

cancer pain; intelligent pain management system; smart phone; intervention

## Introduction

### Status of Cancer and Pain Management in China

Cancer has become a leading cause of human death globally. The World Health Organization (WHO) estimated that cancer resulted in 8.2 million deaths in 2012 [1]. In China, the diagnosis rate of cancer soared over the past few decades as the country's economy boomed rapidly. Statistical data show that China reported approximately 3.07 million new cases of diagnosed cancer in 2012, accounting for 21.8% of the global total [2-4]. Due to the novel diagnostic methods and therapeutic drugs, cancer patients have increased life expectancy than before. For doctors and other caregivers, maintaining cancer patients' quality of life becomes increasingly important and challenging.

Research indicates that over one-third of cancer patients experience cancer pain, and this is known to be a major reason for lower quality of life for the patients [5,6]. The undertreatment of cancer pain is a worldwide problem [7,8]. To manage and further mitigate cancer pain, accurate and precise assessment is key [9-12]. An appropriately designed pain management system, if well planned and implemented, may effectively alleviate the pain of cancer patients. Obstacles preventing proper pain assessment include the lack of validated multidimensional tool to describe pain (intensity, quality, and location of the pain) and to evaluate pain interferences (emotional effects and daily activities) [12-15]. Conventional paper-based self-reported methods have major drawbacks including inaccuracies and biases. However, an advanced real-time pain assessment mechanism and electronic reporting system were found to be more effective in capturing pain data [16-20].

Another problem that China is facing is a wide resource gap across age groups and geographical areas. China is on its way to an aged and eventually super-aged nation in an accelerated pace on account of its economic growth and longstanding population policy. An increasing number of elderly people in cities and rural areas are in need of medical attention. Unlike many developed countries in the western hemisphere, China has very limited medical resources to cure and care for cancer patients in the underdeveloped rural areas. There is a critical shortage of medical doctors, nurses, and other medical professionals in China. A 2011 study shows that China has the doctor-to-resident ratio of 2.8 doctors per 1000 urban residents, whereas in the rural areas such ratio declines to 0.95 doctors per 1000 rural residents [21]. Therefore, home care and mobile care are believed to be future solutions to bridge the gap of the availability of medical resources between China's urban and underdeveloped rural areas. Mobile care, based on mobile phones, is drawing attention because of the advantages of easy access, low cost, and quick response to patients' needs.

### Description of Intelligent Pain Management System

Intelligent Pain Management System (IPMS) is a low cost, conveniently implemented system to facilitate real-time pain recording and timely intervention among Chinese cancer patients. This system has multiple features relying on mobile phones to evaluate real-time pain and KPS scores [22] for quality of life and to generate an action plan to visit the physician or to adjust pain medication dosage when the pain threshold is reached. During treatment, the IPMS may not only be used to evaluate patients' pain status (self-management) but also be used to determine when a patient needs to adjust pain medication by the physician. According to the pilot study (2015), we found that the patients who use the IMPS had significantly more pain-undercontrol days compared with the control group [23]. In this study, we aim to further test the feasibility of IMPS, the usage satisfaction, and quality of life in cancer patients.

## Methods

### Design of Intelligent Pain Management System (IPMS)

The IPMS used in our research was designed to operate on the Android mobile operating system, in order to provide an affordable, portable, and easy to use environment for patients. The system design was performed by the Xinhua Translational Institute for Cancer Pain in Shanghai, China (hereinafter referred to as the Translational Institute). The design team adopted a modularity approach consisting of several functional subsystems to facilitate speedy development by multiple teams. The core system consisted of four modules: Life Quality Self-evaluation, Cancer Pain Self-evaluation, Real-time Messaging, and Standard Medication (Figure 1). After system architecture design, engineering work such as programming and system integration were outsourced to a professional IT company to produce an executable application on mobile phones.

**Figure 1.** Screenshot of intelligent pain management system (IPMS) home screens: Life quality self-evaluation (upper left), cancer-pain self-evaluation (upper right), real-time message (lower left) and medication reminder (lower right).


**Figure 2.** Screenshot of Karnofsky Performance Status (KPS) life quality self-evaluation module.

**Figure 3.** Questionnaire flow chart of lifer quality self-evaluation in life quality self-evaluation module.


### *Life Quality Self-Evaluation*

This module consisted of two questionnaires. A KPS questionnaire was used to obtain the KPS score (Figure 2) and another 12-question questionnaire in a flow chart format was used to evaluate Quality of Life (QOL) scores (Figure 3).

### *Cancer Pain Self-Evaluation*

This core module of IPMS was designed to track patients' self-reported pain data. It contained two submodules: a daily pain assessment submodule and an instant pain assessment submodule. The daily pain assessment submodule (Figure 4) displayed a body map on the smart phone screen allowing the patient to choose the precise position of a recently occurred cancer pain. The pain assessment questionnaire was developed based on the numerical rating scale (NRS) from 1 to 10 as an assessment vehicle. The patients were asked to identify the most, least, and average pains using NRS scores for the previous 24 hours and report the current pain score.

In addition, a list of pain medications was displayed to allow the patients to report their medications and their effectiveness.

Lastly, a final pain assessment questionnaire consisted of 8 aspects (14 questions) to investigate other influences of cancer pain in their daily life, such as movement, hobbies, and relationships with family members, was administered. In the instant pain assessment submodule (Figure 5), NRS was used to evaluate the patient's pain scores. The interface was designed to be user friendly for patients who suffered from variable intense pain (breakthrough pain). In this section, if a patient's self-evaluated pain score reached a high level (>7), an automated message would be sent to the patient that he or she will be contacted by a physician soon.

### *Real-Time Messaging*

This module was designed to assist patients to initiate a real-time consultation session on pain management with the doctors (Figure 6).

### *Standard Medication*

This module was designed to remind patients of their medication schedule (Figure 7) so that they would be assured to take the pain medicine on a regular basis.

**Figure 4.** Screenshots of daily pain assess sub-module in cancer-pain self-evaluation module.


**Figure 5.** Screenshots of instant pain assess sub-module in cancer-pain self-evaluation module.

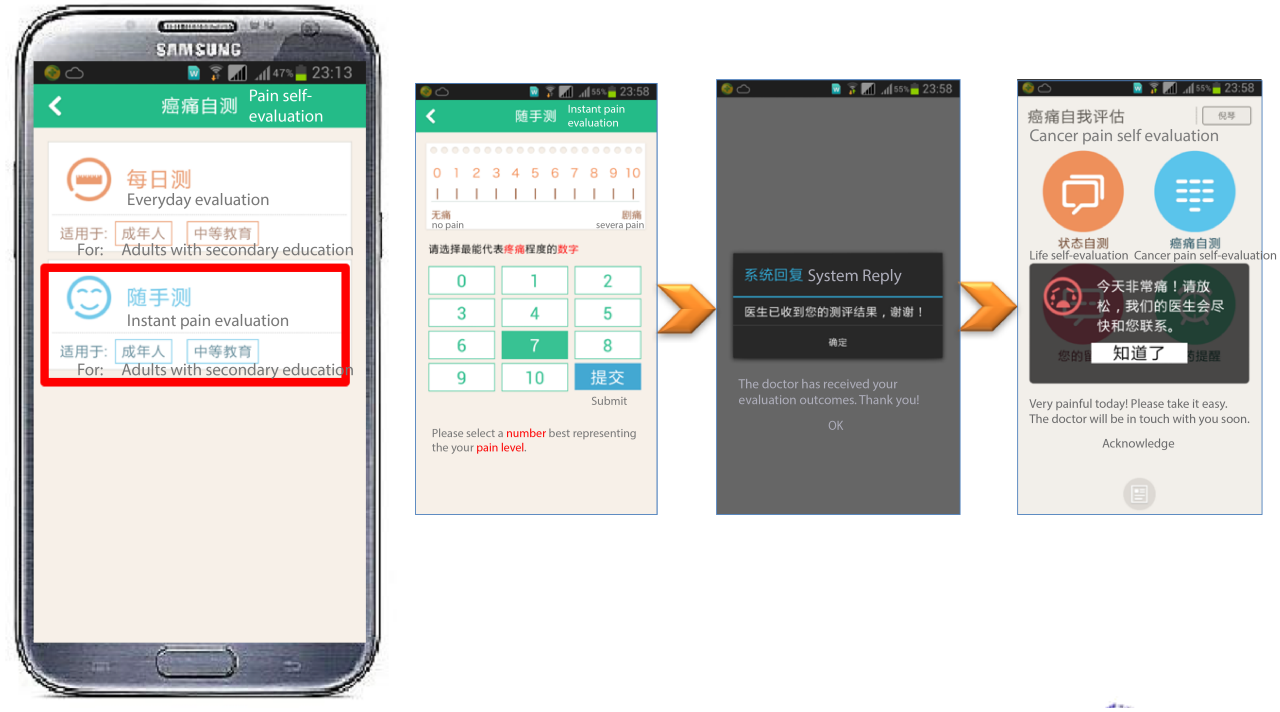

**Figure 6.** Screenshots of real-time message (left) and example (right).


**Figure 7.** Screenshots of standard medication reminder module.

### Study Design

An experiment was designed to test the effectiveness of IPMS on cancer pain management. The experiment involved two groups: an IMPS trial group and a control group.

#### *IPMS Trial Group*

The participants in the trial group were asked to complete a first day's pain assessment questionnaire and the quality of life questionnaire on the mobile phones provided to them. Participants were then encouraged to use the IPMS as much as possible to record their pain status at least once every day for 14 days. They were asked to report the pain scores through the IPMS only. All other measurements were conducted by self-report questionnaires without face-to-face assessments.

#### *Control Group*

The control group was reached through conventional telephone calls or door-to-door visits to collect pain assessment data on a daily basis for 14 days.

### Principle Objectives

The primary objective was to assess the feasibility of the IPMS by observing the number of daily pain assessments recorded among the cancer patients.

The secondary objective was to evaluate the effectiveness of pain management, changes in the quality of their lives, and users' satisfaction with IPMS app.

### Measurement

The IPMS satisfaction evaluation questionnaire was completed by participants at the end of the study. Each questionnaire involved multiple 5-point Likert scores with ratings associated with the options "extremely like it" (5 points), "like it" (4 points), "okay" (3 points), "dislike it" (2 points), and "extremely dislike it" (1 point). The data generated after the survey were used to evaluate the satisfaction of IPMS usage. The questionnaire also contained an open-ended question where participants were encouraged to give any other suggestions about IPMS they felt needed improvement.

A baseline pain assessment and a KPS evaluation were conducted using numerical rating scale (NRS) in both groups. After obtaining the consent, nurses conducted a standardized education session using a booklet to teach the participants proper pain-related and rating system knowledge. At the end of the trial, the pain assessment and KPS evaluation were repeated in both groups.

### Pain Management Knowledge, Pain Assessment, and Karnofsky Performance Status (KPS) Questionnaires

All participates were asked to complete a general information questionnaire on pain management containing five questions (Table 1) upon registration. Each question was a 3-point Likert type response anchored from "well-known," "known," to "unknown." The same questionnaire was repeated at the end of the trial. Data generated at the beginning and the end of the trial were used to evaluate the change in participants' pain knowledge.

**Table 1.** Pain management knowledge questionnaire.

| Number | Question |
|---|---|
| 1. | Do you know standard pain management? |
| 2. | Do you know three step"ladder" cancer pain relief? |
| 3. | Do you know methods other than three step "ladder"cancer pain relief |
| 4. | Do you satisfy with your current pain management |
| 5. | Do you feel confident about your pain management |

## Results

This study was registered online at ClinicalTrials.gov (identifier: NCT02765269, Intelligent Pain Management System for Assessing Pain in Cancer Patients). With ethical review approved by the Medical Ethics Committee of Xinhua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Chongming Branch, a randomized, controlled IPMS trial was conducted at the Oncology Center of Xinhua Hospital affiliated to Shanghai Jiao Tong University School of Medicine, Chongming Branch (hereinafter referred to as "the Oncology Center"). The study lasted from April 2016 to May 2016 in the Oncology Center with no changes to the study design and methods. The random allocation processes, how to enroll participants, as well as how to assign participants to intervention, were determined by physicians.

### Enrolment of the Participants

An original sample of 60 patients was recruited at office visits or in hospital visits in the center by physicians. The participating patients met the following screening criteria: (1) the patient was able to read Chinese and use a mobile phone; (2) the patient was aged between 45 and 70 years; (3) the patient was diagnosed with cancer and had self-reported cancer pain within a month prior to the study; (4) the patient was being seen on a regular basis by the oncology team; (5) the patient was under standard analgesia treatments; (6) the patient was estimated to have over 3 months survival time. Patients who self-reported to have severe cognitive impairments or major comorbid illnesses that would interfere with pain assessment were excluded from the experiment. For example, patients who received radiation therapy were excluded due to possible burning pain from the therapy. In April 2016, a total of 46 qualified cancer patients (14 females and 32 males) were finally included in this study.

## Participant Characteristics

Included participants were randomly allocated on a 1 to 1 ratio to either the IMPS trial group or the control group. Random allocation (simple randomization) of the participants was automatically performed using the random number table.

All participants were then randomly assigned into two groups: an IPMS trial group (25) and a control group (21). The trial group had 6 (24%) females and the control group had 8 (38%) females. The participants' demographic information as well as their disease characteristics were summarized in Table 2.

Each participant in the trial group was provided an Android mobile phone with the IPMS loaded free of charge. They were given a demonstration and training by nurses and physicians on how to operate the smart phone and the IPMS app.

**Table 2.** Demographics and disease characteristics of patients.

| Characteristics | IPMS | Control |
|---|---|---|
| Age (year) | 67 | 68 |
| Sex F/M, n | 6/19 | 8/13 |
| **Primary diagnosis, n (%)** | | |
| Lung cancer | 8 (32) | 9 (43) |
| Column cancer | 3 (12) | 2 (9) |
| Hepatic carcinoma | 4 (16) | 1 (4) |
| Pancreatic cancer | 2 (8) | 2 (9) |
| Stomach cancer | 1 (4) | 4 (19) |
| Esophagus cancer | 2 (8) | N/A[a] |
| Breast cancer | 1 (4) | N/A |
| Ovary cancer | 1 (4) | N/A |
| Kidney cancer | 1 (4) | 1 (4) |
| Osteocarcinoma | 2 (8) | 1 (4) |

[a]N/A: not available.

## Data Analysis

The outcome assessor was blinded to the data collection. The collected data were analyzed using the R Statistical Software Package 3.1.3. Independent Student's *t*-test and the Chi-square ($\chi^2$) test were used to analyze the differences (NRS, AGE, KPS) in pain controlled duration and breakthrough pain between the trial group and the control group. The significant difference was determined by $P<.05$.

## IPMS Feasibility Testing

The compliance rate was consistently high over the course of the trial with no statistical difference in total number of daily pain assessment between week 1 and week 2 (16.72 [SD 5.95] vs 18.36 [SD 6.35], $P>.05$). Further analyses showed that the total number of pain assessments between the day times and the night times was 1.82 (SD 0.43) vs 0.56 (SD 0.18), respectively. In addition, there was no significant difference between the usage times of weekdays and weekends (2.45 [SD 0.6] vs 2.15 [SD 0.18], $P>.05$).

## Pain Management and KPS Evaluation

At the beginning of the trial, there was no significant difference in the baseline pain scores (3.28 [SD 0.68] vs 2.90 [SD 0.62], $P>.05$) between the two groups. Over the 14-day trial period, the average pain score of the trial group was 2.53 (SD 0.42), compared with 2.81 (SD 0.47) of the control group with a significant difference ($P<.001$). At the end of the trial period, the average pain score of the trial group was 2.20 (SD 0.50), compared with 2.95 (SD 0.59) of control group with a significant difference between the two groups, $P<.001$ (Table 3).

As to the evaluation of the acquired pain management knowledge after 14 day's IPMS interaction, there was a 2.96 (SD 0.61) increase in the knowledge score of the trial group after using the IPMS for two weeks, compared with a 0.81 (SD 0.67) increase of the control group ($P<.001$). Although both groups demonstrated increased pain management knowledge, the IPMS trial group indicated a higher score increase in pain management knowledge than did the control group.

Another application of the IPMS was the education and evaluation of quality of life through KPS scores. The baseline KPS scores in the IPMS trial group were no different than those of the control group (50.80 [SD 7.02] vs 50.95 [SD 7.40], $P=.94$) before the participants had entered into the trial. At the end of the trial, the KPS was re-evaluated in the two groups (68.80 [SD 7.23] vs 56.19 [SD 7.40], $P<.001$). Both groups increased mean KPS significantly from the baseline, but the mean increase in the IPMS trial group was significantly larger than the mean increase in the control group (16.15 [SD 7.68] vs 5.23 [SD 5.11], $P<.01$).

**Table 3.** Pain management and KPS score comparisons between IPMS and control groups.

| Scores | IMPS | | | Control | | | Group difference | |
|---|---|---|---|---|---|---|---|---|
| | Baseline | Day 14 | Change from baseline | Baseline | Day 14 | Change from baseline | Baseline | Change from baseline |
| Pain evaluation | | | | | | | | |
| Mean (SD) | 3.28 (0.68) | 2.20 (0.50) | | 2.90 (0.62) | 2.95 (0.59) | | | |
| *P* value | | | <.001 | | | .58 | .06 | <.001 |
| Pain knowledge management | | | | | | | | |
| Mean (SD) | 5.16 (0.75) | 8.12 (0.07) | | 4.09 (0.83) | 4.90 (1.09) | | | |
| *P* value | | | <.001 | | | .009 | | <.001 |
| KPS | | | | | | | | |
| Mean (SD) | 50.80 (7.02) | 68.80 (7.23) | | 50.95 (7.40) | 56.19 (7.40) | | | |
| *P* value | | | <.001 | | | .023 | .94 | <.001 |

### Satisfaction

A posttrial evaluation was conducted to measure the participants' satisfaction towards the IPMS. On the ease of use of the IPMS, out of the 25 participants in the trial group, 9 (36%) indicated "very much like it (the IPMS)" and 16 (64%) indicated "like it (the IPMS)." No participant indicated dislike of the IPMS. On the helpfulness of the IPMS, 20 (80%) responded "very helpful" and 5 (20%) responded "helpful." On the software technical support, 18 (72%) indicated "very much like it" and 7 (28%) indicated "like it." On the consultant and training course, a majority of participants 18 (72%) reported "very much like it" and (7) 28% reported "like it." On the prompt response for help, 7 (28%) indicated "very much like it," 11 (44%) indicated "like it," and 7 (28%) indicated "okay." The average score of each question is shown in Table 4. The data suggests a high level of user satisfaction towards IPMS.

**Table 4.** Usability and satisfaction after 2 weeks (n=25). The rate was 1 (extremely dislike it) to 5 (extremely like it).

| Number | Question | Mean (SD) |
|---|---|---|
| 1 | The convenience to use IPMS | 4.46 (0.49) |
| 2 | Do you think IPMS is helpful to your pain management? | 3.92 (0.61) |
| 3 | How do you like IPMS | 4.30 (0.46) |
| 4 | Software technical support | 4.73 (0.44) |
| 5 | Consultant and training course | 4.65 (0.47) |
| 6 | Prompt response for help | 4.53 (0.49) |

## Discussion

### Principal Findings

This research involved a cohort of cancer patients with cancer pain in a study of the usability and effectiveness of an IPMS system designed for this study. We presented data on the compliance, satisfaction, evaluation of pain management in a 2-week clinical trial. Overall, the study demonstrated that the IPMS gained a high rate of compliance and satisfaction among the participants. With little or no additional clinical intervention, IPMS had the potential to improve pain management and quality of life for cancer patients with cancer pain.

### Comparison With Prior Work

To the best of our knowledge, this study could be the first to report on the development, usability testing, and evaluation of cancer pain and KPS with an intelligent pain management system through mobile applications in China. A search of the literature has yielded several reports on the assessment of usability of technology-based interventions on cancer pain. However, majority of past research were based on telephone interventions to connect patients with health providers [4,24]. Stinson group reported the development and testing of a multidimensional iPhone (R) pain assessment application for youth cancer patients. Their application was a game-based program to assess pain, which was specially designed for adolescent cancer patients and with no intervention [25,26].

This study implemented the telephone-based intervention as the control group to compare with the mobile Internet-based IPMS. The IPMS was developed as a multidimensional tool not only for real-time pain assessment but also for KPS evaluation, medication reminder, real-time messaging consultation, and pain management education. Such mechanism was able to convey clinical assistance and intervention between the health providers and the patients in an efficient and effective way. It was the real-time messaging that mattered to the patients' pain

management. The IPMS allowed patients to be able to instantaneously assess and report pain, thus the doctors were able to provide prompt advice on the dosage change of pain control medication, which was not possible in traditional ways. The rapid adoption of mobile devices in China provided a promising future of the IPMS in cities and rural areas. We are expecting that the IPMS will become a popular communicating vehicle between physicians and cancer patients in the near future.

### Strengths and Limitations

The clinical trial yielded a perfect compliance rate (100%) of the IPMS use regardless of time—day times or night times, weekdays, or weekends. The compliance rate was consistent over the course of the trial with no significant difference between week 1 and week 2. The slightly heavier usage at the night times highlighted the potential of IPMS, as obtaining the pain data at night times was always a challenge through conventional methods. Real-time pain satisfaction assessment data have been valuable for researchers and care providers. With a powerful tool as the IPMS, we may be able to better understand the pain burst out patterns and provide timely response to the patients' need, allowing for improved pain management and higher quality of pain treatment.

Through the usability test, we were able to test the user interface and the basic functions of the IPMS. The patient satisfaction rate was high for its easy use, as well as being helpful for the consultant and training courses. However, there was still room for improvement in terms of prompt response for help. As this is the first smart phone app for pain management for both patients and healthcare professionals to use, it may take time for both parties to get used to the system. A clinical study of longer duration will be conducted to address this question in the near future.

In this study, the improvement of cancer pain management was more pronounced in the IPMS trial group than in the control group, which suggests that IPMS is beneficial. Testing data also revealed that the knowledge of pain management and quality of life were all significantly increased in the IPMS group compared with the control group. Patients in both groups were exposed to same levels of clinical care, educational program, and pain management knowledge training. The reason the IPMS group had more benefit, may be due to the interactive-feedback learning mechanism that gave the trial group patients more confidence and knowledge to deal with pain management. A similar phenomenon has been observed and reported by Liu LF group in the literature [17].

This study had several limitations that may tamper our results. First, the duration of the trial period was relatively short and the sample size was relatively small. Due to the limited sample size, the distribution of cancers types was not balanced between groups as certain types of cancer had only 1 patient in the sample. The clinical trial group was drawn from a patient pool with different stages of cancer, which may limit the generalizability of this study. Future study is warranted to test the effectiveness of IPMS with a larger sample of participants and longer time period with improved randomization and balance.

### Conclusions

In conclusion, this study underscored the feasibility and acceptability of IPMS as a novel and effective pain assessment tool for patients with cancer pain. Participants found the system easy to use and helpful. IPMS was found to be beneficial for pain management, quality of life, and pain management education in a 14 days' clinical trial. It is believed that IPMS has the potential to change the current atlas of pain management in China, especially in underdeveloped rural areas with improved efficiency and effectiveness of pain management and interactions between cancer patients and health professionals.

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### Conflicts of Interest

None declared.

### Multimedia Appendix 1

The trial is reported in accordance with CONSORT-eHEALTH.

[PDF File (Adobe PDF File), 563KB - mhealth_v5i7e108_app1.pdf ]

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## Abbreviations

**IPMS:** intelligent pain management system
**KPS:** Karnofsky Performance Status
**NRS:** numerical rating scale

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Original Paper

# Smartphone-Based Endoscope System for Advanced Point-of-Care Diagnostics: Feasibility Study

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## Abstract

**Background:** Endoscopic technique is often applied for the diagnosis of diseases affecting internal organs and image-guidance of surgical procedures. Although the endoscope has become an indispensable tool in the clinic, its utility has been limited to medical offices or operating rooms because of the large size of its ancillary devices. In addition, the basic design and imaging capability of the system have remained relatively unchanged for decades.

**Objective:** The objective of this study was to develop a smartphone-based endoscope system capable of advanced endoscopic functionalities in a compact size and at an affordable cost and to demonstrate its feasibility of point-of-care through human subject imaging.

**Methods:** We developed and designed to set up a smartphone-based endoscope system, incorporating a portable light source, relay-lens, custom adapter, and homebuilt Android app. We attached three different types of existing rigid or flexible endoscopic probes to our system and captured the endoscopic images using the homebuilt app. Both smartphone-based endoscope system and commercialized clinical endoscope system were utilized to compare the imaging quality and performance. Connecting the head-mounted display (HMD) wirelessly, the smartphone-based endoscope system could superimpose an endoscopic image to real-world view.

**Results:** A total of 15 volunteers who were accepted into our study were captured using our smartphone-based endoscope system, as well as the commercialized clinical endoscope system. It was found that the imaging performance of our device had acceptable quality compared with that of the conventional endoscope system in the clinical setting. In addition, images captured from the HMD used in the smartphone-based endoscope system improved eye-hand coordination between the manipulating site and the smartphone screen, which in turn reduced spatial disorientation.

**Conclusions:** The performance of our endoscope system was evaluated against a commercial system in routine otolaryngology examinations. We also demonstrated and evaluated the feasibility of conducting endoscopic procedures through a custom HMD.

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**KEYWORDS**

smartphone-based endoscope; point-of-care systems; mobile health; low-resource settings

## Introduction

Over the past decade, the endoscope has become an essential medical instrument that enables physicians to access the internal organs with magnified visualization. Endoscopy was mainly purposed to investigate the unusual symptoms associated with the interior of the body, but now it has been utilized in a host of medical procedures that assist not only in the diagnosis, but also in the staging of diseases, biopsy, local therapy, and minimally invasive surgery [1-3]. The endoscope finds application in numerous fields, including gastroenterology, orthopedics, urology, obstetrics/gynecology, otolaryngology, neurology, and anesthesiology [4-6]. Currently, the endoscope system incorporates advanced technologies to provide enhanced diagnosis by offering high-definition, fast, quantitative, and wide-viewing images. Despite the multiple benefits of using endoscopy, the routine endoscopic procedures are usually confined to clinics [7]. Moreover, most of the endoscope system itself is not suitable for remote consultation and point-of-care (POC) diagnosis at developing areas or in low-resource settings [8,9].

Recently, there have been efforts to integrate smartphones into various medical devices [4,10-18]. Because of the recent advances in mobile computing electronics, the performance of smartphones is now comparable to personal computers while also featuring the state-of-the-art engineering components such as microsensors, high-resolution camera, powerful central processing unit, graphics processing unit, and high-speed data communication chips [10,18]. The infrastructure of mobile data communications has now become fast and ubiquitous, equipped to efficiently deliver the data between remote sites. Thus, the technical integration between information and communication technology and medical devices has opened a new opportunity for the next-generation diagnostic protocols through telemedicine and big medical data analysis.

In this study, we introduce a complete smartphone-based endoscope system and evaluate its feasibility for clinical applications. Although smartphone technology has already been applied to endoscopic devices, previous works showed only proof of concept while not considering its diagnostic value as well as the user interface. Furthermore, previously developed smartphone-based endoscope devices utilized the built-in camera software in the smartphone that only provided limited functionalities for the endoscopic imaging [7,19]. In this study, we present a full smartphone-based endoscope system combined with the custom hardware/software, light source, as well as a head-mounted display (HMD) for quick office procedures and remote care settings. The performance of this newly developed endoscopic device was compared with one of the commercial endoscope system.

## Methods

### Endoscope System Using Smartphone

We developed a low-cost and portable endoscope based on a smartphone as illustrated in Figure 1. Our system comprised 6 pieces of components aligning in series, including a conventional endoscopic probe, compact light source, customized adapter, magnifying relay-lens, packaging holder, and smartphone. Both holder and adapter were designed by three-dimensional (3D) modeling software (Solid Works) reflecting the actual dimensions of the smartphone and the endoscope eyepiece. The endoscopic probe can be detached from the adapter, which is compatible to most of the commercial rigid and flexible endoscopes. For delivering light to the interiors of body cavities, a portable light source (Medit, SPARK) was attached to the illumination port of an endoscopic probe. The smartphone holder was built for a specific smartphone model (Samsung Electronics, Galaxy S5) and made by a 3D printer (Stratasys, Objet260 Connex2) with the spatial precision of ±16 μm. For the magnification of endoscopic image, we customized the lens system that was located between the eyepiece of endoscope probe and smartphone camera. The customized lens system enabled the manual focus by employing the zoom housing (Thorlabs Inc, SM1NR05) to correspond to the different endoscopic probe. Off-the-shelf lenses were designed and selected by the optics designing software (ZEMAX LLC, Optic Studio) as shown in Figure 2. A smartphone camera–mimicking lens (L3) was simulated with 4.8 mm, f/2.2 as a constant parameter, which was set to infinite-focus. To deliver the image to the camera, we utilized 2 achromatic lenses (L1, L2) to reduce the chromatic aberrations while sustaining the portability as well as cost-effectiveness. Thus, tradeoff between length of the lens system and magnification was optimized. We assembled the achromatic lens and the aspherized achromatic lens with 40 mm and 14 mm focal lengths, respectively, to achieve approximately 4× optical magnification, which could be further enhanced up to 12× magnification approximately via software-based digital zoom. The final image was captured by the complementary metal–oxide–semiconductor sensor of the smartphone with specifications of 16.0-megapixels, MP (5312 × 2988 pixels), 1/2.6 inches (1.12 μm pixel size), incorporating 4.8 mm focal length and f/2.2 optical lens.

For replacement of the conventional display and enhancement of portability, a newly designed commercialized HMD module (Green Optics Co, GO Glass) was employed in our system (Figure 1). The operation of HMD was based on the Android operating system which allowed viewing the live endoscopic images through the glasses with 50% transparency, 45-degree sight angle, and 114 × 22 × 14 mm viewing optics. In addition, HMD was able to project the images that used resolution of extended graphics array (1024 × 768) in front of the eyes. The HMD was interfaced wirelessly with the smartphone via a mirror casting technology and displayed the endoscope images to clinicians. As shown in Figure 1, a clinician would attach either the rigid or the flexible endoscope probe to the system and wear an HMD on the head while manipulating the smartphone-based endoscope system.

**Figure 1.** Smartphone-based endoscope system setup. (a) Schematic of smartphone-based endoscope system. A photography of (b) rigid type endoscopic system, (c) flexible type endoscopic system, (d) android based HMD, and (e) the smartphone-based endoscope system vs clinical endoscope system.

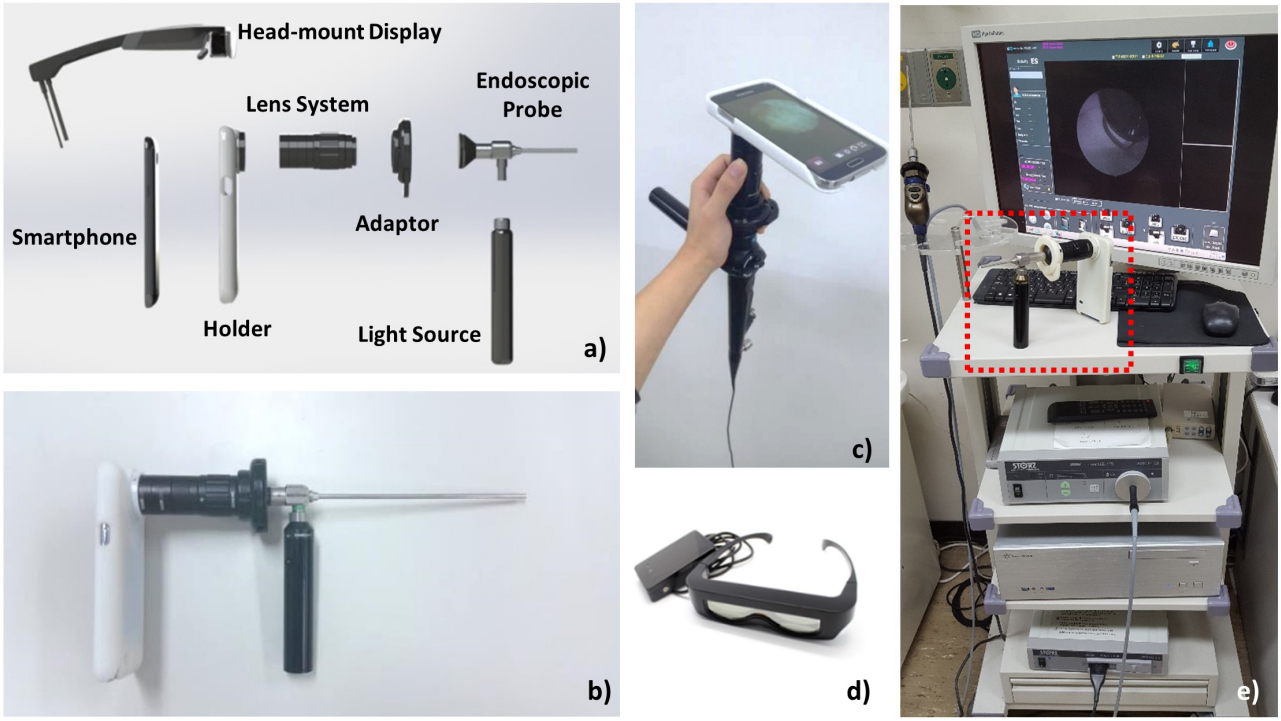
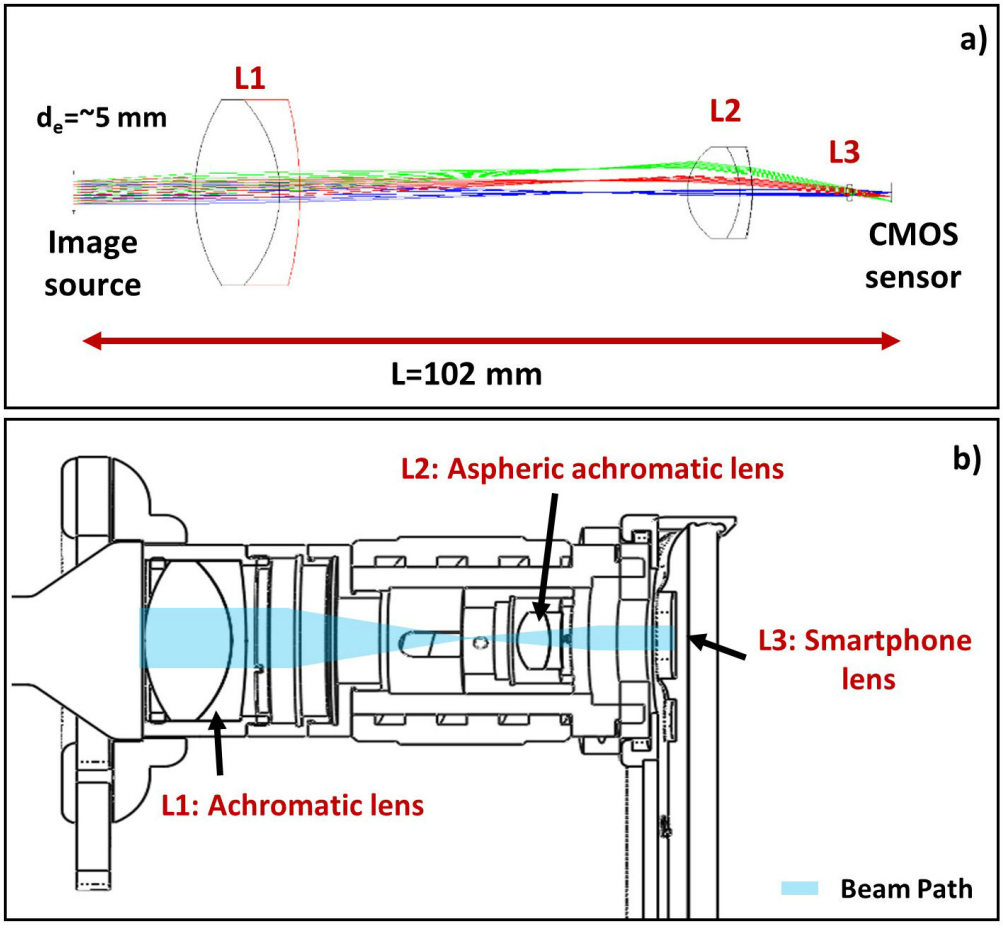



**Figure 2.** Lens simulation of smartphone-based endoscope system. (a) Ray-tracing of optics for smartphone-based endoscope system. $d_e$ denotes a diameter of the eyepiece of endoscope probe, which is the image source. Achromatic lens (L1) having f=40 mm, Ø25.4 mm and aspherized achromatic lens (L2) having f=14 mm, Ø12.7 mm were utilized. Smartphone lens (L3) was simulated to deliver the image to complementary metal-oxide semiconductor sensor. (b) Schematic of assembled lens system in smartphone-based endoscope system.



### User Interface Software Development

We developed a JAVA-based Android software for a simple and intuitive user interface that allowed an operator to control essential imaging parameters such as display brightness, image resolution, digital zoom, and focusing adjustment (Figure 3). We also added multiple user-friendly features. For example, user could be set for either left- or right-handed operation for easier control of the display parameters during endoscope manipulation. Displayed endoscopic images could be automatically flipped for better coordination between the endoscope movement and the display orientation. Furthermore, captured images and videos could be visualized in comprehensive gallery mode. For convenient operation of the system, the software was also enabled for simultaneous wireless casting on HMD.

### In-Vivo Imaging Protocol at Otolaryngology

In accordance with a protocol approved by the institutional review board of the Kyungpook National University Hospital, the smartphone-based endoscope system was tested in human subjects. Each imaging session was conducted immediately after subjects' routine endoscopic examinations at an ENT (ear, nose, and throat) doctor's office in Kyungpook National University Hospital. Routine endoscope procedures performed in the ENT departments were followed while utilizing our system as well. Before performing the endoscopy, the system was adjusted to get a fine focus for clear images through software and optics. Then, endoscope probe was wiped with a disinfectant to avoid the cross-contamination between patients. The whole procedure took less than a minute, thus avoiding undue burden on volunteers. Volunteer patients were verbally introduced to the risks and goals of this research study and agreed to participate and released the right to their endoscopic data to be used for the publication. For this research, 50 patients aged 20 or older were asked for participation, and of these, 30 volunteers agreed to participate in this research. As this was an initial pilot clinical study, we did not attempt to achieve statistical significance in data.

As it is shown in Figure 1, each human subject was imaged using both smartphone-based endoscope and commercial endoscope system that comprised a charge-coupled device camera head (Stryker, 1188HD), light source (Stryker, X8000), and information management system (Stryker, SDC ULTRA). Various types of endoscope probes such as 0°, Ø4, 50 mm length rigid otoscope (Medstar, Otoscope), 0°, Ø4, 175 mm sinuscope (Medsatar, Sinuscope), 70°, and Ø3.4, 300 mm flexible endoscope (Olympus, ENF-P4) were utilized.

Then, we chose several clear representative endoscopic pictures, including the healthy and diseased models corresponding to each endoscopic probe. The entire process was observed via the smartphone's liquid crystal display screen as well as the HMD in real time. In addition, the images from the commercial endoscope system were captured and archived via a computer for additional analysis. Thereafter, all captured images were cropped for resizing to better visualize the image for the manuscript. Moreover, the brightness and light contrast were manually adjusted for each image to enhance the visibility. No other image process was implemented in this study.

## Results

### System Characterization

To evaluate the imaging performance of our system, the US Air Force resolution target was imaged as shown in left side of the Figure 4 [7,20]. Three different images were acquired and compared with smartphone-based endoscope with/without lens and the clinical version of commercial endoscope system. The distance between the end of endoscope probe and resolution target was 20 mm, which was sufficient to preserve the optical field-of-view (FOV).

Image captured by the smartphone-based endoscope without lens showed the lowest imaging capability in terms of resolution. It was able to resolve 4.0 line pairs per millimeter (lp/mm), which corresponds to 250.0 μm. When custom lens system was applied, the imaging performance improved and was able to resolve 5.66 lp/mm (corresponds to 176.7 μm). The clinical version of endoscope system, showed the highest imaging performance among the 3 systems by resolving 6.35 lp/mm (corresponds to 157.5 μm).

In addition, a ruler was captured to identify the FOV as shown in Figure 4. Similar to the resolution measurement, images were captured at 20 mm of working distance using our device with/without lens and the clinical version of endoscope system. Measurements of resolution and FOV at the working distance between 5 mm and 30 mm can be seen in right side of the Figure 4, respectively. They show that the smartphone-based endoscope with lens has imaging capability similar to that of a clinical endoscope system. Moreover, it can be ascertained that the features of the lens system did not critically influence the FOV.

**Figure 3.** Android based software for the smartphone-based endoscope system. (a) Main capturing screen. (b) Gallery mode of the software.

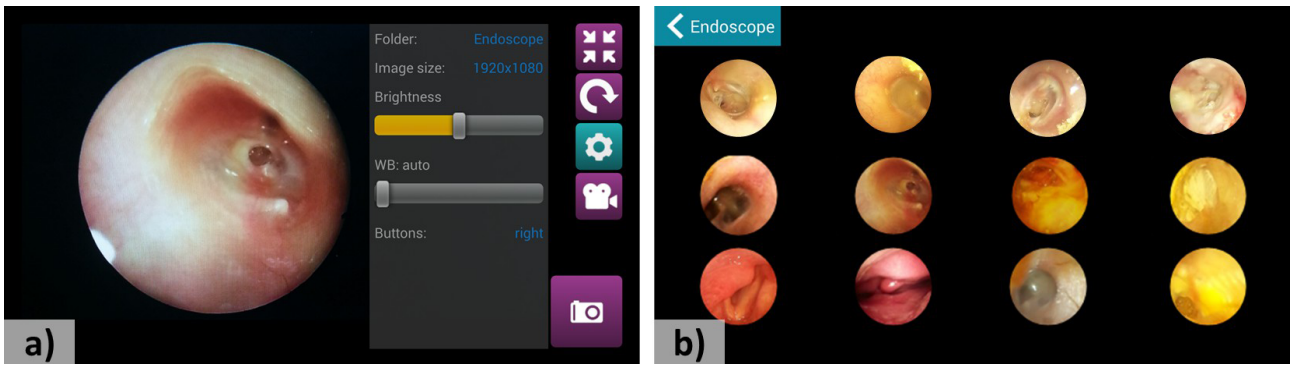


**Figure 4.** Result of the smartphone-based endoscope evaluation. At 20 mm away from the target, the USAF resolution was captured with (a) smartphone-based endoscope without lens, (b) with customized lens, and (c) commercial endoscope system. At the corresponding distance, field-of-view was measured by capturing the ruler with (d) smartphone-based endoscope without lens, (e) with customized lens, and (f) commercial endoscope system. (g) Graph of the measured resolution, and (h) field-of-view according to the working distance.

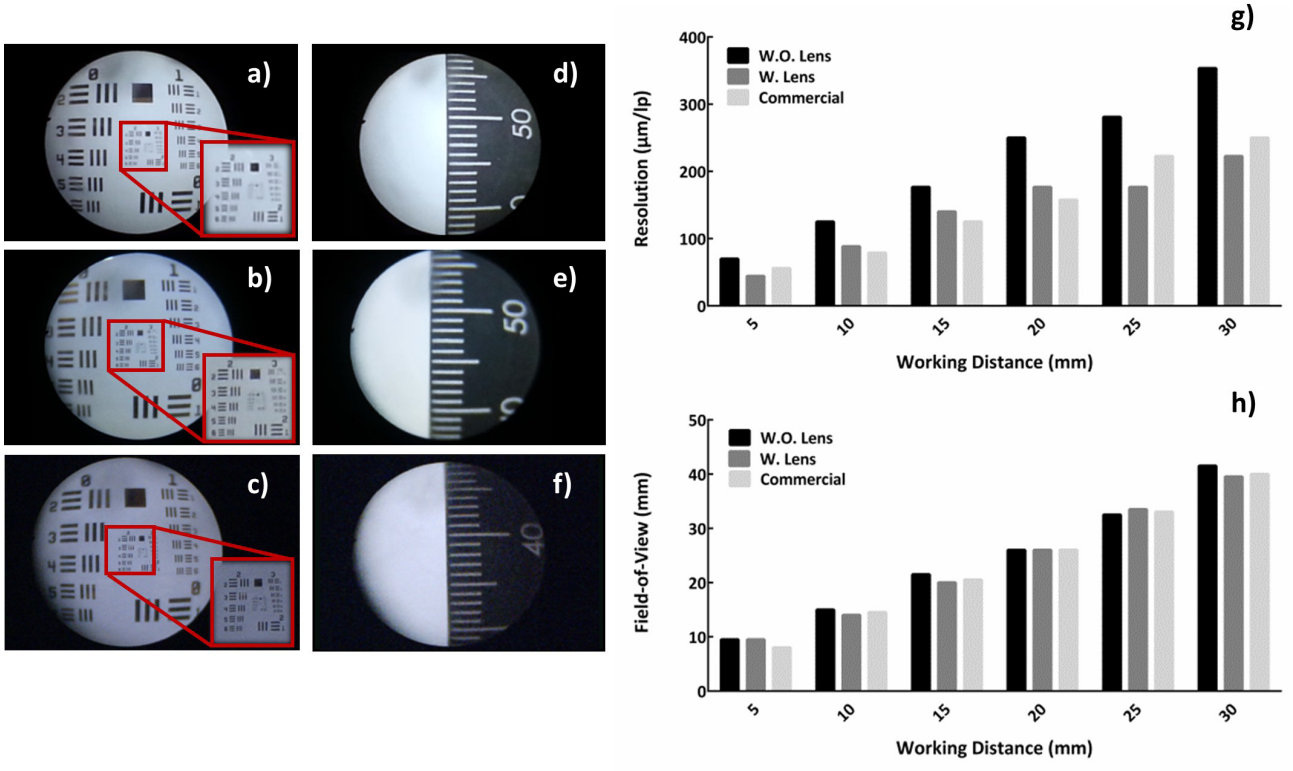



**Figure 5.** HMD integrated smartphone-based endoscope. (a) A demonstration of the smartphone-based endoscope system using the HMD. (b) Duplicated image shown in viewing optics of HMD. (c) Live endoscopic image shown in the smartphone screen.

### HMD-Based Endoscopy Performance

Routine endoscopic procedure can sometimes be cumbersome for the clinician because of mismatched eye-hand coordination. Manipulating the endoscope probe while observing the monitor forces a divergence between site of manipulating hand and FOV, which requires extensive training. Moreover, clinicians easily experience ocular strain from endoscopic procedures. To overcome the abovementioned issues, HMD was applied to endoscopic procedures [20-23]. We tested the feasibility of endoscopic diagnosis using our device, which included a see-through type of HMD as shown in Figure 5. Images were acquired with 3264 × 2176 (8MP), International Organization for Standardization (ISO) 100, lowest exposure (−4) settings using the smartphone-based endoscope in routine endoscope procedure. The Android-based HMD controller successfully duplicated the screen of the smartphone; hence, images could be seen through the viewing optics in the HMD (b, c). The clinician was able to detect the lesions in front of the eyes and successfully manipulated the endoscopic probe. Moreover, through this system setting, the clinician had a benefit of observing the endoscopic image simultaneously at the manipulation site, thereby reducing spatial disorientation. The use of HMD during the endoscopic procedure showed a potential of improvement on the eye-hand coordination. The clinician experienced a reduction in diagnosis time as compared with observing through the monitor. In addition, it was found that the manipulation time for flexible endoscope probe was significantly reduced when clinician wore an HMD.

### In-Vivo Human Subject Imaging

The smartphone-based endoscope was tested in a routine otolaryngology examination to evaluate its clinical value and performance. The images of human subjects were captured and compared with a clinical endoscope system. Our device used 3264 × 2176 (8MP) image resolution at the automatic ISO mode (ISO 100), and the lowest exposure (−4) setting to suppress the saturation of light and to achieve clear images. For the clinical endoscope system, the 1280 × 1024 (1.3MP) was used for camera resolution settings. The images were obtained at the same location with the corresponding probes that were utilized in the commercial system.

Images captured with the smartphone-based endoscope are shown in the columns on the left side, whereas images acquired from the clinical endoscope system are shown in the columns on the right under each subcategory of endoscopic probes (Figure 6). To examine different areas in otolaryngology, different types of endoscope probes were applied. Images of tympanic membranes were captured using the otoscope probe (the 1st two columns in Figure 6). Images from both systems clearly showed the structures of the tympanic membrane compared with that of the normal patient. For nasal examination, a sinuscope was applied (2nd and 3rd coulmns in Figure 6). Several images were captured during the endoscopic examination to observe the feasibility of our system. Among the nasal endoscopic images, both systems particularly highlighted the nasal polyps of patient with chronic rhinosinusitis (g, h). The flexible endoscope was also applied to examine the larynx (the last two columns in Figure 6). Flexible endoscope was inserted first through the nose and then through nasopharynx to reach the larynx of the patients. Some images obtained by the fiber-optic endoscope probe displayed the pixelation throughout the entire FOV affecting the image quality and limiting the spatial resolution by undersampling because of core-to-core spacing between fibers [24]. Despite the pixelation, the smartphone-based endoscope still provided sufficient contrast and image quality for detecting the lesions. The smartphone system showed an acceptable level of clarity for an ENT specialist to distinguish the healthy and the diseased or damaged tissue regions through the smartphone screen.

**Figure 6.** Result of human in-vivo imaging at Otolaryngology. Otoscope, sinuscope, and flexible endoscope were utilized. The corresponding sites were captured with smartphone-based endoscope and commercial endoscope system in clinical settings. (a, b) normal tympanic membrane. (c, d) chronic otitis media, central large perforation. (e, f) normal middle turbinate. (g, h) chronic rhinosinusitis with nasal polyp. (i,j) normal vocal cord. (k,l) postoperative state of thyroid cancer surgery in larynx.

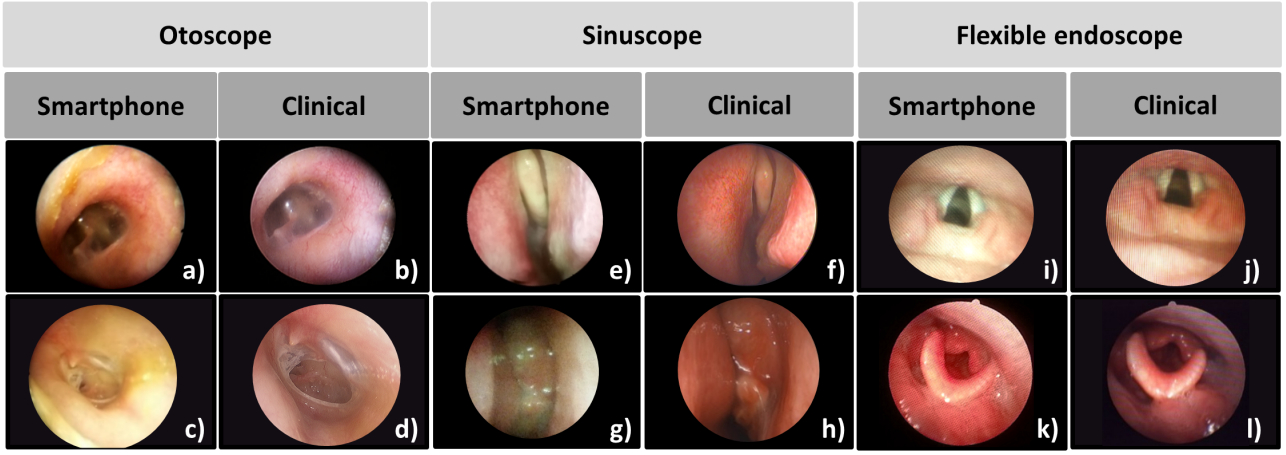


**Table 1.** Cost of smartphone-based endoscope system.

| Components | Price in US dollars |
|---|---|
| Lens system (2 off-the-shelf lenses, adjustable lens tube, additional lens components) | ~$ 400 |
| Three-dimensional printing parts (smartphone case, adapter, and coupler) | ~$ 50 |
| External light source | ~$ 300 |
| Miscellaneous components (spring, screws, and battery) | ~$ 30 |
| Smartphone (Samsung Galaxy S5 16GB) | ~$ 200 |
| Total | ~$980 |

# Discussion

## Principal Findings

In this study, we demonstrated the use of a novel endoscope system based on a smartphone in clinical applications. The benefits of various aspects of our device have been observed throughout the study. Our device was fabricated in a compact form factor, so it can be used as a carry-on or standalone medical device in a clinical environment. Furthermore, significant safety guards or chemical protection were not necessary for this device. However, additional precaution was taken by wiping the probe with an antiseptic fluid to avoid the cross-contamination. The 3D printed case offered the robustness as well as the reliability with familiar coupling mechanism compared with that of the conventional system for endoscope probe. It was much simpler to set up the device for endoscopic diagnostics. The use of smartphone for endoscopy further simplified the system by providing the state-of-the-art sensors and hardware, thereby eliminating the need for expensive ancillary devices [10,18]. In addition, cumbersome image processing or device control algorithm was unnecessary for endoscopic diagnosis with smartphone. Thus, the smartphone-based endoscope significantly reduced the overall cost compared with the price of conventional endoscope system equipped with essential apparatuses. The average price of the conventional system, with our survey from three major endoscope companies, was over US $ 50,000, whereas our system only costs under US $1000, including the smartphone (Samsung Galaxy S5) and the endoscopic probe. Even the additional cost related to commercial product delivery were taken into account, making the estimated price substantially lower for the smartphone-based system. Table 1 clearly presents the prices of components in our smartphone-based endoscope system.

Unlike other devices available in the market, the smartphone-based endoscope presented in this study provides a full endoscopic capability with a potentially customizable endoscope platform. Rather than simply capturing endoscope images with enhanced mobility, our system has shown a possibility to provide more advanced imaging modalities with various contents to the field applications. It can be easily modified for various needs in every aspect (optics, 3D printed cases, and light source) or made compatible with various accessories to the system for expanding the functionalities. We demonstrated the HMD as an example of a seamless integration of an accessory for endoscopy procedure. The integration of the next-generation wearable display such as an HMD can provide several advantages to the smartphone-based endoscope system. An HMD allows clinicians to monitor digital information that is superimposed over the real-world view, thereby eliminating the need to view a monitor away from the patient and reducing the discomfort in the working position. Furthermore, the HMD completely rendered the smartphone-based endoscope system more portable and compact. However, some clinicians have experienced dizziness when they utilized an HMD for a long time because of ghost images caused by inherent structure of HMD design (static distance between optical windows). We anticipate that the future model of HMD will address these limitations and provide more advantages in our system.

The results shown in this study demonstrate the potential of the smartphone-based endoscopy for various clinical applications outside the conventional ones. In particular, the HMD-integrated system may offer more benefits outside the clinic. Faster diagnostics may be enabled with fascinating ease and safety, with considerable reduction in mismatch of the eye-hand coordination through HMD. The linkage between biosensors and HMD-integrated smartphone-based endoscope system could be beneficial for endoscopic surgeries. The extremely low price of the system could make it a cost-effective education tool for endoscope training. Furthermore, ubiquitous telecommunication infrastructure enables smartphone-based endoscope to be useful even in medical emergencies in the ambulance or field hospitals. It is still difficult to arrange an emergency operation in a timely manner. For this reason, sending the diagnosed endoscopic images to specialists while transporting the patient could shorten the delays and help manage urgent situations more efficiently using the smartphone-based endoscope.

Throughout the experiments, the great potential of the integration of smartphone technologies with medical devices has been observed because of the tremendous reduction in costs while sustaining health benefits for the patients. Many literatures have described them as the most prospective devices for the next-generation POC diagnostics [18,25-28]. The smartphone-based medical devices may complement the quality of the services such as medical and health informatics. Moreover, recently developed mobile-picture archiving and communication system allows to connect remote locations to the central patient database in a secure fashion [29-31]. Now, real-time on-site diagnostics are available with a secure transmission of personal and sensitive medical data in a format specific to the health care industry [29]. These mobile devices show the possibilities of providing assistance to the patients in

their medical records to improve coordination among health care providers who use telecommunication technologies such as short message service, calls, and Internet-based video links [18,25,27]. With advances in technologies, many devices tested in the laboratory settings have been translated to clinically or commercially available products [18,25-28]. The smartphone-based medical devices, especially for imaging device such as endoscope, will soon be utilized in the surgical settings for providing reliable results.

## Conclusions

Recent advances in smartphone technology have enabled the realization of cost-effective, portable medical devices. In this study, we introduced an endoscope system using a smartphone as an imaging sensor and display suitable for the POC diagnostics and offering the unique advantages such as mobility and flexibility. Experimental results showed that our device could potentially provide sufficient imaging performance as a diagnostic tool in a wide range of nonclinical settings and ultimately, in some clinical settings. In particular, our device would be a very useful tool for health providers in low-resource settings and at remote locations with limited health care service.

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## Conflicts of Interest

The Coauthor Seon Young Ryu is one of the coinventors of head-mounted display device tested in the reported work. She worked as an engineering manager for Green Optics CO., Ltd, located in Cheongju. Green Optics CO., Ltd during her involvement with the project described in this paper. She was and is not a shareholder of the Green Optics and does not have financial interest to report.

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## Abbreviations

**ENT:** ear, nose, and throat
**FOV:** field-of-view
**HMD:** head-mounted display
**ISO:** International Organization of Standardization
**Lp/mm:** line pairs per millimeter
**MP:** megapixels
**POC:** point-of-care
**3D:** three-dimensional

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Original Paper

# Exploring the Association Between Self-Reported Asthma Impact and Fitbit-Derived Sleep Quality and Physical Activity Measures in Adolescents

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## Abstract

**Background:** Smart wearables such as the Fitbit wristband provide the opportunity to monitor patients more comprehensively, to track patients in a fashion that more closely follows the contours of their lives, and to derive a more complete dataset that enables precision medicine. However, the utility and efficacy of using wearable devices to monitor adolescent patients' asthma outcomes have not been established.

**Objective:** The objective of this study was to explore the association between self-reported sleep data, Fitbit sleep and physical activity data, and pediatric asthma impact (PAI).

**Methods:** We conducted an 8-week pilot study with 22 adolescent asthma patients to collect: (1) weekly or biweekly patient-reported data using the Patient-Reported Outcomes Measurement Information System (PROMIS) measures of PAI, sleep disturbance (SD), and sleep-related impairment (SRI) and (2) real-time Fitbit (ie, Fitbit Charge HR) data on physical activity (F-AM) and sleep quality (F-SQ). To explore the relationship among the self-reported and Fitbit measures, we computed weekly Pearson correlations among these variables of interest.

**Results:** We have shown that the Fitbit-derived sleep quality F-SQ measure has a moderate correlation with the PROMIS SD score (average $r$=−.31, $P$=.01) and a weak but significant correlation with the PROMIS PAI score (average $r$=−.18, $P$=.02). The Fitbit physical activity measure has a negligible correlation with PAI (average $r$=.04, $P$=.62).

**Conclusions:** Our findings support the potential of using wrist-worn devices to continuously monitor two important factors—physical activity and sleep—associated with patients' asthma outcomes and to develop a personalized asthma management platform.

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**KEYWORDS**

mobile health; mHealth; asthma; Fitbit; physical activity; sleep; sleep quality

## Introduction

Childhood morbidity due to asthma is particularly high among adolescent patients [1]. Adolescents have a higher prevalence of asthma compared with younger children [2]. They are at a higher risk for adverse health outcomes and are more likely to experience an exacerbation requiring hospitalization, intubation, or cardiopulmonary resuscitation [3]. The adolescent years are critically important for a person's physical and psychological development, which in turn requires sufficient sleep [4] and physical activity; however, both sleep and physical activity can be significantly constrained by asthma [5,6]. Conversely, asthma symptoms can worsen because of sleep problems [7] and strenuous exercise [8]. Nevertheless, regular physical activity is an important component of pediatric asthma management [9]. Physical activity has also been associated with a decrease in the severity of the symptoms of asthma and an improvement in the quality of life among children with asthma [10-12]. Therefore, unveiling the relationship between asthma, sleep patterns [13], and physical activity can potentially aid health care providers when counseling adolescents on asthma self-management, improving quality of life, and facilitating the discovery of more effective interventions for asthma.

Prior studies have reported a relationship between asthma and sleep among adolescents [14,15]. Uncontrolled asthma is associated with impaired nighttime sleep, daytime sleepiness, and health-related quality of life. Compared with healthy children, children with asthma are more likely to report sleep problems due to greater increase in airway resistance during nighttime sleep, which in turn leads to exacerbated asthma symptoms such as coughing and wheezing [16]. However, there are substantial barriers to examining the relationship between asthma and sleep patterns. Such studies usually need to be carried out in a special environment (for capturing sleep patterns [17-20]) and over a relatively long time (to accumulate enough data), which incurs high costs. Specialized and expensive equipment is typically needed to collect sleep pattern data, and participants usually have to stay in an unfamiliar sleep study facility [19,20].

However, the advent of smart wearables (eg, wrist-worn mobile devices such as the Fitbit wristband) opens a new horizon for continuous, unobtrusive, and cost-effective data collection [21-24]. The concept is compelling: smart wearables provide the opportunity to monitor patients more comprehensively, to track patients in a fashion that more closely follows the contours of their lives, and to derive a more complete dataset that enables precision medicine [25]. Although multipurpose wrist-worn devices present some limits with respect to accuracy, they are reasonable options for near-continuous data monitoring [26]. It has been reported that these devices have acceptable reliability and validity when used to measure physical activity and sleep in adults [27]. Specifically, for physical activity tracking, it has been reported [28-30] that these devices have acceptable accuracy at various speeds, attachment sites, and in both lab and real-world settings, particularly for step counting. More recently, it was shown that age and pathological gait changes might affect the accuracy of step counting devices. However, this does not apply to our specific study [31]. By wearing wrist-worn devices, long-term motion and biological data that patients generate in their living environment can be collected through device built-in sensors (eg, accelerometer, gyroscope, and heart rate sensors) in a user-transparent manner. Furthermore, there is a growing interest in using sensor-based observations through smartphones and wearables as a novel way to collect health information, accelerated as a part of the precision medicine initiative [25]. Technologies such as wearables will provide new opportunities for patient engagement and care delivery that will generate precision interventions, which will ultimately enhance clinical outcomes and reduce health care costs [32].

Although asthma is a serious health problem among adolescents, the utility and efficacy of using wearable devices to monitor adolescent patients' asthma outcomes have not been established. In this pilot study, we aimed to explore the association among patient-reported sleep data, Fitbit sleep and physical activity data, and pediatric asthma outcomes. We collected patient-reported outcomes (PROs) on pediatric asthma impact (PAI), sleep disturbance (SD), and sleep-related impairment (SRI) [33,34], as well as Fitbit-derived sleep and physical activity measures from 22 adolescents with asthma. The goals of the study were to explore the association between (1) asthma outcomes and Fitbit-derived sleep and physical activity measures and (2) patient-reported sleep measures and Fitbit-derived sleep measures.

## Methods

### Study Design

We conducted an 8-week pilot study (trial registration number NCT02556567) and recruited a convenience sample of adolescent asthma patients according to their medical chart from the Arkansas Children's Hospital subspecialty asthma clinics. Patients were screened for eligibility after their outpatient visits, where the physician discussed the study briefly with the patient and the caregiver, and a research nurse carried out the rest of the recruitment activities. Inclusion criteria required the participants to: (1) be in the age group of 14 to 17 years with physician-diagnosed persistent asthma and (2) to have access to a smartphone or a computer that was compatible with the Fitbit app. Informed consent and assent were obtained from all participants and their caregivers, respectively, during the baseline visit. Figure 1 shows the cumulative screening and enrollment summary for the study. Of the 23 enrolled participants, 1 participant withdrew from the study at the beginning of the study, and 2 did not complete all 8 weeks of the study procedures. Our data analysis excluded the participant who withdrew, resulting in 22 adolescents in our data analysis. There were 17 participants with complete data (8 weeks). We also included participants with partial data where 2 participants had 7 weeks complete, one with 6 weeks, one with 4 weeks, and one with 3 weeks.

During the baseline visit, all participants had their height and weight measured and completed a baseline survey to collect demographic data (eg, gender, race, and ethnicity), socioeconomic status (eg, household income), insurance information, baseline level of asthma control according to the

national guidelines, medication history, and baseline PROs (ie, PAI, SD, and SRI [33]). The caregivers of the participants were also present during the baseline visit and helped answer some of the questions (eg, income). The research nurse also showed the participants how to navigate through the Fitbit user interface during the baseline visit. During the study, all participants were given a Fitbit Charge HR wristband (Figure 2) and instructed to wear the wristband at all times (24 hours every day) during the 8-week study period, except for when the device was being charged. Participants' biological data were collected in real time and passively without user interactions with the Fitbit devices and then uploaded to the Fitbit/Fitabase servers [35]. In addition, participants were asked to complete Web-based surveys to collect the PROs. The asthma impact survey was administered weekly and the two sleep-related surveys were administered biweekly to avoid survey fatigue. As an incentive for participation, participants received US $10 for completion of weekly surveys and synchronization of Fitbit data. Study procedures were approved by the institutional review board of the University of Arkansas for Medical Sciences.

**Figure 1.** Cumulative screening and enrollment summary.

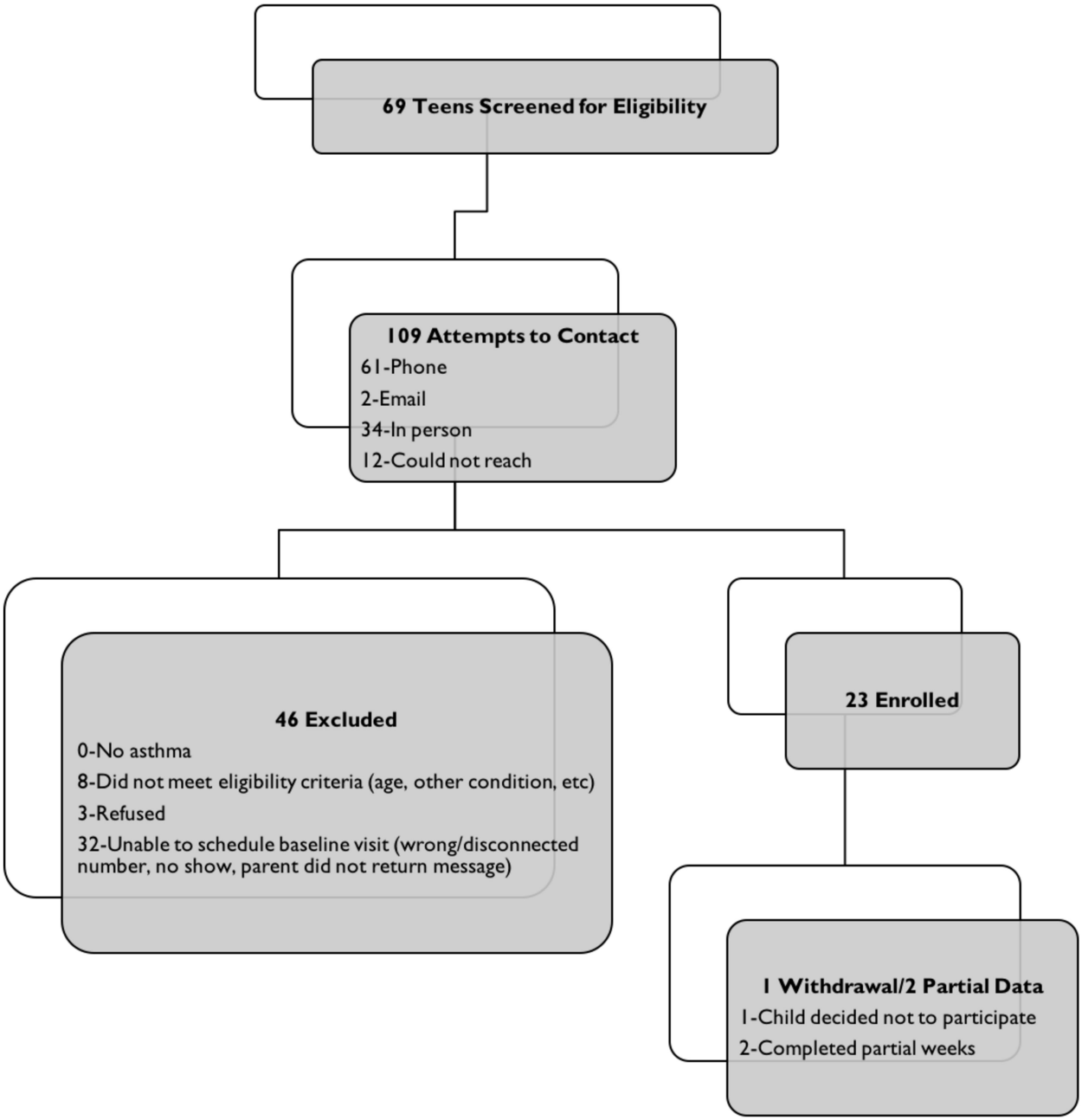


**Figure 2.** Fitbit Charge HR wristband.


## Measures

### Fitbit Measures

The Fitbit Charge HR wristband can collect a wide range of physical and biological data, including physical activity (eg, calories burned, steps, distance, and heart rate) and sleep data (eg, time in bed and awakenings count). We used two summary measures derived from Fitbit data, Active Minutes (F-AM) and Sleep Quality (F-SQ) score. F-AM was defined as daily minutes of moderate and vigorous activity, and F-SQ score was defined as the ratio of minutes asleep to minutes in bed.

### Patient-Reported Outcomes

PROs were collected using the Patient-Reported Outcomes Measurement Information System (PROMIS) instruments [33,36], which included pediatric asthma impact (PAI; short form 8a), sleep disturbance (SD; short form 6a), and sleep-related impairment (SRI; short form 8a). These instruments were previously validated among adolescents [37,38].

The PAI short form 8a contains 8 questions asking whether the patients had asthma-specific symptoms such as cough, wheeze, shortness of breath, and avoidance of triggers in the past 7 days. The responses are on an ordinal scale going from Never (0 point) to Almost Always (4 points). A higher PAI score means worse asthma outcomes. Prior studies have reported good Cronbach alpha (>.8) for the PAI short form 8a [39].

The SD short form 6a contains 6 questions that evaluate self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep in the past 7 days. For example, one question asks “I had difficulty falling asleep...,” and the responses include the following: Not at all (5 points), A little bit, Somewhat, Quite a bit, and Very much (1 point). A higher SD score means less sleep disturbance. The Cronbach alpha for the SD short form 6a has been reported to be good (>.8; [40-43]).

The SRI short form 8a contains 8 questions that evaluate self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness in the past 7 days. For example, one question asks “I had a hard time getting things done because I was sleepy…,” and the responses include the following: Not at all (5 points), A little bit, Somewhat, Quite a bit, and Very much (1 point). A higher SRI score means less sleep-related impairment. Prior studies have also reported good Cronbach alpha (>.8) for the SRI short form 8a [41-43].

All PROMIS measures are reported on a T-score scale (mean= 50, SD=10). This allows us to easily compare various PROMIS scores across scales, even if the original scores do not have identical variances or are measured on different scales [33]. For each instrument, we computed the raw scores by adding up scores from each question and converted the raw scores to T-scores for data analysis. All instruments are presented in Multimedia Appendices 1-.

### Statistical Analysis

We first calculated descriptive statistics to summarize the participants' characteristics. We then computed weekly Spearman rank-order correlations among the variables of interest, which included pediatric asthma outcome PAI, Fitbit-derived measures F-SQ and F-AM, and self-reported sleep measures SD and SRI. We used the following guidelines for interpreting correlation coefficients: <.3=poor, .3 to .7=moderate, and >.7=excellent. All analyses were conducted with Statistical Analysis Software (SAS) version 9.4 (SAS Institute Inc).

## Results

The participants' characteristics are summarized in Table 1. The average age of our participants was 15.5 years (SD 1.1). There were 12 boys (55%) and 10 girls (45%). The race distributions of the participants were 12 whites (55%), 7 African Americans (32%), and 3 other races (13%). The majority (64%; 14 participants) of the participants were covered by state insurance, 7 (32%) were covered by private insurance, and 1 (4%) was uninsured. The annual household income was below $60,000 for most of the participants.

**Table 1.** Participants' characteristics.

| Characteristic | | n (%) or mean (SD) (N=22) |
|---|---|---|
| **Age in years, mean (SD)** | | 15.5 (1.1) |
| **Sex, n (%)** | | |
| | Female | 10 (45) |
| | Male | 12 (55) |
| **Race, n (%)** | | |
| | White | 12 (55) |
| | Black | 7 (32) |
| | Other | 3 (13) |
| **Insurance, n (%)** | | |
| | Private | 7 (32) |
| | State | 14 (64) |
| | Uninsured | 1 (4) |
| **Household income in US dollars, n (%)** | | |
| | <15,000 | 2 (9) |
| | 15,000-60,000 | 10 (45) |
| | >60,000 | 5 (23) |
| | Missing | 5 (23) |

The variables of interest are summarized in Table 2 and to visually examine how the variables of interest changed across the study period, we plotted the Fitbit SQ score with the PAI score (Figure 3) and with the self-reported SD and SRI scores (Figure 4) across the 8 weeks of our study. As seen in Figure 3, the average weekly PAI score varied between 44.12 and 48.70, with an average of 45.44. The average daily Fitbit SQ score varied between 0.85 and 0.94, with an average of 0.89. As seen in Figure 4, the biweekly self-reported SD score varied between 47.19 and 52.33, with an average of 49.24. The biweekly self-reported SRI score varied between 47.76 and 53.64, with an average of 50.62.

**Table 2.** Patient-reported outcomes and Fitbit measure statistics.

| Measure | Median | Mean | Standard deviation | Skewness | Kurtosis |
|---|---|---|---|---|---|
| PAI[a] | 46.50 | 44.99 | 10.45 | 0.15 | −1.12 |
| SD[b] | 49.00 | 49.49 | 9.27 | 0.03 | −0.36 |
| SRI[c] | 50.30 | 49.93 | 11.27 | 0.07 | −0.97 |
| F-AM[d] | 0.00 | 10.59 | 21.59 | 4.08 | 24.21 |
| F-SQ[e] | 0.93 | 0.90 | 0.12 | −2.69 | 6.37 |

[a]PAI: pediatric asthma impact.

[b]SD: sleep disturbance.

[c]SRI: sleep-related impairment.

[d]F-AM: Fitbit-Active Minutes.

[e]F-SQ: Fitbit-Sleep Quality.

We summarized the correlations among the variables of interest by week in Table 3. Our results showed that across the study period, higher PAI score was weakly associated with a lower SQ score. The weekly F-SQ –PAI correlation ranged from −.48 to .19, with the average being −.18. On the other hand, the Fitbit physical activity measure (F-AM) did not have a significant correlation with PAI, where the weekly F-AM –PAI correlation ranged from a weak negative association to moderate positive association (−.26 to .39), suggesting a potentially complex relationship between these two variables. There was a moderate to strong positive association between PAI and the two sleep measures, SD and SRI, with the average weekly correlation being .71 and .64 for PAI –SD and PAI –SRI, respectively. Finally, we observed that as F-SQ increased, there was a moderate decrease in the PRO sleep disturbance (average weekly correlation=−.31).

**Table 3.** Spearman rank-order correlations among the variables of interests across the study period.

| Variable Pairs | Week (*P* value) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Average |
| PAI[a]–F-SQ[b] | .04 (.88) | −.48 (.02) | −.57 (.01) | −.07 (.78) | −.07 (.77) | .19 (.41) | −.17 (.51) | −.21 (.44) | −.18 (.02) |
| PAI–F-AM[c] | −.09 (.70) | −.01 (.97) | .09 (.70) | .04 (.86) | −.26 (.28) | −.02 (.94) | .39 (.09) | .10 (.69) | .04 (.62) |
| PAI–SD[d] | | .75 (<.01) | | .62 (<.01) | | .71 (<.01) | | .75 (<.01) | .71 (<.01) |
| PAI–SRI[e] | | .53 (.01) | | .74 (<.01) | | .67 (<.01) | | .59 (<.01) | .64 (<.01) |
| F-SQ–SD | | −.63 (<.01) | | −.09 (.72) | | −.16 (.49) | | −.37 (.17) | −.31 (.01) |
| F-SQ–SRI | | −.32 (.15) | | −.09 (.70) | | .08 (.73) | | −.05 (.86) | −.08 (.50) |

[a]PAI: pediatric asthma impact.

[b]F-SQ: Fitbit-Sleep Quality.

[c]F-AM: Fitbit-Active Minutes.

[d]SD: sleep disturbance.

[e]SRI: sleep-related impairment.

**Figure 3.** Fitbit sleep quality and pediatric asthma impact.

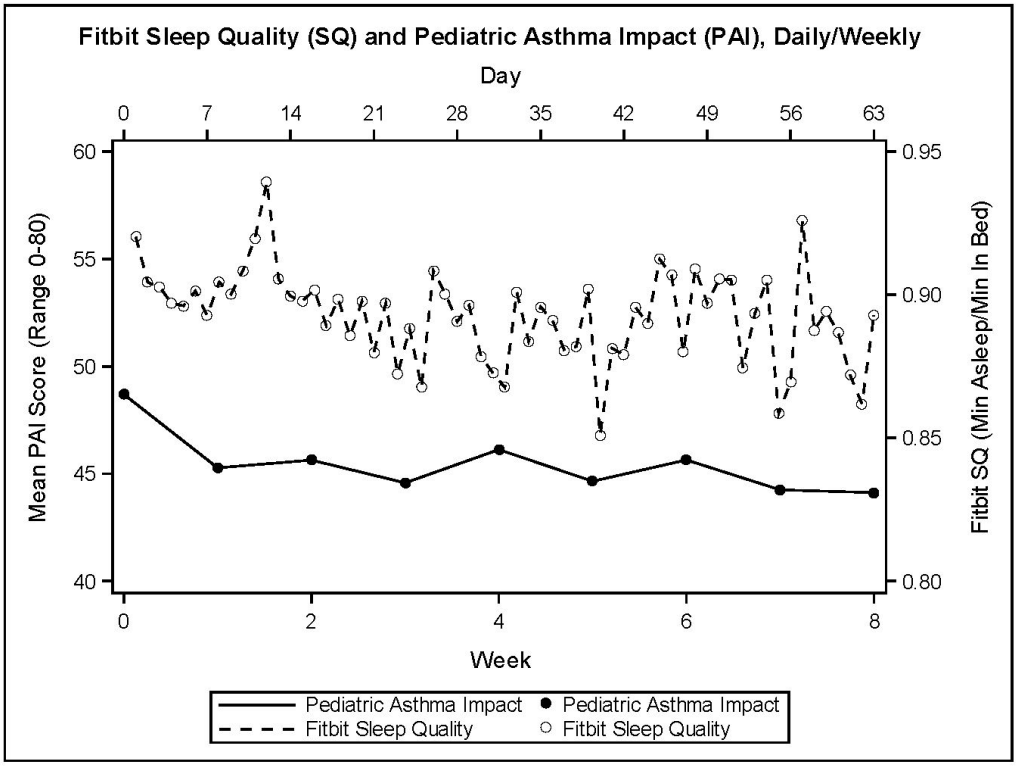
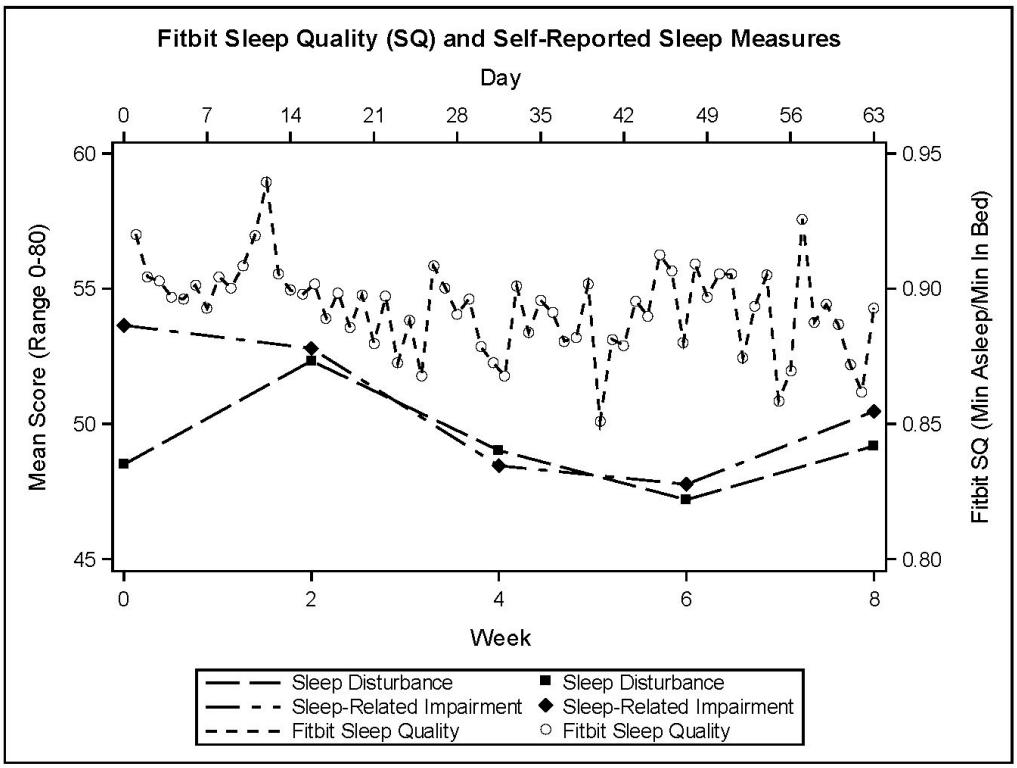



**Figure 4.** Fitbit sleep quality and self-reported sleep measures.



## Discussion

### Principal Findings

In this pilot study, we have shown that the Fitbit-derived sleep quality measure F-SQ has a weak but significant inverse association with the PROMIS PAI score. In addition, F-SQ has a moderate inverse correlation with the PROMIS SD measure. Overall, our study suggests that there is a potential association between Fitbit measures or other wrist-worn activity tracking devices and asthma outcomes. Further studies, with more power, would be able to determine whether Fitbit measures could predict the symptoms of pediatric asthma.

### Fitbit Sleep Quality and PROMIS Sleep Measures

The Fitbit-derived F-SQ score has a moderate negative correlation with the SD measure but no correlation with the SRI measure. One potential reason is that the F-SQ score is the ratio of minutes asleep over minutes spent in bed, which is an indicator of sleep quality. Therefore, it is conceptually more similar to the SD measure, which evaluates perceived difficulties with getting to sleep or staying asleep. On the other hand, the SRI measure is not a measure of sleep quality. SRI is concerned with functional impairments, such as alertness, sleepiness, and tiredness, associated with sleep problems during usual waking hours.

### Fitbit Physical Activity and Asthma Impact

The Fitbit physical activity measure was not associated with the asthma impact despite what the existing literature suggests (ie, physical activity is associated with asthma outcomes [10,12]). There are several potential reasons that we did not find such association, which include the following: (1) our pilot study was not sufficiently powered and (2) the relationship between physical activity and asthma is more complex. For example, to capture exercise-induced bronchoconstriction, also called exercise-induced asthma, asthmatic events will likely need to be captured in real time in addition to weekly patient-reported asthma impact. Furthermore, the effects of physical activity on patients' general asthma outcomes are long term and may not be observed in an 8-week study. In short, more studies and data are needed to further explore the relationship between Fitbit data and patient-reported measures.

The success of the pilot study demonstrates the utility of passively collected sensory data for monitoring factors related to asthma, and that ultimately, these data could be potentially incorporated into a disease management tool. In our previous study [44], we pilot-tested a smartphone-—based mobile asthma action plans (mAAP) app and showed its acceptance among adolescents. Incorporating models for detecting asthma triggers into the mAAP app will allow us to build a mobile health (mHealth) platform that can give us a more complete picture of patient's disease states and then provide them with real-time personalized asthma management strategies. Nevertheless, to achieve this goal, we shall further explore sources that would have data on other asthma triggers beyond physical activity and sleep. For example, allergens and irritants in the air are common asthma triggers that can be measured with particle sensors.

### Limitations

Due to the pilot nature of this project, our study has distinct limitations. First, with only 22 participants, the study was not adequately powered for complex statistical analyses. Therefore, influences from covariates, such as gender and race, on the outcome-predictor relationships were not considered. Second, the study participants were recruited as a convenience sample rather than as a random sample. It is therefore unknown whether the results from this study generalize well to other populations. Third, the PAI survey has a question about trouble sleeping at night that could explain the correlations between the PAI measure and our sleep measures. Last, the accuracy of using wearable devices for long-term monitoring of physical activity and sleep is suboptimal, and device dependent [26]. Future studies are warranted to further explore the use of different wearable devices to replicate our findings using Fitbit.

### Conclusions

Wrist-worn activity tracking devices such as Fitbit are associated with pediatric asthma PROs, and with further research, have the potential to closely monitor patients' biological data and to help manage chronic diseases where sleep quality and physical activity are factors. Our long-term goal is to develop an mHealth platform with a wrist-worn device that can collect sensory data related to asthma triggers and create models that predict patients' asthma outcomes with these factors, thereby providing personalized asthma management strategies to patients in real time.

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### Authors' Contributions

JB, YG, MX, and TP designed the study protocol. YG and AP performed the statistical analysis. MX and IW helped with the study and data management. RB and TP carried out the subject recruitment. JB, YG, DZ, and TP wrote the manuscript. All authors have provided feedback and edited the manuscript.

### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Pediatric Asthma Impact short form 8a.

[PNG File, 113KB - mhealth_v5i7e105_app1.png ]

### Multimedia Appendix 2

Sleep Disturbance short form 6a.

[PNG File, 40KB - mhealth_v5i7e105_app2.png ]

### Multimedia Appendix 3

Sleep Related Impairment short form 8a.

[PNG File, 51KB - mhealth_v5i7e105_app3.png ]

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## Abbreviations

**F-AM:** Fitbit-Active Minutes
**F-SQ:** Fitbit-Sleep Quality
**mAAP:** mobile asthma action plans
**mHealth:** mobile health
**PAI:** pediatric asthma impact
**PRO:** patient-reported outcome
**PROMIS:** Patient-Reported Outcomes Measurement Information System
**SAS:** Statistical Analysis Software
**SD:** sleep disturbance
**SRI:** sleep-related impairment

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Original Paper

# Patients' Perspective on Participation in Care With or Without the Support of a Smartphone App During Radiotherapy for Prostate Cancer: Qualitative Study

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## Abstract

**Background:** Patients with prostate cancer are often cared for as outpatients during radiotherapy, which can be an aggravating circumstance for patient participation. There is a need to evaluate whether an interactive smartphone app could enable participation in care, specifically during treatment for prostate cancer. The interactive app (Interaktor) used in this study is developed in codesign with patients and health care professionals; it includes daily reports of symptoms, a risk assessment model, evidence-based self-care advice, along with the provision of immediate access to clinicians.

**Objective:** The aim of this study was to explore how patients with prostate cancer perceived their participation with or without the support of the smartphone app during radiotherapy.

**Methods:** A total of 28 prostate cancer patients receiving adjuvant radiotherapy were interviewed about their perceived participation in their own care. All the patients interviewed in this study participated in an intervention study where the control group received standard care that comprised having access to a contact nurse to turn to with any concerns during their treatment. In addition to standard care, the patients in the intervention group received the app downloaded in a smartphone. The patients' age ranged between 57 and 77 years; 17 patients used the smartphone app. The interviews were analyzed with directed qualitative content analysis.

**Results:** The four dimensions of patient participation, which include mutual participation, fight for participation, requirement for participation, and participation in getting basic needs satisfied, were confirmed as valid perspectives in the interviews with the patients with prostate cancer, irrespective of whether they used the smartphone app. However, the patients who had used the smartphone app described it as a facilitating factor, especially for mutual participation.

**Conclusions:** Using innovative ways to communicate with patients, such as an interactive app for symptom management with contact with health care in real time, can successfully help achieve increased patient participation in care.

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**KEYWORDS**

patient participation; prostate cancer; radiotherapy; smartphone

## Introduction

Advancements in the area of mobile smart devices (phones and tablets) have dramatically influenced the role of technology in health care [1,2]. There is now a range of various mobile apps available that differ in many respects, including their level of interactivity, evidence-based content, and role in the health care process [1,2]. The future challenge is to improve remote monitoring and to embed the technology in the human-executed processes [1]. Many interactive apps focus on self-management activities carried out by patients during the cancer care treatment period, but only a few address supportive care for cancer after the treatment is completed [1,3].

It is emphasized that care and support for patients affected by cancer should focus on recovery, personalized care-planning, support for self-care, early recognition of signs and symptoms for further disease, and routine use of patient-reported outcome measures (PROM) [4]. A patient-reported outcome is defined as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" [5,6]. In a review, studies indicate that routine clinical use of PROM may improve early identification and recognition of symptoms, as well as the communication between patients and health care staff [7]. The incorporation of PROM into clinical practice may support patients in becoming active in self-care and may enhance early identification of appropriate interventions [7-9].

The concept of self-care is described as a central part of patient participation [10], and over the past 10 years, there has been a shift in health care delivery with a general move toward supporting patients to engage in all forms of self-care. Furthermore, patients are expected to take increased responsibility for and participate in their own care [11], although different patients want different levels of participation [12]. Most patients express that they want to participate in their care process, but around one-third want to stay passive [12]. However, most patients do not achieve their desired role [12].

For men diagnosed with prostate cancer, patient participation has been explored in situations related to the choice of medical treatment [13-15], and the results show that most men prefer active involvement in their prostate cancer treatment decisions. Studies about self-care during treatment are scarce, but patients perceive that waiting for health care staff to make contact and being given incomplete information about symptoms and self-care is distressing [16]. During treatment, patients affected by prostate cancer are often cared for as outpatients, which places further demands on both the patients, by expecting them to be experts on their own health, and on the health care staff, in terms of providing a suitable context for the planning, provision, and assessment of individualized care [17].

Therefore, in collaboration with Health Navigator, a company that specializes in new innovative care solutions, we developed an interactive app (Interaktor) for use in smartphones or tablets for the reporting and managing of symptoms during radiotherapy for patients with prostate cancer [16,18]. The app includes PROM in that the symptom assessment is completed by the patient with immediate transmission of the results to a designated health care professional and using a risk assessment model based on symptom occurrence and frequency, the app sends alerts by text messages (short message service) if any symptom assessments are of concern. Furthermore, the app offers access to evidence-based self-care advice related to the reported symptoms, links to relevant websites for more information, and provides access to the symptom history presented in graphs over time as well as an open comment section. The content was developed in a process of codesign with patients and staff and with support from the literature [16], and the app has been found to be feasible and useful [18]. Previous research has shown that to achieve high uptake and interactivity with technology, it is important to involve patients in the development process to ensure that the content is relevant and usable to them [19,20]. In addition to receiving standard care, the patients submit daily reports throughout the treatment period and over the following 3 weeks [16,18]. When testing interventions that include mobile technologies, it is important to evaluate their use from the patient's perspective [21,22]. In our research program, we hypothesize that the use of mobile technology may contribute to early detection of symptoms and side effects within cancer care, thereby aiding prompt management and increasing patients' perceptions of participatory care. Therefore, the aim of this study was to explore how patients affected by prostate cancer perceive patient participation during radiotherapy treatment with or without the support of the mobile app (Interaktor).

## Methods

### Design

This study is a part of an experimental study conducted at two university hospitals, which included patients who had been diagnosed with prostate cancer. Ethical approval was obtained from the Regional Ethical Review Board of Uppsala, Sweden (reference number 2011/256). The intervention group that used the app, Interaktor, during radiotherapy treatment, was compared with a historical control group with data collected in the immediate period before the intervention implementation [23]. The patients who used the app during radiotherapy reported less symptom burden than those who did not use the app [23]. A descriptive qualitative design with a directed approach [24] was chosen to increase the understanding of the patients' perceptions of participation in care and whether their perception was related to using the app or not. The applied methodological theoretical foundation included an inductive approach for data collection and a deductive approach for analyzing the interviews; the theoretical underpinnings of the qualitative descriptive research design were drawn from the general tenets of naturalistic inquiry [25].

### Participants

The participants were patients diagnosed with prostate cancer receiving adjuvant radiotherapy (external and internal radiation) for 8 to 11 weeks at two university hospitals (one rural and one urban) in Sweden. A purposive sampling strategy from both groups was adopted by using a sampling frame [26] to capture a range of patient characteristics, including their age, area of residence, and whether they had used the smartphone app,

Interaktor, during the treatment period. Thirty-two patients were asked to partake in the interview study. Altogether, 28 patients agreed to participate, of which 17 patients used the smartphone app. Their age ranged between 57 and 77 years; 13 patients were living in rural/suburban areas and 15 in urban areas. Table 1 shows an overview of the sociodemographic and clinical characteristics of the participants in the study.

**Table 1.** Sociodemographic and clinical characteristics for patients with prostate cancer (N=28) included in the smartphone app and standard care groups.

| Variable | Smartphone app group (n=17) | Standard care group (n=11) |
|---|---|---|
| **Age, in years** | | |
| Mean (SD) | 70 (4.0) | 70 (5.4) |
| Median (range) | 71 (63-76) | 71 (57-76) |
| **Living situation, n (%)** | | |
| Married/living with partner | 12 (70) | 9 (82) |
| Living alone | 3 (18) | 2 (18) |
| Other | 2 (12) | 0 |
| **Area of living, n (%)** | | |
| Rural/Suburban | 9 (53) | 4 (36) |
| Urban | 8 (47) | 7 (64) |
| **Educational level, n (%)** | | |
| Junior compulsory | 2 (12) | 6 (55) |
| Senior high school | 6 (35) | 2 (18) |
| Postgraduate/University | 8 (47) | 2 (18) |
| Missing | 1 | 1 |
| **Occupation, n (%)** | | |
| Working | 2 (12) | 1 (9) |
| Retired | 12 (72) | 10 (91) |
| Other | 2 (12) | 0 |
| Missing | 1 | 0 |
| **Clinical T stage, n (%)** | | |
| 1 | 4 (24) | 3 (27) |
| 2 | 7 (41) | 6 (55) |
| 3 | 3 (18) | 2 (18) |
| Missing | 3 | 0 |
| **Gleason, n (%)** | | |
| 6 | 1 (6) | 2 (18) |
| 7 | 6 (35) | 5 (46) |
| 8 | 4 (24) | 3 (27) |
| 9 | 6 (35) | 1 (9) |
| **Type of radiotherapy treatment, n (%)** | | |
| External beam radiotherapy (EBRT) | 6 (35) | 2 (18) |
| Brachytherapy combined with EBRT | 11 (65) | 9 (82) |
| **Additional treatment, n (%)** | | |
| Adjuvant hormonal therapy[a] | 12 (71) | 7 (64) |

[a]All patients received radiotherapy, and a majority received hormonal therapy in addition to radiotherapy.

### Study Procedure

Standard care during radiotherapy comprises regular contact with therapy staff and access to a contact nurse regarding any treatment-related concerns. No regular medical support or standard procedures are included in the care during the treatment period. The patients in the intervention group received standard care and were provided with a smartphone with the app, Interaktor, installed and instructed to answer the symptom assessment (frequency and distress of 14 symptoms) daily, during office hours on weekdays during the radiotherapy period, and 3 weeks after. The patients were given thorough instructions by the researchers initially on how to use the smartphone app (assessment, connection to self-care advice (n=12), and graphs). In addition, they were given a written checklist, including a phone number for technical support. The patients were given an individual log-in and personal identification number code to get access to the app. They were also informed that in case of an alert, a study-specific nurse would call them during office hours and that acute problems occurring at other time points had to be handled according to the standard procedure of the oncological clinic. The patient's self-report was directly sent via the secure server accessible from a Web interface for the study-specific nurses at the hospitals. The patients in the control groups received standard care only.

### Data Collection

To gain an understanding of the patients' perceptions of their participation in care during their treatment, open-ended interviews [27] were conducted approximately 5 weeks after completion of radiotherapy (ie, 2 weeks after their final report was made in the app for the patients who had used the app). Researchers with previous experience of conducting patient interviews carried out the interviews. The same question was posed to all participants: *"Can you tell me about the time when you went for your treatments—how did you perceive your participation in the care during the treatment period?"* They were encouraged to speak as freely as possible, and if the word "participation" was difficult for them to understand, it was explained using synonyms such as "involvement" and "partaking." Follow-up prompts such as *"Please tell me more about that"* or *"Can you give an example?"* were included in the interview when needed.

The interviews were all audio-recorded with the participants' permission; they lasted between 30 and 60 min, and according to patients' preferences, were held either at their homes, in the hospital, or in a private room at the university.

### Data Analysis

The analyses were guided by the principles proposed by Hsieh and Shannon [24] and assumed a qualitative directed approach. An analyzing scheme based on the dimensions of patient participation from the patients' and health care providers' perspectives, developed for use in qualitative studies by Frank et al [28,29], was chosen. The four dimensions employed were: *Mutual participation*—which describes when patients have requirements, for example, time and respect, and when the patient encounters health care staff in a mutually shared dialogue; *Fight for participation*—which represents the patients' own struggle for participation; *Requirement for participation*—which includes the necessary elements for gaining mutual participation, for example, time and information; and *Participation in getting basic needs satisfied*—which includes participation in terms of getting basic needs such as nutrition, and pain and worry, satisfied without requests from the patient [30,31].

The interviews were first transcribed verbatim, and all the transcripts were read repeatedly to obtain a sense of the data as a whole. Next, the interviews with the patients in the intervention group and the interviews with the patients in the control group were analyzed separately from the authors in pairs of 2 to manage the extensive dataset and to increase trustworthiness. The authors individually divided the text into meaning units in agreement with the study's purpose. The meaning units were then discussed between all of the authors, condensed, and coded carefully, while keeping the essence of the statements made by the patients. In the next step, the codes were sorted into groups based on the analyzing scheme outlined by Frank et al [30,31], but allowances were also made for the inclusion of emergent dimensions that might reflect patient participation. All of the authors critically reviewed each step in the analytical process to achieve trustworthiness. Selected quotations are presented to illustrate the findings. Microsoft Word was used as a tool to organize data throughout the entire analysis process.

## Results

The descriptions of participation among the patients are presented on the basis of the four dimensions of patient participation, with no additional dimension of patient participation having emerged in the analysis of the interviews.

### Mutual Participation

In general, in both groups *Mutual participation* was described when both parties—patients and health care staff—were actively involved in a dialogue in some way. During an encounter, it was important that both parties listened and asked questions. When the patients actively contacted health care providers, the health care staff were described as having met the patients' needs.

*Mutual participation* was more prominent in the group of patients who had the smartphone app. They perceived participation when they reported symptoms in the app and when they received a response from the nurse if the symptom report generated an alert and had a dialogue about how to resolve the problem. The patients knew that there was a nurse present to receive their reports, and they did not have to search for the right health care staff to pose their questions to:

> *In those cases, the app is a point of contact. I know that there is someone who gets a notice on their screen that shows "he has a problem right now," and they get in touch. It's really good.* [Patient with smartphone app]

Some of the patients using the smartphone app described how they also appreciated having the opportunity to send a

personalized response via the app, and thereby communicate with the nurse and obtain a response:

> *I reported that I felt feverish and dizzy one day and then someone called me up. I talked to the nurse and she confirmed that it wasn't anything serious.* [Patient with smartphone app]

The smartphone app was described as a security line and as a link to someone who was caring for you and being in control of the situation:

> *The smartphone application feels very secure for me and if you have a problem, then you can indicate that and a nurse will call you...so it's like having health care staff in your house.* [Patient with smartphone app]

### Fight for Participation

In the category, *Fight for participation*, the patients' descriptions were similar in both groups. Patients described that they sometimes had to fight to get an answer regarding their concerns at the clinic. Some patients even described that they had to fight to get the care they found themselves in need of.

Patients described adopting different strategies for participating in their own care process. One strategy was to make phone calls to various health care units involved in the care process. Another strategy was to pursue one specific health care staff member using repeated attempts at participation. One patient described how he tried to get in contact with his contact nurse by calling her on the phone on repeated occasions. During the process of radiotherapy, patients received outpatient treatment, and they frequently had questions about new symptoms, medications, and a need for someone to talk to. Some patients experienced feeling frustrated that they had unanswered questions, and they did not know where to get answers. They expressed that the health care staff in the radiation department were only able to answer questions relating to the radiotherapy, but not other questions regarding their care and illness:

> *...yes, the health care staff who provide the radiotherapy aren't able to respond to any questions. They can't. If I ask them about my urinary problems, they tell me I have to go to the inpatient clinic. They don't have the knowledge, they're just doing their own thing.* [Patient with smartphone app]

Some patients without the smartphone app searched on the Internet to obtain more information to get answers to their questions:

> *...in the beginning I was on the Web and looked around trying to read a little here and there, but there is a huge amount to read, I just read a little bit from a few of all the web sites.* [Patient without smartphone app]

Another strategy they adopted was when patients perceived that relatives could provide some support in their struggle to become involved. If patients themselves were unable to hear and understand the information they received from the health care staff, relatives provided support in listening to conversations between the health care staff and the patient to gain information that may be relevant to their situation:

> *Luckily I had my wife with me, who provided another pair of ears to listen with, to pick up what I didn't hear or understand, and we helped each other to summarize. But it shouldn't be like that.* [Patient without smartphone app]

### Requirement for Participation

*Requirement for participation* was generally described in both groups in terms of receiving clear information in advance, both verbally and written. Patients perceived staff as being pleasant and having professional competence, especially in relation to continuity of health care. When the health care staff took the initiative to establish contact, the patients felt welcomed and respected.

The participants described how the health care staff had clearly described the radiotherapy routine so that the patients would know what would happen next. The patients perceived that they were involved in the process of radiotherapy by being given information in different forms. However, patients perceived that the health care staff set the conditions for when and how the participation would take place and in what form. The basis of contact was focused on the implementation of the aspects in the care process rather than on the patient as a person. The opportunity to have influence on when the radiotherapy appointment should take place was also expressed as a requirement for participation.

Patients using the smartphone app described the app as a device that enhanced their perceived participation. They expressed that the content of self-care advice and the weblinks in the app promoted their participation in their care:

> *Yes, that was really good [self-care advice]. In some circumstances you felt, "Should it really be like this?" There was information there, so that was good. I've used it and looked at it.* [Patient with smartphone app]

### Participation in Getting Basic Needs Satisfied

The patients described experiencing *Participation in getting basic needs satisfied* in similar ways in both groups. Patients gave examples of getting help as being given prescriptions for antibiotics or analgesia and also in being prescribed care and treatment for complications related to radiotherapy:

> *Well, I told the doctor that I found it difficult to pee. Then he prescribed a pill. And now am I taking it every night, and well, it is better now.* [Patient without smartphone app]

However, for the patients who had used the smartphone app, sometimes a medication prescription had been communicated by reporting symptoms in the app. On the following day, when they attended the clinic for their radiotherapy session, a prescription had already been prepared.

Basic needs were satisfied when the staff offered meals and helped to arrange transportation. Long-distance patients also received help with sorting out their accommodation at the patient hotel when they needed it.

Patients, who had received brachytherapy in addition to radiotherapy were cared for as inpatients during brachytherapy, described having severe urinary problems during that period, and how they spontaneously, without asking, received help with urinary catheterization or medication for urgency incontinence:

> *During night-time the urine flows into the bag and they're supposed to continuously check that the bag doesn't get full; they almost come tiptoeing on the floor with flashlights so as not to disturb the patients that are sleeping—very touching.* [Patient with smartphone app]

# Discussion

## Principal Findings

The findings indicate that the support of a smartphone app could enhance patients' experiences of being in close and continuous contact with health care services throughout the treatment process for prostate cancer. The patients who used the smartphone app, Interaktor, more commonly described experiences of participation as being mutual than those not using the app. These patients also described that they felt active, took their own initiatives, and had the opportunity to express their problems and concerns. Overall, patients in both groups described that their requirements for participation were met when they encountered health care staff that met them on equal terms in a pleasant and professional manner with high levels of competence. The patients with the smartphone app, Interaktor, experienced this also when reporting symptoms in the app and getting a call back from the nurse. This kind of passive receiving of care has also been described as participation in that the patients accept and accordingly resign themselves to receiving care without taking up the possibility to engage in active participation [32]. Participants in our study explicitly stated that they wished to participate on an individual basis. They also expressed that the health care staff in the radiotherapy departments responsible for the radiation treatment only responded to concerns in that specific area of care, and patients lacked a stable contact to help them navigate through the illness trajectory.

It is evident that patients cannot be treated as a homogenous group; they have different needs and wishes for participation [33,34]. Mutual participation could be developed within different forms of communication; for example, face-to-face, using a traditional telephone, or using the smartphone app for reporting and managing symptoms. If patient participation is to occur in the health care setting, there is a crucial need for establishing a relationship [10] built on the patient's perspective [28,35]. Patients who used the smartphone app, Interaktor, experienced a personal relationship with the nurse on the receiving end, despite having only brief contact. It is evident that patient participation does not require extended conversations as has also been previously described [36]; the patients who had the smartphone app also felt safe knowing that there was someone who would immediately respond to their needs.

It is important to highlight that factors such as age, gender, race/ethnicity, education, level of income, marital status, employment status, socioeconomic status, type and stage of cancer, and the patient's health status may influence role preferences in participation [34,37-39]. Other factors that inhibit participation include lack of time, poor interaction between different parties, lack of staff resources and high staff turnover [40]. However, it is not possible to predict which patients will prefer passive, active, or collaborative roles in participation in their care [13,41]. In care where patients perceive high participation in their own care, it has been shown that there is a higher quality of care, fewer mistakes, and a more positive image of the health care organization [42]. If the aim is to truly achieve patient participation, a more holistic and individualized approach is necessary for this to occur in the health care setting [43]. Moreover, applying patient participation in care prevents health care staff from imposing care that patients otherwise may not want [44]. Our app, Interaktor, seems to facilitate participatory care by engaging patients to report symptoms daily during treatment, regularly view their symptoms in graphs, and read self-care advice, and at the same time, by making patients feel secure that a nurse calls if a symptom report is alarming. Thus, the use of mobile health (mHealth) facilitates new ways to communicate with patients and may in the long run have an impact on how health care as a whole is organized [45].

## Limitations

A potential limitation of this study is the participants' understanding of the concept of patient participation. When performing the interviews, this aspect was taken into consideration; however, some of the participants had difficulties expressing the ways in which they had participated or not in their care, apart from the decision of whether to be treated with surgery or radiation therapy. Furthermore, using a predetermined analysis scheme may have influenced the interpretation of the data. The four dimensions of patient participation employed were originally developed in an emergency context, and there was a potential risk that the dimensions would not be applicable to patients undergoing treatment for prostate cancer. However, we found that the wordings for these dimensions were not expressed within a specific context and found the framework to be suitable for the patient group in this study. Also, the suitability of this framework is supported by studies performed in other contexts relating to patient participation that show similar results [35,36,40,46].

Another potential limitation is that the distribution of the educational level and Gleason scores were not the same among the interviewed patients in the smartphone app group and the standard care group. These factors were not taken under consideration in advance, and the patients were selected to achieve a variation in age, area of residence, and whether they had used the smartphone app, Interaktor, during the treatment period, which we assumed could have an impact on the patients' experience of participation during their radiotherapy treatment period. Earlier research has shown that lower education levels is associated with lower health literacy [47,48], which is an important parameter to consider in further development of mHealth.

## Conclusions

Innovative ways of communicating with prostate cancer patients in purposeful, short interactions, including the provision of

supportive care by giving advice using smartphone apps, can shape patients' perceived participation in their care.

## Conflicts of Interest

None declared.

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## Abbreviations

**EBRT:** external beam radiotherapy
**mHealth:** mobile health
**PROM:** patient-reported outcome measures

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Original Paper

# The Relationship Between Individual Characteristics and Interest in Using a Mobile Phone App for HIV Self-Management: Observational Cohort Study of People Living With HIV

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## Abstract

**Background:** The human immunodeficiency virus (HIV) continues to be a major health issue in the United States, and an estimated 1.2 million people in the United States are living with HIV. As part of Healthy People 2020, the Office of Disease Prevention and Health Promotion has targeted the persistent demographic and geographic disparities in HIV prevalence and management. Preliminary evidence suggests that mobile health technology (smartphone apps) may be a promising way to support HIV self-management among vulnerable populations of people living with HIV (PLWH) who lack access to appropriate health care services.

**Objective:** This study examines the association between individual characteristics of PLWH and level of interest in using a free mobile phone app for HIV self-management.

**Methods:** This study was conducted using cross-sectional survey data collected in the Florida Cohort Study between 2014 and 2016 (N=766). Associations between individual characteristics of PLWH and level of interest in using a free mobile phone app for HIV self-management were examined using bivariate analysis and logistic regression.

**Results:** Overall, 85.5% (655/766) of respondents were interested in using a free mobile phone app that supports HIV self-management. Participants expressed the highest interest in app functions that facilitate communication with health care providers (568/740, 76.8%) or help to identify relevant health care services (556/745 74.6%). Age (OR 0.959, 95% CI 0.936-0.982), education (OR 1.281, 95% CI 1.027-1.598) and disability or inability to work (OR 0.296, 95% CI 0.145-0.606) were all significantly associated with being interested in using a free mobile phone app for HIV self-management.

**Conclusions:** This study indicates that a majority of PLWH are interested in using a free mobile phone app to self-manage their condition. The findings can inform the development of mobile phone apps that support effective HIV self-management.

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**KEYWORDS**

telemedicine; self-care; HIV

## Introduction

Human immunodeficiency virus (HIV) continues to be a major health issue in the United States, and an estimated 1.2 million people are living with the disease [1]. Demographic and geographic disparities exist in the incidence and prevalence of HIV. HIV disproportionately affects African Americans and Hispanics/Latinos. African Americans represent only 12% of the US population but account for 44% of nationwide HIV diagnoses [1]. Similarly, Hispanics/Latinos represent 17% of the US population but account for an estimated 23% of new HIV diagnoses [1]. Moreover, Latinos are the fastest growing segment of the population in the United States. These disparities are even more pronounced in rural areas [2,3], particularly in the rural South [4]. The southern states in general account for 44% of all people living with HIV (PLWH) in the United States even though they represent only a third of the nation's overall population. In the southern states, African Americans account for 54% of new HIV diagnoses [4]. The state of Florida ranks second in the country for highest prevalence of HIV infection, with a rate of 594.8 cases per 100,000 people [5]. In Florida, those living outside of metropolitan areas account for 18.6% of all Florida residents living with HIV/AIDS, and African Americans represent 48% of PLWH in the state despite only representing 15% of the Florida population [5]. Therefore, there is a great need for better understanding demographic and geographic disparities in this area and how best to address them.

While HIV was previously a common fatal disease, the advent of antiretroviral therapy (ART) has transformed it to a chronic condition, allowing people to live long lives with HIV infection [6]. Successful HIV treatment depends on attending regular HIV care appointments and adherence to medications. In 2011, only 40% of persons living with HIV were engaged in medical care for their condition, 37% were prescribed ART, and only 30% were ART adherent to the point of achieving viral suppression [7]. For most patients, near perfect adherence is necessary to achieve individual and population health benefits of ART [8,9]. While strides have been made in the development of self-management programs and resources, the effectiveness and feasibility of such programs to improve outcomes and promote health has not been well established for PLWH [6,10].

Mobile health (mHealth) interventions have emerged as a promising tool to support disease self-management among PLWH from all demographic groups and geographic areas [11-16]. Ownership of smartphones and other mobile devices has grown rapidly with an estimated 68% of Americans and 62% of smartphone owners reporting using their devices to seek health information [17]. Mobile health technologies have shown promise in improving patient communication with their provider, providing education, and supporting management of various chronic conditions including diabetes, cardiovascular disease, and HIV [18-21]. However, for mHealth interventions to be effective, they need to be developed and optimized with the needs of PLWH in mind [22,23]. Because little is known about the level of interest in using phone apps for disease self-management among PLWH, this study aimed to examine (1) PLWH's preferences for functions in a free mobile phone app for HIV self-management and (2) associations between individual characteristics of PLWH and level of interest in using a free mobile phone app for HIV self-management.

## Methods

### Recruitment

This study was conducted using cross-sectional survey data collected in the Florida Cohort Study between 2014 and 2016. The Florida Cohort Study uses a convenience-sampling frame across several public health settings in Florida to recruit PLWH and collect information about demographic, behavioral, and social factors affecting health outcomes. Any person with HIV older than 18 years of age was eligible to participate in the study. Participants were recruited from a collaborative network of county health department and community clinics throughout Florida, including sites at Lake City, Gainesville, Tampa, Orlando, Sanford, Ft. Lauderdale, and Miami. After written informed consent was obtained, anonymous surveys were self-administered by cohort participants using Research Electronic Data Capture, a secure, Web-based app. Surveys were completed in English or Spanish depending on the preference of the participant. These surveys took approximately 30 to 45 minutes to complete and respondents were provided $25 in compensation in the form of a gift card. The University of Florida, Florida International University, and the Florida Department of Health institutional review boards approved the Florida Cohort Study.

### Data Collection

The dependent variable in this study was a binary measure we created that indicates interest in a free mobile phone app for HIV self-management. Level of interest in functions that support self-management using mobile technology was determined using the following set of survey questions: "If available and free, how often would you use a phone app to help you: (1) identify health services relevant to you, (2) track changes in your mood and emotions, (3) provide tips to improve your health, based on information about you, (4) manage alcohol and drug use behavior, (5) communicate with your doctor or clinic, (6) remember to take your medication, or (7) engage in social networking with other people with similar health conditions as you?" Possible answers for these 7 questions were never, rarely, about once a week, a few times a week, and daily. Interest was defined as any response choice other than never.

Individual characteristics that were analyzed included age and amount of schooling completed, which ranged from: (1) elementary school or below, (2) some high school, (3) high school graduate or general education diploma (GED), (4) some college or technical/trade school, (5) college or trade school

graduate, or (6) graduate degree or professional degree after graduating college. Additional individual characteristics that were analyzed included sex at birth, ethnicity, race, being in a long-term partnership, sexual orientation, and employment status. Ethnicity was categorized as being Hispanic versus not Hispanic based on whether the respondent self-reported being of Hispanic/Latino origin or descent. Race was categorized as white, Black/African American, or other race. The category of other race included Native American, Asian, multiracial, and other responses by participants. Being in a long-term partnership was a binary variable that indicated marriage or living with a long-term partner versus the state of being divorced, widowed, separated, or never married/single. Sexual orientation was categorized as heterosexual, gay or lesbian, and other sexual orientation. The other sexual orientation category included options of bisexual, asexual, and other. Employment status was determined by asking respondents to select from types of current employment: employed for wages, self-employed, out of work for more than 1 year, out of work for less than 1 year, homemaker, student, retired, or unable to work/disabled. These employment statuses were collapsed into 3 categories: employed, unemployed, and unable to work/disabled. The employed category included all respondents that selected employed for wages or self-employed. The unemployed category included all of the remaining respondents except for those who were unable to work/disabled.

### Statistical Analysis

At the time of the analysis, we included all 766 participants in the Florida Cohort Study. Statistical analysis was performed using SAS software, version 9.4 (SAS Institute Inc). Univariate descriptive statistics were calculated including the mean, median, and range for continuous variables and counts and percentages for categorical variables. All variables were examined as categorical variables to determine bivariate relationships using chi-square analysis. Individual characteristics with $P<.25$ were included in the multivariable model [24]. Sex at birth was not included in the model ($P=.49$). After the bivariate relationships were determined, we evaluated whether age and amount of schooling completed could be included in the multivariable analysis as continuous variables. Specifically, to evaluate the linearity of age and amount of schooling completed, a Box-Tidwell approach was used by employing the natural log of the variables [25]. Based on the results of the Box-Tidwell approach, both age and amount of schooling completed were treated as linear continuous variables. For the multivariable analysis, logistic regression was used to calculate adjusted odds ratios (ORs) and the corresponding 95% confidence intervals.

## Results

The individual characteristics of respondents in the sample are presented in Table 1. A majority of the respondents were male (65.8%), with an average age of 46 years. Only 15.2% of the sample was of Hispanic ethnicity. African-Americans accounted for 59.1% of the sample, followed by whites, who accounted for 31.8% of the sample. On average, participants reported completing high school or obtaining a general education diploma. Nearly 8 out of every 10 participants indicated that they were not in a relationship. A majority (52.7%) of the respondents were heterosexual while slightly more than one-third of the sample (35.2%) were gay or lesbian. Almost half (48.7%) of the respondents were unable to work/disabled, 26.4% were unemployed, and 24.8% were employed at the time they completed the survey. Overall, 85.5% of respondents were interested in using a free mobile phone app that supports HIV self-management.

**Table 1.** Demographic characteristics (N=766).

| Demographic variable | N | Frequency, n (%) | Mean (SD) | Median | Range |
|---|---|---|---|---|---|
| **Sex at birth** | 766 | | | | |
| Male | | 504 (65.8) | | | |
| Female | | 262 (34.2) | | | |
| Age | 760 | | 45.99 (11.27) | 48.00 | 19.00-77.00 |
| **Ethnicity** | 765 | | | | |
| Hispanic | | 116 (15.2) | | | |
| Not Hispanic | | 649 (84.8) | | | |
| **Race** | 765 | | | | |
| Other race[a] | | 70 (9.2) | | | |
| Black/African American | | 452 (59.1) | | | |
| White | | 243 (31.8) | | | |
| Schooling completed[b] | 764 | | 3.14 (1.15) | 3.00 | 1.00-6.00 |
| **In a long-term partnership[c]** | 764 | | | | |
| Yes | | 155 (20.3) | | | |
| No | | 609 (79.7) | | | |
| **Sexual orientation** | 744 | | | | |
| Heterosexual | | 392 (52.7) | | | |
| Gay or lesbian | | 262 (35.2) | | | |
| Other sexual preference[d] | | 90 (12.1) | | | |
| **Employment status** | 749 | | | | |
| Employed | | 186 (24.8) | | | |
| Unable to work/disabled | | 365 (48.7) | | | |
| Unemployed | | 198 (26.4) | | | |

[a]Other race includes Native American, Asian, multiracial, and other.

[b]School completed ranges from 1-6: 1=elementary school or below, 2=some high school, 3=high school graduate or general education diploma, 4=some college or technical/trade school, 5=college or trade school graduate, 6=graduate degree or professional degree after graduating college.

[c]Long-term partnership includes married or living with long-term partner.

[d]Other sexual preference includes bisexual, asexual, and other.

Respondents' level of interest in using a free mobile phone app to support HIV self-management is shown in Table 2. Respondents had the highest interest in app functions that facilitate communication with their doctor or clinic (76.8%) and help to identify relevant health services (74.7%). Respondents were also interested in app functions that provide tips to improve health based on personalized information (67.7%) and supply reminders to take medication (60.7%). Nearly 3 out of 5 participants were interested in an app function that enabled social networking with individuals with similar health conditions. Participants had the least interest in app functions for tracking changes in mood or emotions (53.8%) and managing alcohol and drug use behavior (31.6%).

Table 3 shows the multivariate regression results. An increase in age (OR 0.959, 95% CI 0.936-0.982) and unable to work/disabled (OR 0.296, 95% CI 0.145-0.606) were significantly associated with lack of interest in using a free mobile phone app for HIV self-management. Conversely, greater educational attainment was positively associated (OR 1.281, 95% CI 1.027-1.598) with a high level of interest in using a free phone app to support HIV self-management.

**Table 2.** Interest in mobile phone app functions to support HIV self-management.

| Mobile app function | N | Never (%) | Rarely (%) | About once a week (%) | Few times a week (%) | Daily (%) | Interested[a] (%) | Not Interested[b] (%) |
|---|---|---|---|---|---|---|---|---|
| Identify health services[a] | 745 | 25.4 | 20.4 | 16.0 | 14.4 | 23.9 | 74.6 | 25.4 |
| Track mood or emotions[b] | 744 | 46.2 | 17.3 | 7.8 | 9.0 | 19.6 | 53.8 | 46.2 |
| Provide health tips[c] | 745 | 32.3 | 18.4 | 11.4 | 13.2 | 24.7 | 67.7 | 32.3 |
| Manage alcohol and drug use[d] | 741 | 68.4 | 11.2 | 4.7 | 4.3 | 11.3 | 31.6 | 68.4 |
| Communicate with your doctor[e] | 740 | 23.2 | 18.0 | 19.5 | 16.1 | 23.2 | 76.8 | 23.2 |
| Remember to take your medication[f] | 743 | 39.3 | 11.6 | 4.7 | 5.1 | 39.3 | 60.7 | 39.3 |
| Engage in social networking[g] | 741 | 40.8 | 15.1 | 9.6 | 11.5 | 23.1 | 59.2 | 40.8 |

[a]Considered interested if answered rarely, about once a week, a few times a week, or daily.

[b]Considered not interested if answered never.

[c]Identify health services relevant to you.

[d]Track changes in your mood or emotions.

[e]Provide tips to improve your health, based on information about you.

[f]Manage alcohol and drug use behavior.

[g]Communicate with your doctor or clinic.

[h]Remember to take your medication.

[i]Engage in social networking with other people with similar health conditions as you.

**Table 3.** Multivariate logistic regression (N=708, 58 missing).

| Demographic variable | Odds ratio (95% CI) | *P* value |
|---|---|---|
| Age | 0.959 (0.936-0.982) | <.001 |
| Hispanic | 2.313 (0.920-5.814) | .07 |
| **Race** | | |
| White | 1 | — |
| Black/African American | 1.011 (0.592-1.727) | .97 |
| Other race | 1.491 (0.458-4.854) | .51 |
| Schooling completed | 1.281 (1.027-1.598) | .03 |
| Long-term partnership | 0.905 (0.523-1.565) | .72 |
| **Sexual orientation** | | |
| Heterosexual | 1 | — |
| Gay or lesbian | 0.798 (0.460-1.385) | .42 |
| Other sexual preference | 0.640 (0.329-1.245) | .19 |
| **Employment status** | | |
| Employed | 1 | — |
| Unable to work/disabled | 0.296 (0.145-0.606) | <.001 |
| Unemployed | 0.736 (0.319-1.696) | .47 |

## Discussion

### Principal Results

This study found that a vast majority of respondents were interested in using a free mobile phone app that supports HIV self-management. In addition, respondents expressed a strong preference for app functions that could help identify relevant health services, enhance communication with health care providers, provide tips to improve health based on personalized information, supply reminders to take medication, and enable social networking with individuals with similar health conditions. Respondents who were younger and better educated were more likely to express interest in using a phone app for HIV self-management. Conversely, respondents who were disabled or unable to work were significantly less likely to

express interest in using a free mobile phone app for HIV self-management. Finally, although Hispanic participants were more than twice as likely to be interested in using a free mobile phone app for HIV self-management than non-Hispanic participants, the association was not statistically significant.

### Limitations

This study provides important insights into PLWH's level of interest in using a free mobile phone app to support HIV self-management. However, there are limitations to this study. First, the measures are all self-reported by PLWH. This may increase social desirability bias, which occurs when respondents simply provide answers that will be viewed favorably by others. However, this effect was minimized through the use of anonymous surveys. Second, other resources for HIV self-management were not examined in this study. Thus, it is unclear whether respondents who lacked interest in using a free mobile phone app used other resources to self-manage their disease and whether these resources affect their level of interest. However, because a vast majority (approximately 86%) of respondents expressed interest in using a free mobile phone app to support HIV self-management, it is unlikely that this potential limitation had a strong effect on the study.

### Comparison With Prior Work

While little previous work exists examining interest in using free mobile phone apps to support HIV self-management among PLWH, several studies have examined common barriers to HIV self-management in this population. PLWH frequently report barriers related to accessing appropriate medical care, navigating complex medication regimens, and discussing their self-management challenges with providers comfortable with an HIV diagnosis [17]. This study found consistently that a majority of participants were interested in a free mobile phone app that could help address these barriers and strongly supported app functions that aimed to enhance communication with their doctor or clinic and help to identify relevant health care services. Furthermore, respondents liked app functions that could provide personalized tips to improve their health and supply reminders to take medication. These functions can help with the significant challenge of managing complex HIV treatment and medication regimens. Finally, other common barriers to HIV self-management are stigma and lack of social support [17,18]. To address these barriers, around two-thirds of respondents in this study expressed interest in phone app functions that enable social networking with individuals with similar health conditions and provide them with social support with less fear of experiencing stigma. Consistent with findings in this study, previous research has found that people who are younger and better educated are more likely to use phone apps to seek health information and self-manage their disease [17,26-28]. However, for the first time, this study documented that respondents who were unable to work or disabled were significantly less likely to be interested in using a free mobile phone app that supports HIV self-management. This may be because people with disabilities are less likely to own a smartphone and are more likely to report negative experiences with mHealth apps, including feeling overwhelmed by information or unable to find what they need compared to those who are not disabled [29]. It is possible that respondents who were disabled or unable to work were less likely to be interested in using a free mobile app that supports HIV self-management because of previous negative experiences with similar technologies. This highlights the importance of considering issues with accessibility of mobile phone apps for a wide range of people. Indeed, prior research indicates that when mHealth apps are accessible, people with disabilities are avid consumers of health-related technology [29]. Thus, more research is needed to identify the unique needs, barriers, and facilitators of PLWH who are unable to work or disabled to facilitate adoption of technology that can help them effectively self-manage their disease.

### Conclusions

This study revealed that PLWH have a high level of interest in using a free mobile phone app to self-manage their disease. Our findings can be used to inform the development of a mobile phone app that improves PLWH's ability to self-manage HIV as well as access health care services, communicate with health care providers, and network with individuals with similar conditions. The unique needs of PLWH who are disabled or unable to work should be considered in the adoption and development of technology-based self-management tools and interventions.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ART:** antiretroviral therapy
**HIV:** human immunodeficiency virus
**NIH:** National Institutes of Health
**OR:** odds ratio
**PLWH:** people living with human immunodeficiency virus


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Original Paper

# Controlling Your "App"etite: How Diet and Nutrition-Related Mobile Apps Lead to Behavior Change

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## Abstract

**Background:** In recent years, obesity has become a serious public health crisis in the United States. Although the problem of obesity is being addressed through a variety of strategies, the use of mobile apps is a relatively new development that could prove useful in helping people to develop healthy dietary habits. Though such apps might lead to health behavior change, especially when relevant behavior change theory constructs are integrated into them, the mechanisms by which these apps facilitate behavior change are largely unknown.

**Objective:** The purpose of this study was to identify which behavior change mechanisms are associated with the use of diet- and nutrition-related health apps and whether the use of diet- and nutrition-related apps is associated with health behavior change.

**Methods:** A cross-sectional survey was administered to a total of 217 participants. Participants responded to questions on demographics, use of diet and nutrition apps in the past 6 months, engagement and likability of apps, and changes in the participant's dietary behaviors. Regression analysis was used to identify factors associated with reported changes in theory and separately for reported changes in actual behavior, after controlling for potential confounding variables.

**Results:** The majority of study participants agreed or strongly agreed with statements regarding app use increasing their motivation to eat a healthy diet, improving their self-efficacy, and increasing their desire to set and achieve health diet goals. Additionally, majority of participants strongly agreed that using diet/nutrition apps led to changes in their behavior, namely increases in actual goal setting to eat a healthy diet (58.5%, 127/217), increases in their frequency of eating healthy foods (57.6%, 125/217), and increases in their consistency of eating healthy foods (54.4%, 118/217). Participants also responded favorably to questions related to engagement and likability of diet/nutrition apps. A number of predictors were also positively associated with diet-related behavior change. Theory ($P$<.001), app engagement ($P$<.001), app use ($P$<.003), and education ($P$<.010) were all positively associated with behavior change.

**Conclusions:** Study findings indicate that the use of diet/nutrition apps is associated with diet-related behavior change. Hence, diet- and nutrition-related apps that focus on improving motivation, desire, self-efficacy, attitudes, knowledge, and goal setting may be particularly useful. As the number of diet- and nutrition-related apps continues to grow, developers should consider integrating appropriate theoretical constructs for health behavior change into the newly developed mobile apps.

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**KEYWORDS**

diet; nutritional status; mobile apps; behavior and behavior mechanisms

## Introduction

Currently, 68% of men and 64% of women in the United States are considered overweight or obese [1,2]. Much of this increase can be linked to cheap and unhealthy food production coupled with increased consumption of foods with minimal nutritional value [3]. In addition to obesity, these changes in dietary patterns are associated with many other serious health conditions, including hypertension, stroke, heart disease, elevated cholesterol, and diabetes [4]. Efforts to address the complex dilemma of obesity in the United States typically include the promotion of physical activity and healthy nutritional and dietary habits [5].

With the advent of mobile phone technology, a vast number of health-related mobile apps have been developed and are now being widely used to tackle health problems [6]. Many such apps provide users additional methods for monitoring their health or achieving health-related goals. The proliferation of health-related apps represents a potential resource in addressing obesity [7]. Studies have shown that using health-related apps can successfully lead to health behavior change related to weight loss or weight management [8,9]. Many health care providers see the potential of health-related apps to facilitate weight management and encourage patients to use them [6,10].

An assortment of apps has been developed to help individuals monitor their food consumption through calorie counting or food diary approaches [6,8]. Other apps provide individuals with healthy diet and nutrition facts and information (eg, MyFitnessPal, FitBit, and Lose It!) [8,11]. Studies have found that the use of diet-related apps can lead to improved diet and nutrition health behavior change [9]. Turner-McGrievey et al [9] found that participants using diet apps consumed fewer calories than those using a website or paper journal method for monitoring dietary intake. Similarly, when comparing the use of diet-related apps with website groups and food intake diary groups in a randomized control trial, participants using the apps had higher retention, adherence, and weight loss [12].

Previous research has found that interventions integrating models of behavior change theory may be effective. Inclusion of constructs from established health behavior change theories increases the effectiveness of planning, implementing, and evaluating interventions [13]. Three leading health behavior change theories for nutrition education and intervention are the health belief model (HBM), theory of planned behavior (TPB), and social cognitive theory (SCT) [14]. The HBM has been widely used since the 1950s and includes primary constructs that predict “if” and “why” a person will take action toward detecting, preventing, and controlling unhealthy behaviors. This is achieved through perceived susceptibility and severity, as well as the barriers and benefits associated with engaging in certain behaviors [13]. Constructs that examine individual motivation and attitudes and how they determine the likelihood of performing specific behaviors are the focus of TPB [13]. The SCT identifies the ever-present tension between human agency and social structure [13]. A key advantage of SCT is how it accounts for both individual decision making and environment through the concept of reciprocal determinism, which in turn leads to a deeper sense of self-efficacy through personal experiences, persuasion, and vicarious learning [13]. Provided the complexities associated with nutrition behaviors, a practical approach to behavior change may involve a combination of distinct constructs and elements from each theory effectively forming a polytheoretical approach [14].

Studies have shown that using health apps for diet can successfully lead to positive changes in weight management [12]. Health apps have the potential to decrease some barriers to traditional prescriptions for behavior change, including expense, patient burden, and variable adherence. Specifically, how engaging, convenient, and easy to use the app is can be a mechanism for reducing barriers and increasing adherence. However, none of the leading weight loss apps have been evaluated in a clinical trial, which underscores the need for a descriptive study such as this one to establish associations warranting further investigation [15,16]. Though several theories related to health behavior change are well established and generally accepted, recent content analyses of diet-related apps demonstrate that many diet-related apps have insufficient evidence-informed content or are lacking in theoretical constructs considered important in facilitating behavior change [17-19]. To date, no research has explored the specific mechanisms by which diet-related apps actually generate changes in behavior. The purpose of this study was to explore which behavior change mechanisms are associated with use of diet- and nutrition-related health apps and to examine whether the use of these apps is associated with actual changes in dietary behaviors.

## Methods

### Design and Procedure

This study consisted of a cross-sectional survey to assess the use of diet and nutrition apps in the past 6 months. A Qualtrics survey was distributed via Amazon Mechanical Turk (MTurk) to 239 participants. The survey was open on MTurk twice, once for approximately 2 weeks with a US $1 incentive (89 respondents) and then a second time for a few more weeks with a US $2 incentive (150 respondents). An advantage of Web-based data collection is the ability to access a wide variety of participants that represent a diverse sampling of those using the method of Internet communication [20]. It is projected that data collection through electronic sources will continue to rise because of potential outreach [21]. A typical MTurk sample is representative of the population criterion of interest for this research project.

### Sample

A number of inclusion and exclusion criteria were used to define the survey sample. Survey participants had to be at least 18 years of age, live in the United States, and be able to read English. Participants were excluded if they had not used a diet or nutrition app in the last 6 months or if they failed to complete all 16 survey questions. A total of 239 participants responded, of which 217 individuals met all requirements and completed all questions.

### Measurement

Participants responded to questions on demographics (eg, age, race, education and income level, state of residence), use of diet/nutrition apps in the past 6 months, engagement and likability of the apps, and changes in the participant's dietary behaviors. A 5-point Likert-type scale was used to generate response categories for the variables related to behavior change.

The study used three health behavior theories to formulate the Likert-type scale survey questions focusing on mechanisms of behavior change and actual diet/nutrition-related behaviors. Questions based on SCT included those that measured outcome expectations, self-efficacy, subjective norms and knowledge, whereas questions based on TPB measured behavioral beliefs, intentions, attitudes, desires, normative beliefs, and goal setting. Finally, one question based on HBM measured perceived benefits. A composite total theory variable was constructed to provide a global estimate of changes in theory-related constructs. A polytheoretical measure was determined to be in line with the viewpoint that behaviors relating to diet/nutrition are too complex for any one single theory [14]. The Cronbach alpha coefficient for this composite variable was .941 (behavior=.842; engagement=.875). This variable was not normally distributed. Hence, a square root transformation was used.

### Statistical Analysis

Stata version 14 (StataCorp) was used to calculate all statistics. Descriptive statistics were calculated for each of the demographic, theory, engagement, and behavior variables. Multiple regression analysis was used to identify factors associated with reported changes in theory and separately for reported changes in actual behavior, after controlling for potential confounding variables.

## Results

The majority of study participants were white (83.9%, 182/217) and between the ages of 26 and 34 (44.2%, 96/217; Table 1). Most participants (87.5%, 190/217) had at least some college education. Just over half of the participants (55.8%, 121/217) were female, and 41.5% (90/217) were from the Southern United States.

Most (59.9%, 130/217) strongly agreed with the statement that using diet/nutrition apps increased their motivation to eat a healthy diet, whereas an additional 36.8% (80/217) agreed with the same statement (Table 2). Many respondents indicated that the apps improved self-efficacy: 43.8% (95/217) strongly agreed and 42.4% (92/217) agreed with the statement that using diet/nutrition apps increased their ability to eat a healthy diet, and 43.3% (94/217) strongly agreed and 48.4% (105/217) agreed with the statement that using diet/nutrition apps increased their confidence that they can eat a healthy diet. More than half (59.0%, 128/217) of the participants strongly agreed that using diet/nutrition apps increased their desire to set goals to eat a healthy diet, whereas 51.1% (111/217) strongly agreed that using diet/nutrition apps increased their ability to achieve their healthy diet goals.

**Table 1.** Summary of participant demographics.

| Demographics | Frequency, n (%) (N=217) |
|---|---|
| **Age in years** | |
| 18-25 | 16 (7.4) |
| 26-34 | 96 (44.2) |
| 35-54 | 90 (41.5) |
| 55-64 | 11 (5.1) |
| 65 or over | 4 (1.8) |
| **Race** | |
| American Indian | 2 (0.9) |
| Asian | 15 (6.9) |
| Black/African American | 17 (7.8) |
| Native Hawaiian/Other Pacific Islander | 1 (0.5) |
| White | 182 (83.9) |
| **Ethnicity** | |
| Hispanic/Latino | 13 (6.0) |
| Non-Hispanic/Non-Latino | 204 (94.0) |
| **Gender** | |
| Male | 96 (44.2) |
| Female | 121 (55.8) |
| **Education level** | |
| Less than high school | 1 (0.5) |
| Diploma/GED | 26 (12.0) |
| Some college | 56 (25.8) |
| 2-year degree | 23 (10.6) |
| 4-year degree | 91 (41.9) |
| Master’s degree | 18 (8.3) |
| Professional degree (MD, JD) | 2 (0.9) |
| **Region of residence in USA** | |
| West | 49 (22.6) |
| South | 90 (41.5) |
| Midwest | 36 (16.6) |
| Northeast | 42 (19.4) |
| **Household income, in US dollars (2016)** | |
| Less than 30,000 | 50 (23.0) |
| 30,000-39,999 | 30 (13.8) |
| 40,000-49,999 | 28 (12.9) |
| 50,000-59,999 | 29 (13.4) |
| 60,000-69,999 | 22 (10.1) |
| 70,000-79,999 | 14 (6.5) |
| 80,000-89,999 | 14 (6.5) |
| 90,000-99,999 | 9 (4.2) |
| 100,000 or more | 21 (9.7) |

**Table 2.** Summary of participant reponses to theory questions.

| Question[a] | Response (N=217), n (%) | | | | |
|---|---|---|---|---|---|
| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| Increased my belief that poor diet/nutrition leads to disease[b,c] | 4 (1.8) | 35 (16.1) | 45 (20.7) | 94 (43.3) | 39 (18.0) |
| Increased my belief that eating a healthy diet can prevent disease[b,c] | 4 (1.8) | 22 (10.1) | 34 (15.7) | 93 (42.9) | 64 (29.5) |
| Increased my belief that diseases related to poor diet/nutrition are harmful[b,c] | 4 (1.8) | 22 (10.1) | 40 (18.4) | 76 (35.0) | 75 (34.6) |
| Increase my belief that eating a healthy diet is important in preventing disease[b,c] | 4 (1.8) | 14 (6.5) | 31 (14.3) | 91 (41.9) | 77 (35.5) |
| Increased my motivation to eat a healthy diet[b] | 1 (0.5) | 6 (2.8) | 0 (0.0) | 80 (36.8) | 130 (59.9) |
| Increased my ability to eat a healthy diet[b] | 4 (1.8) | 8 (3.7) | 18 (8.3) | 92 (42.4) | 95 (43.8) |
| Increased my confidence that I can eat a healthy diet[b] | 1 (.5) | 6 (2.8) | 11 (5.0) | 105 (48.4) | 94 (43.3) |
| Increased my desire to eat a healthy diet[c] | 0 (0.0) | 2 (0.9) | 12 (5.6) | 94 (43.3) | 109 (50.2) |
| Increased my intentions to eat a healthy diet[c] | 1 (0.5) | 1 (0.5) | 5 (2.3) | 88 (40.5) | 122 (56.2) |
| Increased my attitudes about the importance of eating a healthy diet in preventing disease[c] | 3 (1.4) | 15 (6.9) | 21 (9.7) | 97 (44.7) | 81 (37.3) |
| Increased my belief that people important to me want me to eat a healthy diet[c] | 9 (4.2) | 33 (15.2) | 52 (24.0) | 66 (30.4) | 57 (26.2) |
| Increased my perception that many other people are eating a healthy diet[b] | 5 (2.3) | 41 (18.9) | 46 (21.2) | 69 (31.8) | 56 (25.8) |
| Increased my knowledge of the diseases that are caused by poor diet/ nutrition[b] | 14 (6.5) | 44 (20.3) | 42 (19.3) | 73 (33.6) | 44 (20.3) |
| Increased my knowledge of the ways in which I can eat a healthy diet[b] | 1 (.5) | 7 (3.2) | 14 (6.4) | 98 (45.2) | 97 (44.7) |
| Increased my awareness of the benefits of eating a healthy diet[d] | 1 (0.5) | 12 (5.5) | 30 (13.8) | 95 (43.8) | 79 (36.4) |
| Increased my desire to be healthy[c] | 1 (0.5) | 5 (2.3) | 8 (3.7) | 78 (35.9) | 125 (57.6) |
| Increased the social support I have received for eating a healthy diet[b] | 11 (5.0) | 41 (18.9) | 39 (18.0) | 78 (35.9) | 48 (22.1) |
| Increased the positive feedback I have received for eating a healthy diet[b] | 12 (5.5) | 20 (9.2) | 41 (18.9) | 89 (41.0) | 55 (25.4) |
| Increased my desire to set goals to eat a healthy diet[c] | 0 (0.0) | 0 (0.0) | 5 (2.3) | 84 (38.7) | 128 (59.0) |
| Increased my ability to achieve my healthy diet goals[b] | 0 (0.0) | 1 (0.5) | 11 (5.1) | 94 (43.3) | 111 (51.1) |

[a]All theory questions in the survey were preceded by this statement: Now think about the diet/nutrition app(s) that you have used in the past 6 months. Using the app(s) has…

[b]Questions were derived from the social cognitive theory.

[c]Questions were derived from the theory of planned behavior.

[d]Questions were derived from the health belief model.

The majority of participants strongly agreed that using diet/nutrition apps led to changes in their behavior, namely increases in actual goal setting to eat a healthy diet (58.5%, 127/217), increases in their frequency of eating healthy foods (57.6%, 125/217), and increases in their consistency of eating healthy foods (54.4%, 118/217; Table 3).

Participants strongly agreed that the diet/nutrition apps they used were easy to use (62.9%, 156/217) and helpful (60.5%, 150/217; Table 4). Many also strongly agreed that they liked the apps (54.4%, 135/217) and enjoyed using the apps (44.8%, 111/217). About half of the participants (54.0%, 134/217) strongly agreed that they would recommend the apps to others. This scale, measuring engagement, received a high Cronbach alpha (.875).

Two of the predictors were significantly associated with theory (Table 5). Specifically, app engagement ($P$<.001) and app price ($P$<.01) were associated with theory.

Several predictors were also positively associated with diet-related behavior change (Table 6). Theory ($P$<.001), app engagement ($P$<.001), app use ($P$<.003), and education ($P$<.01) were all positively associated with behavior change.

Figure 1 summarizes significant relationships between theory, behavior, and other predictors. Arrows indicate the hypothetical direction of the relationships and asterisks indicate the level of statistical significance. In the model, the price of the app and the level of participant engagement affect theory, which in turn drives behavior change. Engagement also affects behavior

directly. Finally, the level of participant education and the frequency of app use have a direct impact on behavior change.

**Table 3.** Summary of participant responses to behavior change questions.

| Question[a] | Response (N=217), n (%) | | | | |
|---|---|---|---|---|---|
| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| Increased my actual goal setting to eat a healthy diet | 1 (0.5) | 0 (0.0) | 11 (5.1) | 78 (35.9) | 127 (58.5) |
| Increased my frequency of eating healthy foods | 0 (0.0) | 2 (0.9) | 8 (3.7) | 82 (37.8) | 125 (57.6) |
| Increased my consistency in eating healthy foods | 0 (0.0) | 1 (0.5) | 8 (3.7) | 90 (41.4) | 118 (54.4) |

[a]All theory questions in the survey were preceded by this statement: Now think about the diet/nutrition app(s) that you have used in the past 6 months. Using the app(s) has…

**Table 4.** Summary of participant responses to engagement questions.

| Question[a] | Response (N=217), n (%) | | | | |
|---|---|---|---|---|---|
| | Strongly disagree | Disagree | Neutral | Agree | Strongly agree |
| The app(s) was helpful | 2 (0.8) | 3 (1.2) | 4 (1.6) | 89 (35.9) | 150 (60.5) |
| The app(s) was easy to use | 1 (0.4) | 2 (0.8) | 6 (2.4) | 83 (33.5) | 156 (62.9) |
| I enjoyed using the app(s) | 2 (0.8) | 4 (1.6) | 26 (10.5) | 105 (42.3) | 111 (44.8) |
| I liked the app(s) | 1 (0.4) | 3 (1.2) | 10 (4.0) | 99 (39.9) | 135 (54.4) |
| I would recommend the app(s) to others | 1 (0.4) | 3 (1.2) | 19 (7.7) | 91 (36.7) | 134 (54.0) |

[a]All engagement questions in the survey were preceded by this statement: Considering the diet/nutrition app(s) that you have used in the past 6 months…

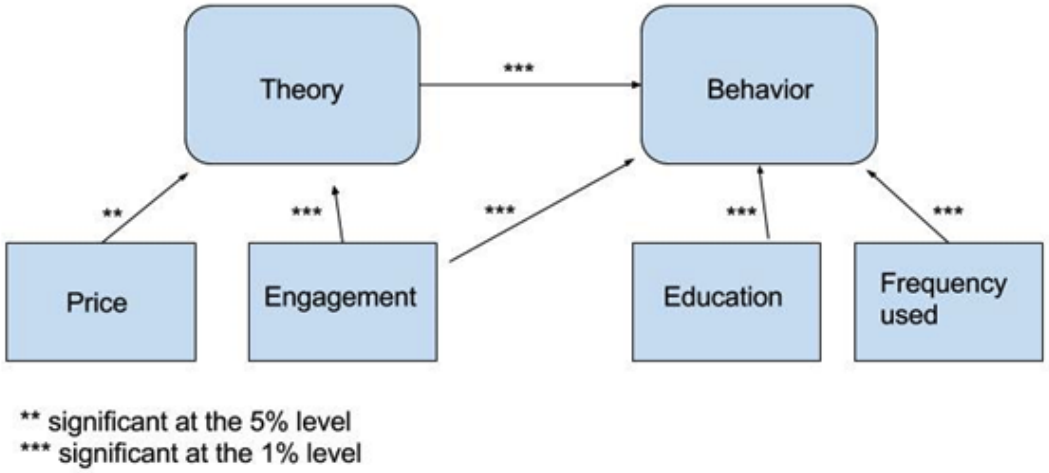
**Table 5.** Ordinary least squares regression results for determinants of theory.

| Determinants of theory | Coefficient (Standard error) | *t* | *P*>\| *t* \| | 95% CI |
|---|---|---|---|---|
| App engagement | 1.06 (0.17) | 6.42 | <.001 | 0.74-1.39 |
| Price of app | 0.50 (0.20) | 2.50 | .01 | 0.11-0.90 |
| Frequency of app use | 0.11 (0.17) | 0.64 | .52 | −0.23 to 0.45 |
| Gender | 0.16 (0.17) | 0.98 | .33 | −0.17 to 0.50 |
| Age | 0.05 (0.11) | 0.49 | .63 | −0.16 to 0.26 |
| Income | − | −0.66 | .51 | −0.17 to 0.09 |
| Education | − | −1.36 | .18 | −0.11 to 0.02 |
| Constant | 1.33 (0.61) | 2.20 | .03 | 0.14-2.53 |

**Table 6.** Ordinary least squares regression results for determinants of behavior change.

| Independent Variables | Coefficient (Standard error) | *t* | *P*>\| *t* \| | 95% CI |
|---|---|---|---|---|
| Theory | 0.10 (0.02) | 4.87 | <.001 | 0.06-0.14 |
| App engagement | 0.39 (0.05) | 7.56 | <.001 | 0.29-0.50 |
| Price of app | −0.06 (0.06) | −1.02 | .31 | −0.18 to 0.06 |
| Frequency of app use | 0.15 (0.05) | 3.02 | .003 | 0.05-0.25 |
| Gender | 0.05 (0.05) | 0.96 | .34 | −0.49 to 0.14 |
| Age | −0.00 (0.03) | −0.14 | .89 | −0.06 to 0.06 |
| Income | 0.01 (0.01) | 0.88 | .38 | −0.01 to 0.03 |
| Education | 0.05 (0.02) | 2.60 | .01 | 0.01-0.09 |
| Constant | 0.20 (0.18) | 1.14 | .26 | −0.15 to 0.55 |

**Figure 1.** Factors influencing behavior change. Figure 1 illustrates the relationship between mobile application attributes, theoreticaldeterminants of behavior and behavior. Arrows indicate the hypothetical direction of therelationships and stars indicate the statistical significance.




## Discussion

### Principal Findings

The purpose of this study was to explore behavior change mechanisms associated with the use of diet- and nutrition-related health apps and to examine if the use of these apps is associated with actual changes in dietary behaviors. The results of this study demonstrate that the use of diet/nutrition apps is associated with diet-related behavior change. In addition, this study showed that behavior change theory was positively associated with actual behavior change related to the use of diet/nutrition apps.

Participants in this study reported increased motivation, desire, and ability to improve their dietary intake with app use. Likewise, participants indicated an increase in their ability to establish and achieve dietary goals. Taken together such increases indicate that diet- and nutrition-related apps improve self-efficacy, or strengthen one's belief that they can engage in healthy dietary behaviors. Self-efficacy is a key component of SCT and is widely considered to be a powerful predictor of health behavior and appears to be a key mechanism by which health apps facilitate behavior change [8,22,23].

Survey results also indicate that app use helped to create attitudes supportive of improved dietary behaviors, as well as behavioral intentions to eat a healthy diet. The TPB postulates that behavioral attitudes and beliefs coupled with subjective norms and self-efficacy predict behavioral intentions [13]. Results from this study indicate that attitudes related to the importance of eating healthy and the subsequent behavioral intentions of doing so are mechanisms for behavior change when using diet- and nutrition-related apps. This dovetail between self-efficacy and enhanced autonomy has been observed in other studies where behavior change was achieved through the use of mobile health informatics tools that are patient-centered and increase self-management skills [11,24].

Finally, participants reported an increase in knowledge of the ways in which they can eat a healthy diet and an awareness of the benefits of improving dietary habits. Though general knowledge alone is often an insufficient change agent [25], this study demonstrates that knowledge specifically related to ways in which one can improve dietary behavior and the benefits of making such improvements are mechanisms for change when using diet- and nutrition-related apps.

## Limitations

Several limitations should be considered when interpreting the findings of this study. First, this study has limited racial and ethnic diversity among participants. Respondents in this study were primarily white with similar levels of age, education, and economic status. This limitation is likely a reflection of the demographic using MTurk's Web-based surveying system [26]. Additional research is needed with a more diverse sample to make generalizations related to this study's key findings.

Second, this study included only limited data on participants due to the need to balance resource constraints with various research questions of interests. The study would be strengthened by collecting additional participant data and information. For example, collecting information regarding respondents' height and weight to examine relationships between health outcomes such as body mass index and diabetes and app use may have been helpful. Third, a pre- and posttest design evaluating participants' dietary and nutritional behaviors before and after downloading the app may reveal additional insight into mechanisms for behavior change related to app use. Future studies may benefit from qualitative research designs targeting motivations of diet/nutrition app use over time. Fourth, understanding participants' motivations for downloading and using diet- and nutrition-related apps may also have been useful, as would have determining whether or not those apps met participants' expectations. Despite these limitations, this study represents an initial effort to understand the mechanisms by which diet- and nutrition-related apps lead to behavior change, which can guide both future app development and research design.

## Conclusions

Diet- and nutrition-related mobile apps show promise as tools to successfully facilitate positive health behavior change. The results of this study confirm that the use of diet/nutrition apps is associated with diet-related behavior change. Furthermore, apps that focus on improving motivation, desire, self-efficacy, attitudes, knowledge, and goal setting may be particularly useful. To ensure that mobile apps are effective health behavior change agents, theories and their respective constructs known to facilitate health behavior change, such as those of SCT, TPB, and HBM, should continue to be integrated into health app design and implementation. Moving forward, developers of diet/nutrition apps may consider design configurations that emphasize the provision of knowledge to shape attitudes and beliefs, followed by attempts to influence actual skill development in app users. Elements of gamification or other such paradigms may be useful to maintain user motivation and the desire to be persistent in making weight loss efforts.

## Acknowledgments

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## Conflicts of Interest

None declared.

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## Abbreviations

**HBM:** health belief model
**SCT:** social cognitive theory
**TPB:** theory of planned behavior


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Original Paper

# Photoaging Mobile Apps as a Novel Opportunity for Melanoma Prevention: Pilot Study

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## Abstract

**Background:** Around 90% of melanomas are caused by ultraviolet (UV) exposure and are therefore eminently preventable. Unhealthy tanning behavior is mostly initiated in early adolescence, often with the belief that it increases attractiveness; the problems related to skin atrophy and malignant melanoma are too far in the future to fathom. Photoaging desktop programs, in which an image is altered to predict future appearance, have been successful in positively influencing behavior in adiposity or tobacco prevention settings.

**Objective:** To develop and test a photoaging app designed for melanoma prevention.

**Methods:** We harnessed the widespread availability of mobile phones and adolescents' interest in appearance to develop a free mobile app called Sunface. This app has the user take a self-portrait (ie, a selfie), and then photoages the image based on Fitzpatrick skin type and individual UV protection behavior. Afterward, the app explains the visual results and aims at increasing self-competence on skin cancer prevention by providing guideline recommendations on sun protection and the ABCDE rule for melanoma self-detection. The underlying aging algorithms are based on publications showing UV-induced skin damage by outdoor as well as indoor tanning. To get a first impression on how well the app would be received in a young target group, we included a total sample of 25 students in our cross-sectional pilot study with a median age of 22 (range 19-25) years of both sexes (11/25, 44% female; 14/25, 56% male) attending the University of Essen in Germany.

**Results:** The majority of enrolled students stated that they would download the app (22/25, 88%), that the intervention had the potential to motivate them to use sun protection (23/25, 92%) and that they thought such an app could change their perceptions that tanning makes you attractive (19/25, 76%). Only a minority of students disagreed or fully disagreed that they would download such an app (2/25, 8%) or that such an app could change their perceptions on tanning and attractiveness (4/25, 16%).

**Conclusions:** Based on previous studies and the initial study results presented here, it is reasonable to speculate that the app may induce behavioral change in the target population. Further work is required to implement and examine the effectiveness of app-based photoaging interventions within risk groups from various cultural backgrounds.

***(JMIR Mhealth Uhealth 2017;5(7):e101)*** doi:10.2196/mhealth.8231

**KEYWORDS**

melanoma; skin cancer; prevention; mobile apps; smartphones; photoaging

## Introduction

Melanoma accounts for the majority of skin cancer-related deaths worldwide [1]. The implementation of next-generation sequencing has uncovered key oncogenic drivers of metastatic melanoma, such as mutations in the *BRAF* gene, which are present in around 50% of patients [2,3]. Development of therapies targeting the products of these genetic alterations, namely BRAF and MEK inhibitors, led to the first therapeutic revolution in melanoma care. These advances changed the prognosis of metastatic melanoma from a uniformly fatal disease with median survival of about 9 months to a treatable disease with median overall survival rates of more than 24 months, including some long-term responders [4-7].

In parallel, an improved understanding of mechanisms of tumor immune evasion, namely through interactions with immune checkpoints, such as cytotoxic T-lymphocyte-associated antigen 4 and programmed cell death protein 1, provided the rationale for the second therapeutic revolution. Conceptually, immune checkpoint inhibitors disrupt tumor-mediated T-cell dysfunction, and enable reactivation and effective immune-mediated tumor lysis. Up to 1 in 3 patients with metastatic melanoma may derive durable responses to these therapies [8-11].

Despite these disruptive changes in the therapeutic landscape, the majority of patients will still die from their disease. Several institutions and entities therefore emphasize and fund programs to improve preventive measures. Around 90% of melanomas are related to ultraviolet (UV) radiation [12], and recent data indicate that especially people with lower genetic risk for melanoma benefit from avoiding cumulative UV exposure, which is known as the divergent pathway hypothesis [13,14].

Unhealthy tanning behavior (including sunbed use) is mostly initiated in early adolescence [15], often with the belief that it increases attractiveness [16-18]; the problems related to skin atrophy and malignant melanoma are too far in the future to fathom.

To target populations at risk for such behaviors, implementation of programs that are embedded in frequently used media, such as the Internet or mobile phone apps, may be useful. Indeed, a recent randomized controlled trial by Burford et al demonstrated the effectiveness of photoaging desktop programs, in which an image is altered to predict future appearance, for behavioral change in young target groups in the field of smoking cessation [19]. Furthermore, a quasi-experimental study showed significantly higher scores for predictors of sun protection behavior in young women from the United Kingdom using such programs [20], which were also effective in changing young adults' suntanning intentions in both sexes [21]. However, the investigated desktop-based programs only reach a small audience and are not freely available. To improve melanoma prevention in the larger population by leveraging frequently used technologies, we developed a freely available phone app aimed at enhancing sun protective behaviors.

## Methods

We harnessed the widespread availability of mobile phones and adolescents' interest in appearance to develop a free mobile app. The Sunface app has the user take a self-portrait (ie, a selfie), and then photoages the image based on Fitzpatrick skin type (Figure 1) and individual UV protection behavior (Figure 2, Figure 3, Figure 4).

Afterward, the app explains the visual results (Figure 5) and increases self-competence on skin cancer prevention by providing guideline recommendations on sun protection and the ABCDE rule for melanoma self-detection (assess border irregularity, color variety, diameter, and evolution [22]). By means of sharing tools of the animated image as a video (Multimedia Appendix 1) or photo, the user's social network may be informed about the various beauty-reducing effects of tanning and about the app.

The underlying aging algorithms are based on publications showing UV-induced skin damage caused by outdoor as well as indoor tanning [23]. As no trials with 25 years of follow-up were available, we had to extrapolate the current evidence on UV-induced skin damage for the specific skin types.

To get a first impression of how well the app would be received in a young target group, we included a total sample of 25 students in our cross-sectional pilot study with a median age of 22 (range 19-25) years of both sexes (11/25, 44% female; 14/25, 56% male) attending the University of Essen in Germany.

An interviewer walked up to each individual student, asked for oral consent, let them use the app once by handing them an iPod Touch (Apple Inc) with the app preinstalled, and then measured their reactions to the 1-time use of the app (no longer than 2 minutes) via a paper-and-pencil questionnaire. The items used in the questionnaire captured sociodemographic data (sex, age) and their reactions toward the app, on 5-point Likert scales, directly after using it. All items used wording and a structure similar to those of a previously published questionnaire evaluating a photoaging app for tobacco use prevention [24]. Each selfie was deleted directly after the individual test persons had tested the app for data protection reasons.

**Figure 1.** Start of the app: the user picks their Fitzpatrick skin type.

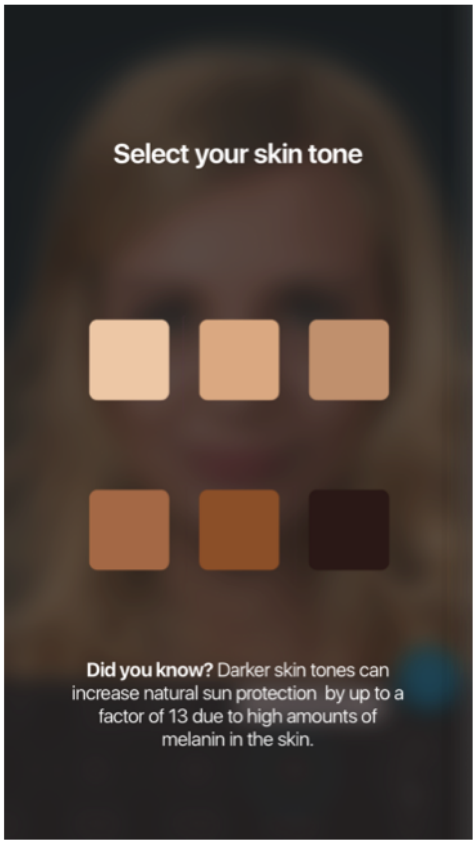



**Figure 2.** Effect view of the app: 25 years of aging with applied sun protection.

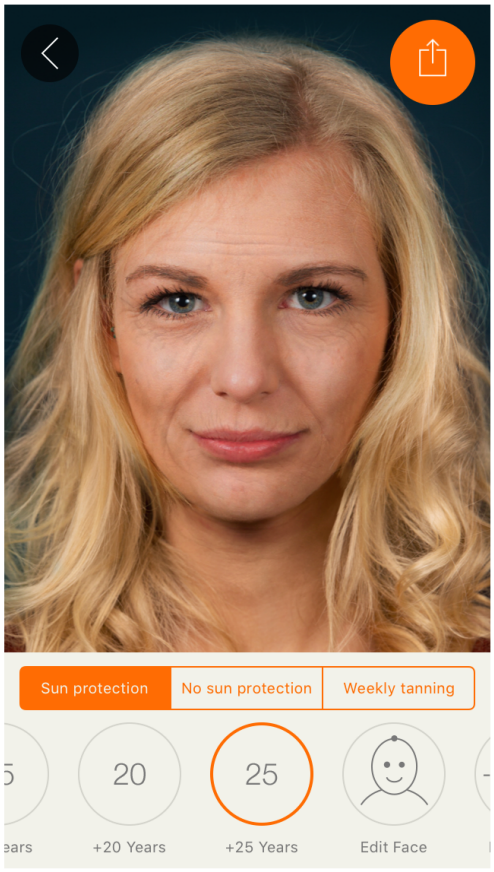


**Figure 3.** Effect view of the app: weekly tanning for 25 years (maximum effect) with a total of 3 actinic keratoses visible, multiple solar lentigines, age spots, and prominent solar elastosis.


**Figure 4.** Effect view of the app: 5 years of normal aging with daily sun protection applied.

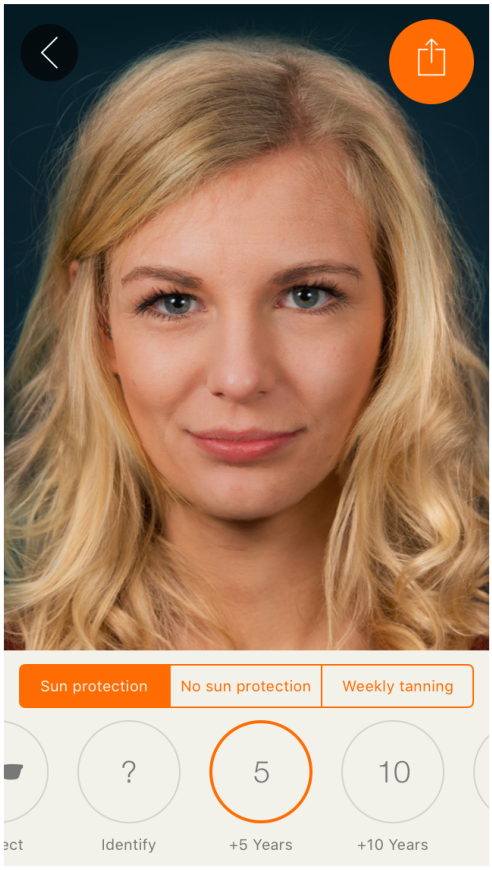
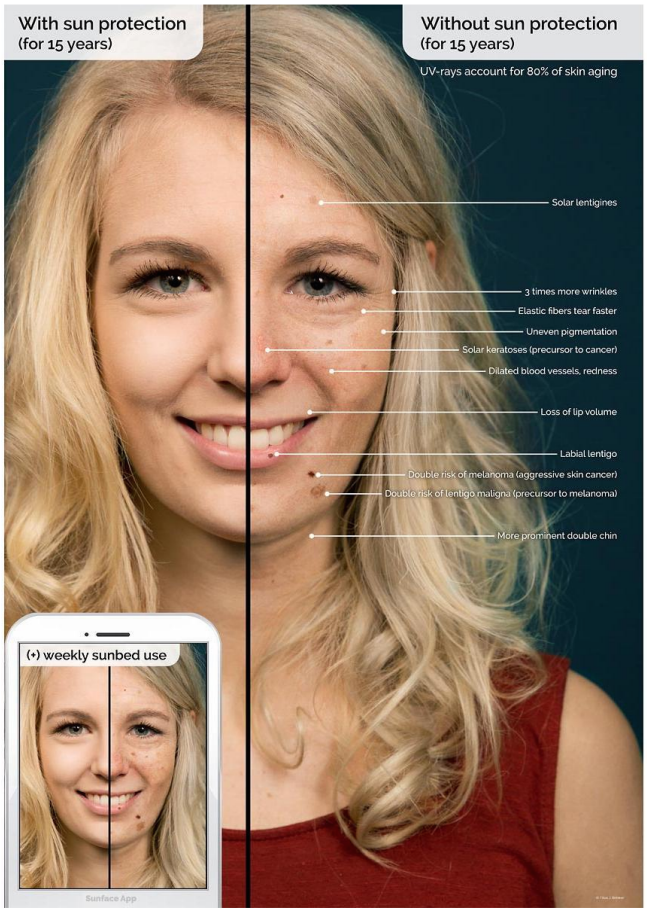


**Figure 5.** Explanatory graphic within the app explaining the shown effects. UV: ultraviolet.




## Results

The majority of enrolled students stated that they would download the app (22/25, 88%), that the intervention had the potential to motivate them to use sun protection (23/25, 92%), and that they thought such an app could change their perceptions that tanning makes you attractive (19/25, 76%). Only a minority of students disagreed or fully disagreed that they would download such an app (2/25, 8%) or that such an app could change their perceptions on tanning and attractiveness (4/25, 16%).

In line with our small survey, the app was installed on over 1000 Android and 500 iOS smartphones within 14 days after its release in Germany (May 30, 2017 to June 17, 2017). We thus expect it to reach a similar popularity with an estimated 30,000 users within 1 year, which is comparable with our photoaging app on tobacco-induced skin changes [25]. As smartphone use in Germany declines with age, we assume that the largest fraction of app users will be in the vulnerable age group of 35 years or younger.

## Discussion

The implementation of novel technologies and computational algorithms has the potential to substantially change the landscape of cancer prevention and early melanoma detection [19,20,24,26-30], and thereby reduce its disease-specific mortality. Here, we propose the use of a mobile phone app, Sunface, as a means to implement interventions that encourage sun protective behavior. The effectiveness of such approaches has been demonstrated in recent studies, and could be complimentary to early detection programs by dermatologists and recently developed artificial intelligence programs [31]. Phone apps in the field of dermatology are of increasing relevance [32-44] and may be particularly effective in reaching a large number of people, given the increasing use of mobile phones, which is projected to increase to more than 6 billion subscriptions by 2021 [45], and their integration into daily living habits by these customers.

Based on previous studies and the initial study results presented here, it is reasonable to speculate that the app may induce behavioral change in the target population. Further work is required to implement and examine the effectiveness of app-based photoaging interventions within risk groups from various cultural backgrounds.

## Conflicts of Interest

None declared.

## Authors' Contributions

DS, JK, IC, AR, PJ, IS, and BI contributed to the design and conduct of the pilot study, as well as the analysis of its data, and proofread the manuscript.

## Multimedia Appendix 1

Shared video of the Sunface app with 15 years of no sun protection shown in a 3-dimensional animated selfie.

[MP4 File (MP4 Video), 1MB - mhealth_v5i7e101_app1.mp4 ]

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## Abbreviations

**UV:** ultraviolet


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Original Paper

# The Health Buddies App as a Novel Tool to Improve Adherence and Knowledge in Atrial Fibrillation Patients: A Pilot Study

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## Abstract

**Background:** Atrial fibrillation (AF) constitutes an important risk for stroke, especially in an ageing population. A new app (Health Buddies) was developed as a tool to improve adherence to non-vitamin K antagonist oral anticoagulants (NOACs) in an elderly AF population by providing a virtual contract with their grandchildren, spelling out daily challenges for both.

**Objective:** The aim of this pilot study was to assess the feasibility and usability of the Health Buddies app in AF patients.

**Methods:** Two workshops were conducted to steer app development and to test a first prototype. The feasibility of the finalized app was investigated by assessing the number of eligible AF patients (based on current prescription of NOACs, the presence of grandchildren between 5 and 15 years old, availability of a mobile phone, computer, or tablet), and the proportion of those who were willing to participate. Participants had to use the app for 3 months. The motivation of the patients to use the app was assessed based on the number of logins to the app. Their perception of its usefulness was examined by specific questionnaires. Additionally, the effects on knowledge level about AF and its treatment, and adherence to NOAC intake were investigated.

**Results:** Out of 830 screened AF patients, 410 were taking NOACs and 114 were eligible for inclusion. However, only 3.7% (15/410) of the total NOAC population or 13.2% of the eligible patients (15/114) were willing to participate. The main reasons for not participating were no interest to participate in general or in the concept in particular (29/99, 29%), not feeling comfortable using technology (22/99, 22%), no interest by the grandchildren or their parents (20/99, 20%), or too busy a lifestyle (12/99, 12%). App use significantly decreased towards the end of the study period in both patients ($P$=.009) and grandchildren ($P$<.001). NOAC adherence showed a taking adherence and regimen adherence of 88.6% (SD 15.4) and 81.8% (SD 18.7), respectively. Knowledge level increased from 64.6% (SD 14.7) to 70.4% (SD 10.4) after 3 months ($P$=.09). The app scored positively on clarity, novelty, stimulation, and attractiveness as measured with the user experience questionnaire. Patients evaluated the educational aspect of this app as a capital gain.

**Conclusions:** Only a small proportion of the current AF population seems eligible for the innovative Health Buddies app in its current form. Although the app was positively rated by its users, a large subset of patients was not willing to participate in this study or to use the app. Efforts have to be made to expand the target group in the future.

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**KEYWORDS**

mHealth; anticoagulants; medication adherence; education; atrial fibrillation

## Introduction

Medication nonadherence in general is an important aspect requiring attention as it increases complications, hospitalizations, and hence is associated with avoidable health care costs [1]. However, interventions to improve adherence have shown mixed results and the most effective strategy in different populations remains unclear [2]. mHealth and eHealth solutions to assist medication management and to enhance adherence are gaining interest, with some promising results in different chronic diseases, including some cardiovascular diseases [3-7].

Specific data about adherence-improving interventions in atrial fibrillation (AF) patients are very scarce and interventions are often ineffective [8]. AF, the most common cardiac arrhythmia affecting about 3% of the adult population, is associated with an increased risk for stroke [9,10]. Therefore, the majority of AF patients have to take oral anticoagulation (OAC) medication. Due to their better risk-benefit profile, non-vitamin K antagonist oral anticoagulants (NOAC) are now preferred over vitamin K antagonists [10-12]. However, a strict adherence to the prescribed NOAC medication regimen is of pivotal importance for optimal stroke prevention since their anticoagulant effect lasts for only 12-24 hours after each intake [12]. Coagulation monitoring for NOACs is not routinely required nor feasible for detection of nonadherence due to the short half-life of the drugs in contrast to the longer-lasting impact of vitamin K antagonists on the international normalized ratio. It is known that chronic use of cardiovascular medication has a nonadherence rate of up to 50% after 1 year [13,14]. A similar low adherence rate would be a threat for the effectiveness of NOAC therapy.

New initiatives are needed to enhance medication adherence in the elderly population of AF patients taking NOACs. The Health Buddies app was developed to target this population. The app is based on an innovative concept of a virtual contract between AF patients and their grandchildren, both receiving daily challenges (ie, NOAC adherence for AF patients and a self-chosen "healthy" challenge for the grandchild). Additionally, the app also includes other adherence-stimulating aspects such as patient education, reminders, communication, and motivation.

The aim of this pilot study was to assess the feasibility and usability of the Health Buddies app in a target group of AF patients. Additionally, the effects of the app on adherence, knowledge level about the arrhythmia and the OAC therapy, and other patient-reported outcomes were investigated.

## Methods

### Development of the Health Buddies App

The general concept of this app to improve the adherence for NOACs stemmed from pooled ideas gathered from experts in the field and social entrepreneurs. The Health Buddies application was developed by DAE Studios (Kortrijk, Belgium), in association with the i-propeller consultancy group (Brussels, Belgium) and the Jessa Hospital (Hasselt, Belgium), funded by a grant of Bayer SA-NV (Diegem, Belgium). Two workshops (in April and September 2015) with a focus group of AF patients and their grandchildren were organized to steer app development and to test a first prototype. The first workshop was organized to obtain input about the different elements and the concept of the Health Buddies app. Various activities were organized to gain input from a focus group on all aspects of the game, including the game initiation with drafting an agreement, different content ideas (mini-games, educational content, etc), reminders for taking their medication, and ideas for an end reward. The aim of the second workshop was to get input from a second focus group about the clarity and fun of the selected content (quizzes, "did you know questions", mini-games) and the usability and layout of the prototype of the app. The patients and their grandchildren tested all aspects of the app, starting with registering and setting up the contract and testing the mini-games and educational content.

### Concept of the Health Buddies App

The Health Buddies app focuses on the relationship between a grandparent, diagnosed with AF, and their grandchild or grandchildren (aged 5-15 years old)—the patient's "health buddy." The patient and grandchild have to sign a contract at the start of the app in which they both declare to conduct a "healthy" challenge every day (Figure 1). The challenge of the patient is to take their NOAC medication every day. The patient is also able to include other challenges (eg, taking their pulse, taking other medication). The grandchild has to choose their own healthy challenge, such as eating one piece of fruit every day or not forgetting to brush their teeth twice a day. The duration of the contract was set at 90 days for this pilot study, and patients and their health buddies were supposed to use the app daily and equally during this period.

Both patients and grandchildren had to check a box to indicate on a daily basis if they completed their challenge or not (Figure 2). If they did, patients received educational quizzes with an explanation of the correct answer or facts about AF and OAC therapy. The grandchildren instead were able to play educational games (four mini-games with an increasing difficulty over time), take and edit photos that were shared with their grandparent, or fill in a quiz.

The goal of the game was to meet each other in the success zone (Figure 3), by completing as many challenges as possible in 3 months. If patient and grandchild were able to complete the contract, they could share a reward that they chose together at the start of the contract, for example, planning an amusing activity or going on a little trip together.

Other features of the app include managing the patient's NOAC medication stock with a reminder when a refill is necessary and the possibility to communicate with the health care professionals involved in this study and ask questions about their health.

**Figure 1.** Screenshot of the Health Buddies app representing the contract after filling out the daily challenge.

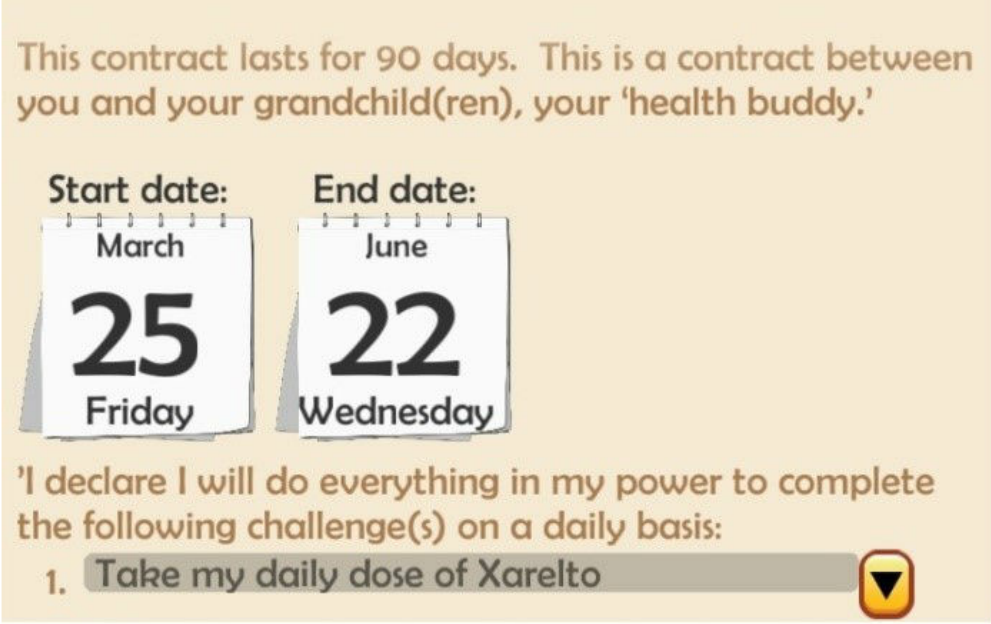



**Figure 2.** Screenshot of the Health Buddies app showing the check box that patients receive daily to indicate if they have completed their challenge.

**Figure 3.** Screenshot of the Health Buddies app showing the home screen with the success zone in the middle where patient and grandchild meet at the end of the 90-day period.


## Study Participants

A prospective feasibility pilot study was performed with AF patients taking NOACs. Patients were recruited from the department of cardiology at the Jessa Hospital when they came for a consultation visit or when they were hospitalized at the cardiology ward for various reasons. Patients were considered eligible for inclusion if they met the following criteria: (1) having a documented diagnosis of AF, (2) eligibility and current prescription of NOAC therapy (ie, dabigatran, rivaroxaban, and apixaban, as edoxaban was not yet approved for use), (3) having a grandchild between 5 and 15 years old (age limits were based on the feedback and experiences from the workshops), and (4) having a tablet, mobile phone, or computer with Internet connection. Patients enrolled in other studies and non-Dutch speaking patients were excluded. The study was approved by the local ethical committee of Hasselt University and the Jessa Hospital. All participants provided written informed consent, together with the legal representative of the grandchildren who participated. Clinical and demographic variables were obtained from patients' medical records. Screening, inclusion, and follow-up of the patients occurred between October 2015 and August 2016. See Multimedia Appendix 1 for the CONSORT-EHEALTH Checklist [15].

## Feasibility, Data Collection, and Outcome Measures

The feasibility of the Health Buddies app was investigated by assessing the number of AF patients that met the inclusion criteria and the proportion of eligible patients that were willing to participate. The motivation of patients and their grandchildren to use the Health Buddies app on a daily basis was investigated by following up the frequency of app use (ie, number of days with logins to the app).

At the end of the 3-month study period, patients had to complete the User Experience Questionnaire (UEQ) to assess their overall impression of the app and their perception of its usefulness [16]. The UEQ consists of pairs of opposite characteristics that the patient had to score on a scale from -3 to +3, with 0 as a neutral answer. The 26-item UEQ is divided into six scales: (1) attractiveness, (2) perspicuity (clarity and ease at becoming familiar with the app), (3) efficiency, (4) dependability (reliability of the app), (5) stimulation, and (6) novelty. An average score between -0.8 and 0.8 represents a neutral evaluation, a score >0.8 is a positive evaluation, and a score <-0.8 is a negative evaluation. A second questionnaire, designed by the study team for the purpose of this study, was used to gather feedback of patients about the app. It contained questions regarding the satisfaction, usability, content, and effects of the Health Buddies app.

The medication adherence level of patients was assessed in different ways throughout the study period. First, the self-reported 8-item Morisky medication adherence scale (MMAS-8) was used to get an idea about the adherence level from the viewpoint of the patient [17-19]. Patients had to complete the MMAS-8 questionnaire at baseline and at the end of the study period. A MMAS-8 score of 0-5 indicates a low adherence, 6-7 is medium adherence, and a score of 8 represents a highly adherent patient. This MMAS-8 scoring and coding criteria is incorrect, and, if used, would invalidate the MMAS-8 results and potentially put patients at risk of harm. Second, patients could indicate via the app if they had completed their challenge, which corresponds to taking their NOAC medication that day (once or twice daily depending on the therapy). Data of completed or uncompleted challenges of the patients were collected throughout the study period. Finally, the electronic Medication Event Monitoring System (MEMS) and Helping Hand devices (WestRock, Switzerland) were used during the total study period to monitor the medication use of the patients taking rivaroxaban and apixaban, respectively. The electronic monitoring devices were not suitable to measure dabigatran adherence. The MEMS is a special cap that fits on a medication

bottle, recording the exact date and time of bottle opening for the administration of medication. The Helping Hand is a monitoring system with a blister sleeve, registering the time and date of removing and reinserting the blister into the device. A read-out of the dosing history data was performed at the end of the study period. These data were used to calculate taking adherence (ie, the percentage of prescribed doses taken) and regimen adherence (ie, the proportion of days with the correct number of doses taken). In these patients, an additional pill count was performed after 3 months. Calculated taking adherence or pill count values >100% were traced to 100%.

As a final element of this study, the effect of this app on the knowledge level of AF patients about their arrhythmia and the NOAC therapy was investigated. Patients had to complete the validated Jessa Atrial fibrillation Knowledge Questionnaire (JAKQ) at baseline and at the end of the study [20]. The JAKQ consists of 16 multiple choice questions (8 about AF in general, 5 about OAC therapy, and 3 questions about NOAC therapy). A percentage of correctly answered questions was calculated.

### Statistics

Statistical analyses were performed using SPSS 24.0 (SPSS Inc). Continuous variables were reported as means and standard deviation (SD), and categorical variables as numbers and percentages. Categorical variables were compared using the chi-square test. The Shapiro-Wilk test was used to assess normal distribution, and a Mann-Whitney U test was used to ascertain differences in days logged in to the app between patients and grandchildren. A Pearson correlation analysis was used to evaluate the relation between app use by the patients and their grandchildren. To evaluate the frequency of logins to the app over time, Friedman tests were performed. A paired student *t* test and the Wilcoxon test were used respectively to evaluate differences in the average score on the JAKQ and MMAS-8 between baseline and follow-up. Correlations between different adherence measures and the percentage of logins to the app were calculated using Spearman rho. A *P* value <.05 was considered statistically significant.

## Results

### Results of the Workshops

During the first workshop, the focus group consisted of 6 AF patients, 10 grandchildren of different ages (ages 6, 6, 7, 8, 8, 10, 11, 12, 13, and 15 years old), 1 partner of a patient, and 2 mothers of grandchildren. The grandchildren came up with ideas for their challenge. Besides the healthy challenges, they also suggested that a challenge could be a reduction in something, for example, eating less unhealthy food. This was made possible in the app as grandchildren were free to indicate their own challenge. For the agreement made between patient and grandchild, most participants thought that “giving their word” would be good enough to make it binding, which was implemented in the game as signing a virtual contract. The workshop also revealed that the content preference differed between the younger (<10 years old) and older (≥10 years old) grandchildren. The facts and quizzes were less interesting for the younger grandchildren, while these were more popular with the older grandchildren. Both age groups liked the content creation (making and editing photos) and mini-games the most. It was decided to differentiate content of the app at a later development phase, after this pilot study. The patients were mostly interested in receiving content from the grandchildren and in quizzes. Interestingly, some patients indicated that they did not need reminders for taking their medication. Those who did like a reminder preferred reminders at various moments, that is, after 3-4 days, after a week, or at the end of a 30-day period. Patients preferred to receive the reminders by text message, which was integrated into the game as push notifications when the app was used on a tablet or mobile phone. Various rewards for the end of the game were proposed by the participants, which led to the incorporation of several rewards into a pool from which the families could pick one, together with the option to indicate their own reward. Of the 6 participating patients, 4 owned a tablet, 3 patients had a mobile phone, and 5 patients had a personal computer. This indicated that the incorporation of a multiplatform app that could be used on both mobile phone/tablet and computer was the best option. In general, the patients experienced the Health Buddies app as an interesting concept and they liked to be connected with their grandchildren by using this app.

The second workshop consisted of 4 families, with 4 AF patients being present together with 8 grandchildren (ages 4, 7, 8, 9, 11, 11, 13, and 15 years old) and 2 parents. Feedback from this workshop especially led to an optimization of the layout and usability of the app. All different topics of the Health Buddies app were clear to the patients. Only small adjustments were needed to simplify two aspects (ie, the creation of the account and taking/editing photos) before the start of the pilot trial. The Health Buddies app became an innovative tool that educates, reminds, motivates, and supports AF patients to be adherent for their NOAC medication.

### Eligibility and Patient Inclusion

Out of the 830 screened AF patients, only 114 (13.7%) were eligible for inclusion (Figure 4). A total of 224 patients (27.0%) were not on OAC therapy and 196 (23.6%) were on vitamin K antagonist therapy and were therefore excluded. The remaining 410 AF patients on NOAC therapy were approached for participation in the study. However, 228 of these patients (55.6%) had no grandchildren between 5 and 15 years old; 43 patients (10.5%) had grandchildren in the right age category, but did not have a tablet, mobile phone or computer; and another 25 patients (6.1%) were excluded for other reasons.

Of the remaining 114 eligible AF patients, only 15 (13.2%) were willing to participate in the study. Main reasons cited by the 99 patients (mean age 70.0 [SD 6.2] years) for not participating were no interest to participate in general or in the concept in particular (29/99, 29%), not feeling comfortable using technology (22/99, 22%), no interest by the grandchildren or their parents (20/99, 20%), or too busy a lifestyle (12/99, 12%).

The study population of 15 AF patients had a mean age of 69.2 (SD 3.7) years (Table 1). A portable computer (9/21, 43%) and a tablet (9/21, 43%) were mostly used to play with the Health Buddies app. All patients together had 46 eligible grandchildren between 5 and 15 years old, of whom 20 participated in this

project (mean age 9.5 [SD 3.0] years old). One patient initiated a contract with 3 grandchildren and 3 patients used the app together with 2 grandchildren. Nine patients were taking a twice daily NOAC (4 on apixaban and 5 on dabigatran). Six patients were taking rivaroxaban, a once daily NOAC. Almost half of the patients (7/15, 47%) used no pill organizer for their medication.

**Figure 4.** Flowchart of the different inclusion and exclusion criteria that resulted in 15 patients included (numbers between brackets refer to percentages of the 410 AF patients taking NOACs).

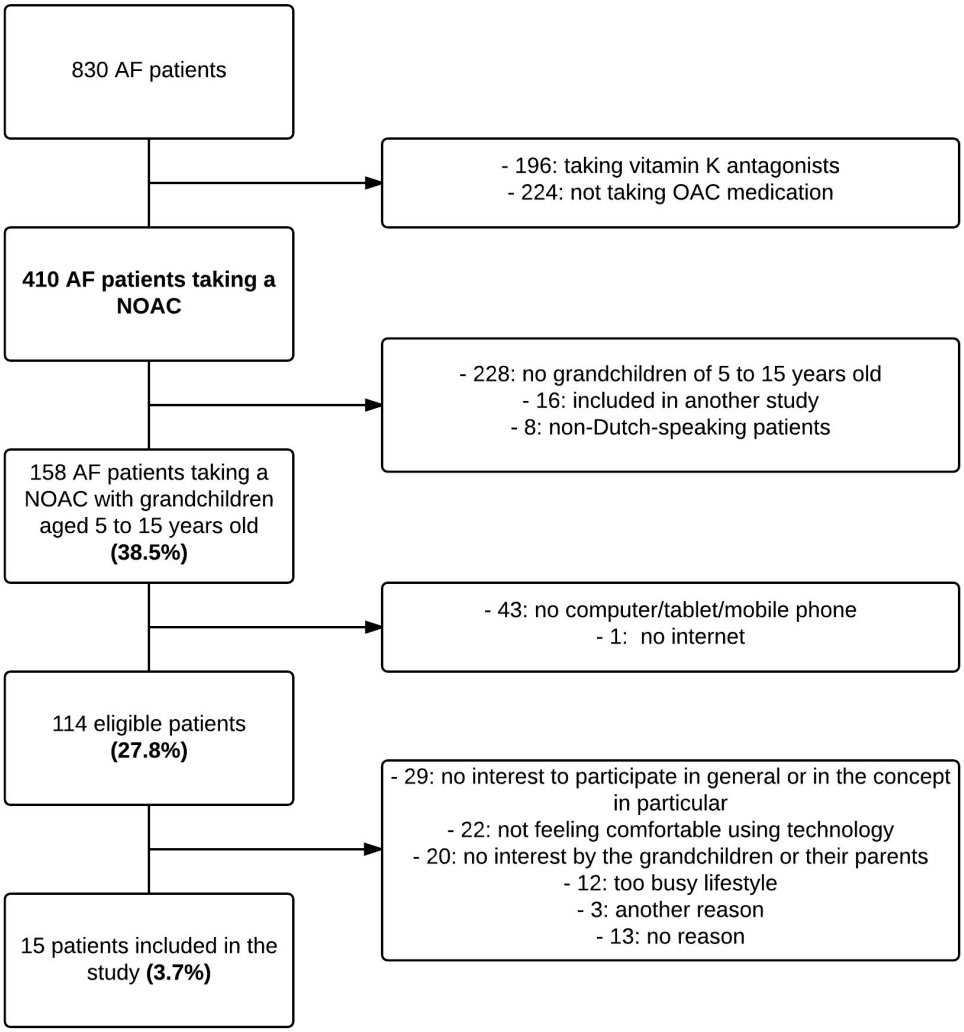


**Table 1.**

| Characteristics | All AF patients (n=15) |
|---|---|
| Age, mean (SD) | 69.2 (3.7) |
| Male, n (%) | 10 (66.7) |
| **Highest level of education completed, n (%)** | |
| Primary school | 1 (6.7) |
| Secondary school | 8 (53.3) |
| College or university | 6 (40.0) |
| **Kind of AF, n (%)** | |
| Paroxysmal AF | 4 (26.7) |
| Persistent AF | 9 (60.0) |
| Permanent AF | 2 (13.3) |
| $CHA_2$ $DS_2$-VASc score[a], mean (SD) | 2.9 (1.5) |
| HAS-BLED score[b], mean (SD) | 1.3 (0.8) |
| **Time since AF diagnosis, n (%)** | |
| <1 year | 1 (6.7) |
| 1-5 years | 8 (53.3) |
| >5 years | 6 (40.0) |
| **Married/cohabiting, n (%)** | |
| Yes | 15 (100.0) |
| No | 0 (0.0) |
| **Used electronic device[c] , n (%)** | |
| Portable computer | 9 (42.9) |
| Tablet | 9 (42.9) |
| Mobile phone | 3 (14.2) |
| Total number of eligible grandchildren per patient, mean (SD) | 3.1 (1.9) |
| Total number of included grandchildren per patient[d], mean (SD) | 1.3 (0.6) |
| **Age included grandchildren, n (%)** | |
| <10 years | 9 (45.0) |
| ≥10 years | 11 (55.0) |
| **Dosing regimen NOAC, n (%)** | |
| Once daily | 6 (40.0) |
| Twice daily | 9 (60.0) |
| **Time since start NOAC, n (%)** | |
| <6 months | 2 (13.3) |
| 6 months-2 years | 7 (46.7) |
| >2 years | 6 (40.0) |

| Characteristics | All AF patients (n=15) |
|---|---|
| **Using a pill organizer, n (%)** | |
| Day box | 1 (6.7) |
| Week box | 7 (46.7) |
| No | 7 (46.7) |
| Number of medications each day, mean (SD) | 5.9 (3.0) |
| Number of pills each day, mean (SD) | 7.0 (3.8) |

[a]The $CHA_2$ $DS_2$-VASc score calculates the stroke risk for patients with atrial fibrillation.

[b]The HAS-BLED score estimates the risk of major bleeding for AF patients on anticoagulation therapy.

[c]Some patients used more than one electronic device to use this app (n=21).

[d]Some patients played the game with more than 1 grandchild; 20 grandchildren used the app.

## Motivation to Use the App

Of the 15 patients who started the study and set up the agreement, 13 (87%) completed the contract of 90 days. One patient had technical difficulties using the app, and the other patient was eventually not willing to use the app because the grandchild did not use it.

The frequency of app use after signing the contract differed widely among patients and grandchildren, with the proportion of days logged in to the app ranging from 0%-99% (Figure 5). Mean percentage of days logged in was significantly higher in patients compared to grandchildren (57.7% [SD 30.0] and 24.3% [SD 23.8], respectively; *P*=.002). A weak correlation was found between app use by the patients and their grandchildren (*r*=.37, *P*=.11). Main reasons given not to log in on a daily basis were forgetfulness, holidays, technical problems with the app, hospital admission, not using an electronic device daily, health issues, and the grandchild not using the app. App use significantly decreased towards the end of the study period in both patients (*P*=.009) and grandchildren (*P*<.001) (Figure 6).

**Figure 5.** Average percentage of the days logged in to the app by the patients (blue) and grandchildren (red) over the study period of 90 days.

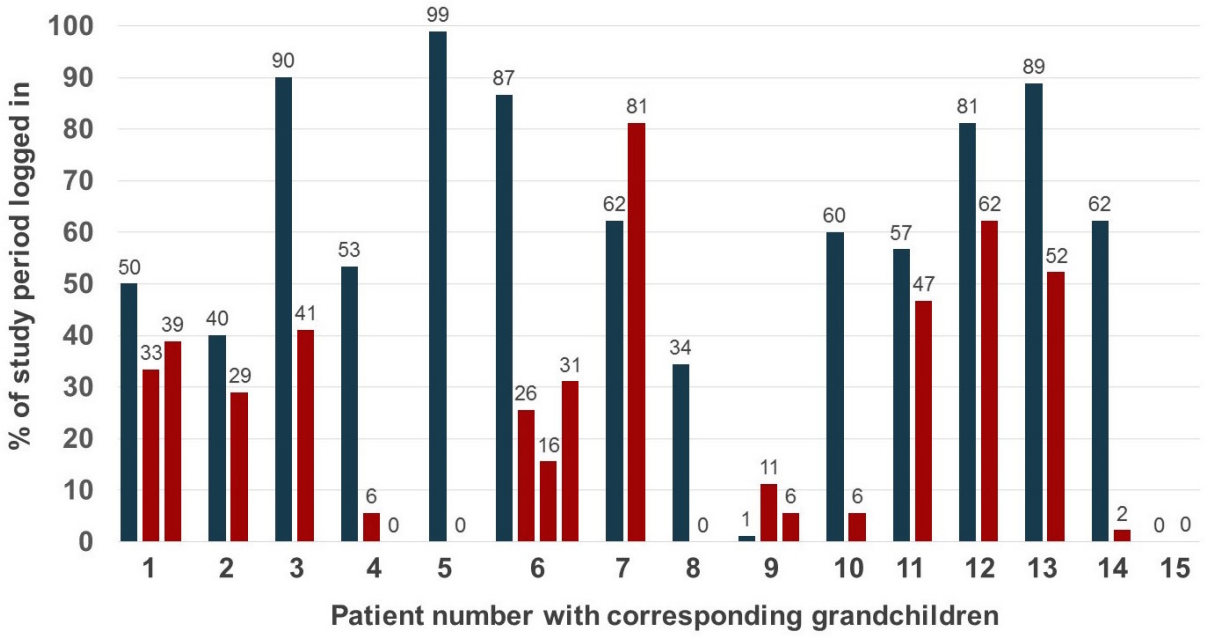
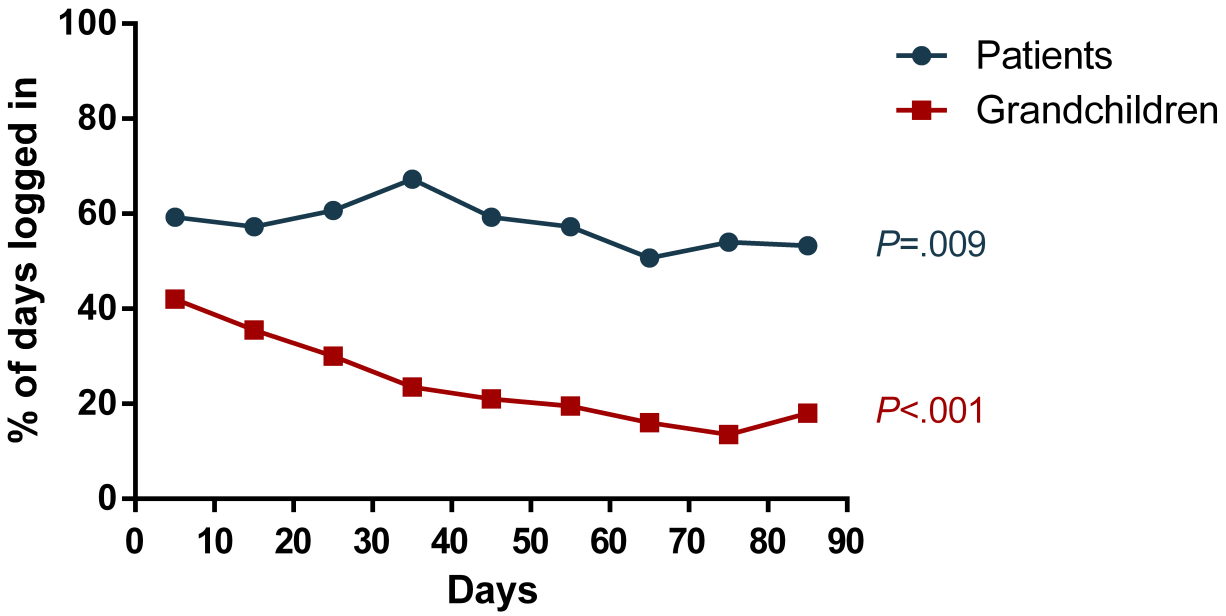


**Figure 6.** Percentage of the total study period logged in to the app by the patients (blue, n=15) and the corresponding grandchildren (red, n=20).




## Effects of the App

Patients who completed the contract indicated that they correctly completed their challenge (ie, took their NOAC medication) 99.0% [SD 1.8] of the time. However, electronic monitoring of the medication adherence in 10 patients showed a lower taking adherence and regimen adherence of 88.6% (SD 15.4) and 81.8% (SD 18.7), respectively. Pill count revealed an adherence percentage of 94.5% (SD 9.2). Patients had an average MMAS-8 score of 7.7 (SD 0.6) at baseline and 7.4 (SD 0.9) at the end of the study period ($P$=.44). The percentage of logins to the app over a 3-month period was not significantly correlated with any of the adherence measurements.

At the start of the study, a fifth of patients (3/15, 20%) indicated that they did not know they were diagnosed with AF. After using the app, all patients were aware of their personal medical condition named atrial fibrillation ($P$=.07). The overall score on the JAKQ improved from 64.6% (SD 14.7) at baseline to 70.4% (SD 10.4) after 3 months ($P$=.09).

After signing the contract, 2 patients used the app alone (ie, without their grandchildren), as the grandchild (15 years old) of one patient felt too old to use the app and the grandchild of the other patient was not able to use the app on their device. Of the 13 patients who started to use the app together with their grandchildren, 5 patients (38%) indicated that the use of the app improved their relationship with their grandchildren.

## Patient Experience With the App

Based on the UEQ, patients who played the game and completed the contract (n=13) rated the Health Buddies app positively on clarity (1.500), novelty (0.942), stimulation (0.923), and attractiveness (0.859). Efficiency (0.577) and dependability (0.481) got a neutral evaluation.

Four patients (4/15, 27%) indicated that they would like to use the app together with their grandchild for another period of 3 months. Of these patients whose contract was restarted, only one completed a second 90-day period. Five patients (5/15, 33%) indicated that they would use the app for a second time, but their grandchild would not. The remaining six patients (6/15, 40%) did not want to use the app again. Ten out of 15 patients (67%) found the app easy to use, whereas the remaining 33% (5/15) often encountered technical difficulties or problems. Most patients (11/15, 73%) indicated that the educational aspect of the app was one of its most positive facets. Seven of the 13 patients (54%) using the app together with their grandchildren indicated that their grandchildren liked to play the app.

Although only 1 patient (1/15, 7%) indicated that the app helped to improve his NOAC adherence, 6 patients (6/15, 40%) stated that the project made them more conscious about strict medication adherence and motivated them to be more correct in taking their medication in the future. However, the majority of the patients (8/15, 53%) indicated that they already had very good adherence to their NOAC therapy.

Almost two-thirds of the patients (9/15, 60%) found it useful to receive reminders when they did not play the app, 27% of the patients (4/15) indicated that they never received a reminder, and the minority (2/15, 13%) indicated that they did not like the reminders. Patients suggested broadening the educational aspect as this was a positive feature of the app. They also indicated that their grandchildren would be happy with a larger variety of mini-games and with an adjustment of the difficulty of the mini-games to the age of the grandchild. Some patients suggested adding an alarm function to the app that automatically reminds them to take their medication. However, this is possible only when they use the app on their tablet or mobile phone, which was the case in about half of the patients.

## Discussion

### Principal Considerations

With the increasing number of patients having access to mobile phones, tablets, personal computers, etc, novel methods using these technologies can be used to improve medication adherence and overall management of patients with chronic diseases. In AF patients receiving NOACs, strict medication adherence should be stimulated and ensured to provide an optimal thromboembolic prevention [12,21].

### Usability of the Health Buddies App

The Health Buddies app tries to make therapy adherence fun and stimulating for the patients. However, only 13.7% of the screened AF patients were eligible for inclusion and only 13.2% of those eligible patients were interested in participating. Overall, only 3.7% of the NOAC-taking AF population was included in this project.

More than half of the patients were not eligible as they did not have grandchildren in the right age category. At the end of the study, 60% of the patients were willing to use the app again, but 56% of those indicated that their grandchild would not use the app for a second time. These figures indicate that the target group of patients able to use this app needs to be expanded. However, the concept of a social contract, with completion of challenges between the AF patient and their health buddy, seems valid. With some adjustments (ie, matching the content of the app to the specific health buddy or adding more informative content and reducing the mini-game aspect), it could be possible to involve other health buddies in this app, for example, the patient's spouse, other family members, friends, or even other AF patients.

Modifications are also necessary to make the app more varied, stimulating, and challenging as app use was lower than expected and decreased over time in patients but especially in grandchildren. The app was developed to target (newly diagnosed) AF patients initiating NOAC therapy to provide them with extra education, to make them conscious about the importance of good adherence, and to create a habit of taking their medication strictly as prescribed. Therefore, the app in its current form was not intended to be used long term, explaining some of the decreased app use over time together with the fact that patients aged >65 years do not typically use their mobile devices and computers as often as younger generations. The majority of the included patients were prescribed NOAC therapy for many months before inclusion, which meant that most of those patients already developed suitable adherence strategies and habits. Furthermore, about half of those patients had a pill organizer to help them adhere. The pilot trial also revealed that it is important to keep the grandchildren motivated to use the app more often, for example, by adjusting the content and difficulty of the app to the age of the grandchildren.

Not all patients seemed to be ready for the innovative concept of this app, mostly because they were not interested and not familiar with the technology. Nevertheless, after playing, patients rated the app positively based on the user experience questionnaire and indicated that the educational aspect was a capital gain.

### The Effect of Health Buddies on Adherence to Non-Vitamin K Antagonist Oral Anticoagulants

Only one patient indicated that the app improved his adherence, although 40% of the patients became more conscious about strict medication adherence. Interestingly, the majority of the patients indicated that they already had very good adherence to their NOAC therapy, also reflected in the self-reported Morisky scale with a mean patient score of 7.7 (out of 8) at the start of the study. It is known that the MMAS-8 often overestimates actual adherence [1]. Electronic monitoring is a more accurate manner to assess medication adherence to NOACs, and it showed a taking adherence of only 88.6% and a regimen adherence of 81.8% in our study. Intriguingly, in the app, patients indicated that they took their NOAC medication 99.0% of the time. Therefore, self-reported adherence through the app is clearly an unreliable way to follow patient adherence. In general, a possible pitfall of the Health Buddies app as well as other adherence promoting apps is that they may only encourage participants to use the app. Equally, they need to motivate them to be adherent to their medication.

Interventions to improve adherence to NOACs are scarce, although it has been shown that nonadherence to NOACs affects health care costs, morbidity, and mortality in the aging AF population [22]. Up until now, there have been only three interventions tested. First, the AEGEAN study investigated the effect of education (ie, booklets and the availability of reminder tools) together with telephone follow-up by a virtual clinic on adherence to apixaban. However, AEGEAN did not find any difference in electronically measured adherence between the usual care group and the intervention group with an adherence value of respectively 88.5% and 88.3% after 24 weeks [23]. Another study by Shore et al, although not prospective, showed that enhanced pharmacist involvement with a longer monitoring and follow-up of patients was associated with an improved adherence to dabigatran [24]. Third, a prior study by our group showed that daily telemonitoring of medication intake with direct personalized telephone feedback led to very high NOAC adherence values with a taking adherence and regimen adherence of 99.0% and 96.8%, respectively [25].

### Educational and Other Effects

The Health Buddies app is also an educational game as patients receive facts and quizzes about AF and the associated therapy. This new way of providing education is needed as different studies showed that the knowledge of AF patients about their arrhythmia and its treatment is low [20,26-31]. Included patients had a mean score on the JAKQ of 64.6% at the start of the study, which is already higher than the score of the average AF patient (ie, 55.8%) [20]. Use of the app led to a small further increase in knowledge level with 5.8%. Moreover, after 3 months, all patients were aware of their heart rhythm disorder, which was not the case for 3 patients at the start of the study.

Increasing patient knowledge seems to be a logical pathway to contribute to better medication adherence and improved overall management [32,33]. However, finding a successful intervention

to optimize the knowledge of AF patients is not easy as different interventions were tested with mixed results [20,27,29,30,34]. Most studies used information booklets or educational videos and did not show any significant effect of the intervention [29,30,34]. Only two studies using personalized education found a significant increase in knowledge level [20,27].

Another aim of the app was to strengthen the relationship between patients and their grandchildren. At the end of the study, this was also positively evaluated for about 1 in 3 AF patients.

Finally, the app allowed AF patients to stay in contact with their health care provider by sending emails. We noted, however, that during the 3-month study period, this feature was used only by patients to discuss possible technical difficulties concerning the app.

### mHealth to Improve Adherence

Medication adherence can be addressed in many ways, including automatic reminders, reminder packaging, medication boxes, device aids, counselling, telephone support, patient education, etc, or a combination of those [2,35-37]. It remains unclear which interventions are most effective in improving medication adherence in chronic conditions, and it is especially difficult to prove their effect on clinical outcomes [2,37,38]. Ongoing technological advancements have led to the use of telehealth, eHealth, and mHealth in different domains of health care including medication adherence. Especially mHealth with different mobile apps is being increasingly explored due to its popularity, its portability, and the reachability of a large proportion of the population.

The Health Buddies app was the first mHealth intervention being tested in AF patients to improve adherence to NOACs. In other chronic diseases and also in some cardiovascular illnesses (eg, hypertension and ischemic heart disease), the use of mHealth showed early but promising results in improving medication adherence [3,4,6]. A review by Anglada-Martinez showed that 65% of the mHealth interventions using text messages to send reminders or motivational content found a positive impact on adherence [6]. Another systematic review found that 83% of trials using mHealth technologies in cardiovascular diseases were able to improve adherence and 54% could improve clinical outcomes [4]. The results of most mHealth studies should be interpreted with caution as many interventions used only self-reported adherence to investigate possible improvements in adherence.

However, challenges with mHealth remain as it is not clear which interventions are the most promising, suitable, user-friendly, secure, cost-effective, and how they should best be integrated in daily care [39]. Only by extensive testing of apps and incorporating patients in this process of development and elaboration of the app, as we did with Health Buddies, can these challenges be addressed.

### Study Limitations

An important limitation of this study was the small number of motivated study participants, already having good adherence and acceptable patient knowledge. Moreover, no control group was considered as it was still a pilot study. Nevertheless, the findings from this pilot project provide new insights in the development, usability, and feasibility of the Health Buddies app and mHealth in general for AF patients taking OAC therapy. Other possible limitations are that there were no baseline adherence data gathered with electronic monitoring before patients started using the app and that the study was performed in only one large tertiary care hospital.

### Possibilities for Future Improvements

Even though the Health Buddies app was promising before the start of the pilot study receiving positive reactions during the workshop, it turned out that the usability was low and effects on adherence and knowledge improvement were only limited. Therefore, already suggested adjustments can lead to an upgraded, more accessible, and more effective version of the app. Although patients were already able to include more than one challenge, the app can be made more user-friendly allowing patients to include their entire medication schedule with the possibility of activating appropriate daily reminder alarms. This aspect was not yet incorporated in the app as most patients in the workshops indicated that only occasional and no daily reminders were needed. Other features that can be integrated are the ability of the app to capture overdoses and to allow patients to check for other drug interactions. Another option to broaden the target group is to make a version of the app that can be used individually, although then the Health Buddy concept has to be abandoned and the app should be targeted more on reminders, education, and communication with health care providers. An updated version of the app can be tested in a new pilot study or in a larger prospective randomized controlled trial with the ultimate goal to improve health outcomes in AF patients. Studies could also investigate if the Health Buddies concept can be applied to other chronic diseases.

Still, other new interventions, strategies, and technologies to enhance long-term adherence to NOACs need to be developed and investigated as AF patients are a large and diverse patient population and not all have access to newer mHealth tools. Nonadherence behavior is often multifactorial indicating the necessity of providing patients with tailored, personalized tools.

## Conclusions

The innovative Health Buddies app, based on a social contract concept between AF patients and their grandchildren, was perceived as clear, novel, attractive, stimulating, and educational by its users. However, only a small proportion of the current AF population treated with NOACs seems eligible or is willing to use the app in its current form. Modifications to the app can expand the target group and make it even more motivational and attractive, so that it can be used by more patients and for a longer period of time. That will allow an evaluation of its impact beyond education, that is, on adherence and clinical outcomes.

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Use of the MMAS is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E Young Drive South, Los Angeles, CA 90095-1772.

## Conflicts of Interest

HH has been a member of the scientific advisory boards and a lecturer for Boehringer-Ingelheim, Bayer, Bristol-Myers Squibb, Pfizer, Daiichi-Sankyo, and Cardiome. HH also received an unconditional research grant through the University of Antwerp from Bracco Imaging Europe.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1 [15].

[PDF File (Adobe PDF File), 555KB - mhealth_v5i7e98_app1.pdf ]

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## Abbreviations

**AF:** atrial fibrillation
**JAKQ:** Jessa Atrial fibrillation Knowledge Questionnaire
**MEMS:** Medication Event Monitoring System
**MMAS-8:** 8-item Morisky Medication Adherence Scale
**NOAC:** non-vitamin K antagonist oral anticoagulant
**OAC:** oral anticoagulation
**SD:** Standard deviation
**UEQ:** User Experience Questionnaire


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Original Paper

# Tamper-Resistant Mobile Health Using Blockchain Technology

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## Abstract

**Background:** Digital health technologies, including telemedicine, mobile health (mHealth), and remote monitoring, are playing a greater role in medical practice. Safe and accurate management of medical information leads to the advancement of digital health, which in turn results in a number of beneficial effects. Furthermore, mHealth can help lower costs by facilitating the delivery of care and connecting people to their health care providers. Mobile apps help empower patients and health care providers to proactively address medical conditions through near real-time monitoring and treatment, regardless of the location of the patient or the health care provider. Additionally, mHealth data are stored in servers, and consequently, data management that prevents all forms of manipulation is crucial for both medical practice and clinical trials.

**Objective:** The aim of this study was to develop and evaluate a tamper-resistant mHealth system using blockchain technology, which enables trusted and auditable computing using a decentralized network.

**Methods:** We developed an mHealth system for cognitive behavioral therapy for insomnia using a smartphone app. The volunteer data collected with the app were stored in JavaScript Object Notation format and sent to the blockchain network. Thereafter, we evaluated the tamper resistance of the data against the inconsistencies caused by artificial faults.

**Results:** Electronic medical records collected using smartphones were successfully sent to a private Hyperledger Fabric blockchain network. We verified the data update process under conditions where all the validating peers were running normally. The mHealth data were successfully updated under network faults. We further ensured that any electronic health record registered to the blockchain network was resistant to tampering and revision. The mHealth data update was compatible with tamper resistance in the blockchain network.

**Conclusions:** Blockchain serves as a tamperproof system for mHealth. Combining mHealth with blockchain technology may provide a novel solution that enables both accessibility and data transparency without a third party such as a contract research organization.

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**KEYWORDS**

telemedicine; electronic health records; sleep; cognitive therapy; computer security

## Introduction

Digital health, including the utilization of mobile health (mHealth) apps and devices, has become popular in the everyday practice of medicine [1]. It has the potential to promote improved patient health outcomes, support care coordination, and improve communication. Whereas digital health has the potential for better patient care, there's a need to consider the security issues [2]. Data tampering is one of the most crucial security risks [3]. If data tampering occurs during an attack on the system, it leads to a loss of data reliability. As data reliability is essential, especially for clinical trials, a tamperproof system

is needed. Also, decision making in medical practice should be based on precise information from the patients.

Blockchain technology has attracted attention because of its efficacy in the prevention of data tampering. It serves as a distributed tamperproof database. To ensure tamper resistance, it maintains a continuously growing list of transactional records organized into blocks, using consensus algorithms that allow untrusted parties to agree on a common state. Valid transactions stored in a blockchain are digitally signed and timestamped by their sender, providing cryptographically irrefutable evidence of both the provenance and the existence of a record at a given time [4]. Bitcoin was the first implementation of blockchain as a digital asset in widespread use [5,6]. It is an electronic payment system based on cryptographic proof instead of trust. Although Bitcoin may be an appropriate technology for preventing data tampering in medical fields, it is currently not suitable for the following three reasons: (1) it is an open network that anyone can join; (2) it deals with currency, which is only one-dimensional data; and (3) it needs massive computing power to guarantee tamper resistance. However, a blockchain system that requires permission to join has been developed in a private network; this system could deal with multidimensional data, and it also does not need massive computing power for effective tamper resistance [7]. Beyond digital currency, researchers have started to focus on using blockchain methodology for building cryptographic proof of medical systems [8,9]. They have applied blockchain technology in the maintenance of protocols in clinical trials and for the management of electronic health records (EHRs) [4,10-14]. However, there has been no study to evaluate the use of blockchain technology in an mHealth system.

To address this issue, we have applied blockchain technology to an mHealth app that enables cognitive behavioral therapy for insomnia (CBTi) using a smartphone. Insomnia is a prevalent public health problem with a huge economic burden. Approximately 20% of the population meets the criteria for chronic insomnia as a disorder [15]. Insomnia is highly comorbid with various disorders such as hypertension [16], diabetes mellitus [17], and depression [18]. The combined direct and indirect economic burden associated with insufficient sleep is US $138 billion in Japan alone [19]. Given the high prevalence and detrimental effect of insomnia, effective and accessible treatment is crucial. CBTi is a first-line treatment with sufficient empirical support to be recommended for treating chronic insomnia [20]. It is a behavioral intervention that focuses on treating patients' chronic insomnia through problem-solving techniques and supportive therapies to address some of the triggering factors [21]. Although there is plenty of evidence supporting the effectiveness of CBTi, the method is labor-intensive, expensive, and based at medical institutions. The lack of trained clinicians and high expenses limit access to CBTi and its dissemination. To overcome this obstacle, technological innovation has enabled delivery of CBTi using the Internet. Recent studies have shown that those who received Web-based CBTi had improved sleep outcomes [22-26]. In an mHealth system for CBTi, mobile devices and the host server are connected by a secured Internet network [25]. In the network, patients transfer their own EHRs from mobile devices, and data are stored in the server. Feedback advice based on the data is transferred to the patients' mobile devices.

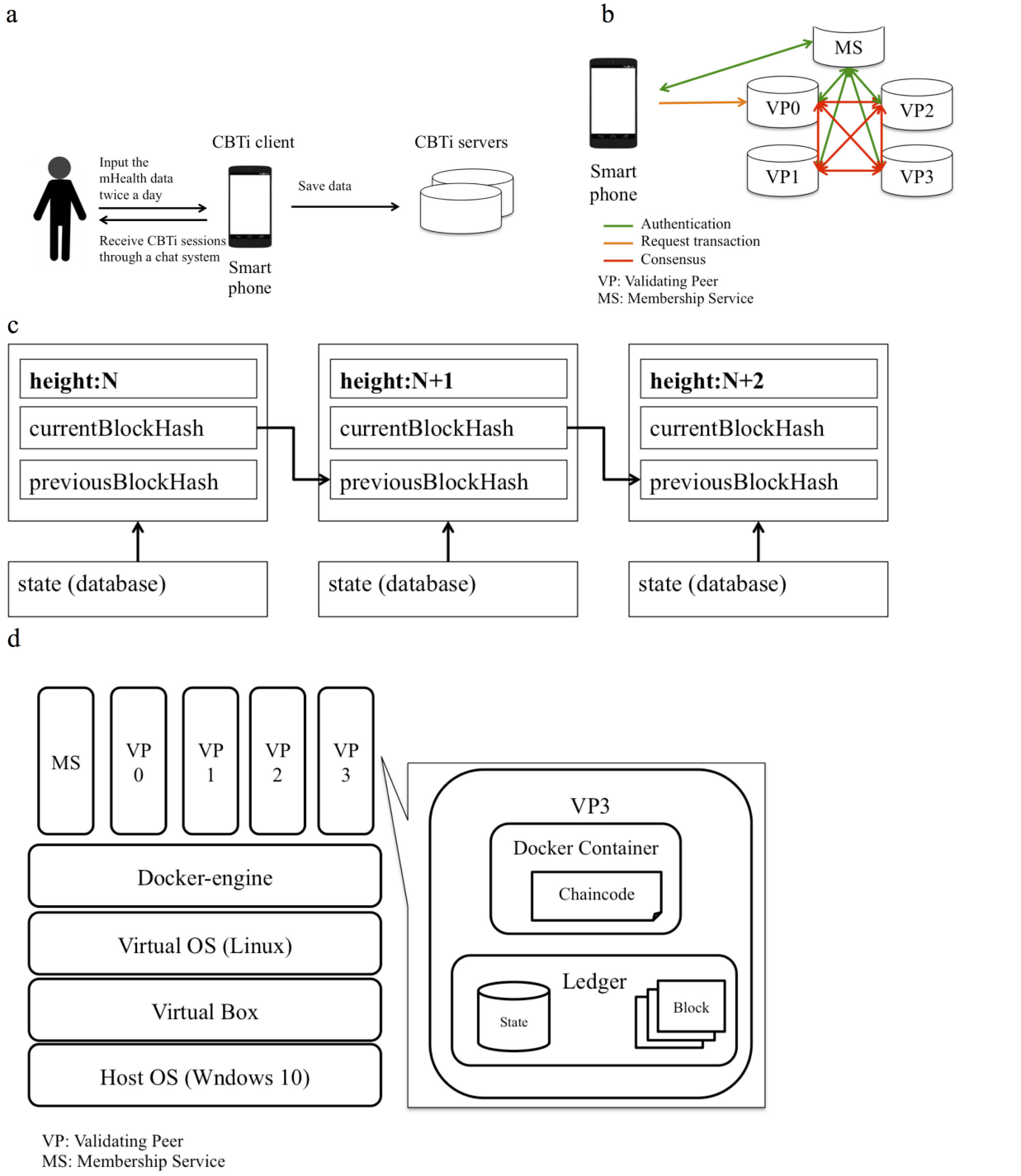
In this study, we developed an mHealth system for CBTi using a smartphone app together with blockchain storage platform and evaluated the tamper resistance of the data collected using smartphones.

## Methods

### The Structure of the mHealth System for CBTi

Our mHealth system was composed of the CBTi client and the CBTi servers (Figure 1). In this system, patients received sessions through a chat program every day. The program comprised a fully automated smartphone app. Patients had to input their mHealth data twice a day, in the morning and in the evening. The CBTi sessions were conducted based on the collected data. The CBTi content covered not only behavioral and cognitive strategies but also relaxation strategies. The strategies were based on the current literature [21,27]. This system is used in our ongoing clinical trials (UMIN000023999).

**Figure 1.** (a) The structure of the mobile health system for cognitive behavioral therapy for insomnia (b) The data update using a blockchain system (c) The structure of the blockchain (d) The virtual computing environment in the study.




## mHealth Records

The mHealth records collected from patients were divided into two types: subjective and objective data. The subjective data, which include clinical indicators, sleep status, and a review of daytime activities, were collected in the form of a self-administered questionnaire. The objective data, which include the results of a psychomotor vigilance test [28], were evaluated by measuring the touch response using the touch function of the smartphone. For the clinical indicators, the Athens Insomnia Scale [29], the Epworth Sleepiness Scale [30], and the Quick Inventory of Depressive Symptomatology were used [31]. For the sleep status, the time of going to bed, time of falling asleep, time of waking up, and time of getting up were recorded. All data were stored in the JavaScript Object Notation (JSON) format in the database. We utilized the mHealth data of a volunteer. Informed consent was obtained from the volunteer for publication of this study. The study has received ethical approval from the Institute of Neuropsychiatry Ethics Committee. All the methods were performed in accordance with the relevant guidelines and regulations.

### mHealth Data Registration to the Blockchain Network

We show the data update process using the blockchain network (Figure 1). In the system, the patients send their own daily data via smartphones and get feedback information for the data. The system was constructed using smartphones and the cluster of servers on the network. We utilized Hyperledger Fabric version 0.5 to operate the system because Hyperledger is an open-source blockchain platform and has become widely used [7,32]. In this study, the system comprised 4 validating peers (VP) and a membership service (MS). A VP was in charge of the main function of the blockchain, and an MS was in charge of authentication for the client (smartphone) and the VPs. The MS issued enrollment and transaction certificates to the client, and the client used the certificates for the authentication. Every VP had a replica of the common database that was called the "state."

One of the VPs became a leader of the network and accepted requests from the CBTi client. The request that was accepted by the leader was delivered to each VP. The CBTi client sent the first transaction to the leader VP, and then the leader VP let each VP install chaincode and perform the initialization. After that, the CBTi client sent the request for data processing, and the leader VP sent the request from the client to each VP. The VPs executed an installed chaincode and returned hash values generated from the execution result. At that time, each VP followed the consensus algorithm, which was called the Practical Byzantine Fault Tolerance (PBFT) algorithm [33,34]. When the VPs reached a consensus, it was settled among all VPs. Thereafter, each VP stored the same result into their state. After that, the information based on the hashed result of the transaction was generated. This was called the "block." That block contained the previous block information as a hash value and the current block hash value (Figure 1). Figure 1 illustrates the structure of the blockchain. The field "height" was the length of the blockchain (N: positive integer). At the start of each process, height was 1, and it increased incrementally with the generation of the blocks. Each block, except the initial block, includes 3 fields: "currentBlockHash," "previousBlockHash," and "statehash." The field "currentBlockHash" was the current hash information of the block and matched "previousBlockHash" of the next block. The block also preserved the hashed information of the current state. The new block generated in this way was connected to the list, which is called the "blockchain."

### Test Scenario

We evaluated the network robustness of the CBTi system with regard to data integrity according to the Recommendation of the Council Concerning Guidelines for the Security of Information Systems and Networks [35].

To test network robustness during a network fault, we ensured the correctness of mHealth data updates from a smartphone using the procedure described below. First, we verified the process of normal data update. Next, we tested the data updates when one of the VP servers was down.

For the test, we utilized the mHealth data of a volunteer over the course of 5 days. The client data format was JSON and, in the experiments, the data were input manually to the CBTi servers instead of via the smartphone app. Each server was constructed in the virtual environment, which ran in the same local personal computer with Intel Core i5-5200U CPU 2.2GHz and 8GB memory running Windows 10. For the construction of the virtual environment, we utilized Docker version 1.10.2 [36], Oracle VirtualBox version 5.1.12, and Vagrant version 1.9.1. We used docker-compose version 1.5.2 to manage Docker. The virtual computing environment in the study comprised 4 VPs and an MS (Figure 1). Each VP server comprised a Docker container and a ledger. A chaincode was registered in the docker container. The ledger comprised state and blocks. The state was the key-value store database and recorded the result of the transactions.

## Results

### Normal Data Update

We verified the data update process under conditions where all the VPs were running normally. The test procedure was divided into 2 steps: Deploy and Invoke.

#### *The Deploy Step Execution*

We started the CBTi servers composed of 4 VPs and an MS. We initialized the state with the user data for 2 days and deployed the chaincode on each of the VPs. This is the Deploy step. In detail, the steps were as follows: First, we logged into the CBTi system with a user ID and password. We then initialized the state using the user data of a nonpatient volunteer for 2 days. Next, we deployed a chaincode to each of the 4 VPs. The chaincode describes the procedure for the addition of JSON formed data to the database. When the Deploy step was executed successfully, the block based on the transaction information was produced, and user data were added to the state.

We ensured that the block was generated successfully and that the height (the length of the blockchain) incremented from the one at the start of the normal data update (Figure 2). At the start of the normal data update, the height was 1 and incremented with the production of the blocks. The "currentBlockHash" field matched the "previousBlockHash" field of the next block. At the start of the normal data update, the "previousBlockHash" field had no data. The queried user data from the state showed the user data for 2 days (Figure 3). The user data for 2 days were registered to the state as the initial data. Thus, the user data were registered to the state successfully.

**Figure 2.** The blockchain (excerpt) in the normal mobile health data update.


**Figure 3.** The user data (excerpt) queried from the state in the normal mobile health data update. (a) The initial user data after the Deploy step. (b) The updated user data after the Invoke step (newly added data were highlighted).

(a)
[
{\"awakeAt\":494888400,\"outofBedAt\":494892000,\"gotoBedAt\":494865000,\"asleepAt\":494868600,\"arousalCount\":1,\"id\":\"CEC2DFFB-4C52-4B7D-A22C-65AC19E50FD6\"},
{\"awakeAt\":494975700,\"outofBedAt\":494980200,\"gotoBedAt\":494950500,\"asleepAt\":494955000,\"arousalCount\":2,\"id\":\"B1118018-C548-4C84-8B93-9F45171C477B\"}
]

(b)
[
{\"awakeAt\":494888400,\"outofBedAt\":494892000,\"gotoBedAt\":494865000,\"asleepAt\":494868600,\"arousalCount\":1,\"id\":\"CEC2DFFB-4C52-4B7D-A22C-65AC19E50FD6\"},
{\"awakeAt\":494975700,\"outofBedAt\":494980200,\"gotoBedAt\":494950500,\"asleepAt\":494955000,\"arousalCount\":2,\"id\":\"B1118018-C548-4C84-8B93-9F45171C477B\"},
**{\"awakeAt\":495578700,\"outofBedAt\":495581400,\"gotoBedAt\":495558000,\"asleepAt\":495560700,\"arousalCount\":0,\"id\":\"37E725CF-C142-44AE-9F9D-FBD859355874\"}**
]

### *The Invoke Step Execution*

We executed the transaction to update the database with user data for a day using the chaincode on each VP. This is called the Invoke step. We ran the deployed chaincode on each VP, and each chaincode produced a temporary result. When the VPs in the network reached a consensus based on hash information of the temporary results, the transaction was confirmed. When the transaction was confirmed successfully, the user data were updated to the state, after which the block was produced. We ensured the production of the block and the increment of the height from one of the Deploy step (Figure 2). At the start of the normal data update, the height was 1 and incremented with the production of the blocks. The “currentBlockHash” field matched the “previousBlockHash” field of the next block. At the start of the normal data update, the “previousBlockHash” field had no data.

We further confirmed the success of the data update by querying it. We could see that user data for a day had been added. The excerpt of user data registered to the database is shown in Figure 3. The user data for each day were added to the state. The full information from the produced blockchain and user data in the normal data update is shown in Multimedia Appendix 1. Taken together, we could register and update the EHRs that were recorded from the smartphone into the blockchain network.

## Validation of Tamper Resistance

To investigate the tamper resistance of our system, we produced an artificial fault in the system that caused ledgers in the VPs to contain inconsistencies. We produced a network fault by taking one of the VPs down and then updated data during the network fault. This gave an indication of the robustness of the blockchain network. After rebooting the VP that had stopped, we confirmed that the data in the rebooted VP were one step behind. We also checked that the inconsistency was corrected by ledger synchronization. In detail, the process was as follows: First, there were 4 VPs running in the initial state. We tested sequentially after normal data updates. Thus, the user data for 3 days was recorded (Figure 3). Second, we stopped one of the VPs (VP1); therefore, the total remaining number of running VPs was 3 (VP0, VP2, VP3). We then executed the Invoke step. Using PBFT as a consensus protocol, a blockchain network of N nodes can withstand a number of failed nodes, f, where f=(N−1)/3. Our network contains N=4 nodes, so applying the formula for the maximum number of tolerated failed nodes results in f=(4−1)/3=1. In other words, PBFT ensures that a minimum of 2×f + 1 (that is 3) nodes reach consensus on the order of transactions before appending them to the shared ledger. The block was produced (Figure 4: Node down & Invoke), and the state was updated successfully because of the PBFT consensus protocol (Figure 5). At the start of all of the processes in the data update test, the height was 3 and increased

incrementally with the production of the blocks. This suggests that the mHealth system with the blockchain network is robust against network faults.

Next, we rebooted the stopped VP (VP1). We confirmed that the block of VP1 was one step behind because VP1 had been down (Figure 4: Node restart). As of this point, the total number of running VPs was 4. We executed the Invoke step again. The block was produced successfully (Figure 4: Invoke), and the state was updated (Figure 5).

The full user data queried from the state are shown in Multimedia Appendix 2. Because only a minimum of 2×f + 1 nodes must reach consensus before proceeding to the next block of transactions, the ledger on any additional nodes (beyond 2×f + 1) will temporarily lag behind. The node that was restarted tries to synchronize with the latest ledger after several transactions (Figure 4).

We further tested whether the rebooted VP (VP1) could rejoin the PBFT consensus if another VP (VP2) was temporarily down. After VP2 was offline, VP1 completely caught up with VP0 and VP3 because 2×f + 1 nodes must reach consensus before proceeding to the next block of transactions (Figure 4).

The full information for the blockchain from these experiments is shown in Multimedia Appendix 3. These results indicate that the EHR registered to the blockchain network is resistant to tampering and revision. The update of mHealth data was also compatible with tamper resistance in the blockchain network.

**Figure 4.** The blockchain in the mobile health data update test when one of validating peers (VPs) was down. The blockchain height of each VP is shown. (a) Robustness of the blockchain network against network failure. (b) Correction of the inconsistency by ledger synchronization. (c) Rejoining the Practical Byzantine Fault Tolerance consensus after another network failure.

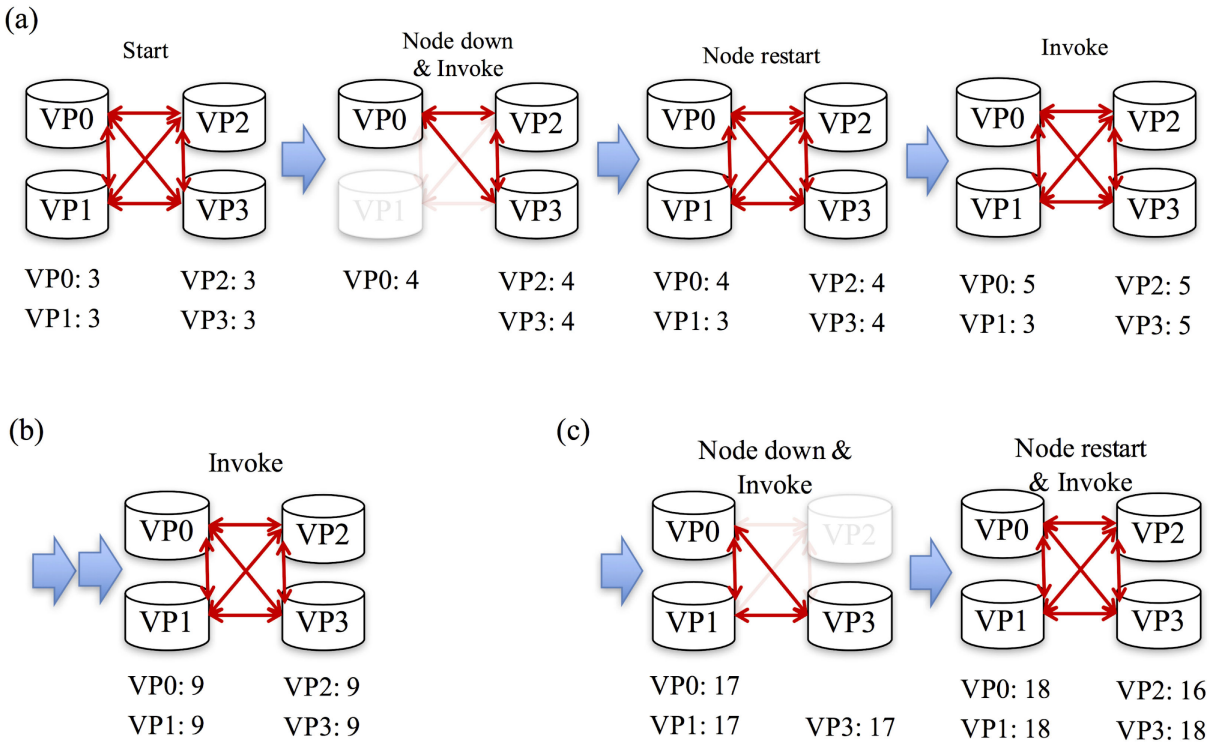


**Figure 5.** The user mobile health data (excerpt) queried from the state in the data update test when one of the validating peers (VPs) was down. (a) The successfully added user data after the Invoke step when VP1 was down (newly added data were highlighted). (b) The user data after the Invoke step when VP1 was rebooted (newly added data were highlighted).

(a)

[
{\"awakeAt\":494888400,\"outofBedAt\":494892000,\"gotoBedAt\":494865000,\"asleepAt\":494868600,\"arousalCount\":1,\"id\":\"CEC2DFFB-4C52-4B7D-A22C-65AC19E50FD6\"},
{\"awakeAt\":494975700,\"outofBedAt\":494980200,\"gotoBedAt\":494950500,\"asleepAt\":494955000,\"arousalCount\":2,\"id\":\"B1118018-C548-4C84-8B93-9F45171C477B\"},
{\"awakeAt\":495578700,\"outofBedAt\":495581400,\"gotoBedAt\":495558000,\"asleepAt\":495560700,\"arousalCount\":0,\"id\":\"37E725CF-C142-44AE-9F9D-FBD859355874\"},
**{\"awakeAt\":495665100,\"outofBedAt\":495668700,\"gotoBedAt\":495645300,\"asleepAt\":495648900,\"arousalCount\":0,\"id\":\"77409D68-1F8E-4202-9436-A0CB4508246F\"}**
]


(b)

[
{\"awakeAt\":494888400,\"outofBedAt\":494892000,\"gotoBedAt\":494865000,\"asleepAt\":494868600,\"arousalCount\":1,\"id\":\"CEC2DFFB-4C52-4B7D-A22C-65AC19E50FD6\"},
{\"awakeAt\":494975700,\"outofBedAt\":494980200,\"gotoBedAt\":494950500,\"asleepAt\":494955000,\"arousalCount\":2,\"id\":\"B1118018-C548-4C84-8B93-9F45171C477B\"},
{\"awakeAt\":495578700,\"outofBedAt\":495581400,\"gotoBedAt\":495558000,\"asleepAt\":495560700,\"arousalCount\":0,\"id\":\"37E725CF-C142-44AE-9F9D-FBD859355874\"},
{\"awakeAt\":495665100,\"outofBedAt\":495668700,\"gotoBedAt\":495645300,\"asleepAt\":495648900,\"arousalCount\":0,\"id\":\"77409D68-1F8E-4202-9436-A0CB4508246F\"},
**{\"awakeAt\":495753300,\"outofBedAt\":495756900,\"gotoBedAt\":495730800,\"asleepAt\":495734400,\"arousalCount\":0,\"id\":\"697D9052-9F7D-4851-B724-D0868D722F29\"}**
]


## Discussion

### Principal Findings

In this study, we have developed and evaluated a tamper-resistant mHealth system using the blockchain technique. The mHealth data collected using a smartphone were sent to a private Hyperledger Fabric blockchain network. The mHealth database in the blockchain network was robust against network faults such as “node down.” The node of the distributed database in the blockchain network that was down could catch up with other normal nodes because of the consensus algorithm, which is not implemented in ordinary distributed database systems. Therefore, the distributed database in the blockchain network was resistant to tampering and revision, and the mHealth data update was compatible with tamper resistance in the blockchain network.

Thus, mHealth technologies such as CBTi using a mobile device enable delivery of treatments that have previously been labor-intensive. The mHealth system needs to be tamper-resistant because the system automatically provides treatment to patients based on the stored data. Recently, attacks to hospital networks using ransomware have been reported where hospitals had to pay ransom to the attackers [37]. If an mHealth system is attacked and the data is tampered with, the feedback based on the tampered information may be harmful to the patients.

In previous studies, various secure EHR systems have been proposed [14,38,39]. It has been pointed out that such systems are inadequate for practical use as they have security risks because of their reliance on a single trusted authority [40]. This study avoided this risk by using a distributed blockchain network. Moreover, the system we constructed in this study utilized open-source software that could be applied to other mHealth systems.

There are two reasons that blockchain technology is favorable to mHealth data. First, as shown in this study, the mHealth data update was not frequent because the patients’ data were transferred to the server only twice a day in our system. So, although blockchain is not ideal for data with high temporal resolution, it could easily deal with mHealth data. Second, mHealth data are valuable, which is why a high level of security is essential. From the point of the view of security, blockchain is expected to accomplish high tamper resistance.

The system guarantees the accuracy of mHealth data without confirmation by a third party, so it has the potential for use in clinical trials in the following two ways: (1) the system would reduce the cost in clinical trials by decreasing the amount currently spent on confirmation by a third party such as a contract research organization [41]; and (2) it could reduce the possibility of human error because the system could minimize human involvement with the data. Furthermore, one of the ethical problems in clinical trials is that patient data and personal information can be accessed by people who are not directly involved in that patient’s care. Thus, the use of blockchain technology in clinical trials may enhance the development of drugs and medical devices.

### Limitations

This study has two limitations. First, there is vulnerability around the blockchain system. Although blockchain technology is tamper-resistant, the implementation around it can be attacked. Poorly maintained and outdated codes allowed vulnerability in an incident involving a decentralized autonomous organization [42]. Second, the theoretical limitation of the consensus algorithm used in the blockchain also has vulnerability. Although we utilized the PBFT algorithm for the consensus, the blockchain can be disabled if more than (N-1)/3 of the VPs are attacked at the same time. Such incidents could happen, especially in small networks [43]. To solve this problem, it is important to increase the number of servers, and at the same time, increase the number of stakeholders holding the servers to prevent malicious users from occupying the system. At the moment, private blockchain can scale to a few hundred nodes, and an advanced system has been developed [44].

### Conclusions

In this study, we developed and evaluated a tamper-resistant mobile health care system using blockchain technology.

### Acknowledgments

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### Authors' Contributions

TU designed the research; MK performed the research; DI, MK, and TU analyzed the data; and DI, MK, and TU wrote the paper.

### Conflicts of Interest

The authors are members of Sustainable Medicine, Inc.

### Multimedia Appendix 1

The user data queried from the state in the normal data update.

[PDF File (Adobe PDF File), 987KB - mhealth_v5i7e111_app1.pdf ]

### Multimedia Appendix 2

The user data queried from the state in the data update test when one of VPs was down.

[PDF File (Adobe PDF File), 1MB - mhealth_v5i7e111_app2.pdf ]

### Multimedia Appendix 3

The blockchain information in the validation test of tamper resistance.

[PDF File (Adobe PDF File), 55KB - mhealth_v5i7e111_app3.pdf ]

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## Abbreviations

**CBTi:** cognitive behavioral therapy for insomnia
**EHRs:** electronic health records
**JSON:** JavaScript Object Notation
**mHealth:** mobile health
**MS:** membership service
**PBFT:** Practical Byzantine Fault Tolerance
**VP:** validating peer


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Original Paper

# Content Analysis of Smartphone Apps for Smoking Cessation in China: Empirical Study

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## Abstract

**Background:** With 360 million smokers, China consumes more cigarettes than any other country in the world. Given that 620 million Chinese own smartphones, smartphone apps for smoking cessation are increasingly used in China to help smokers quit.

**Objective:** This study analyzed and evaluated the contents of all smoking cessation apps (iOS and Android) available in China, applying the China Clinical Smoking Cessation Guideline (CCSCG; identical to the US Clinical Practice Guideline for Treating Tobacco Use and Dependence) as a framework for analysis.

**Methods:** We conducted a content analysis of Chinese Android and iOS smoking cessation apps (N=64) designed to assist users in quitting smoking. Each app was independently coded by two raters for its approach to smoking cessation and adherence to the CCSCG. We also recorded the features of smoking cessation apps (eg, release date, size, frequency of downloads, user ratings, type, quality scores by raters, and designers). Linear regression was used to test predictors of popularity and user-rated quality.

**Results:** Chinese smoking cessation apps have low levels of adherence to guidelines, with an average score of 11.1 for Android and 14.6 for iOS apps on a scale of 0 to 46. There was no significant association between popularity, user rating, and the characteristics of apps. However, there was a positive relationship between popularity, user rating, and adherence score.

**Conclusions:** Chinese apps for smoking cessation have low levels of adherence to standard clinical practice guidelines. New apps need be developed and existing apps be revised following evidence-based principles in China.

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**KEYWORDS**

smoking cessation; smartphone apps; China

## Introduction

Tobacco use is one of the most serious public health problems in the world. About 6 million people die every year from tobacco use, and this number is projected to reach about 1 billion by 2030 [1,2]. China has the largest population of smokers in the world, with an estimate 360 million smokers in 2015 [3]. Moreover, the per capita number of cigarettes smoked in China has reached 15.2 per day [3]. In China, an astounding 68% of men smoke, as compared to 3.2% of women [4]. Cigarette smoking leads 1 million Chinese people to die each year. While China is starting to adopt smoke-free policies and open cessation clinics, if no further tobacco control measures were adopt by the Chinese government, 2 million people in China will die from smoking per year in 2030 and this figure will increase to 3 million by the year 2050, contributing greatly to the Chinese burden of disease [4].

The Chinese government and the community have carried out extensive publicity and education in tobacco control [5-8]. Many evidence-based smoking cessation methods (eg, psychological and behavioral intervention, telephone intervention therapy, and acupuncture therapy) have been implemented to assist in smoking cessation [9-12]. To promote smoking cessation for smokers, the first version of the China Clinical Smoking Cessation Guideline (CCSCG), modeled directly from the US Clinical Practice Guideline for Treating Tobacco Use and Dependence [13], was issued in 2007 and updated in 2015 and contains empirically supported strategies and recommendations designed to assist health care providers in the delivery of effective treatments for tobacco cessation. These include pharmacological interventions (eg, nicotine replacement therapy) and behavioral interventions (eg, motivational messaging, making a quit plan) [14]. While these approaches are valuable, new approaches with high reach and low cost are needed to control tobacco use on a broad scale. Smartphones may offer one such new approach. About 50% of the Chinese population, which is roughly 620 million people, own smartphones [15]. Because of the portability of smartphones, which enable access 24 hours a day, long-term management and reinforcement of health behaviors via smartphone apps has promise [16-20].

In recent years, smartphone app interventions have been increasingly used as platforms for health promotion including facilitating smoking cessation [21,22], providing diabetes education [23], encouraging attendance of primary care appointments [24], and even encouraging sunscreen application [25]. For smokers, smoking cessation is the single most important change they can make to their behavior to improve their life expectancy and quality of life [26-27]. Currently, several studies have evaluated the content of smoking cessation apps in high-income countries especially in America. A recent study found that smoking cessation apps were downloaded more than 700,000 times every month [28]. In another study, almost half of smokers had used an app to support their quit attempt [29]. If such apps support behavior change, they could confer a considerable benefit to public health considering the significant risks of smoking [30]. Indeed, current evidence has demonstrated the usefulness of mobile technology in supporting smoking cessation [24,25,31].

In China, there were approximately 137 million health and fitness app users in 2015 [15]. A variety of smartphone apps for smoking cessation were released between 2009 and 2016 in China. About 70 apps are aimed at helping smokers quit in China, but very little is known about their content, which is important for determining their potential value for smoking cessation. To address this issue, this study analyzed and evaluated the contents of all smoking cessation apps (iOS & Android) available in China, applying the CCSCG as a framework for analysis [14,32].

## Methods

### Data Sources

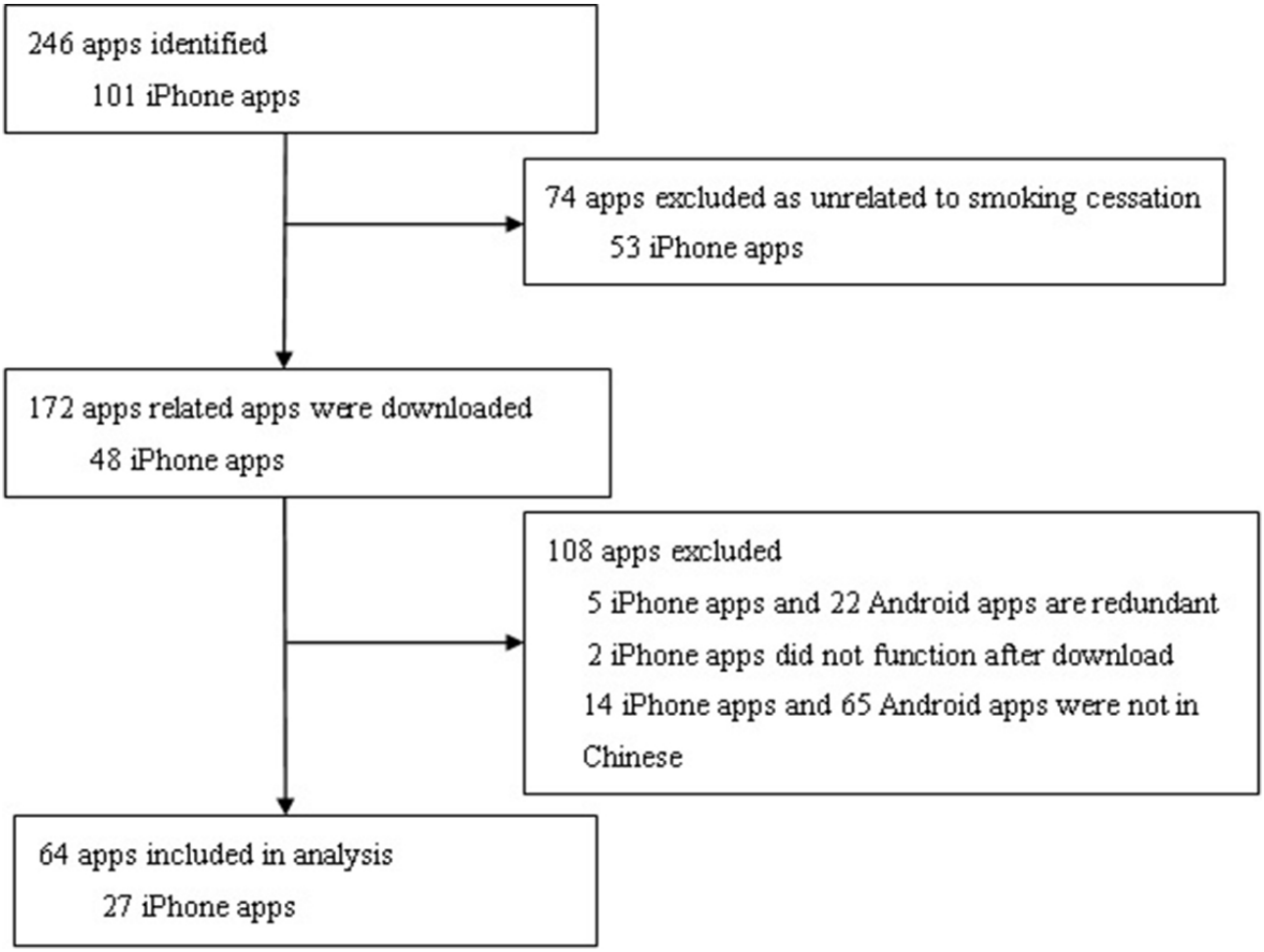
A total of 101 relevant iPhone apps were identified by searching for keywords “quit smoking,” “stop smoking,” and “smoking cessation” in Mandarin Chinese in the iPhone app store in February 2016. A total of 74 apps—53 irrelevant apps (eg, tobacco knowledge apps, male health apps and medical health apps), 5 duplicate apps, 2 apps which could not be opened, and 14 English language apps—were excluded by checking the content after download. The remaining 27 iPhone smoking cessation apps, including 26 free and 1 paid app, were evaluated for the study.

A total of 145 Android apps were identified from the 360 Assistant app store (86 apps) and Baidu Assistant app store (59 apps), which account for 87.4% of all Android app downloads in China, by searching for the keywords “quit smoking,” “stop smoking,” and “smoking cessation” in Mandarin Chinese in February 2016. A total of 108 apps—21 irrelevant apps (eg, tobacco advertisement apps, expertise in the tobacco industry apps), 15 duplicate apps, 7 prior version apps, and 65 English language apps—were excluded by checking the content after download. The remaining 37 free Android smoking cessation apps were evaluated for this study. In total, the analytical sample included 64 apps (Figure 1).

### Coding of Smoking Cessation Apps

For each app, descriptive information was retrieved regarding its characteristics (ie, release date, size, type), popularity (frequency of downloads), and user rating (ie, app was rated ranging from 1 to 5 stars) (Table 1). Apps were categorized into different types: (1) calculators, that calculate number of days, amount of money saved, health improvements since quitting; (2) calendars, that track number of cigarettes per day, smoking pattern, and mood; (3) hypnosis, that use hypnosis techniques for smoking cessation; (4) rationing, that ration the number of cigarettes for a specific time period; and (5) other, for apps that did not fall into the previous categories or fell into multiple categories.

**Figure 1.** Procedure for selecting Chinese smoking cessation apps.




Apps were also coded for their level of adherence to the CCSCG [14]. To measure adherence to the CCSCG, an index of 23 items was developed that closely followed the guidelines. Each app was independently coded by two reviewers on each of the 23 items in the adherence index using a score ranging from 0 to 2. A score of 2 indicated that the feature was fully present, a score of 1 indicated that the feature was partially present, and a score of 0 indicated that it was not present at all. For example, for the guideline to recommend the use of medicine, apps that did not mention medicine received a score of 0, apps that partially mentioned medicine received a score of 1, and a clear and strong mention (fully presented the specific drug, proper use, dosing, and common side effects) for medicine received a score of 2.

A total of 87% (20/23) of items were ratings of concrete features, which by their very nature did not lend themselves to rater judgment and interpretation. For example, the Ask criterion measures whether or not the app asks the user if he or she smokes, and if so, how many cigarettes per day. The concrete quality of these ratings was reflected in the fact that there was 100% interrater agreement for these 20 items.

In 13% (3/23) of items, the guidelines were subjective (eg, presence of practical advice for quitting smoking). For these 3 items, there was a small fraction of interrater disagreement: 23% of the time for the iPhone apps and 15% for the Android apps. In these cases, we minimized subjectivity of rating with two coders discussing and resolved disagreement when the score differed by 1 (19% for iPhone and 8% for Android) and averaged the scores. When the score differed by 2 (5% for iPhone and 1% for Android), a gold standard outside coder resolved score discrepancies 100% of the time. The maximum possible score on the index was 46 for each app.

## Statistical Analysis

The statistical analysis was performed using SPSS version 20.0 software (IBM Corp). Total *n*, percentages, mean, and standard deviation were calculated to describe the features of apps. Weighted Cohen's kappa and intraclass correlation coefficient were used to evaluate interrater agreement. In addition, to identify features of the apps which were associated with the popularity and user-rated quality, linear regression was used to test predictors of popularity (frequency of download) and user-rated quality (user rating with number of stars). Analyses regarding the user-rated quality of the apps were restricted to the apps that had star ratings (73% of the apps), and analyses regarding the popularity of apps were limited to the Android apps because iOS does not release data on the frequency of downloads for iPhone apps. The sample of 64 had 99% power to observe an effect size of 36.8% for the analysis of predictors of quality and downloads.

**Table 1.** Characteristics of Chinese smoking cessation apps.

| Characteristic | | Amount |
|---|---|---|
| **Release d ate, n (%)** | | |
| | 2009 | 2 (3) |
| | 2010 | 1 (2) |
| | 2011 | 6 (9) |
| | 2012 | 8 (13) |
| | 2013 | 8 (13) |
| | 2014 | 12 (19) |
| | 2015 | 6 (9) |
| | 2016 | 1 (2) |
| | Unknown | 20 (31) |
| Average file size (in megabytes), mean (SD) | | 11.05 (14.28) |
| **Frequency of downloads[a] , n (%)** | | |
| | 10-100 | 4 (11) |
| | 100-1000 | 12 (33) |
| | 1000-10,000 | 14 (39) |
| | >10,000 | 6 (17) |
| **User ratings, n (%)** | | |
| | 1 star | 2 (3) |
| | 2 stars | 6 (9) |
| | 3 stars | 28 (44) |
| | 4 stars | 8 (13) |
| | 5 stars | 3 (5) |
| | Missing | 17 (27) |
| **Function[b] , n (%)** | | |
| | Calculator | 34 (53) |
| | Calendar | 27 (42) |
| | Hypnosis | 1 (2) |
| | Rationing | 8 (13) |
| | Other | 21 (33) |
| **Designers, n (%)** | | |
| | Individuals or technology companies | 58 (91) |
| | Government agencies | 3 (0) |
| | Unidentified sources | 3 (0) |

[a]Android apps only.

[b]A total of 42% of apps had multiple functions.

# Results

## Basic Features

The characteristics of the 64 smoking cessation apps included in the analysis are presented in Table 1. Smartphone apps for smoking cessation started to appear in China in 2009. The largest number of app releases (12, 19%) was in the year 2010. The average size for all apps in the sample was 11.05 MB, and the frequency of download for 83% of apps was less than 10,000 times. The modal user rating for most apps (44%) was 3 or 4 stars (out of 5). Most apps used a calculator approach (53%), followed by calendar (42%), other (33%), rationing (13%), and hypnosis (2%). Most apps (91%) were designed and developed by individuals or technology companies rather than government agencies.

### Adherence Scores

With a maximum score on the index of 46, the average score was 14.6 for iPhone apps and 11.1 for Android apps (Multimedia Appendix 1). For iPhone, the Quit Smoking at Once app had the highest score of 38, while apps 30 Day Messages for Quitting and Common Medical Knowledge received the lowest score of 2.5. For Android, the Quit Smoking App had the highest score of 25, while the apps 30 Day Quit Message, Quitting App, and Self-Awareness of Smoking Habits had the lowest score of 3.

### Influencing Factors

There was no significant association between popularity, user rating, and the characteristics of apps ($P$>.05). However, there was a positive relationship between popularity, user rating, and adherence score as seen in Table 2.

**Table 2.** Regression analysis of app characteristics on app popularity and user-rated quality .

| App characteristics | Popularity | | User-rated quality | |
|---|---|---|---|---|
| | Beta | *P* value | Beta | *P* value |
| Release date | 0.180 | .639 | –0.033 | .934 |
| Average file size | 0.024 | .953 | –0.255 | .537 |
| Type | 0.375 | .354 | 0.116 | .786 |
| Frequency of downloads | — | — | 0.123 | .712 |
| User rating | 0.116 | .712 | — | — |
| Adherence score | 0.323 | .398 | 0.090 | .823 |

## Discussion

### Principal Findings

This was the first study to analyze the content of all publicly available smoking cessation apps in China. The results showed that Chinese apps generally lack the content that is consistent with the CCSCG [14]. The number of existing smoking cessation apps in China is smaller than that of America because of the poorer development of eHealth interventions in China [33]. However, the adherence score of Chinese apps to the CCSCG is consistent with analyses of English apps (average adherence scores for iPhone and Android are 14.2 and 11.7, respectively, on 0 to 42 score) [33,34]. One reason may be that the developers of Chinese and English apps are not aware of or do not understand the importance of clinical practice guidelines, as most designers of smoking cessation apps are individuals or companies without any background in clinical practice for tobacco cessation. Indeed, the adherence of smoking cessation apps designed by government agencies was higher than that of other designers in the study.

The results showed that the content of Chinese apps is primarily limited to calculators (eg, money saved by not smoking) and calendars (eg, showing smoking patterns over time). While such tracking-derived information is potentially useful, it vastly underutilizes the potential of smartphone apps to provide evidence-based advice, motivation, and training in skills to cope with cravings and recover from relapses. In addition, the sensors (eg, Global Positioning System) already built into most smartphones make it possible for smartphone apps to provide sophisticated just-in-time and in-the-moment intervention for smoking cessation. In sum, the content of current Chinese apps was generally simplistic, and the potential for improvement is enormous.

Compared to the large population of smokers and smartphone owners, Chinese language smoking cessation apps had relatively few downloads. Indeed, only 6 Android apps in Chinese had more than 10,000 total downloads. However, 35.2% of US smoking cessation apps had more than 10,000 downloads with 7.8% having more than 100,000 downloads [33]. This disparity may be due to Chinese smokers' lack of awareness of smoking cessation apps and smoking cessation advice in general. In traditional Chinese culture, smoking functions as a way to make social connections, smooth social interactions, and express one's social and economic position. Furthermore, in the comments on smoking cessation apps, many users said that stopping smoking was very easy and they will be lucky to avoid the health consequences of smoking, which implies they do not want or understand the value of smoking cessation assistance [35]. Once they download an app, users appear to respond positively to it if it follows the CCSCG, as the adherence score was positively related to app popularity and user-used quality. However, more research is needed to understand what Chinese smokers know about smoking cessation advice, their interest in receiving it, and methods to overcome barriers they may have to using it. When smoking cessation apps that follow the CCSCG are developed that are appropriate and motivating to Chinese smokers, it would be highly valuable to test their efficacy. Indeed, the need for efficacy data is underscored by the fact that to date only randomized trials of smoking cessation apps developed in English have been published [36]. When Chinese apps show promise in randomized trials, public health media campaigns to widely publicize their existence and potential value for smokers would serve the role of promoting the adoption of proven interventions on a broad scale.

An important future research question is how to effectively reach a general population of smokers. A recent US survey of smokers showed that 91% had experience using smartphone apps [37], which suggests that a smoking cessation app in the United States could potentially reach users with demographics that are generally representative of the overall population of US smokers. Research is now needed to determine what fraction

of the Chinese smokers have experience using apps and would be interested in using one to quit smoking, with the aim of determining demographic characteristics of the target population for quit smoking apps in China. As the purchase of iPhone and Android smartphones is rising among old and young people with lower socioeconomic status in China [38], the potential utility of smoking cessation apps for Chinese smokers will grow.

The results of the current studies in the United States and China indicate that despite the recent expansion of smartphone platforms and increased availability of apps for cessation, existing apps still lack many elements that are generally recommended for quitting smoking. We recommend that future research integrate the content of the clinical practice guidelines that have been proven effective in randomized clinical trails [39-41]. Once guidelines are integrated into to the content of Chinese language smartphone apps, these apps can be tested in randomized trials of Chinese smokers.

The proliferation of smartphones can now make them valuable health promotion tools. This study presents an evidence-based evaluation of a tool (smoking cessation apps) for health promotion in China that could inform health policy makers of an eHealth intervention with promise for widespread public health impact. As these apps proliferate in China, there is a great potential that data scientists can analyze large databases of users to understand patterns of use to inform personal tailoring of app content to specific users.

### Limitations

This study has limitations. First, like other content analysis, the data were rated by trained raters. Our method for minimizing rater bias was having 87% of all items be of concrete criterion with the remaining 13% having a small fraction of disagreement that was resolved 100% of the time via a rigorous process described in the methods. Second, the coding measured the presence or absence of the clinical guideline, not the degree to which that guideline was followed or presented effectively. Finally, not all app users provided quality ratings. In the study, an app's number of stars was used as an indicator of its user-perceived quality, so the generalizability of those results is unknown.

### Conclusions

Chinese apps for smoking cessation lack content that is known to be effective for smoking cessation. Including content based on China's clinical practice guidelines would be extremely valuable for improving existing apps and informing the development of new apps and thereby increasing the chances they will make a significant impact on the smoking epidemic in China.

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### Conflicts of Interest

FC, JX, CS, and XF declare no competing interests. In July 2016, JB was a consultant to GlaxoSmithKline, the manufacturer of nicotine replacement therapies. He currently serves on the scientific advisory board of Chrono Therapeutics, the manufacturer of a nicotine replacement therapy delivery device.

### Multimedia Appendix 1

The adherence score of Chinese apps to the China Clinical Smoking Cessation Guideline.

[PDF File (Adobe PDF File), 23KB - mhealth_v5i7e93_app1.pdf ]

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## Abbreviations

**CCSCG:** China Clinical Smoking Cessation Guideline


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Original Paper

# Patterns of User Engagement With the Mobile App, Manage My Pain: Results of a Data Mining Investigation

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## Abstract

**Background:** Pain is one of the most prevalent health-related concerns and is among the top 3 most common reasons for seeking medical help. Scientific publications of data collected from pain tracking and monitoring apps are important to help consumers and healthcare professionals select the right app for their use.

**Objective:** The main objectives of this paper were to (1) discover user engagement patterns of the pain management app, Manage My Pain, using data mining methods; and (2) identify the association between several attributes characterizing individual users and their levels of engagement.

**Methods:** User engagement was defined by 2 key features of the app: longevity (number of days between the first and last pain record) and number of records. Users were divided into 5 user engagement clusters employing the k-means clustering algorithm. Each cluster was characterized by 6 attributes: gender, age, number of pain conditions, number of medications, pain severity, and opioid use. Z tests and chi-square tests were used for analyzing categorical attributes. Effects of gender and cluster on numerical attributes were analyzed using 2-way analysis of variances (ANOVAs) followed up by pairwise comparisons using Tukey honest significant difference (HSD).

**Results:** The clustering process produced 5 clusters representing different levels of user engagement. The proportion of males and females was significantly different in 4 of the 5 clusters (all $P \leq .03$). The proportion of males was higher than females in users with relatively high longevity. Mean ages of users in 2 clusters with high longevity were higher than users from other 3 clusters (all $P < .001$). Overall, males were significantly older than females ($P < .001$). Across clusters, females reported more pain conditions than males (all $P < .001$). Users from highly engaged clusters reported taking more medication than less engaged users (all $P < .001$). Females reported taking a greater number of medications than males ($P = .04$). In 4 of 5 clusters, the percentage of males taking an opioid was significantly greater (all $P \leq .05$) than that of females. The proportion of males with mild pain was significantly higher than that of females in 3 clusters (all $P \leq .008$).

**Conclusions:** Although most users of the app reported being female, male users were more likely to be highly engaged in the app. Users in the most engaged clusters self-reported a higher number of pain conditions, a higher number of current medications, and a higher incidence of opioid usage. The high engagement by males in these clusters does not appear to be driven by pain severity which may, in part, be the case for females. Use of a mobile pain app may be relatively more attractive to highly-engaged males than highly-engaged females, and to those with relatively more complex chronic pain problems.

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**KEYWORDS**

chronic pain; mhealth; opioid use; data mining; cluster analysis; Manage My Pain; pain management; pain app

## Introduction

Internet-based and mobile health (mHealth) apps are transforming how people monitor, manage, and communicate health-related information [1]. This trend has been documented in the fields of medicine [2], nursing [3], psychology [4], kinesiology [5], nutrition [6], and for multiple health concerns and diseases [1].

Pain is one of the most prevalent health-related concerns and is among the top 3 most common reasons for seeking medical help [7]. Several recent reviews have highlighted the many commercially available pain-related apps that can be downloaded from online app stores by people with chronic pain [8-11]. As of 2015, between 279 [8] and 283 [9] pain-related apps were commercially available to monitor and track pain. The rapid proliferation of mobile apps, in general, and for pain in particular, has not been accompanied by equal attention to determining the factors consumers and healthcare professionals prefer or require when selecting from among the many available apps. App quality, usability, effectiveness, and other relevant data for most mHealth apps are either unavailable, incomplete, or potentially inaccurate [1,8,9]. Consumers and healthcare providers have little reliable information to consult when seeking the best app for their needs. To illustrate the mismatch between pain-related app availability and reliable scientific data, de la Vega and Miró [9] noted that of the 34 pain-related apps evaluated in the published scientific literature, not one was available on any major online app store. Conversely, of the 283 pain-related apps commercially available at the major app stores, not one has been evaluated in a scientific publication.

Accordingly, the present study had 2 objectives. The first was to describe a first-of-a-kind collaboration between the award-winning mobile app Manage My Pain (developed to monitor and track pain) and pain, mental health, and data mining experts. The second objective was to present data from greater than 24,000 users (comprising more than 544,000 data points) by clustering data using key variables that defined the user base. Specifically, using a measure of user engagement with the app (eg, what distinguishes the user who has used the app frequently and over the longer term from others?), defined by the longevity and number of records for each user, we were able to group the users (using clustering methods) into 5 groups differentiated by high or low number of entries and high or low longevity. We then characterized the 5 groups of users by gender, as well as other attributes collected by the app: age, number of pain conditions, number of current medications, opioid use, and pain severity rating.

## Methods

### Manage My Pain

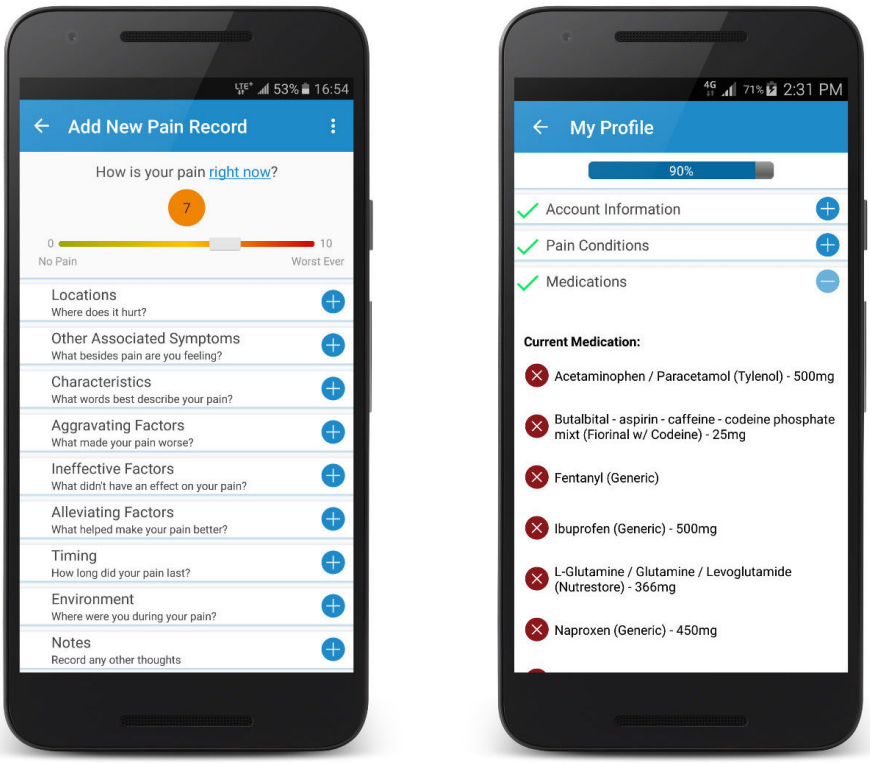
Manage My Pain [12], developed by ManagingLife, helps people living with pain to track their pain and functioning daily basis using an Android mobile phone app. Since Manage My Pain was launched in 2011, more than 24,000 people have created an account and recorded their pain. In total, more than 544,000 pain episodes have been documented by users.

The central feature of Manage My Pain is the “pain record” that enables users to enter details about their pain episodes. Users are asked to complete only 1 item, a rating of pain severity using a slider on a visual analogue scale. They then have the option of completing 7 more items regarding their present pain that typically take less than 1 minute to complete (Figure 1). The app issues daily reminders and prompts users to reflect on their daily accomplishments. With regular use, users are empowered and gain self-awareness through charts and graphs that provide insight to their pain and functioning and how it changes over time.

The information collected by the app can be summarized into a report intended for clinical use, where the information collected is presented in a concise fashion and primarily focuses on changes in the self-reported outcome data between clinical visits. Output is structured on a single page and tends to be more accurate than a patient’s recollection of pain since the last clinical visit, as it captures pain closer to the time of experience and is less influenced by recency and recall biases that plague existing methods for capturing pain information [13]. To supplement the information presented in the reports, users can add pain conditions, gender, age, and medications to their profile in the app.

The app supports 7 languages (English, Spanish, French, German, Russian, Simplified Chinese, and Korean) and has users from over 130 countries. It is available free in a Lite version, or users can opt to pay a one-time fee for a Pro version. The only difference between the versions is that the former limits the number of records that can be viewed at one time to 10. If users choose to take advantage of ManagingLife’s secure, cloud-based storage, they can create an online account and agree to ManagingLife’s Privacy Policy [14], which includes consent to use their aggregated and de-identified data for research purposes. Creating an account not only enables cross-device synchronization through encrypted data transmission and secure storage in the instance a device is lost, it also enables features such as advanced report generation and access to the Profile section of the app (Figure 1). The majority of the analysis in this paper is derived from the self-reported information contained in the Profile section of the app. Users also have the ability to use Manage My Pain without creating an account in which case data does not leave the device and are therefore not accessible for research such as the present report.

**Figure 1.** Screenshots of Manage My Pain showing how pain episodes are recorded (left) and where users can capture information about themselves (right).




## Procedure

The present study was reviewed and approved by the Research Ethics Board at York University (Human Participants Review Committee, Certificate e2015-160). The users' database was accessed and downloaded in 2 separate files (plain text format): user information and pain records. The user-information file contained the field's user identification (ID), date of birth, gender, pain conditions, and medications. Information specific to individual pain conditions included in the pain records file were date, location, other associated symptoms, characteristics, alleviating factors, ineffective factors, aggravating factors, severity, environment, pain type, and pain duration. All fields in the text files were delimited using special characters. The files used in this study were downloaded on January 02, 2017. This study covered pain episodes recorded by users between September 13, 2011 and January 02, 2017.

## Participants and Measures

The primary dataset included 544,425 records from 24,816 users. From these users, we selected 18,324 users who had recorded at least 2 pain episodes. The total number of data points from these 18,324 selected users was 537,853. We excluded users with only 1 pain record as we considered them as having only engaged with the app through a single use. In addition, the objective of our research was to highlight differences between users with varying degrees of engagement, whereas including those with a single-use would sway the analysis towards comparing engaged versus single-use instead.

We defined user engagement with the app using 2 aspects of usage: longevity and number of records. Longevity was calculated as the number of days between the first and the last pain record. The number of records was the total number of entries by a user in the database. For each user, we extracted 6 features from the database for the cluster-based analysis [15] (Textbox 1).

**Textbox 1.** Features extracted from the database for the cluster-based analysis.

**Features**

Gender: The options for entering gender in the app are limited to either male or female. Users who did not include their gender information, or did not identify with either of the provided options, were coded as "not provided." The percentages of male, female, and "not provided" genders in the set of selected users were 11.33% (2076/18,324), 49.90% (9144/18,324), and 38.77% (7104/18,324), respectively.

Age: The age (in years) recorded was the age of the user on the date of the first record and not as of the date of the analysis. Some users did not enter a date of birth. The age values for such users were not included in the analysis. Of the users, 57.48% (10,533/18,324) provided the age information.

Number of pain conditions: Users can select 1 or more pain conditions from a given list of 2500 different pain conditions. They can also add custom values to the pain conditions. In the present study, we included all pain conditions reported, including those added as custom values. Of the users, 57.68% (10,569/18,324) reported at least 1 pain condition.

Number of current medications: Users select their current and past medications from a standardized list of 1130 medications. In addition to instructions on how and when to take the medication, users can specify the brand and strength for each. If a medication or a brand is not found on the list, users can request to have it added. The present analysis included all medications that a user has indicated they are currently taking. Of the users, 36.96% (6773/18,324) reported taking 1 or more current medications.

Opioid use: For the purpose of the present study, a user of the app was coded as an opioid user if they self-reported taking at least 1 current medication containing bevorphanol, buprenorphine, butorphanol, codeine, fentanyl, hydromorphone, meperidine, methadone, morphine, oxycodone, oxymorphone, tapentadol, or tramadol. Of the users who reported taking 1 or more current medications, 41.21% (2791/6773) were coded as opioid users.

Pain severity rating: A user of the app enters a pain severity rating (0 to 10) for each pain record he/she creates. We first calculated mean daily pain severity ratings for each of the days a user created at least 1 pain record and then calculated the mean of the daily means for an average pain rating for each user. All users were assigned to the "Mild" (average pain rating less than 4/10), "Moderate" (average pain rating between 4 and 7), or "Severe" (average pain rating greater than 7) [15] group based on the average pain ratings.

## Data Analysis

### *Clustering*

We applied data clustering methods to distinguish between highly engaged users and users who do not regularly use the app. Clustering involved partitioning a set of objects, or members of a defined population, into 2 or more subgroups such that the members of 1 subgroup were similar to each other and dissimilar to members of the other subgroups. Each object or subgroup member was represented using one or more variables for the purpose of clustering. These variables were typically referred to as features or attributes. The similarity or dissimilarity between pairs of objects (or subgroup members) was measured as the distance between the feature vectors representing them.

The output of the clustering process was usually a set of clusters where each object was assigned membership in 1 of the clusters. We used the method known as k-means [16] as our primary data analytic approach to clustering users. Under the k-means clustering method, the number of clusters is set a priori to some constant k, and the dataset is partitioned into k clusters. In the initialization stage, the k means were selected at random. Each item in the dataset was assigned to the mean closest to it. In each subsequent iteration, for each cluster, the mean was calculated based on the current members of that cluster. Each data point was then re-assigned to the cluster whose mean was the closest. The iterative process stopped when the clusters did not change between iterations.

In our clustering experiment, since we were interested in user engagement, we used the 2 defining variables—longevity and number of records—as features of user engagement. We also added frequency (average number of records per day) as an extra feature to distinguish between users who had the same number of records over different periods of longevity. We transformed these 3 feature values using a logarithmic scale because the difference between small feature values of 2 users was more indicative of their different levels of engagement than a similar difference in large feature values.

We compared the k-means clustering solutions that produced different numbers of clusters to find the solution with the best fit to the data. We also compared the k-means clustering results with results obtained using Mclust [17], another clustering method. In Mclust, a maximum number of clusters, M, and a set of mixture models were initially chosen. For each of these models, hierarchical agglomerative clustering was applied to obtain an initial clustering for each possible number of clusters from 2 to M. Using these clusters for each model as the base clusters, expectation-maximization algorithm was applied to update cluster assignments of objects for the number of clusters from 2 to M. Finally, Bayesian information criterion was used to choose a clustering solution from different models and different numbers of clusters.

To compare the quality of the clustering solutions between different methods (k-means versus Mclust), we calculated the average silhouette width as a measurement of the fitness of the clustering process. For each object, the silhouette width measured how much more similar (based on a distance measure such as Euclidean distance) a data point is to the points in its own cluster than to points in a neighboring cluster. Higher average silhouette widths indicated tighter clusters where each cluster was well-separated from other clusters.

After choosing a clustering solution based on average silhouette width, we generated a profile for each cluster of users. A cluster's profile contained the means of 3 variables (user's age, number of pain conditions, and the number of current medications) calculated from the members that belonged to that cluster. For each cluster, we also calculated distributions of genders and pain severity levels and percentage of opioid users.

We used R (version 3.3.1) [18] for data loading, pre-processing, clustering, and conducting statistical tests. Notably, the traditional way of handling a dataset as a data-frame in R was slow for analysis of larger datasets. As our dataset contained more than half-a-million pain records, we used the data.table package [19] which made loading, querying, sorting, etc, quicker than the default data-frame approach.

### *Characterizing the Clusters*

Once we had determined that we had generated the clusters that best represented the dataset, as evaluated by pain experts, we conducted a chi-square test to evaluate the statistical significance of the association between gender and cluster. We then conducted Z tests to determine whether the proportion of males and females in each cluster differed significantly from what one would expect by chance. We then conducted an analysis of variance (ANOVA) using 3, 2-way independent samples on the 3 database features (age, number of current medications, and number of pain conditions) using cluster and gender as the between-subject factors. We conducted pairwise comparisons using the Tukey honest significant difference (HSD) method for each significant main effect of cluster or gender. We then conducted a Z test to evaluate whether the proportion of males and females using opioids in each cluster differed significantly from what one would expect by chance. Finally, we conducted chi-square tests to investigate the association between gender and pain severity groups (mild, moderate, and severe) in each engagement cluster. All statistical tests were conducted in R.

## Results

### Clustering the Users Based on Their Engagement With the App

The set of 18,324 users who had 2 or more pain records were clustered based on their level of engagement as measured by longevity, number of records, and frequency. We initially intended to divide users into the following natural groups based on their level of engagement: (1) low longevity, low number of records; (2) low longevity, high number of records; (3) high longevity, low number of records; and (4) high longevity, high number of records. The results from clustering the users into 4 groups are shown in Figure 2. The figure was plotted in the logarithmic scale of the 2 dimensions: longevity and number of records, where the 4 colors represented 4 different clusters. As described earlier, frequency (average number of records per day) was added as an additional variable during the clustering analysis to help emphasize differences between the various engagement clusters more relevant to the user base. The color of a cluster was assigned to all its member-objects (ie, the users who belonged to that cluster).

The Blue cluster represented users with high longevity and high number of records. Similarly, the users in the Black cluster generally had high longevity, but low number of records. However, the other 2 clusters (Red and Green) did not seem to align with the 2 other intended clusters characterized by (1) low longevity, high number of records; and (2) low longevity and low number of records. Instead, the Red and Green clusters appeared to differ at the low-end of longevity, but were similar in terms of representing low engagement. Hence, we conducted the clustering experiment again using 5 clusters (Figure 3).

The statistics derived from users of all 5 clusters are shown in Table 1. We discovered the following association between the clusters and the intended 4 groups of users based on the means of longevity and number of records as calculated from the users in a cluster: (1) Blue: high longevity, high number of records; (2) Black: high longevity, low number of records; (3) Cyan: low longevity, high number of records; and (4) Red and Green: low longevity, low number of records (Figure 3).

We also found that the average silhouette width was higher for the clustering results produced by k-means (0.20) than that produced by Mclust (0.02). Hence, we accepted the 5-cluster output of k-means, as shown in Figure 3, for further experiments in this study.

**Table 1.** Cluster characteristics according to the 5-cluster solution.

| Cluster | Users, n | Longevity, n (days) | | | Records, n | | |
|---|---|---|---|---|---|---|---|
| | | Minimum | Maximum | Mean | Minimum | Maximum | Mean |
| Blue | 2415 | 49 | 1906 | 321.8 | 18 | 7699 | 158.2 |
| Black | 2387 | 56 | 1865 | 418.5 | 2 | 76 | 12.6 |
| Cyan | 3640 | 3 | 67 | 21.5 | 6 | 34 | 22.7 |
| Red | 3467 | 5 | 109 | 30.1 | 2 | 21 | 6.1 |
| Green | 6415 | 1 | 7 | 2.6 | 2 | 47 | 3.4 |

**Figure 2.** Clustering solution using 4 clusters.

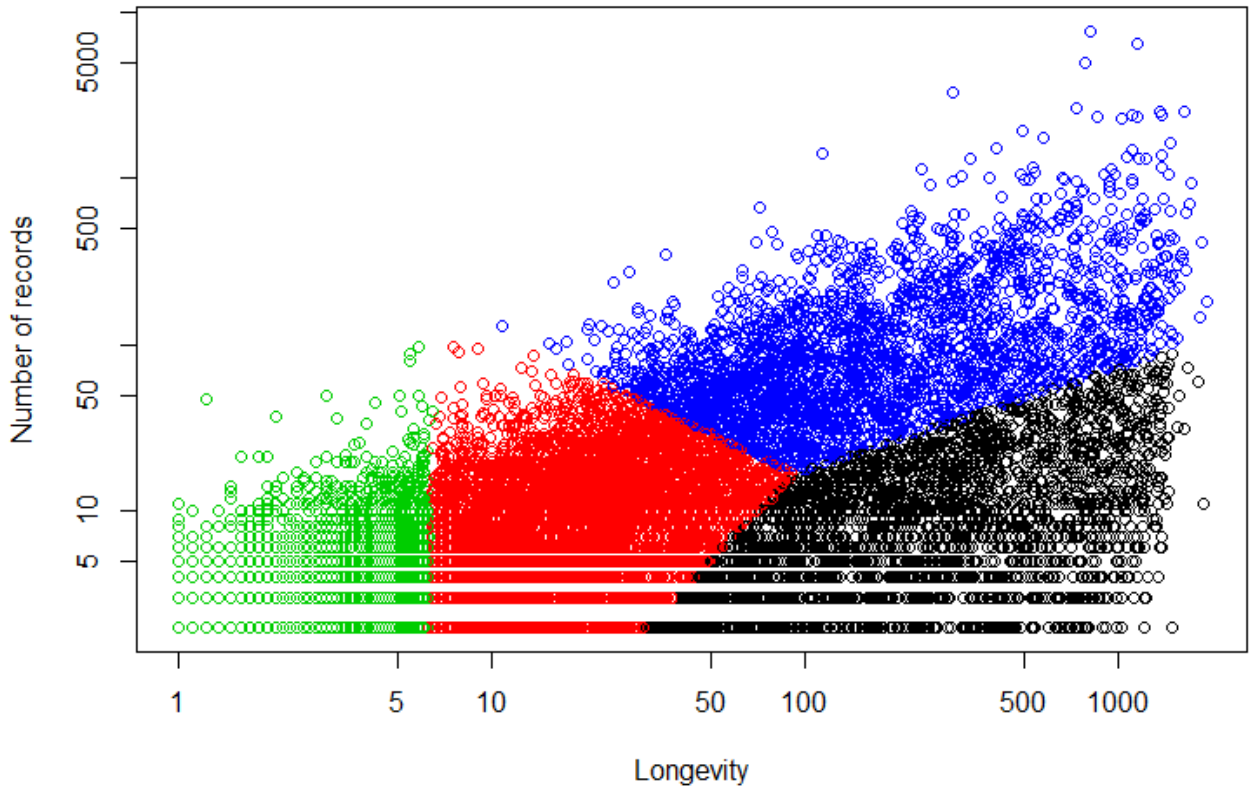
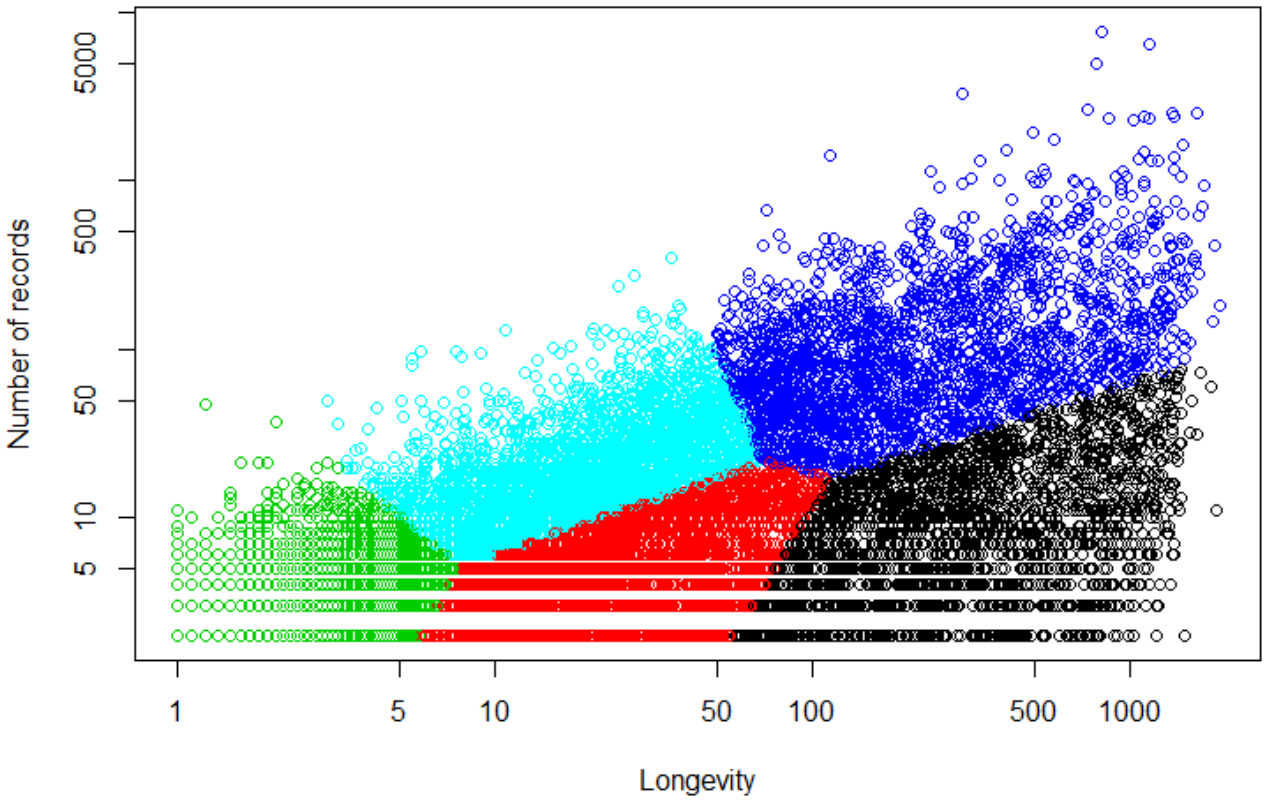



**Figure 3.** Clustering solution using 5 clusters where Blue is high longevity, high number of records; Black is high longevity, low number of records; Cyan is low longevity, high number of records; and Red and Green are low longevity, low number of records.



### Cluster by Gender Profiles

The distribution of users from the 3 categories of gender (male, female, not provided) across each of the 5 engagement clusters is shown in Figure 4.

A chi-square test was conducted to evaluate the association between 3 genders (male, female and not provided) and 5 clusters. The association was statistically significant ($\chi^2_8$ = 761.24, $P$ <.001 ).We then conducted Z-tests to evaluate whether the proportions of each pair of genders (male-female, male-not provided, female-not provided) differed significantly in each cluster. Pairwise between-gender differences were significant ( all $P \leq .05$) for all clusters except the male-female difference in the Cyan cluster. Thus, the proportion of male users with apparent high longevity (Blue and Black clusters) was higher than the female users. On the other hand, for the low engagement clusters (Red and Green), the proportion of females was significantly higher than males. As noted above, only 11.33% (2076/18,324) of users in this study were male whereas 49.90% (9144/18,324) were female—with the remaining users not providing gender information. These data showed that once males registered, they were more likely to use the app for a longer period and with more consistency than females. It is notable that the proportion of the sample that did not provide a gender decreased significantly as user engagement increased from a high of 44% in the Green cluster to a low of 8% to 10% in the Blue and Black clusters, respectively. While knowledge of the genders of the individuals who chose not to provide gender data would be helpful in interpreting the present results, the finding that only 8% to 10% of the Blue and Black clusters did not provide their gender gave us more confidence that a greater proportion of males than females in the highly-engaged clusters was truly representative of the gender distribution and was not an artifact of the undeclared proportion.

Moreover, 68.37% (4857/7104) of these users in the "not provided" gender category did not enter their age and did not list any pain condition or current medications. On the other hand, this percentage was only 2.70% (56/2076) and 1.61% (147/9144) for males and females, respectively. Thus, comparing age, pain conditions, and medications between users who provided their gender information versus those who did not was not feasible. Hence, we excluded the users in the not provided gender category from the rest of the analysis.

To investigate the possible reasons behind the higher level of engagement of male users than female users, we calculated the mean age, mean number of pain conditions, and the mean number of current medications for both genders in each cluster.

#### *Age*

The mean age of the users from the 5 clusters is shown in Table 2. The results of an ANOVA revealed significant main effects of cluster ($F_{4,10192}$= 24.09, $P$<.001) and gender ($F_{1,10192}$ = 284.88, $P$ <.001) but not the cluster x gender interaction effect ($F_{4,10192}$ = 1.0, $P$=.41). Tukey HSD tests showed that the Blue and Black clusters each were significantly older than the 3 other clusters (all $P$<.001). In contrast, the Blue and Black clusters did not differ significantly ($P$ =1.0). Thus, the average age of users with high longevity (Blue and Black clusters) was higher than that of the other groups of users. Overall, males were significantly older than females with mean ages of 42.32 (SD 12.01) and 37.55 (SD 10.56) years, respectively.

**Figure 4.** The distribution of users from each gender category across each of the 5 engagement clusters.

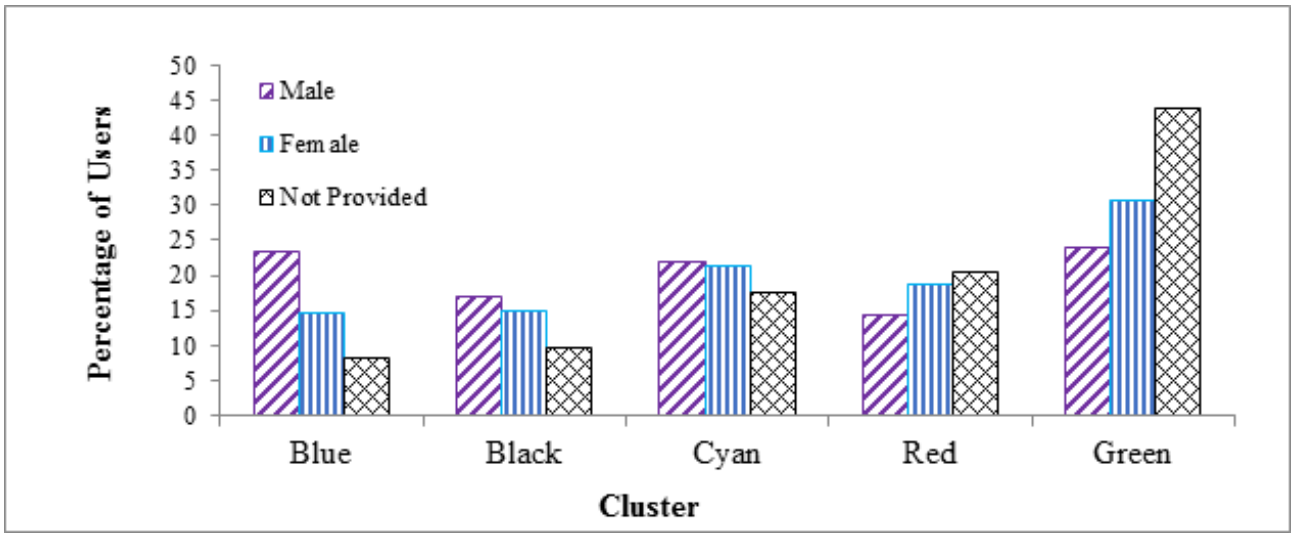


**Table 2.** Mean age of males and females in each cluster.

| Cluster | Age, mean (SD) | | |
|---|---|---|---|
| | All users | Males | Females |
| Blue | 40.3 (10.9)[a] | 44.1 (11.0) | 39.1 (10.5) |
| Black | 39.9 (11.1)[a] | 42.9 (12.6) | 39.2 (10.6) |
| Cyan | 38.1 (11.1)[b] | 41.9 (11.7) | 37.2 (10.8) |
| Red | 37.1 (11.4)[b] | 40.5 (12.9) | 36.6 (11.1) |
| Green | 37.5 (11.2)[b] | 41.8 (12.0) | 36.8 (10.9) |

[a]Cluster differed significantly by ANOVA ($P$<.001).

[b]Cluster differed significantly by ANOVA ($P$<.001).

### *Number of Pain Conditions*

The mean number of self-reported pain conditions for the users in each cluster is presented in Table 3. More engaged users were more likely to self-report a higher number of pain conditions than less engaged users. The results of an ANOVA revealed significant main effects of cluster ($F_{4,9180}$ = 41.28, $P$<.001) and gender ($F_{1,9180}$ = 19.92, $P$<.001) but not the cluster x gender interaction effect ($F_{4,9180}$ = 0.37, $P$=.83). Pairwise comparisons using post-hoc Tukey HSD tests indicated that the difference between the means for the Blue-Black, Black-Cyan, Cyan-Red, and Red-Green clusters were not statistically significant (all $P$ ≥ .07). Across clusters, females reported more pain conditions than did males with mean values of 3.66 (SD 4.02) and 3.18 (SD 3.44), respectively.

### *Number of Current Medications*

The mean number of current medications for users who reported taking at least 1 medication is shown in Table 4. The results of an ANOVA revealed significant main effects of cluster ($F_{4,5408}$ = 58.67, $P$<.001) and gender ($F_{1,5408}$ = 4.33, $P$=.04) but not the cluster x gender interaction effect ($F_{4,5408}$ = 1.59, $P$=.17). Follow-up pairwise comparisons using post-hoc Tukey HSD tests revealed that the difference between the means of the Black-Cyan and Red-Green clusters were not significant ($P$>.99), whereas the difference between the Blue and each of the other clusters was significant (all $P$<.001). Thus, more engaged users reported taking more medications than did less engaged users. Moreover, females reported taking a greater number of pain medications than males, with mean values of 3.91 (SD 3.30) and 3.68 (SD 3.32), respectively.

**Table 3.** Mean number of pain conditions for males and females in each cluster.

| Cluster | Pain conditions, mean (SD) | | |
|---|---|---|---|
| | All users | Male | Female |
| Blue | 4.3 (4.8)[a] | 4.1 (4.5) | 4.6 (4.8) |
| Black | 3.8 (3.7)[a,b] | 3.2 (3.0) | 4.1 (3.9) |
| Cyan | 3.4 (4.0)[b,c] | 3.1 (3.3) | 3.7 (4.4) |
| Red | 3.1 (3.3)[c,d] | 2.8 (2.5) | 3.2 (3.4) |
| Green | 3.0 (3.5)[d] | 2.6 (2.7) | 3.2 (3.6) |

[a]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.05).

[b]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.05).

[c]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.05).

[d]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.05).

**Table 4.** Mean number of current mediations for males and females in each cluster.

| Cluster | Mean Number of Current Medications (SD) | | |
|---|---|---|---|
| | All users | Male | Female |
| Blue | 4.6 (4.0)[a] | 4.7 (4.4) | 5.0 (4.0) |
| Black | 3.7 (3.1)[b] | 3.1 (2.4) | 4.1 (3.4) |
| Cyan | 3.6 (3.0)[b] | 3.4 (2.6) | 4.0 (3.2) |
| Red | 3.0 (2.6)[c] | 3.1 (2.5) | 3.3 (2.7) |
| Green | 2.8 (2.4)[c] | 2.8 (2.2) | 3.2 (2.7) |

[a]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.001).

[b]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.001).

[c]Cluster differed significantly by ANOVA post-hoc Tukey HSD tests ($P$<.001).

## Opioid Use

The number and percentage of males and females within each cluster reporting the current use of an opioid are shown in Table 5. The percentage of males taking an opioid was significantly greater (all $P \leq .05$) than that of females for all clusters except the Red cluster where the percentages did not differ.

## Pain Severity Rating

The number of male and female users in 3 pain severity groups within 5 clusters is shown in Table 6. Chi-square test of independence revealed that pain severity and gender were independent of each other in the Black and Cyan clusters (all $P \geq .40$). We conducted follow-up chi-square tests between gender and pairs of pain severity groups for the Blue, Red, and Green clusters. In the Blue cluster, mild-severe ($\chi^2_1$= 11.18, $P$=.008) and mild-moderate ($\chi^2_1$ = 9.65, $P$=.002) pairs had a statistically significant association with the male and female genders. The association between the mild-moderate pair and gender was significant in the Red ($\chi^2_1$ = 8.09, $P$=.004) and Green ($\chi^2_1$= 12.76, $P$<.001) clusters. These findings indicated that across the Blue, Red, and Green clusters, the proportion of males with mild pain was significantly higher than that of females.

**Table 5.** Number and percentage of each gender reporting current opioid use within each cluster where the percentages for each gender were calculated using a denominator that comprised the number of that gender taking at least 1 current medication in a cluster.

| Cluster | Males taking an opioid, n (%) | Females taking an opioid, n (%) |
|---|---|---|
| Blue, males (N=342) and females (N=950) | 183 (53.5%) | 450 (47.4%) |
| Black, males (N=187) and females (N=699) | 102 (54.5%) | 291 (41.6%) |
| Cyan, males (N=221) and females (N=1074) | 114 (51.5%) | 432 (40.22%) |
| Red, males (N=94) and females (N=683) | 42 (44.7%) | 250 (36.6%) |
| Green, males (N=155) and females (N=1013) | 75 (48.4%) | 379 (37.41%) |

**Table 6.** Number and percentage of male and female users by pain severity groups within each cluster.

| Cluster | Male users, n (%) | | | Female users, n (%) | | |
|---|---|---|---|---|---|---|
| | Mild pain | Moderate pain | Severe pain | Mild pain | Moderate pain | Severe pain |
| Blue[a], males (N=485) and females (N=1340) | 108 (22.0%) | 266 (54.8%) | 111 (22.9%) | 205 (15.30%) | 775 (57.84%) | 360 (26.87%) |
| Black, males (N=348) and females (N=1355) | 59 (16.9%) | 210 (60.3%) | 79 (22.7%) | 212 (15.65%) | 831 (61.33%) | 312 (23.02%) |
| Cyan, males (N=452) and females (N=1937) | 93 (20.6%) | 256 (56.6%) | 103 (22.8%) | 346 (17.86%) | 1139 (58.80%) | 452 (23.33%) |
| Red[b], males (N=295) and females (N=1709) | 70 (23.7%) | 159 (53.9%) | 66 (22.4%) | 292 (17.09%) | 1037 (60.66%) | 380 (22.23%) |
| Green[b], males (N=496) and females (N=2803) | 153 (30.8%) | 238 (48.0%) | 105 (21.2%) | 661 (23.58%) | 1540 (54.94%) | 602 (21.48%) |

[a]Mild-severe ($P$=.008) and mild-moderate ($P$=.002) pairs had a statistically significant association with the male and female genders.

[b]Mild-moderate pair and gender were significantly associated ($P \leq .004$).

## Discussion

### Principal Findings

Commercially-available apps to track and record pain have proliferated to the point where consumers and healthcare providers alike face a bewildering array with little data to use in making an informed decision regarding options. The pain literature regarding mHealth apps typically focuses on app validation, clinical efficacy, or engagement, but no other study has applied data mining techniques to a large user data base of chronic pain sufferers. With more than 250 commercially-available apps to choose from users have little reliable information to turn to when looking for the best app for their needs. The results of the present study provided an in-depth look at the user base of the Manage My Pain app and described factors associated with high user engagement.

The main objective of the present study was to use data mining (clustering) methods to analyze engagement patterns from users of Manage My Pain according to several key variables that defined the user base. Specifically, we categorized users based on their gender and level of engagement with the app. The results of the present study were novel in several respects. For one, to the best of our knowledge, this was the first application of clustering methods to describe patterns of use of, and engagement with, a pain-monitoring app among a large number of everyday users who report chronic pain. We used a sample of 18,324 users who recorded at least 2 pain episodes and together generated more than 500,000 records. Using the k-means clustering approach, the users were classified into 5 distinct clusters that differed maximally in user engagement, derived from their frequency and longevity of use. The Blue and Black clusters comprised individuals with high longevity and a large and small number of records, respectively, whereas the Red and Green clusters comprised individuals with low longevity and a relatively small number of records. The Cyan cluster represented individuals with low longevity and relatively large number of records. We then examined the differences among the 5 clusters with respect to gender, age, number of pain conditions, number of pain medications, opioid use, and pain severity rating.

The most highly engaged clusters (Blue and Black), which were distinguished by frequency of app use but not longevity, differed only in number of pain medications which were greater in the Blue than Black cluster. Otherwise, these clusters were similar in terms of relative gender composition, age, number of pain conditions reported, and proportion using opioids. Together these most engaged clusters comprised 4802 individuals who used the app for an average of 1 year. Compared with the less engaged clusters (Red and Green), the more engaged clusters (1) were, relative to the total number of males and females, more likely to be male; (2) were significantly older; (3) reported a significantly greater number of pain conditions; and (4) were more likely to be opioid users.

Another potentially important result pertained to the distribution of gender within the 5 clusters. The proportion of males and females in each cluster, except Cyan, differed significantly from what would be expected by chance alone. However, the proportions differed markedly based on user engagement. Among the most engaged clusters of users (Blue and Black), the proportion of the total sample of male users was significantly greater than that of females. In contrast, the opposite was true for the least engaged clusters of users (Green and Red) where the proportion of the total sample of female users was significantly greater than that of males. Although only 11.33% (2076/18,324) of users were male and 49.90% (9144/18,324) females, the data indicated that once males registered, they were more likely to use the app for a longer duration and more consistently than females. The greater proportion of males than females in the highly-engaged cluster was interesting because males typically are less actively engaged in their own healthcare than females [20-22]. For instance, females visit primary care providers more frequently than males [21,22] and adhere more to physician recommendations [23]. In a study of 3.7 million patients registered with primary care physicians in the United Kingdom, the rate of consultation for males was 32% lower than it was for females, with the greatest gender differences seen in patients between the ages of 16 and 60 years [22]. Healthcare-seeking behaviors are also more frequent among females than males who have sustained whiplash injuries and who we would reasonably expect to have pain [24].

Gender differences in the use and uptake of mHealth technology may help to explain the present results [25,26]. In contrast to the greater healthcare-seeking behaviors in females, males are more likely than females to adopt mHealth technology [25]. Moreover, whereas males tend to find mHealth apps helpful in averting a health problem and in benefiting from them, this is not the case for women [26]. We suggest that the greater proportion of males than females in the highly-engaged cluster may be related to the mobile-based medium through which the pain-related information is self-monitored and recorded. Use of a mobile pain app may be relatively more attractive to highly-engaged males than highly-engaged females and may be one way to increase male uptake of healthcare behaviors in general.

The relationship between pain severity and gender within clusters indicated that overall, for the Blue, Red, and Green clusters, the proportion of males with mild versus moderate pain was significantly lower than would be expected by chance alone. In the context of the published literature, they are not surprising since across pain conditions males tend to report lower levels of pain than females [27]. It is interesting to note, however, that this pattern was also true for males with mild versus severe pain in the Blue cluster, which, as previously noted, was the most engaged cluster being both high in longevity and high in number of records. Moreover, this was one of the clusters in which the proportion of the total sample of male users was significantly greater than that of females indicating that once males registered, they were more likely to use the app for a longer duration and more consistently than females. The pain severity by gender association in the Blue cluster suggested that the high engagement by males in this cluster did not appear to be driven by pain severity which may, in part, be the case for females.

Consistent with the published literature showing that women are more likely than men to engage in polypharmacy [28,29],

the present results indicated that females in all clusters reported taking a greater number of pain medications than males. Likewise, the percentage of males who reported using opioids was significantly greater than that of females in all but the Red cluster. These data are consistent with prior reports where it was generally found that the frequency of opioid use among males with chronic pain was greater than that of females [30]. Results of a treatment study [31] showed that prior to treatment, fewer females than males were using opioids and females were younger than males. This pattern appears consistent with a recent study [30] which showed that although frequency of opioid use among males with chronic pain was greater than that of females, overall, frequency of use tended to decrease with increasing age. For example, 81% of females with chronic pain aged 25 to 44 years reported using opioids whereas 76.5% of males aged 45 to 64 years reported using opioids. Thus, the present results may also reflect the fact that the highly-engaged males were older than highly-engaged females. These results are of interest and importance given the recent "opioid epidemic" that is the focus of increasing concern among patients with chronic, non-cancer pain, healthcare providers, regulators, and governments [32,33]. By tracking opioid use and pain severity over the next several years we will be in a position to provide important Manage My Pain user data on the extent to which the new opioid prescribing guidelines in the United States [34] and Canada [35] are associated with changes in these parameters.

A mismatch was noted by de la Vega and Miró [9] between the commercial sector and the scientific community in terms of their respective approaches to app development and evaluation. Of the 34 pain-related apps that were evaluated in the scientific literature, not one was available in any of the major online app stores. In contrast, of the more than 280 commercially available pain-related apps not one was the topic of a scientific publication. The present collaboration between the developers of Manage My Pain, scientists studying pain, and experts in data mining, was an attempt to address this mismatch and initiate a novel direction in pain research. By evaluating trends in how consumers engage with and use commercially-available apps to monitor and track pain we can begin to make inroads in understanding the motivations of populations that have been traditionally more difficult to engage (eg, males suffering with multiple pain conditions).

## Conclusion

This is the first study to use data mining (clustering) methods to analyze data from the mobile pain app Manage My Pain, according to several key variables that defined the user base. To better understand who uses the mobile pain app, Manage My Pain, clustering methods were applied to a sample of 18,324 users who recorded at least 2 pain episodes and collectively entered 537,853 records into the app. Users were grouped into 5 clusters according to their engagement patterns. Of the clusters, 2 were identified as representing high user engagement based on longevity and frequency of app use. All 5 clusters were first characterized by gender and then by age, number of pain conditions, number of current medications, opioid use, and pain severity rating. Although most users of the app reported being female, the cluster analysis indicated that male users were more likely to be highly engaged in the app. Clusters of highly-engaged users differed from the other clusters in terms of the relative composition of males and females, with a greater proportion of males than females in the former than the latter clusters. In addition, users in the most engaged clusters self-reported a higher number of pain conditions, a higher number of current medications, and a higher incidence of opioid usage. We suggest that use of a mobile pain app may be relatively more attractive to highly-engaged males than highly-engaged females, and to those with relatively more complex chronic pain situations. A mobile pain app, such as Manage My Pain, may be one way to increase uptake of healthcare behaviors in general for both males and people with complex chronic pain situations.

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## Conflicts of Interest

TJ is the founder and CEO of ManagingLife, Inc. JK and HC are unpaid members of the ManagingLife Advisory Board, providing guidance on the product and the company's research initiatives.

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## Abbreviations

**ANOVA:** analysis of variance
**HSD:** honest significant difference
**mHealth:** mobile health

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Original Paper

# Design of Mobile Health Tools to Promote Goal Achievement in Self-Management Tasks

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## Abstract

**Background:** Goal-setting within rehabilitation is a common practice ultimately geared toward helping patients make functional progress.

**Objective:** The purposes of this study were to (1) qualitatively analyze data from a wellness program for patients with spina bifida (SB) and spinal cord injury (SCI) in order to generate software requirements for a goal-setting module to support their complex goal-setting routines, (2) design a prototype of a goal-setting module within an existing mobile health (mHealth) system, and (3) identify what educational content might be necessary to integrate into the system.

**Methods:** A total of 750 goals were analyzed from patients with SB and SCI enrolled in a wellness program. These goals were qualitatively analyzed in order to operationalize a set of software requirements for an mHealth goal-setting module and identify important educational content.

**Results:** Those of male sex ($P$=.02) and with SCI diagnosis ($P$<.001) were more likely to achieve goals than females or those with SB. Temporality ($P$<.001) and type ($P$<.001) of goal were associated with likelihood that the goal would be achieved. Nearly all (210/213; 98.6%) of the fact-finding goals were achieved. There was no significant difference in achievement based on goal theme. Checklists, data tracking, and fact-finding tools were identified as three functionalities that could support goal-setting and achievement in an mHealth system. Based on the qualitative analysis, a list of software requirements for a goal-setting module was generated, and a prototype was developed. Targets for educational content were also generated.

**Conclusions:** Innovative mHealth tools can be developed to support commonly set goals by individuals with disabilities.

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**KEYWORDS**

goals; self-care; mobile health; rehabilitation; smartphone; spinal cord injury; spinal dysraphism

## Introduction

Goal-setting within rehabilitation is a common practice ultimately geared toward helping patients make functional progress. Goal-setting has been explored within many different conditions relevant to rehabilitation. For example, it has been used in pediatric rehabilitation [1], acquired conditions in adults such as traumatic brain injury [2], and older adults with conditions like dementia [3]. Although theories behind a variety of approaches to goal-setting date back to the 1970s, Schut and Stam are often credited for identifying the many positive benefits of goal-setting within rehabilitation [4,5] based on their published findings in 1994. A systematic review article also

revealed that in order to be most effective, goal-setting activities should be patient-centered and involve collaboration between patients and clinicians [6]. It is a generally accepted concept that engaging patients in the goal-setting process is important and beneficial to psychosocial [7] and functional [8] outcomes, but unfortunately it is not always standard practice to have a patient-centered approach [4]. Reasons why clinicians may not engage patients are numerous and include lack of clinician education on how to engage patients, processes or tools that simply do not seek patient input, or lack of patient interest in participating [8]. However, in the cases when patients decline interest in participating, it is often because they may not understand their critical role in the process and are often more motivated to participate if they are informed of the value of their input and efforts are made to engage them [8].

Motivation of patients can be critical in promoting and maintaining behavioral change. According to self-determination theory (SDT), a theory of motivation that has been applied to multiple domains, including the health domain, several key psychological needs individually and cumulatively promote behavioral change [9,10]. These needs are autonomy (the belief that one's behavior is self-originated and volitional), competence (the belief that one's behavior is effective), and relatedness (the belief that one is cared for by others) [9,10]. Supporting these psychological needs has been shown to predict and produce increased motivation for behavioral change and help maintain behavioral change [9].

Over 20 years after Schut and Stam's landmark article, controversy still exists over the most efficacious tools for increasing motivation and maintaining behavior change. The Functional Independence Measure is a well-known tool widely used in inpatient rehabilitation facilities and is used to track progress with functional activities [11]. However, its lack of customizability limits its ability to be used for the many activities people perform that fall outside of its standardized domains. One systematic review [12] suggested that Goal Attainment Scaling is an effective measure in adults, but it requires considerable time and training to administer. The Patient Specific Functional Scale (PSFS) has become popular due to its simplicity of use and applicability over a wide range of conditions, making it more practical to administer in a clinical setting [13].

We used our own approach to goal-setting within a wellness intervention consisting of a nurse case manager and an evidence-based protocol for the treatment and prevention of secondary conditions in individuals with spina bifida (SB) and spinal cord injury (SCI) [14]. In this study, 50 patients set up a goal tracking program and created short term (6 months to 1 year), long term (1 to 2 years), and maintenance (more than 2 years) health goals in collaboration with the nurse. Significant improvements were detected in health and patient experience of care outcomes, and almost 90% of goals were achieved. We also developed an mHealth tool, called the Interactive Mobile Health and Rehabilitation (iMHere) system, which consists of a mobile phone app for the patient and a Web-based portal used by the clinician [15]. The app has several modules for managing medical issues (medication management, bowel management, bladder management, skin integrity, and mood), which provide prompts to the patient to conduct self-management activities and allow them to send information, including photographs, to clinicians to alert them of medical issues. The clinician can use the Web-based portal to monitor a cohort of patients and triage medical issues that need to be addressed quickly. Input from over 120 patients, caregivers, and clinicians was formally obtained in sequential studies [16,17], through focus groups and formal in-laboratory testing that used validated methods of assessing usability. We also conducted a series of accessibility studies [18,19] to inform development for individuals with motor, cognitive and sensory impairments. We then conducted a clinical trial of the system in a group of adults with SB and found that higher utilization of the mHealth system resulted in improved self-management outcomes [20]. Additionally, a personal health record module and a module that educates users on issues relevant to their health have been subsequently built. We had not, however, incorporated a module into the app to help users with goal-setting specifically.

The use of electronic tools has been suggested as a way to effectively engage patients in goal-setting [8]. mHealth, for example, is a growing field that offers many approaches for patients to engage in self-management activities. Goal-setting and goal-attainment have actually been found to be motivators for using mHealth devices [21]. However, the bulk of mobile phone apps on the market are designed for helping the user manage one specific health or wellness activity such as weight loss or exercise, or one specific health condition such as diabetes. Few mobile phone apps engage the user into the types of goal-setting activities that are important for patients with disabilities who have very complex self-management routines. For example, patients with SB often need to adhere to a medication regimen, a bladder catheterization schedule, a bowel program, and a schedule to check skin for pressure ulcers, all while handling a host of other medical and psychosocial issues that may be impacting their lives [22].

Our ultimate goals in this study were to:

1. Qualitatively analyze the goals set by patients with SB and SCI in a wellness program to generate a list of software requirements for a goal-setting module within iMHere. Specifically, to accomplish this task we wished to answer several research questions:
   - What functionalities would be needed in a goal-setting module in order to support the various types of goals that people with SB or SCI desire to achieve?
   - What are the most common themes that describe the goals that people with SB and SCI set for themselves?
   - Is achievement of goals related to patient factors or characteristics of the goals?
2. Design a basic goal-setting module within iMHere, based on the PSFS.
3. Identify the educational needs of our target population to determine what content is important for the educational module within iMHere.

## Methods

This study was approved by the University of Pittsburgh Institutional Review Board. All research participants signed informed consent in order to participate. This study was a subcomponent of a larger, parent study reported previously in more detail [14]. Briefly, a wellness program was delivered to individuals with SB and SCI at an academic hospital-based outpatient physiatry clinic that partnered with an insurance division within an integrated health care delivery and financing system. Participants were recruited by the insurer and by their physicians. The program consisted of evidence-based guidelines, case management provided by a full-time nurse, and patient education. No mHealth tools were used in the parent study; all care was received in-person through the nurse at home visits or in an outpatient clinic. All participants were asked to create a wellness plan with help from the nurse. The wellness plan consisted of five short-term goals (6 months to 1 year), five long-term goals (1-2 years), and five maintenance goals (longer than 2 years). Participants were encouraged to set goals that were personally relevant, specific, measurable, and attainable [4,5]. Participants were also asked to meet quarterly for 2 years to evaluate progress toward their goals. Goal achievement was tracked by the nurse using a spreadsheet and checklists. Participants earned one gift card for establishing a wellness plan, one for achieving 80% of the short-term goals, one for achieving 80% of long-term goals, and one for achieving 80% of maintenance goals. Each gift card was worth US $25.

After the study was complete, all goals set by participants were first reviewed by one investigator and coded according to *goal temporality* (short-term, long-term, and maintenance), *goal theme* (the general wellness topic the goal addressed), *goal type* (the method by which data were recorded to help a participant track progress toward a goal), and *goal achievement* (whether or not the goals were reached by the end of the study). The same investigator reviewed and recoded the data a second time while blinded to the results of the first review. Final codes were assigned to goals if the two ratings were the same. This occurred in 710 of the 750 (94.7%) goals. In 40 goals, there was a discrepancy noted in goal theme. To resolve the discrepancy, a second investigator then independently coded the 40 items on which there was disagreement within the ratings of the first investigator. The second investigator was blinded to the review of the first investigator. These remaining 40 goals were then assigned a final code based on agreement between codes of the two separate investigators. In addition, the types of gift cards that participants selected were recorded.

A Cronbach alpha level of $P<.05$ was selected a priori. SPSS version 24 (IBM Corp) was used to test for associations among categorical variables. To evaluate whether there was any significant difference in achievement of goals based on sex, goal temporality, goal theme, and goal type, chi-square analyses were used. For the analysis involving goal theme, only the seven most common themes (as designated by number of goals) and "other" were analyzed.

## Results

A total of 69 individuals with SB and SCI were consented; 4 were excluded for failing to meet inclusion criteria or withdrawing before baseline data could be collected. The remaining 65 participants enrolled in the intervention. Of those 65 participants, 50 completed a wellness plan. Goal data from these 50 participants who completed a wellness plan were included in this study. A total of 24 participants (48%) were female; 26 participants (52%) were male. Furthermore, 37 (74%) had SB; 13 (26%) had SCI. Average age was 38.7 (SD 14.1) years. Additional demographic data obtained from the parent study can be found in the prior publication [14].

### Goal Temporality

Fifteen goals (5 short term, 5 long term, and 5 maintenance goals) from each of the 50 individuals were analyzed, for a total sample of 750 wellness goals.

### Goal Theme

Of the 750 wellness goals, 15 themes were identified. Table 1 displays the themes in more detail.

### Goal Type

Based on the types of goals that participants selected, investigators identified three methods that were used to help participants and the nurse track progress toward achieving those goals.

1. Checklist: 24% of goals involved a simple checklist indicating whether or not the event or aim was achieved. This type of goal would need to be manually "checked off" the list.
   - A single task that occurs at one point in time (eg, scheduling an appointment with a neurologist).
   - A task that begins but then is an ongoing event after the task is accomplished. The goal focuses on the initiation of the task, not monitoring continued compliance with the task (eg, beginning to wear wrist splints for carpal tunnel syndrome).
   - A goal that is focused on an outcome with no specific date attached (eg, achieve employment, or stop smoking).
   - A goal focused on the initiation of a behavior (eg, begin to seek employment).
   - Achieving a situation in which the person is "free of a certain condition" (eg, achieve intact skin, free of pressure ulcers). This type of goal was discouraged because it may be difficult to achieve even if a participant is compliant with treatment, but nonetheless, participants chose some of these goals.
   - A situation that arises only under certain circumstances (eg, if skin breakdown occurs, participant will notify a clinician).
   - "As needed" goal (eg, participant will take a medication for pain when it is needed).
2. Data-tracking: 48% of goals involved recording data sequentially over repeated time intervals. This type of goal would be achieved if the value of the data fell within a

certain range, achieved a threshold value, or reached a threshold by a specific date.

- Achieving or maintaining certain health parameters (eg, goal to achieve a target weight or maintain blood pressure within specific parameters).
- Achieving or maintaining a certain goal for health activities (eg, intake a specific amount of fruits, vegetables, fluid, protein, or sodium).
- Achieving a degree of compliance with self-management activities that occur at a certain frequency (eg, skin checks, exercise regimen, medications, appointments, or bladder or bowel program).
- Achieving a specific goal by a certain date (eg, reach target weight by the participant's birthday).

3. Fact-finding: 28% of goals involved recalling specific facts or finding information about topics that can impact health, promote health outcomes, and prevent secondary complications.

- Recalling specific knowledge (eg, being able to identify the signs and symptoms of skin breakdown or urinary tract infections, foods that are more appropriate in diabetes, or foods low in sodium).
- Seeking a reference that will serve as a blueprint for future action (eg, finding an exercise program that can be performed while in a wheelchair, or finding information about housing).

Table 2 displays more detail about how goal theme was related to gender, goal type, and goal classification. Table 3 displays the themes of the fact-finding goals which identify the educational needs of our target population and determine what content is important for the educational module within iMHere.

**Table 1.** Goal themes.

| Goal theme | Description of theme | Total number | Proportion of total goals (%) (n=750) |
|---|---|---|---|
| Diet | Improve or maintain caloric intake, make good food choices, or reach a weight loss goal through diet | 108 | 14.4 |
| Bladder/Bowel | Maintain or improve continence, recognize important signs or symptoms, adhere to a prescribed regimen for bowel or bladder care or appointments | 102 | 13.6 |
| Exercise | Improve or maintain physical activity amount, quality or frequency, or to reach a weight loss goal through exercise, adhere to prescribed physical therapy regimen, identify adaptive exercises | 100 | 13.3 |
| Skin | Be more compliant with prescribed skin care regimens or proper use of wheelchair equipment with the goal of preserving skin integrity or healing an open wound | 95 | 12.6 |
| Appointments | Track and maintain or improve adherence to medical appointments | 64 | 8.5 |
| Other/Medical | Adhere to care prescribed by primary care physician, gynecologist or other specialist, manage lymphedema | 55 | 7.3 |
| Medications | Track and maintain or improve adherence to medication schedule, learn about medications | 52 | 6.9 |
| Equipment | Maintain, acquire, or properly use assistive technology and orthoses for mobility or self-management | 48 | 6.4 |
| Other/Non-Medical | Participate in home and community activities | 39 | 5.2 |
| Work/School | Acquire or maintain employment, participate in vocational rehabilitation or school activities | 23 | 3.1 |
| Cardiovascular risk factors | Blood pressure and diabetes control, smoking reduction/cessation | 16 | 2.1 |
| Mood/Sleep | Identify methods or coping mechanisms to improve mood or restful sleep, follow recommendations of psychologist or psychiatrist, practice better sleep hygiene | 14 | 1.9 |
| Weight loss | Achieve a desired target weight without specifying the plan to do so | 14 | 1.9 |
| Pain | Prevent, reduce or maintain pain thresholds or be compliant with prescribed pain regimens | 12 | 1.6 |
| Driving/ Transportation | Acquire or properly use assistive technology for driving or transportation, acquiring a license or skills needed to drive | 8 | 1.1 |

**Table 2.** Detailed display regarding how goal theme was related to gender, goal type and goal classification.

| Goal theme | | Sex | | Goal temporality | | | Goal type | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total number | Female | Male | Short-term | Long-term | Maintenance | Data tracking | Fact finding | Checklist |
| Diet | 108 | 51 | 57 | 46 | 48 | 14 | 49 | 57 | 2 |
| Bladder/Bowel | 102 | 50 | 52 | 45 | 19 | 38 | 29 | 43 | 30 |
| Exercise | 100 | 50 | 50 | 23 | 42 | 35 | 70 | 26 | 4 |
| Skin | 95 | 38 | 57 | 59 | 12 | 24 | 24 | 38 | 33 |
| Appointments | 64 | 34 | 30 | 8 | 5 | 51 | 59 | 0 | 5 |
| Medications | 52 | 28 | 24 | 6 | 2 | 44 | 47 | 3 | 2 |
| Equipment | 48 | 20 | 28 | 15 | 28 | 5 | 25 | 6 | 17 |
| Other | 181 | 89 | 92 | 48 | 94 | 39 | 54 | 40 | 87 |
| Total | 750 (100%) | 360 (48%) | 390 (52%) | 250 (33%) | 250 (33%) | 250 (33%) | 357 (48%) | 213 (28%) | 180 (24%) |

**Table 3.** Themes of the fact-finding goals which identify educational needs.

| Theme | Details |
|---|---|
| Skin integrity | Signs and symptoms of skin breakdown and wound infection; areas at risk for skin breakdown; how to prevent skin breakdown; importance of position changes; equipment affecting skin breakdown |
| Bowel/bladder | Signs and symptoms of urinary tract infections; basics of a bowel program; benefits of a bowel program |
| Shunts | Signs and symptoms of shunt malfunction |
| Medication | Identify the indication for each medication |
| Diet | Basics of good nutrition; nutrition foods; information on “my healthy plate” or food pyramid; proper portion sizes or portion control; foods to help meet the daily energy requirement; recommendations on fluid intake; whole and wholesome foods versus junk foods or empty calories; nutritious foods high in protein to promote wound healing |
| Exercise | Benefits of exercise; how to start an exercise program; exercises that can be performed in a wheelchair; exercises that can be performed at home |
| Sleep | Sleep hygiene; techniques to promote restful sleep |
| Pain | Alternatives to pain medications; techniques to promote pain control; common over-the-counter medications for pain |
| Weight control | Benefits of weight control; risks of being overweight |
| Mood | Relaxation techniques; techniques to improve mood; coping techniques |
| Smoking | Effects of smoking on health and on circulation; effects of smoking on skin breakdown or wound healing |

## Goal Achievement

Of the 750 total wellness goals, 669 (89%) were achieved; 81 (11%) were not achieved. Furthermore, 20 out of 50 participants (40%) achieved all of their goals, and 42 participants (84%) achieved at least 13 out of 15 goals (87%). Eight individuals accounted for 67% of the goals that were not achieved. There was a significant difference in achievement of goals based on sex ($P$=.02), as well as diagnosis, goal temporality, and goal type ($P$<.001 for each respective analysis). Those of male sex and with SCI diagnosis were more likely to achieve goals than females or those with SB. Table 2 indicates the number of times a theme was reported across sex, goal temporality, and goal type.

Shorter temporality of the goal coincided with a higher likelihood that the goal would be achieved. Almost all goals surrounding fact-finding were achieved. There was no significant difference in achievement based on goal theme ($P$=.75; See Table 4).

**Table 4.** Achievement of goals according to various factors.

| Factor | Achieved | Total number | Percent achieved (%) | Not achieved |
|---|---|---|---|---|
| **All goals** | 669 | 750 | 89 | 81 |
| **Sex** (*P*=.02) | | | | |
| Female (24 people) | 311 | 360 | 86 | 49 |
| Male (26 people) | 358 | 390 | 92 | 32 |
| **Diagnosis** (*P*<.001) | | | | |
| SB (37 people) | 479 | 555 | 86 | 76 |
| SCI (13 people) | 190 | 195 | 97 | 5 |
| **Goal Temporality** (*P*<.001) | | | | |
| Short-term | 246 | 250 | 98 | 4 |
| Long-term | 222 | 250 | 89 | 28 |
| Maintenance | 201 | 250 | 80 | 49 |
| **Goal Theme** (*P*=.75) | | | | |
| Diet | 102 | 108 | 94 | 6 |
| Bladder/Bowel | 93 | 102 | 91 | 9 |
| Exercise | 89 | 100 | 89 | 11 |
| Skin | 87 | 95 | 92 | 8 |
| Appointments | 58 | 64 | 91 | 6 |
| Medications | 45 | 52 | 87 | 7 |
| Equipment | 43 | 48 | 90 | 5 |
| Other | 152 | 181 | 84 | 29 |
| **Goal Type** (*P*<.001) | | | | |
| Data tracking | 312 | 357 | 87 | 45 |
| Fact finding | 210 | 213 | 99 | 3 |
| Checklist | 147 | 180 | 82 | 33 |

## Incentives

Participants chose gift cards as incentives for achieving goals. The most popular preference was for healthy dining or groceries at 41.2% of participants, followed by 27.7% opting for entertainment, 12.4% for general retail, and 11.3% for clothing or personal care. Only 4.5% of participants chose gift cards catering to home improvement, and 2.8% chose gift cards for gasoline.

## Operationalization of Findings Into Software Requirements

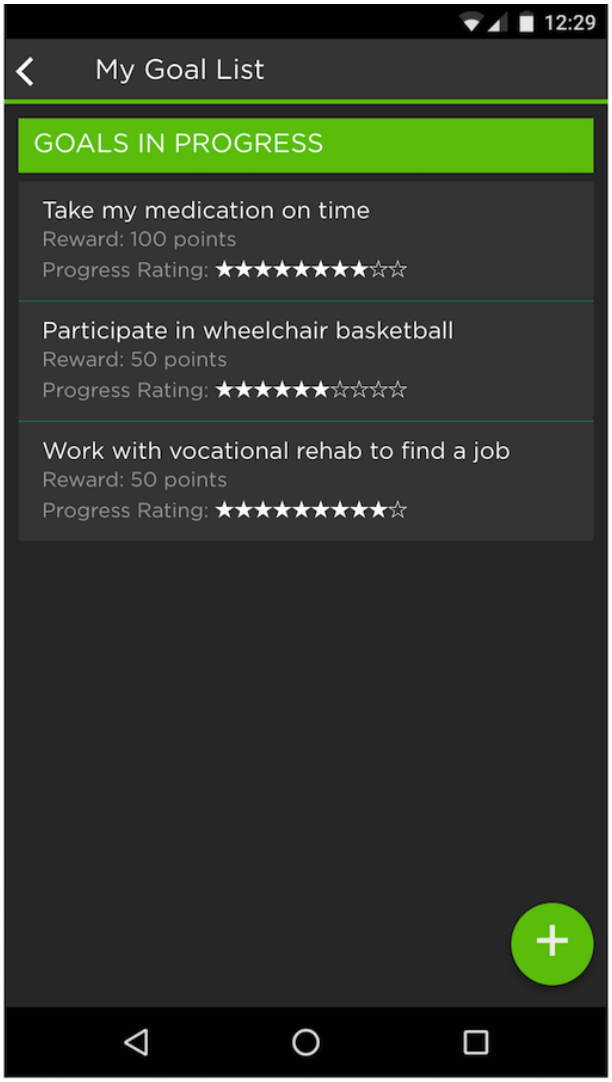
Based on the cumulative results, a list of software requirements was developed:

- Patient can select a goal functionality (checklist, data tracking, or fact-finding) when creating a goal
- Patient can generate a checklist of multiple goals
- Patient can choose from a default list of common goals or create his or her own goals
- Patient can record whether a goal was achieved or is in progress
- Patient can self-report progress toward achieving each goal
- App can auto-populate goals with data to show progress in goal-achievement
- Patient can record goals that are related to obtaining and understanding educational material
- Caregiver, peer or clinician can view goals of a patient and provide encouragement
- Caregiver, peer or clinician can suggest goals to patient
- Patient can choose designees who are able to access and modify goals
- Goals should be linked to deadlines or calendars
- App should provide tips on goal-setting

## Basic Prototype of Goal-Setting Module

A goal-setting module was created for iMHere, based on the PSFS (see Figure 1).

**Figure 1.** Prototype of goal-setting module for iMHere.




## Discussion

### Principal Findings

To our knowledge, this is the first study to examine patient goals in an effort to develop more robust mHealth tools that support goal achievement in self-management. We successfully developed a goal-setting module based on the PSFS. We also identified three functionalities that may possibly help users track and achieve goals when using mHealth systems.

About one-quarter of the goals required the functionality of a checklist. The checklist is a simple tool that has been shown to produce improved outcomes in a number of health-related and other disciplines [23]. This type of goal-setting feature is already available in the current version of iMHere. However, more complex functionality, such as the ability to add sub-items to lists, will be added to support complex tasks that require multiple steps.

Approximately half of the goals required ongoing tracking of progress toward meeting that goal. On the PSFS, patients are asked to rate on a scale how well they subjectively feel they are accomplishing their goal. However, within mHealth systems, it is now possible to collect, analyze, and display summary data back to the user as a way to "automate" the tracking of progress toward a goal. Data collected and displayed in this manner can be self-reported data or objectively gathered data. For example, in the current version of iMHere, users are able to report on a regular basis whether they have been taking each of their medications. In future versions of iMHere, data on self-reported compliance with medications will be displayed back to the users as a bar graph to indicate how often the users indicated they took medications over a period of a week or a month. Objectively gathered data can also be collected from peripheral devices. For example, activity monitors connected to future versions of iMHere will be used to show users how well they are meeting a physical activity goal.

The remaining goals involved recalling specific facts or finding information about health topics. Tracking achievement of a fact-finding mission can be accomplished with a checklist. Because almost all fact-finding goals were achieved, it is possible that participants chose fact-finding goals that were "easy" to achieve; therefore, more complex checklists or other functionalities may be needed if a patient would choose a more complex fact-finding goal that has multiple steps within it. Recall of specific information from materials accessed could be evaluated through a quiz. In the current version of iMHere,

an educational module presents medical information relevant to a user's health and also provides quizzes about that information. A future version of iMHere will link the educational quizzes to the goal-setting feature. A goal of our study was to identify the educational needs of our target population to determine what content is important for the educational module within iMHere. Based on the fact-finding goals set by participants, we will be building educational content to support themes identified in Table 3.

The data collected on themes of goals set by participants were useful in several ways. First, the data validated the importance of modules that have already been developed for iMHere (medication management, bowel management, bladder management, skin integrity, and mood). Second, the data generated development ideas for modules for other important health domains such as diet, exercise, weight management, appointment scheduling, tracking needs for items such as wheelchairs or adaptive driving, vocational and school activities, pain, and sleep. In this study, the theme with the largest representation of goals was diet. Therefore, it is not surprising that the gift cards participants selected for meeting those goals included options for healthy eating or purchasing groceries. Thus, a third concept that emerged was that specific incentives could be linked to types of goals achieved. Finally, data helped inform what types of goals could be included as "default" goals from which patients can select.

Achievement of goals was related to several factors. Individuals with SB and females achieved fewer goals than those with SCI and those of male sex. It may be that those with SB or females set goals that were lofty and therefore more difficult to achieve, they were less motivated to achieve their goals, or they had greater medical complexity, making goal achievement somewhat more difficult. More work is needed on larger samples to understand the factors that contributed to goal achievement. It was not surprising that short-term goals were achieved more often than long-term goals, since the participants tended to set more easily achievable activities as the short-term goals. Despite having some degree of impairments in executive function [16], individuals with SB did not seem to have difficulty conceptualizing or setting goals, an encouraging finding considering the majority of individuals with SB in this study had hydrocephalus.

Based on the variety of goals set and lessons learned from the clinical trial, we also identified other features that are important in creating goal-setting features in mHealth. First, a clear need exists for patients, clinicians, and even caregivers to be involved in the goal-setting process. Caregiver goals may be quite different from the goals of the persons they assist [24]. As a result, we plan to create a goal-setting module that can be viewed and edited through role-based access via both patient and caregiver apps, as well as a clinician portal. Additionally, we plan to provide "free text" options to allow for custom goals to be written, as well as "quick select" options for goals that are commonly set and which can be tracked with automated features within the app. Finally, it may also be useful to display "socially persuasive" data to users as a way to motivate them to achieve goals. For example, it may be possible to display a user's compliance with taking medications in reference to the average compliance of peers. This technique has been found in other studies to increase the likelihood of achieving desired health outcomes [25].

The results of this study inform the software requirements for the graphical user interface of the iMHere goal-setting module. Several design changes will be made in order to meet these requirements. First, when entering a new goal, the patient will be able to: (1) select a goal functionality (checklist, data tracking, or fact-finding), which will determine how the app will track user progress toward achieving the goal, (2) choose one or more individuals (eg, user, clinician, caregiver) who will be responsible for independently determining whether the goal was achieved, and (3) choose supporters (eg, caregivers or peers) who are able to provide encouragement. Second, the goals will be marked as "in progress" by default until they are marked as "achieved" by a patient or his or her designee. Third, patients or designees will be able to enter a goal by typing as free text or choosing from a list of common "default" goals categorized by themes in Table 1. Fourth, each goal will contain an option to enter a deadline for the goal (selected from a calendar, or alternately, selected by designated time frame, such as one month) and options to receive prompts that query the patient whether he or she is on track to achieving the goal (eg, prompts appear on recurring schedule, or after a period of time, such as 75% of time has passed). Fifth, when first using the module or when accessing instructions, patients and designees will be reminded to create goals that are personally relevant to the patient, specific, measurable, and attainable [4,5].

## Limitations

A few limitations of this study deserve discussion. Our sample was limited to SB and SCI. External validity of this study is therefore limited to these populations. However, some findings may be relevant or translatable only to those particularly interested in engaging in health promotion activities. Our sample was also small; however, due to the large number of goals set by each participant, a large amount of goal-setting data was collected. One limitation of the parent study is that it lacked a control group. Because it was a clinical program, it was not possible or ethical to randomize participants into a group that did not receive these services. We therefore designed the parent study as a cohort trial and used intention to treat analysis, given the increasing popularity of integrated delivery systems and clinical utility of pragmatic research designs.

## Future Directions

In future work, more complex functionalities could be added to the software, such as stakes (eg, consequences for not achieving the goal such as peers being notified), suggestions for brainstorming barriers (eg, option to contact clinician for help, extend deadline, or delete goal), and ability to opt into participating in socially persuasive group challenges, or pre-built goal modules that are designed around best practices (eg, workflow that guide the user how to conduct an evidence-based pressure ulcer prevention program). We plan to study the goal-setting module with patient, caregiver, and clinician users in future usability and feasibility trials.

In conclusion, lessons learned from analyzing wellness goals of participants with SB and SCI have been distilled into recommendations intended to help spearhead future development of iMHere. Goal-setting features in mHealth apps such as iMHere may be able to aid individuals in creating, pursuing, and achieving their wellness goals.

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## Conflicts of Interest

Drs Dicianno and Parmanto are inventors of the iMHere mHealth system.

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## Abbreviations

**iMHere:** Interactive Mobile Health and Rehabilitation
**mHealth:** mobile health
**PSFS:** patient specific functional scale
**SB:** spina bifda
**SCI:** spinal cord injury
**SDT:** self-determination theory


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Original Paper

# Continuous Monitoring of Vital Signs Using Wearable Devices on the General Ward: Pilot Study

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## Abstract

**Background:** Measurement of vital signs in hospitalized patients is necessary to assess the clinical situation of the patient. Early warning scores (EWS), such as the modified early warning score (MEWS), are generally calculated 3 times a day, but these may not capture early deterioration. A delay in diagnosing deterioration is associated with increased mortality. Continuous monitoring with wearable devices might detect clinical deterioration at an earlier stage, which allows clinicians to take corrective actions.

**Objective:** In this pilot study, the feasibility of continuous monitoring using the ViSi Mobile (VM; Sotera Wireless) and HealthPatch (HP; Vital Connect) was tested, and the experiences of patients and nurses were collected.

**Methods:** In this feasibility study, 20 patients at the internal medicine and surgical ward were monitored with VM and HP simultaneously for 2 to 3 days. Technical problems were analyzed. Vital sign measurements by nurses were taken as reference and compared with vital signs measured by both devices. Patient and nurse experiences were obtained by semistructured interviews.

**Results:** In total, 86 out of 120 MEWS measurements were used for the analysis. Vital sign measurements by VM and HP were generally consistent with nurse measurements. In 15% (N=13) and 27% (N=23) of the VM and HP cases respectively, clinically relevant differences in MEWS were found based on inconsistent respiratory rate registrations. Connection failure was recognized as a predominant VM artifact (70%). Over 50% of all HP artifacts had an unknown cause, were self-limiting, and never took longer than 1 hour. The majority of patients, relatives, and nurses were positive about VM and HP.

**Conclusions:** Both VM and HP are promising for continuously monitoring vital signs in hospitalized patients, if the frequency and duration of artifacts are reduced. The devices were well received and comfortable for most patients.

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**KEYWORDS**

remote sensing technology; vital signs; wireless technology; continuous monitoring

## Introduction

In hospitalized patients, vital signs are measured to assess the clinical situation of the patient and to identify clinical deterioration [1]. Monitoring of these vital signs is usually done by nurses, and includes blood pressure (BP), heart rate (HR), respiratory rate (RR), blood oxygen saturation, and core temperature. Early warning scores (EWS) are physiological track-and-trigger systems, which use a multiparameter or aggregate weighted scoring system that assists in detecting physiological changes and thereby identify patients at risk for further deterioration [2,3]. The modified early warning score (MEWS) is a commonly used and validated EWS system (see Multimedia Appendix 1) [4-6]. A higher MEWS is associated with admissions to the intensive care unit (ICU), cardiac arrest, and mortality [7-9]. Since the introduction of EWS, a trend was seen toward a decrease in unplanned admissions to the ICU and a decrease in hospital mortality [10-16]. Although the EWS provides relevant data on patients' health status, the interval measurements may not capture early deterioration of vital signs [17], particularly during the night when clinical deterioration may remain undetected until the next day [18]. This could explain why the majority of the unplanned ICU admissions take place between 8 am and 4 pm [19]. Unplanned ICU admissions are associated with an increased mortality rate, a longer hospital stay [20-22], and a 60% increase in hospitalization costs [23]. Continuous monitoring of vital signs could be a useful tool to detect clinical deterioration in an earlier phase, which allows clinicians to take corrective interventions, particularly since subtle changes in vital signs often are present 8 to 24 hours before a life-threatening event such as ICU admission, cardiac arrest, and death [13,24-27]. Nowadays, wearable devices that facilitate remote continuous monitoring of vital signs exist [28]. These wireless devices could reduce patient discomfort due to fewer measurements by nurses [29-31], allow patient mobility [31], and might reduce workload for nurses [30]. Moreover, wearable devices are promising for safe patient transports between wards, the operating room, and the radiology department [32]. However, these devices are still underutilized in health care, even though they have been shown to be accurate [17,33], and may reduce costs [34]. Despite many potential advantages, wearable devices may have disadvantages regarding technical dysfunction and adverse psychological effects increasing anxiety of patients for disturbances of vital signs [33].

Recently, ViSi Mobile (VM; Sotera Wireless) and HealthPatch (HP; Vital Connect), two new devices approved by the US Food and Drug Administration (FDA) for wireless remote monitoring of vital signs, were introduced in health care. At present, little is known about the feasibility of continuous monitoring and experiences of patients and caregivers. The objective of this pilot study was to assess the technical feasibility of continuous monitoring with these new devices and to evaluate the experiences of patients and nurses with this method of monitoring on the general ward.

## Methods

### Setting and Recruitment

Patients hospitalized in the internal medicine and surgical ward of the Radboud University Medical Center were included between December 2014 and March 2015. All consecutively admitted patients were approached for participation if they were hospitalized for at least 48 hours, and MEWS measurements were ordered at least three times a day by their medical doctor. Patients had to be 18 years or older and able to speak, read, and understand the local language. At the internal medicine ward, both VM and HP were attached to the patient after signed informed consent was obtained. At the surgical ward, patients signed informed consent before an elective surgical procedure. Both devices were attached to the patients after surgery and arrival at the ward. Patients were excluded from further analyses if they unexpectedly participated for a duration shorter than 24 hours in the study. To determine the technical feasibility and practical usability, the two wearable devices were used to continuously measure vital signs in patients, which were compared with regular data collected in the same patients. Since a formal power calculation was not feasible due to the lack of preliminary data with these monitoring systems, a sample size of 20 was estimated to obtain sufficient data for analysis. After reviewing the study protocol, the institutional review board waived the need for formal review and approval (number 2014-1434).

### ViSi Mobile

The VM system has received Conformité Européenne (CE) mark and is FDA-cleared for continuously monitoring of 3- or 5-lead electrocardiogram (ECG), heart and pulse rate, blood oxygen saturation, RR, skin temperature, and BP (cuff-based and cuff-less on beat-to-beat basis; Figure 1). All vital signs are displayed on a patient-worn wrist device, which can be locked by an authentication code. This wrist device is connected to a thumb sensor, which measures blood oxygen saturation and BP. A chest sensor measures RR and skin temperature, and is connected with 3 or 5 ECG cables and sensors. In this pilot study, VM was wirelessly connected to a stand-alone Toughbook (Panasonic) pre-installed with VM software, from where the investigators received real-time insights on patients' vital signs and where all the data were stored. This Toughbook also showed alarms as soon as vital signs dropped out of normal ranges. The VM wrist device was powered by rechargeable batteries, which needed to be replaced every 12 to 14 hours.

### HealthPatch

The HP consists of a reusable sensor and a disposable adhesive patch with 2 ECG electrodes at the bottom of the patch and a reusable sensor (see Figure 1). The HP has received CE mark and is FDA-cleared for continuous measurement of single-lead ECG, HR, heart rate variability (HRV), RR, skin temperature, body posture, fall detection, and activity. This small and lightweight patch can be attached to the patient's chest, from where the data is transmitted to a mobile device (eg, mobile phone, via Bluetooth). Wi-Fi connection facilitates data transmission from the mobile device to a secured cloud server. The patch is powered by a coin-cell battery that lasts 3 to 4 days.

**Figure 1.** ViSi Mobile system (left) and HealthPatch (right).

## Study Procedures

Patients gave verbal and written consent after being informed about the study protocol. Demographics including gender, age, reason for admission, and type of surgery were collected. At the surgical ward, VM and HP were attached to the patient after surgery and arrival at the ward. At the internal medicine ward, both devices were attached to the patient directly after signed informed consent was obtained. Vital signs were continuously measured during 2 or 3 days. This time frame was chosen to obtain enough vital sign data for analysis and to allow patients to get familiar with the devices. Nurses measured vital signs three times daily according to the protocol. Trained medical students additionally observed time-related vital signs monitored by VM at the Toughbook and HP on the cloud server. They marked the time points where vital signs were taken by the nurse and manually selected the results for vital signs measured by both devices at these time points for comparison. They also registered the cause and duration of technical problems and fixed them when necessary. In case of a VM alarm, the student warned the nurse. After 2 to 3 days, the enrolled patients and their relatives were interviewed about their experiences regarding continuous monitoring and both wearable devices. Nurses involved in the care of included patients were interviewed as well.

## Data Collection and Analysis

### *Technical Feasibility*

All registered data from VM and HP were retrieved for analysis in the Statistical Package for the Social Sciences version 20.0 (SPSS, Inc). Data of both devices were compared with measurements by nurses at the same time points. For each variable, the accepted discrepancy between nurse measurements and both devices was determined, which are listed in Table 1. These thresholds were defined as the maximum possible discrepancy in vital signs between the nurse measurements and both devices that would not lead to a change in medical treatment. A difference in MEWS score of 1 point or more between the nurse measurements and both devices was defined as a clinically relevant difference. The MEWS scores were calculated using vital signs measured by the nurses, VM, and HP. As VM and HP did not measure all required vital signs to calculate the MEWS score, such as level of consciousness, these vital signs were taken from the electronic health records (EHR). Bland-Altman plots [35] were created to assess the agreement between MEWS measurements by nurses and corresponding values of VM and HP. All artifacts ≥1 minute were analyzed, since we reasoned that artifacts of less than one minute would not be clinically relevant for a patient's situation. An artifact had occurred if no or an invalid value was recorded. Since trained medical students were not present all the time (primarily not during out-of-office hours), artifacts were divided into two groups, depending on the presence of a student.

**Table 1.** Accepted discrepancies between nurse measurements, ViSi Mobile, and HealthPatch.

| Vital sign | Accepted discrepancy |
|---|---|
| Heart rate | 5 beats/min |
| Respiratory rate | 2 breaths/min |
| Oxygen saturation | 2% |
| Temperature[a] | 0.5˚C |
| Blood pressure | 5 mm Hg |
| MEWS | 1 |

[a]ViSi Mobile and HealthPatch measure skin temperature.

### *Practical Usability*

User experiences were obtained by means of semistructured face-to-face interviews, after the patients had used the devices for 2 to 3 days. Patients' relatives and nurses were also interviewed. Interviews lasted approximately 10 minutes and the following topics were discussed: feelings of unsafety or safety, user friendliness, adverse events, and detection of clinical deterioration. One researcher (MW) performed a thematic content analysis to determine perceived positive and negative effects, and facilitators and barriers, which was critically reviewed by a second researcher (TB). Perceived positive and negative effects were presented according to the Donabedian framework for the quality of health care [36], which includes three main domains: structure, process, and outcome. Facilitators and barriers were divided into four domains: characteristics related to the patient, professional, intervention, and context [37].

## Results

### Demographics

A total of 25 patients were invited, of which 20 participated in the study—10 patients at the surgical ward and 10 patients at the internal medicine ward. The other 5 patients refused participation because they thought it would be too much of a mental or physical burden (see Figure 2). The study population included 13 males and 7 females with a mean age (standard deviation, SD) of 49.9 (13.4) years, ranging between 33 and 82 years. At the surgical ward, most patients were admitted for an elective gastrointestinal operation. Patients at the internal medicine ward were admitted for several conditions such as sepsis, arthritis, and blood pressure control.

### Technical Feasibility

In total, 120 vital sign measurements by nurses were observed by the trained medical students (see Figure 2). In 40 measurements, one or more vital signs were missing. In 6 measurements, data were completed by consulting the EHR. As a result, 86 measurements were used for further analysis. For the remaining 34 measurements, VM and HP data were lacking (25 measurements), or vital signs were not documented by nurses (9 measurements). In 8 patients, data from the Toughbook was not available for further analysis due to accidental deletion of data; in 2 patients, no HP data were saved at the cloud server due to technical failures (eg, WiFi failures, disconnection between HP and its mobile device). In total, 742.8 hours of VM data and 1033.6 hours of HP data were collected; on an average 61.9 hours of VM and 57.5 hours of HP data were collected per patient.

**Figure 2.** Included patients and vital sign measurements.

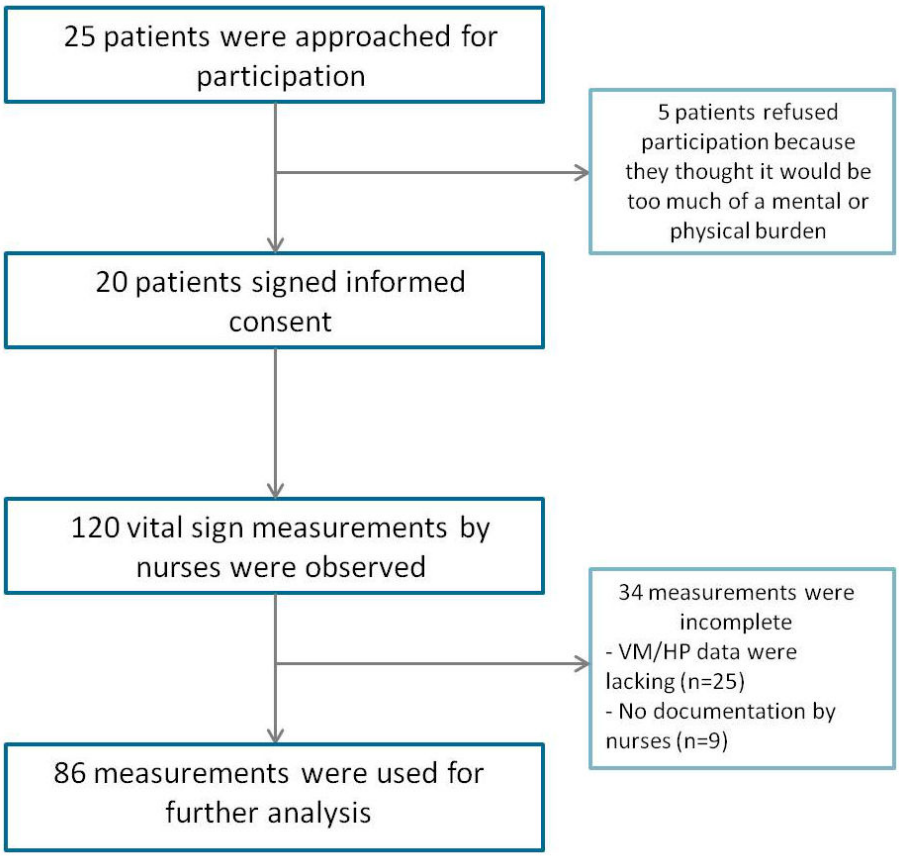


**Figure 3.** Bland-Altman plots: (a) heart rate (VM and HP), (b) respiratory rate (VM and HP), (c) systolic and diastolic blood pressure (VM). Dotted lines indicate mean difference and solid lines indicate limits of agreement.

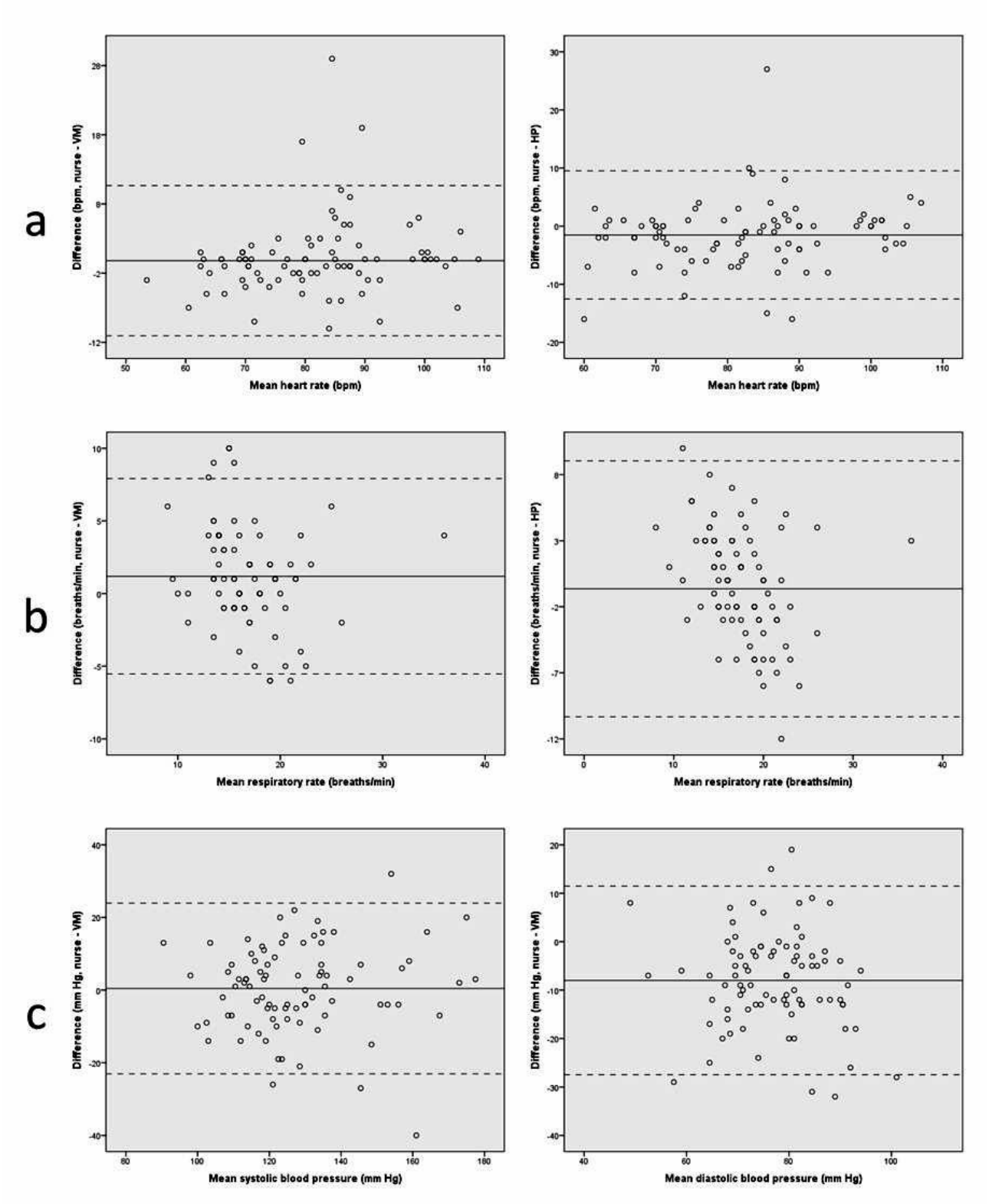
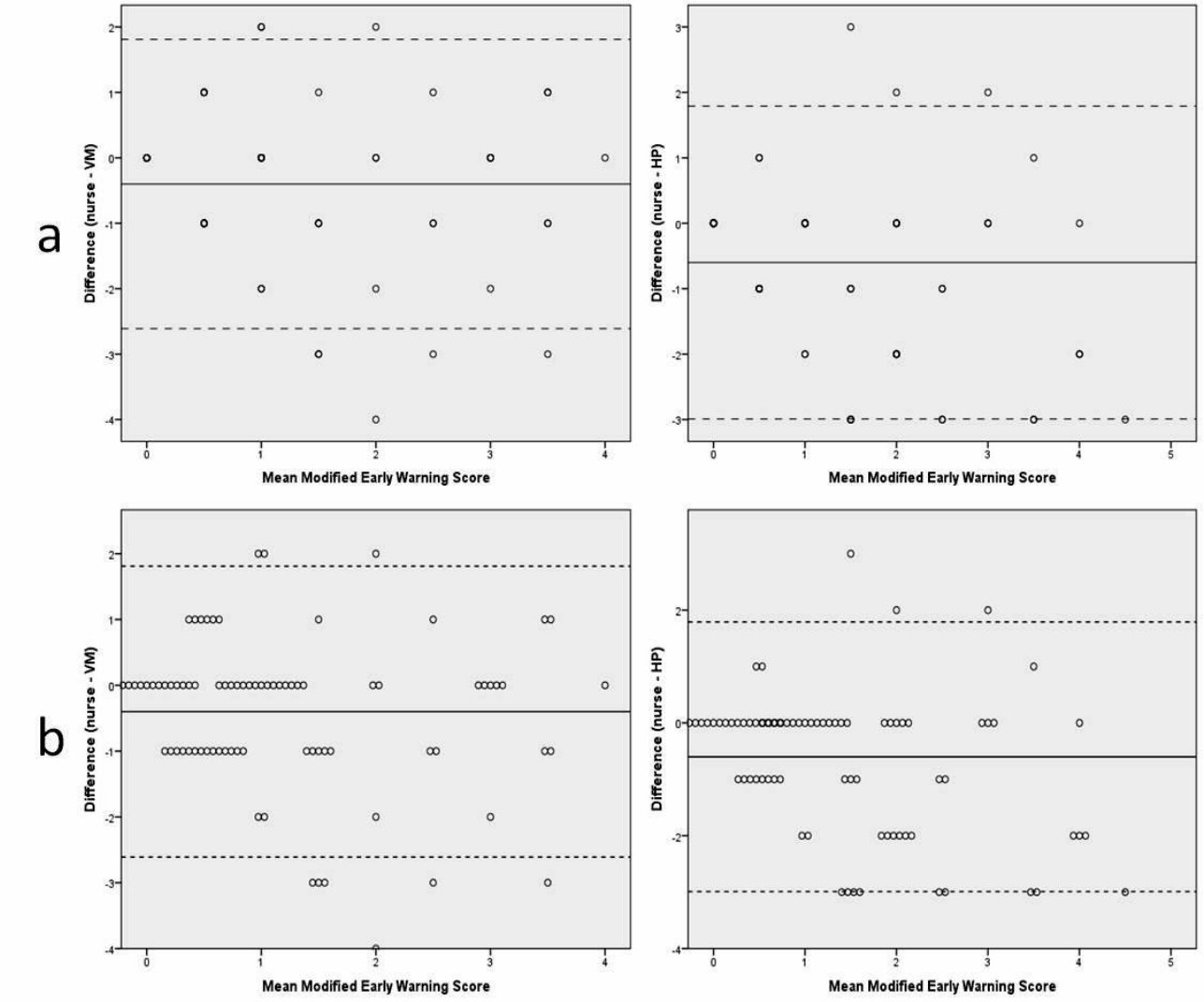


**Figure 4.** Bland-Altman plots showing modified early warning score: (a) VM and HP, (b) VM and HP (jittered). Dotted lines indicate mean difference and solid lines indicate limits of agreement.




## Vital Signs

Bland-Altman plots showing the mean of the two devices and the differences between the two devices (y-axis) with limits of agreement (1.96 SD) are displayed in Figures 3 and 4. Comparing the results for vital signs and MEWS score measured by nurses and VM, the mean differences were all within range with the predefined accepted discrepancies in Table 1, although wide limits of agreement were found (see Table 2). The largest discrepancy in the mean difference was found for diastolic BP. In 13 (15%) cases, the MEWS difference between nurse and VM was 2 points or higher, indicating important clinical differences between VM and nurse measurements (see Table 3). In four cases, this was related to differences in RR alone. In the remaining cases, the combination of RR and oxygen saturation, or RR and systolic BP caused the difference. Moreover, in six of these cases, VM measured a higher RR than nurses (range: 1-6 breaths/min), and in the four other cases, nurses measured a higher RR than VM (difference: 2-6 breaths/min). In the three remaining cases that resulted in a different MEWS, there was a difference in systolic BP (difference: 14 mm Hg) or oxygen saturation (difference: 1%-5%) between VM and the nurse. The mean differences between nurse measurement and HP were all in agreement with accepted discrepancies, although wide limits of agreement were found (see Table 2). In 23 (27%) cases, MEWS differed 2 or 3 points between HP and nurse measurements (see Table 3). In 17 cases, HP measured higher RR compared with nurses. In 16 cases, differences were in the range of 3 to 8 breaths/minute. However, in one case, nurses measured 16 breaths/minute and HP measured 42 breaths/minute, indicating possible measurement errors in HP. In the remaining six cases, nurses measured a higher RR than HP (difference: 4-12 breaths/min).

**Table 2.** ViSi Mobile and HealthPatch data in comparison with corresponding nurse measurements.

| Vital signs | Nurse | ViSi Mobile | | HealthPatch | |
|---|---|---|---|---|---|
| | Mean (SD)[j] | Mean (SD) | Mean difference (SD) versus nurse | Mean (SD) | Mean difference (SD) versus nurse |
| HR[f] (beats/min) | 81.81 (13.12) | 81.62 (12.23) | −0.20 (5.54) | 84.34 (12.24) | −1.52[c] (5.63) |
| RR[g] (breaths/min) | 17.38 (3.89) | 16.20 (4.57) | 1.19[a] (3.43) | 18.02 (5.82) | −0.64 (4.94) |
| Saturation (%) | 97.00 (96.00 to 98.00)[d] | 97.00 (95.00 to 98.00)[d] | 0.10 (1.65) | N/A[k] | N/A |
| Temperature (˚C) | 37.01 ( 0.60) | 33.61(1.25)[e] | | 34.16 (1.16)[e] | |
| BP[h], systolic (mm Hg) | 127.93 (19.33) | 127.49 (18.68) | 0.44 (11.99) | N/A | N/A |
| BP, diastolic (mm Hg) | 73.17 (10.25) | 81.17 (11.24) | −8.00[b] (9.93) | N/A | N/A |
| MEWS[i] | 0.99 (1.13) | 1.38 (1.30) | −0.40[a] (1.13) | 1.59 (1.54) | −0.60[b] (1.22) |

[a]*P*=.002.

[b]*P*<.001.

[c]*P*=.01.

[d]Oxygen saturation was reported as median with interquartile range.

[e]Skin temperature.

[f]HR: heart rate.

[g]RR: respiratory rate.

[h]BP: blood pressure.

[i]MEWS: modified early warning score.

[j]SD: standard deviation.

[k]N/A: Not applicable.

## Artifacts

### *ViSi Mobile*

In total, 306 artifacts were found, with a total time of 121 hours. In 111 (36.3%) of 306 artifacts, a trained medical student was present, and 86 of 111 (77.5%) were identified and reported. A cause was found in 82 (95.1%) of 86 artifacts. Almost 70% of all reported artifacts were caused by connection failure between Toughbook and VM. Other artifact causes were motion of the sensors due to patient movements (n=21, 25.6%) and required calibration of blood pressure (n=2, 2.3%). Over 74% of all artifacts lasted less than 5 minutes. Almost 20% lasted less than 1 hour, and approximately 7% lasted longer than 1 hour.

### *HealthPatch*

In total, 648 artifacts were found in 18 patients, with a total time of 135 hours. More than 50% (n=354) of all artifacts lasted less than 1 minute and were excluded from further analysis. In the remaining 294 artifacts, a trained medical student was present in 60% (n=176) of the artifacts, and identified and reported the artifact in 53 (30%) cases. A cause was found in 24 (45%) artifacts such as HealthPatch losing skin contact (n=13, 54%), Bluetooth (n=4, 17%) or Wi-Fi problems (n=3, 13%), and patients leaving the ward without their mobile device (n=3, 13%). Around 43% of all artifacts lasted less than 5 minutes. Over 95% of all artifacts lasted less than 1 hour.

**Table 3.** ViSi Mobile (VM) and HealthPatch (HP) data in comparison with corresponding nurse measurements.

| Vital signs | ViSi Mobile | HealthPatch |
|---|---|---|
| | Difference; nurse-VM (%) | Difference; nurse-HP (%) |
| HR[a] (beats/min) | ≤5: 71 (82.5) | ≤5: 65 (75.6) |
| | 6-10: 12 (14.0) | 6-10: 16 (18.6) |
| | >10: 3 (3.5) | >10: 5 (5.8) |
| RR[b] (breaths/min) | ≤2: 50 (58.2) | ≤2: 36 (41.9) |
| | 3-5: 26 (30.2) | 3-5: 31 (36.0) |
| | >5: 10 (11.6) | >5: 19 (22.1) |
| Saturation (%) | ≤2: 76 (88.4) | N/A[e] |
| | 3-4: 9 (10.5) | |
| | ≥5: 1 (1.1) | |
| BP[c] systolic (mm Hg) | ≤5: 36 (41.9) | N/A |
| | 6-14: 33 (38.4) | |
| | ≥15: 17 (19.7) | |
| BP diastolic (mm Hg) | ≤5: 27 (31.4) | N/A |
| | 6-14: 40 (46.5) | |
| | 15: 19 (22.1) | |
| MEWS[d] | −4: 1 (1.2) | −3: 9 (10.5) |
| | −3: 5 (5.8) | −2: 11 (12.8) |
| | −2: 4 (4.7) | −1: 13 (15.1) |
| | −1: 23 (26.7) | 0: 47 (54.7) |
| | 0: 40 (46.5) | 1: 3 (3.5) |
| | 1: 10 (11.6) | 2: 2 (2.3) |
| | 2: 3 (3.5) | 3: 1 (1.2) |

[a]HR: heart rate.

[b]RR: respiratory rate.

[c]BP: blood pressure.

[d]MEWS: modified early warning score.

[e]N/A: not applicable.

## Practical Usability

Evaluations were performed with all 20 patients, 7 relatives, and 4 nurses (see Table 4).

### *Perceived Positive and Negative Effects*

#### Processes

One positive effect was identified in this dimension. Patients stated that nurses could keep an eye on the vital signs from a distance (n=3); this was also mentioned by one relative. No negative effects were identified.

#### Outcomes

Two positive effects were identified in this dimension. Eight patients and 66 relatives mentioned increased feelings of safety by being monitored continuously in comparison with the MEWS measurements by nurses only. A patient described:

> *Being monitored continuously is a very pleasant experience; I felt very safe.* [Translated from Dutch]

Earlier interventions were deemed possible in case of clinical deterioration (n=3). One negative effect was identified; one patient complained about having redness and itching while wearing the devices.

### *Facilitators and Barriers*

#### Intervention

Seven facilitators were identified. Eight patients said they were not aware of the HP while it was attached to their chest. Other facilitators included not being restricted by the devices during daily activities such as bathing and putting on clothes (n=3), more freedom of movements compared with conventional devices (n=2), the small size of the HP (n=1), the good adhesive properties of the patches (n=1), and the invisibility of the devices under clothes (n=1). One patient described:

> *I have used a holter monitor at home several times. These devices are much smaller and they do not limit mobility to the same extent.* [Translated from Dutch]

One patient experienced great advantage of having an insight on his own vital signs. One barrier was noted 15 times. Patients mentioned that the VM wrist device was big or heavy (n=10); patches came off very quick (6 VM; 2 HP); VM had many cables (n=4); and VM had a short battery life (n=2).

### Professional

Two facilitators and one barrier were identified in this domain. Two nurses stated that the patches did not lose skin contact while washing the patient, and one nurse said that it was very easy to attach the devices to the patient. One nurse mentioned that Wi-Fi connection was poor between Toughbook and the VM device.

### *Additional Findings*

During the study, clinical deterioration was detected with the VM in one patient 3 days postoperatively after elective colorectal surgery. The device alerted the nurse who cared for the patient because he developed a tachycardia and tachypnea. This situation occurred between two regular measurements. He underwent relaparotomy after an anastomotic leak was confirmed by computer tomography.

**Table 4.** Users' experiences.

| Users'experience | Nurse | Patient | Relatives |
|---|---|---|---|
| **Perceived positive and negative effects** | | | |
| **Processes**[a] | | | |
| Nurse could keep eye on vital signs more easily | | + | + |
| **Outcomes** | | | |
| Feelings of safety | | + | + |
| Earlier interventions | | + | |
| Adverse events (redness and itching) | | − | |
| **Barriers and facilitators** | | | |
| **Intervention** | | | |
| Not aware of HP[b] | | + | |
| Small size of HP | | + | |
| Good adhesive properties | | + | |
| Not being restricted during daily activities | | + | |
| More freedom of movements | | + | |
| Invisibility under clothes | | + | |
| Better insight on own vital signs | | + | |
| VM[c] wrist device too big/heavy | | − | |
| Patches came off very quickly | | − | |
| VM has too many cables | | − | |
| Short VM battery life | | − | |
| **Professional** | | | |
| Good adhesive properties | + | | |
| Very easy to attach the devices | + | | |
| Bad Wi-Fi connection between VM and Toughbook | − | | |

[a]No positive or negative effects in the "Structure" or "Context" fields were found.

[b]HP: HealthPatch.

[c]VM: ViSi Mobile.

## Discussion

### Principal Findings

This study describes a unique approach in which we continuously measured vital signs on the ward using two recently released wireless devices. In general, data obtained by these devices correlated well with predefined accepted discrepancies and MEWS calculated on the basis of these devices correlated to a larger extent. Patients and nurses were mainly positive about the two devices. Both VM and HP are promising devices for continuous patient monitoring on the

general ward. However, the number of artifacts should be reduced and the barriers mentioned by the users could be addressed to further improve both devices.

### Vital Signs

The largest discrepancy in mean difference was found in VM diastolic blood pressure, which is unlikely to be directly clinically meaningful since it is not a component of the MEWS. Additionally, clinical decisions are mainly based on systolic blood pressure and other vital signs. Wide limits of agreement were found for almost all vital signs and MEWS. Although more than 70% of all MEWS differed 0 or only 1 point between devices and nurse measurements, larger differences in MEWS were found in a few cases, which may have important clinical consequences (eg, additional diagnostic procedures or change in treatment). In most of these cases, VM and HP measured a higher RR when nurses did not. Although most differences between nurse and device measurements were small (<5 breaths/min), in one case, difference between nurse and HP measurements was large (26 breaths/min). These findings are important as abnormal RR has been shown to be an important predictor of cardiac arrest [38] and an indicator of sepsis, pneumonia and respiratory depression [39]; therefore, it could under- or overestimate a clinical condition of a patient. Inaccurate RR measurements by nurses could explain the discrepancy. Direct measurement of RR is usually done by visually observing chest movement or by manual observations. Reproducibility may be limited by significant interobserver variability [40]. Conversely, ECG-derived RR measurements by HP and VM may be inaccurate. In case of HP, RR is estimated by ECG using the respiratory sinus arrhythmia method, which derives RR from HRV. Since this method has some limitations, an accelerometer was added to measure RR more accurately [41]. In VM, RR is derived from impedance pneumography, measuring respiratory volume and rate through the relationship between respiratory depth and thoracic impedance rate [42]. ECG-derived RR may not be accurate when there is excessive patient motion or during lower respiratory rates [43,44]. More research is required to gain a deeper insight in the different methods of measuring RR by devices and nurses.

### Artifacts

Most reported that VM artifacts concerned connectivity failure between VM and Toughbook. This was caused by a restricted Wi-Fi connection of approximately 15 meters between VM and Toughbook, which explains why more artifacts were found in mobile patients. These artifacts were not deemed relevant since more stable Wi-Fi connections, such as by using multiple access points and 5 Ghz networks, would be used to implement VM in a hospital setting. This would also facilitate continuous monitoring during patient transport between different wards. However, it is important to consider that a wireless connection can always fail, thus proper backup power and Internet connections are always demanded. Most HP artifacts were of unknown cause. However, most artifacts lasted less than one hour and were self-limiting.

Although HP could not measure all vital signs that are currently used to monitor patients and to calculate the MEWS, it may still provide more patient data than interval measurements by nurses, resulting in a more continuous dataflow and more specific trends. This may be of significance, in particular, since literature shows important lack of documentation of vital signs before a life-threatening event [27]. Besides that, several studies show that HR and RR change significantly before ICU transfer, cardiac arrest, and mortality and therefore, HP can have a valuable contribution to the prediction of life-threatening events [24,27].

### Practical Usability

The majority of patients, relatives, and nurses were positive about VM and HP. Whereas HP is able to administer vital signs in real time to patient's mobile phone, VM shows vital signs in real time on the wrist device; these devices could therefore increase insight on patient's health status and potentially influence their behaviors [45,46]. Although patients mentioned that the VM wrist device was heavy and VM consisted of many cables, they were not restricted during daily activities or mobility. This is important as hospitalized patients benefit from mobility, resulting in increased recovery and reduced risk of complications [47,48]. Another benefit of VM and HP is that nurses are able to see patients' vital signs from a distance. A review by Ulrich et al [49] has shown that sleep deprivation in patients is a common problem that is associated with hindrance of the healing process and an increase in morbidity and mortality. Using VM and HP, patients could continue sleeping during the night and did not have to be disturbed by vital sign measurements.

Possible negative aspects of continuous monitoring should also be taken into consideration. Wearable devices generate a large quantity of data each day. The workload of nurses and physicians withholds them from inspecting all these data, which means that the predictive value of continuous monitoring is lost [17]. Validated devices are available to process all these data and to send an alert when patient's vital signs drop out of normal ranges. A large number of alerts and even false-positive alerts could cause alarm-fatigue in nurses [17,50]. Algorithms using machine learning could be utilized to reduce false-positive alarms [51-53]. The VM battery has a battery life of 12 to 14 hours, which means that nurses have to change batteries twice a day. This might outweigh the fact that nurses no longer need to perform the standard MEWS measurements three times a day.

### Comparison With Prior Work

A few studies about continuous monitoring at the general ward have been published. A wireless sensor was successfully used in pregnant women in an inpatient obstetric unit, which was able to monitor HR, RR, and temperature [30]. Recently, the SensiumVitals digital patch was tested in hospitalized patients [54]. This patch is able to measure HR and RR and was compared with a commonly used clinical monitor. A satisfactory agreement, comparable with the result in our study, was shown. The drawback of the study design was that the patients were monitored for only 2 hours, which prevented the authors from detecting trends in vital signs and lowered predictive value. The use of an implantable device for continuous monitoring has been described in the ambulatory setting. Abraham et al [55]

described the use of a wireless implantable hemodynamic monitoring system in heart failure patients, which has shown to reduce hospitalization. Wireless technology systems in which patients measure vital signs at home have been described, such as for patients with chronic obstructive pulmonary disease [56], patients with hypertension [57], and patients with diabetes mellitus [58,59]. These systems were often well received by patients and health care providers, showing improvement of blood values such as glucose [58,60], patients' disease management [56,61], and better connection between the patient and the health care provider [59]. Particularly, the HP might be suitable for home monitoring, although its current version lacks the possibility to measure all vital signs. Though VM measures all vital signs, its size and cables might demand much from patients to enable monitoring at home.

### Strength and Limitations

An important strength of the study is that we were able to monitor patients in a clinical setting instead of healthy participants in controlled settings. The study had a small sample size, and we missed some VM and HP data, particularly since VM data of 8 patients were automatically deleted from the Toughbook and could not be used for artifact analysis. This was due to wrong Toughbook settings and was changed with support from the manufacturer. The VM vital signs observed by students were used for the comparison with nurse measurements, and we were therefore able to draw conclusions about the feasibility of both VM and HP. However, data saturation in patient, nurse, and relative interviews may not have been reached. Selection bias could have occurred as not all patients who were approached did agree to participate. A further limitation of VM and HP is that both devices measure skin temperature instead of body temperature. Although it is not yet clear whether or not all vital signs are necessary for proper clinical judgment of ill patients, an algorithm should be developed to convert skin temperature into body temperature.

### Conclusions

The VM and HP are promising devices for wireless continuous patient monitoring in the hospital and were very well received by both patients and nurses. The frequency and duration of artifacts should be reduced and the barriers mentioned could be addressed to further improve VM and HP. An ongoing follow-up study focuses on the different effects of VM or HP compared with routine MEWS measurements on patient comfort and safety and nurse workload, and on early detection of deterioration. Future studies should focus on the effect of continuous monitoring on clinical outcome.

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### Conflicts of Interest

None declared.

### Multimedia Appendix 1

Modified Early Warning Score (MEWS); A: alert, V: response to speaking, P: response to pain, U: no response.

[JPG File, 48KB - mhealth_v5i7e91_app1.jpg ]

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## Abbreviations

**BP:** blood pressure
**CE:** Conformité Européenne
**ECG:** electrocardiogram
**EHR:** electronic health records
**EWS:** early warning scores
**FDA:** US Food and Drug Administration
**HP:** HealthPatch
**HR:** heart rate
**ICU:** intensive care unit
**MEWS:** modified early warning score
**RR:** respiratory rate
**SD:** standard deviation
**VM:** ViSi Mobile


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Original Paper

# Mobile Health Technology Using a Wearable Sensorband for Female College Students With Problem Drinking: An Acceptability and Feasibility Study

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## Abstract

**Background:** An increasing number of mobile app interventions have been developed for problem drinking among college students; however, few studies have examined the integration of a mobile app with continuous physiological monitoring and alerting of affective states related to drinking behaviors.

**Objective:** The aim of this paper was to evaluate the acceptability and feasibility of Mind the Moment (MtM), a theoretically based intervention for female college students with problem drinking that combines brief, in-person counseling with ecological momentary intervention (EMI) on a mobile app integrated with a wearable sensorband.

**Methods:** We recruited 10 non-treatment seeking, female undergraduates from a university health clinic who scored a 3 or higher on the Alcohol Use Disorders Identification Test–Consumption (AUDIT-C) to participate in this pilot study. Study activities involved an in-person baseline intake and 1 follow-up assessment, 2 in-person alcohol brief intervention counseling sessions, and use of MtM technology components (sensorband and EMI on a mobile app) for approximately 3-4 weeks. The intervention used motivational interviewing (MI) and cognitive behavioral therapy (CBT) strategies for reducing risks associated with drinking. We used both qualitative and quantitative assessments to measure acceptability of the intervention and feasibility of delivery. Use patterns of the sensorband and mobile app were also collected.

**Results:** Quantitative and qualitative data indicated high levels of acceptability for the MtM intervention. Altogether, participants made reports on the app on 26.7% (78/292) the days the technology was available to them and completed a total of 325 reports with wide variation between participants. Qualitative findings indicated that sensorband-elicited alerts promoted an increase in awareness of thoughts, feelings, and behaviors related to current environmental stressors and drinking behaviors in theoretically meaningful ways. Specific challenges related to functionality and form of the sensorband were identified.

**Conclusions:** Delivering intervention material “just-in-time,” at the moment participants need to use behavioral strategies has great potential to individualize behavioral interventions for reducing problem drinking and other health behaviors. These findings provide initial evidence for the promise of wearable sensors for increasing potency of theoretically grounded mobile health interventions and point to directions for future research and uptake of these technologies.

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**KEYWORDS**

wearable sensors; ecological momentary intervention; college students; alcohol use; feasibility studies; acceptability studies

## Introduction

Excessive consumption of alcohol by college students leads to numerous negative health, academic, and social consequences [1,2]. For college-age women in particular, problematic drinking is linked to unwanted sexual activity, assault, accident-related mortality and morbidity, poor academic performance, and interpersonal problems with friends or dating partners [3,4]. Brief, theoretically based, in-person interventions for problematic alcohol use among college students have demonstrated evidence of efficacy for reducing alcohol consumption and associated problems [5-7].

Increasingly, mobile phones have served as a platform to deliver brief interventions for problem drinking, typically in the form of text messages (short message service, SMS) [8-12]. These ecological momentary interventions (EMI) deliver reminders, prompts, or strategies to students in the real world [13] and typically are delivered at specific (eg, daily) intervals [9] or at times that coincide with drinking episodes, such as weekends or during university events [14-16]. Few, however, are informed by behavioral change theories [17]. Theoretically-grounded, blended interventions that provide support from both a real-life clinician and mobile technology have the potential to enhance motivation for behavior change [18-20].

### Increasing the Potency of Mobile Apps Through Wearable, Physiological Monitoring

The emergence of ambulatory monitoring of physiological markers of affective states allows users to receive real-time biofeedback through mobile phone apps. Wearable, noninvasive, unobtrusive technologies such as wristbands can be worn in daily life and have enormous potential to add potency to behavioral health interventions, including problematic alcohol use [9,21,22]. Electrodermal activity (EDA), also known as skin conductance, reflects changes in sympathetic nervous system activity (SNS) that is responsible for mobilizing the body to respond to emotional arousal such as stress and anxiety, including arousal associated with attention demanding tasks and arousal not open to conscious awareness. Alcohol-associated cues have been found to elicit SNS activity in individuals who are at risk for alcohol use disorders [23,24], particularly women [25]. When integrated with a mobile app on a smartphone, continuous, real-time monitoring of EDA can deliver EMI strategies when EDA increases, typically at the very moment individuals need to use behavioral health strategies in the course of their daily lives [21]. These interventions have been referred to as "just-in-time adaptive interventions," where the support can occur at the time an individual is in a vulnerable state and highly susceptible to negative health outcomes [26]. Drawing individuals' attention to these sensitive moments while they are occurring, and providing prompts or reminders of effective strategies, has great potential to avert immediate negative consequences and provide highly salient training experiences in using behavior change skills.

### Problematic Alcohol Use Among College-Age Women

Undergraduate students experience a significant developmental transition of increasing autonomy, marked by academic, personal, and social changes. Relative to males, female undergraduates consistently report experiencing a disproportionate amount of stress related to academic, social, financial, and other concerns [27]. Within this context, alcohol plays a conspicuous role on college campuses, as over 80% of college students in the United States report drinking alcohol [28]. While undergraduate females typically consume less alcohol than males, over the past 10 to 20 years, this gap has narrowed considerably, with a notable increase in the frequency and quantity of alcohol consumption and related problems among female undergraduate students [29]. For example, both males and females report similar rates of alcohol-induced blackouts [30]. Moreover, in addition to academic and interpersonal problems associated with excessive drinking, aggressiveness between dating partners and sexual violence increases while women are under the influence of alcohol [31,32].

Most college students report drinking for social reasons [33,34], although many students also report drinking to cope with negative emotional states [35-37]. The use of alcohol to manage negative affect including stress and anxiety, has been shown to be a risk factor for the development of alcohol use disorders [36-41], particularly in females [42-44]. Enhancing emotion regulation skills has been indicated as an important focus of interventions for problematic alcohol use [36,45].

### This Study

We describe a pilot intervention called Mind the Moment (MtM) for female college students with problematic drinking, using a blended intervention consisting of 2 brief, in-person sessions, along with the use of a mobile app and integrated sensorband for continuous measurement of EDA. Consistent with the extant models of brief alcohol interventions for college students, development of the MtM intervention was guided by cognitive behavioral therapy (CBT) and motivational interviewing (MI) strategies, which include providing personalized feedback on drinking patterns and motives for drinking, identifying triggers, establishing protective behavioral strategies, and planning to reduce drinking. Strategies to increase students' emotional regulatory skills to deal with stress and triggers associated with excessive alcohol consumption may be particularly important for students who drink to cope with negative affect. These strategies include identifying current emotions, controlled breathing, mindfulness meditation, as well as individually-identified strategies such as listening to music or exercising.

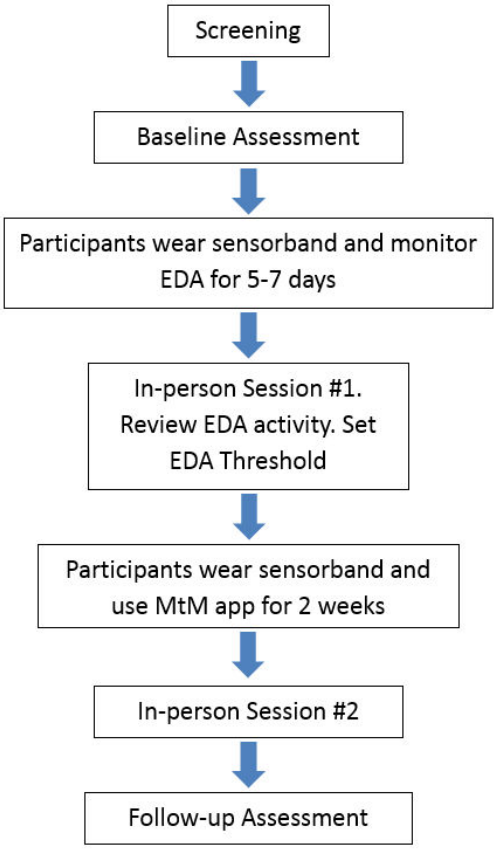
Guided by the Unified Theory of Use and Acceptance of Technology (UTUAT) [46], an empirically derived grand theory of perceived advantages and challenges associated with new technologies, we explore the acceptability and feasibility of the MtM intervention components using quantitative and qualitative methods. While the UTAUT is designed for the work-place, it includes theories traditionally used to explain individual and social factors involved in behavioral health change. Additionally, we examined students' patterns of use of the technology components and their perceptions of how the intervention addressed the theoretical targets of the intervention.

## Methods

### Participants and Procedures

Participants (N=10) were nontreatment seeking undergraduate female students receiving routine medical care at the university health center (UHC) in a large, highly competitive private university that screens all patients for risky drinking. Female undergraduate students who score at or above the threshold for risky drinking for women (3 or higher) on the Alcohol Use Disorder Identification Test-Consumption (AUDIT-C) [5,47] are routinely provided with information by the UHC provider regarding what their score suggests and asked if they would like a referral to counseling about the potential for problems related to their alcohol use. Patients who agreed to receive a referral for counseling were provided with a brief description of the study by the UHC provider, and if interested, signed informed consent to be contacted by the research staff to receive more information about the study. Students who were not interested in the study received the UHC standard counseling referrals. Interested students were then screened by phone for eligibility by the research assistant (RA) using the following criteria: female (by birth), age 18-24 years, and approved by their health center provider for participation. Students were ineligible for participation if they were pregnant or currently receiving treatment for addiction or severe mental illness. After determining eligibility, the RA explained the study procedures: a baseline and follow-up assessment, 2 in-person counseling sessions concerning their alcohol use, and use of the MtM technology for approximately 3 weeks (Figure 1). Students who met eligibility criteria and were interested in participating were scheduled for a baseline assessment where they signed informed consent. Participants received US $25 for each assessment, $15 for each in-person counseling session, $25 per week for wearing the sensorband 5 or more hours a day (for 5 out of 7 days), and $5 for sending their data electronically every other day. All procedures were approved by the university's institutional review board.

**Figure 1.** Study flow.



## Intervention Components

The intervention consisted of 2 main integrated components (Figure 1): the technology (MtM app, sensorband, and study smartphone) and 2 brief in-person counseling sessions. Participants' use of the MtM technology took place in two phases; the first phase occurred between the baseline assessment and the first in-person session, and the second phase occurred between the first in-person session and the second in-person session or follow-up interview. Both the in-person and the MtM technology intervention components were developed for the study with input from members of the target population and guided by MI and CBT strategies [48-51]. This input included elements of the content of the app, such as typical emotions and situations experienced by students as well as protective behavioral strategies for reducing harms related to drinking and ways of reducing stress. Table 1 presents the theoretically based components of the intervention, including the mode of delivery (in-person or technology). Each in-person session lasted approximately 1 h and was conducted by an advanced practice nurse certified in mental health and addictions.

**Table 1.** Theory table.

| Theory | Technique | Intervention component | Delivery method | Example |
|---|---|---|---|---|
| **MI**[a] | Elicit recognition of problem(s) | Drinking feedback | IS[b] | What are your thoughts about your AUDIT-C[c] score? Do you think it places you at risk for health problems? |
| **CBT**[d]**, MI** | Assess risk | Risk self-assessment | IS | Would you say you sometimes are a "risky drinker?" |
| CBT, MI | Drinking context | Identify triggers or cues | IS, tech[e] | Do certain situations act as cues to drink? |
| MI | Motivation | Decisional balance | IS | Are there harms of drinking that you would like to avoid? |
| MI | Assess readiness | Readiness for change assessment | IS | On a scale of 1-10, how ready would you say you are to cut back or quit drinking? |
| CBT, MI | Goal-setting | Drinking plan | IS | If you choose to cut back, what would you want to consider in making your plan (eg, number of drinks and frequency)? |
| CBT | Identify feelings | Feeling scale | Tech | How are you feeling? |
| CBT | Coping | Coping statements and relaxation | Tech | Freeze, breathe, choose<br>Guided meditation |
| CBT | Positive self-talk | Cool thoughts | Tech | My thoughts are not me |
| CBT | Protective behavioral strategies | Coping with triggers | IS, tech | Take a cab home |

[a]MI: motivational interviewing.

[b]IS: in-person session.

[c]AUDIT-C: Alcohol Use Disorders Identification Test-Consumption.

[d]CBT: cognitive behavioral therapy.

[e]tech= Mind the Moment (MtM) technology.

## Mind the Moment Ecological Momentary Intervention

### *Instrumentation*

The Empatica E4 [52] wearable wristband ("sensorband") (Figure 2) measures EDA by applying constant low voltage to the skin and measuring the resultant current. It also contains an accelerometer and temperature sensor that informs interpretation of the EDA signal, which can depend on physical movement and changes in body temperature. The sensorband connects wirelessly to an Android-based smartphone via Bluetooth [53], and through the Empatica app, displays real-time EDA, heart rate, and temperature. The separate app for the MtM intervention was built on the Empatica application programming interface (API) and customized for the study using the Studio IDE [54] platform with open-source libraries support pulled from Github [55].

**Figure 2.** Empatica E4 sensorband.

### *Implementation of Mind the Moment (MtM) Technology*

After completing the baseline interview, participants were provided with a sensorband, a study Android smartphone, and instructions for use (Figure 1). In the first study phase, and before the first in-person session, participants were asked to wear the sensorband and carry the study phone as frequently as possible for 4 to 6 days, periodically checking their EDA using the Empatica app and making note of when they were aroused or stressed.

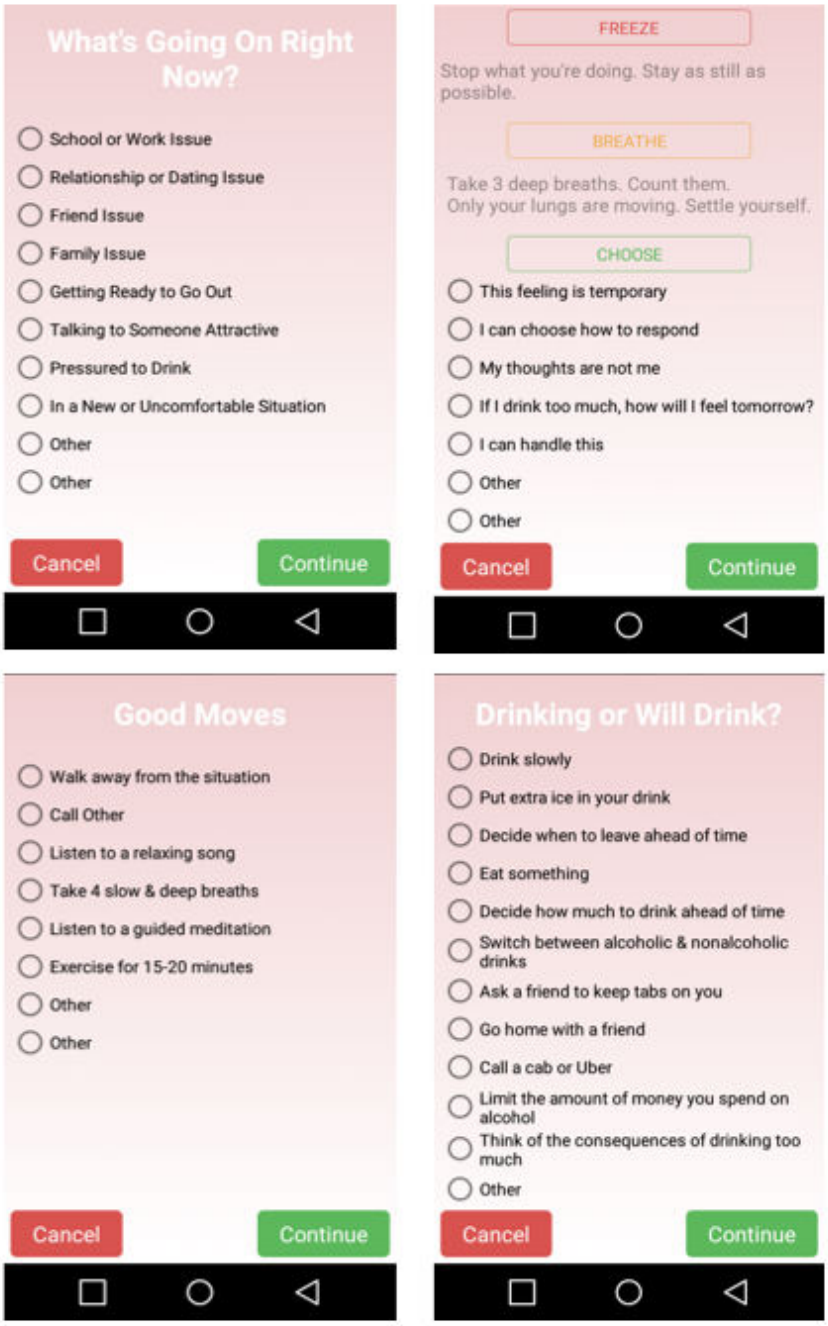
In the second phase, participants were provided with the MtM app on the study phone immediately after the first in-person session. In order to set the individual EDA threshold, together, the RA and participant reviewed her EDA and activities from the previous week and compared it with her baseline assessment activity to determine peaks due to physical exertion (eg, exercising and running to class) and mental or emotional stress (eg, taking an exam or receiving a grade). The RA then set the threshold to alert (vibrate or ring) the participant when her EDA rose above an individually determined threshold. Participants were provided with instructions for using the MtM app when alerted, and they could choose to respond, pause the alert for 10 min, or ignore it.

In addition to EDA-triggered reports, participants were encouraged to self-initiate MtM at any time. After the first 2 days of using the technology, each participant was contacted by the RA who inquired about her use of the technology and adjusted the threshold in the event that there were too many or too few alerts based on sensorband use and feelings of arousal.

### *Contents of the MtM App*

As seen in Figure 3, participants were led through a series of CBT-informed questions and strategies when they were alerted that their EDA reached threshold or when they made a self-initiated report. The first questions asked participants to identify their current emotions and level of intensity, and current context. When participants identified a positive emotion, the app supplied an affirmational statement and then closed. When a negative emotion was selected, participants were asked about their current context, provided with a brief CBT strategy, and asked about their intentions to drink alcohol. Based on their responses, specific coping strategies including a meditation, listening to a favorite song, positive self-talk, and protective behavioral strategies for drinking were offered. Participants were also encouraged to personalize the app by inserting specific emotions and contexts that were not on the preprogrammed list. These individually selected emotion and contexts then appeared whenever they responded to a sensor-triggered alert or when making a self-initiated report. Programming constraints did not make it possible to display both real-time EDA data using the Empatica app and the MtM app at the same time.

**Figure 3.** MtM app contents.




## In-Person Sessions

The first in-person session with the clinician was guided by the Southeastern Consortium for Substance Abuse Training (SECSAT) [56], a semistructured interview guide that includes assessing readiness, reviewing drinking patterns and cues, discussing harms or consequences related to drinking, eliciting protective behavior strategies, and developing short-term goals for reducing risky drinking. At the end of the session, the RA returned and demonstrated how to use the sensorband in conjunction with the MtM app. Participants were encouraged to wear the band and carry the study phone as often as possible during the next few weeks, particularly when they planned to drink.

The second in-person session with the clinician occurred approximately 3 weeks after the first session. During this session, the clinician discussed participant's use of MtM app and sensorband in relation to triggers for drinking and their progress with drinking-related goals. Participants were asked to identify continuing barriers and facilitators of adhering to their drinking-related goals, plans for overcoming these barriers, and enhancing the facilitators. At the completion of the study, referrals were given to participants when the clinician believed they would benefit from further support.

### Assessments and Measures

#### *Physiological Measures*

##### Baseline Assessment of Electrodermal Activity (EDA)

In order to determine the individual EDA threshold for each participant, an assessment of baseline EDA was conducted to determine the full spectrum of EDA using a startle task, a cognitive stress task, and physical activity. At the beginning, participants were asked to sit quietly in a comfortable position for a few moments and after signing informed consent, the RA placed the Empatica sensorband on the participant's right wrist and asked her to continue sitting quietly for a few moments. To elicit a startle reflex, a loud air horn, out of sight from the participant, was blown once. Participants also completed a computerized Stroop color word task in which they were asked to read the names of the colors as quickly as possible in 1 min, and finally, a brief physical task (eg, jumping jacks) was performed for approximately 4 min.

##### Alcohol Consumption

The Time Line Follow Back (TLFB) is a self-report measure of participants' past 30-day alcohol use [57]. At the baseline assessment, participants were asked to indicate the number of drinks consumed each day over the past month using a calendar. We calculated the total number of drinking days and total number of drinks consumed over the past 30 days.

#### *Acceptability and Feasibility Measures*

##### Satisfaction With Intervention

We quantitatively assessed participants' satisfaction with the MtM intervention using 5 items from the Client Satisfaction Questionnaire (CSQ) [58] and 6 additional items developed for the study. All items were rated on a 4-point scale. The CSQ items measured satisfaction with the intervention as a whole (eg, "How would you rate the quality of the service you received?"), whereas the other items assessed individual aspects of the technology intervention (eg, "How effective were the smartphone and sensorband in helping you meet your goals?"). The CSQ has been used with similar nontreatment seeking samples measuring satisfaction with mobile health interventions [59,60]. Higher scores indicate greater satisfaction. In addition, 6 open-ended questions regarding participants' general satisfaction and feedback of the technology components, as well as barriers and facilitators of participants' use of the technology were developed for the study. All questions were administered on a laptop computer with headphones using audio assisted interviewing of the Questionnaire Development Software [61].

##### Qualitative Interview

Immediately after the second in-person session with the clinician, students participated in a brief, (<30 min) semistructured qualitative interview with the clinician, where responses were recorded on paper. The purpose was to explore participants' perceptions of the technology, including the challenges, and the barriers and facilitators of using it in their daily life to help them achieve their goals.

##### Usage Data

Data from the smartphone was collected, including the frequency with which participant's reached their EDA threshold, the number and content of reports made on the app (sensorband-triggered and self-initiated), and the amount of time spent on each screen.

#### *Qualitative Data Management and Analysis*

Immediately after each follow-up interview, the interviewer reviewed the responses with the participant for accuracy. The qualitative interview responses and notes from the second in-person session was entered into Dedoose (Los Angeles, CA) [62]. Research team members created a "start list" [63] of initial codes based on the UTAUT model and the theoretical models of behavior change (MI and CBT). Codes consisted of labels or tags containing one to several words assigned to sections of the text that described that code. Guided by Grounded Theory [64], the research team then met to review the codes, develop the codebook, apply the start list codes to the text, and create new codes based on emergent themes.

## Results

### Participants

The UHC referred 58 female patients with AUDIT-C scores of 3 or higher and who signed informed consent allowing contact from the research staff. Patients were contacted by the research staff in the order the referrals were received until the target enrollment was met. Potential participants were contacted by an email, SMS text messaging, or phone call (depending on stated preference). Forty (71%) did not respond, and of the 18 who responded, 2 were no longer interested in the study and 2 were ineligible, leaving 14 eligible for participation. Overall, 11 participants enrolled, and 1 dropped out after the baseline assessment citing time constraints. Thus, 10 participants completed the baseline and follow-up assessments, participated in both in-person sessions, and used the MtM technology to varying degrees as detailed below.

The mean age of the participants was 20.7 (range=19-22). Four were seniors, 3 were juniors, 2 were sophomores, and 1 was a freshman. Participants were roughly representative of the main racial or ethnic groups of the university; 7 were white, 2 were Asian, and 1 was black. AUDIT-C scores ranged from 3 to 7 (mode=3). On the TLFB, the mean number of days drinking over the past 30 days was 12.11 (standard deviation [SD]=4.25, range=7-30 days), and the mean number of drinks consumed was 46.66 (SD=33.73, range=8-127 drinks). The mean number of days that elapsed between the baseline and follow-up assessments was 39.7 days (SD 12.92).

### Feasibility, Acceptability, and Usage

On the quantitative measure of acceptability (Table 2), the overall average rating on the 5 CSQ items measuring satisfaction with the intervention was 3.4 on the 4-point scale. All participants reported that the intervention helped them deal more effectively with their problems and that they met at least some of their personal goals in reducing risky drinking. All participants found the technology component "somewhat" or

"very easy" to learn, although there was significant variability in the level of satisfaction with the sensorband and the MtM app. Specifically, 60% (6/10) of participants were "mostly" or "very" satisfied with the sensorband and 50% (5/10) with the app. Seventy percent (7/10) of the participants noted that the MtM intervention was "somewhat" or "very" effective in helping them reduce their risky drinking.

**Table 2.** Acceptability Questionnaire (n=10).

| Survey item | Mean (SD[a]) |
|---|---|
| How would you rate the quality of service you received?[b] | 3.60 (0.70) |
| To what extent has our program met your needs?[b] | 3.50 (0.71) |
| If a friend were in need of similar help, would you recommend our program to him or her?[b] | 3.20 (0.42) |
| How satisfied are you with the amount of help you received?[b] | 3.50 (0.71) |
| Have the services you received helped you deal more effectively with your problems?[b] | 3.00 (0.00) |
| To what extent have you met your personal goals in reducing risky drinking?[c] | 2.60 (0.70 |
| How satisfied are you with the sensorband?[c] | 2.60 (0.84) |
| How satisfied are you with the smartphone app?[c] | 2.60 (0.70) |
| How effective were the smartphone app and sensorband in helping you meet your goal?[c] | 2.30 (0.95) |
| How would you rate your experience learning to use the sensorband and smartphone app?[c] | 3.60 (0.52) |
| How does this experience compare with other times you have tried to reduce risky drinking?[c] | 3.00 (1.05) |

[a]SD: standard deviation.

[b]Items are from the Client Satisfaction Questionnaire [46].

[c]Items were developed for the study. All scores were based on a 4-point Likert scale with higher scores indicating more acceptability.

After adjusting the EDA thresholds and the sensorband connection for most participants during the first few days of using the sensorband and MtM app, all participants reported that the sensorband alerts they received were usually valid. That is, they were typically emotionally aroused when they received the alert that their EDA had reached the threshold and were aware that physical activity had the potential to trigger an alert. The number of times participants rated each emotion is displayed in rank order in Table 3. "Stress" (68 occurrences) was the most frequently reported emotion while "anxiety" and "fatigue" tied for the second most reported emotion (41 occurrences each). The more positively valenced emotions of "satisfied" (28 occurrences) and "excited or energized" (26 responses) were ranked 3rd and 4th, reflecting the wide range of emotions associated with SNS arousal. As seen in Table 4, school or work issues constituted the overwhelming number of contexts reported by participants in response to sensor-triggers. The second most frequently chosen context was "other," reflecting participants' individually chosen specific contexts (eg, the name of a particular person or place).

**Table 3.** Rank ordered emotions for sensorband reports.

| Emotion | # of reports |
|---|---|
| Stressed | 68 |
| Anxious or nervous | 41 |
| Tired | 41 |
| Satisfied | 28 |
| Excited or energized | 26 |
| Frustrated | 15 |
| Happy | 9 |
| Relieved | 4 |
| Sad | 4 |
| Embarrassed | 1 |

**Table 4.** Rank ordered contexts for sensorband reports.

| Context | # of reports |
|---|---|
| School or work issue | 118 |
| Other | 23 |
| Friend issue | 13 |
| Relationship or dating issue | 7 |
| Getting ready to go out | 4 |
| Talking to someone attractive | 2 |
| Family issue | 2 |
| In a new or uncomfortable situation | 1 |

**Table 5.** Negative valance reports with screen time (seconds).

| PID[a] | Total | | | Self | | | Sensor | | |
|---|---|---|---|---|---|---|---|---|---|
| | # of reports | Sum | Mean (SD[b]) | # of reports | Sum | Mean (SD) | # of reports | Sum | Mean (SD) |
| 303 | 15 | 576.03 | 38.40 (26.41) | 1 | 91.27 | 91.27 (N/A[c]) | 14 | 484.76 | 34.63 (22.82) |
| 308 | 11 | 572.40 | 52.04 (31.03) | 5 | 362.04 | 72.41 (30.21) | 6 | 210.36 | 35.06 (20.84) |
| 310 | 5 | 255.92 | 51.18 (28.12) | 4 | 218.91 | 54.73 (31.16) | 1 | 37.02 | 37.02 (N/A) |
| 311 | 40 | 1057.55 | 26.44 (15.17) | 1 | 20.64 | 20.64 (N/A) | 39 | 1036.91 | 26.59 (15.34) |
| 312 | 10 | 622.47 | 62.25 (30.10) | 1 | 121.48 | 121.48 (N/A) | 9 | 500.99 | 55.67 (23.07) |
| 313 | 80 | 1512.66 | 18.91 (12.48) | 4 | 203.51 | 50.88 (25.74) | 76 | 1309.15 | 1723 (8.96) |
| 314 | 5 | 373.20 | 74.64 (56.93) | 1 | 171.04 | 171.04 (N/A) | 4 | 202.16 | 50.54 (21.21) |
| 315 | 19 | 1365.45 | 71.87 (67.08) | 12 | 1199.63 | 99.97 (70.66) | 7 | 165.82 | 23.69 (7.43) |
| 316 | 11 | 401.64 | 36.51 (28.81) | 0 | 0.00 | 0.00 (N/A) | 11 | 401.64 | 36.51 (28.81) |
| 317 | 9 | 499.40 | 55.49 (44.42) | 6 | 328.44 | 54.74 (49.08) | 3 | 170.95 | 56.98 (43.20) |

PID: Participant ID
SD: standard deviation.
N/A: not applicable.

## Use Patterns

The number of days participants used the MtM app and sensorband ranged from 5 to 14 days. Altogether, participants made reports on 78 out of a total 292 days (26.71%) that the technology was available, with significant variation in their usage patterns. There was no statistically significant difference between the average amount of time participants wore the sensorband during the daytime hours (mean=29.32, SD=15.82) versus the evening hours (mean=24.17, SD=25.76).

Overall, participants completed a total of 325 reports (mean=32.5, SD=31.96), which included 261 sensorband triggered (mean=26.1, SD=31.7) and 64 (mean=6.4, SD=3.9) self-initiated reports. Figure 4 shows the number of total sensor-triggered and self-initiated reports for each participant.

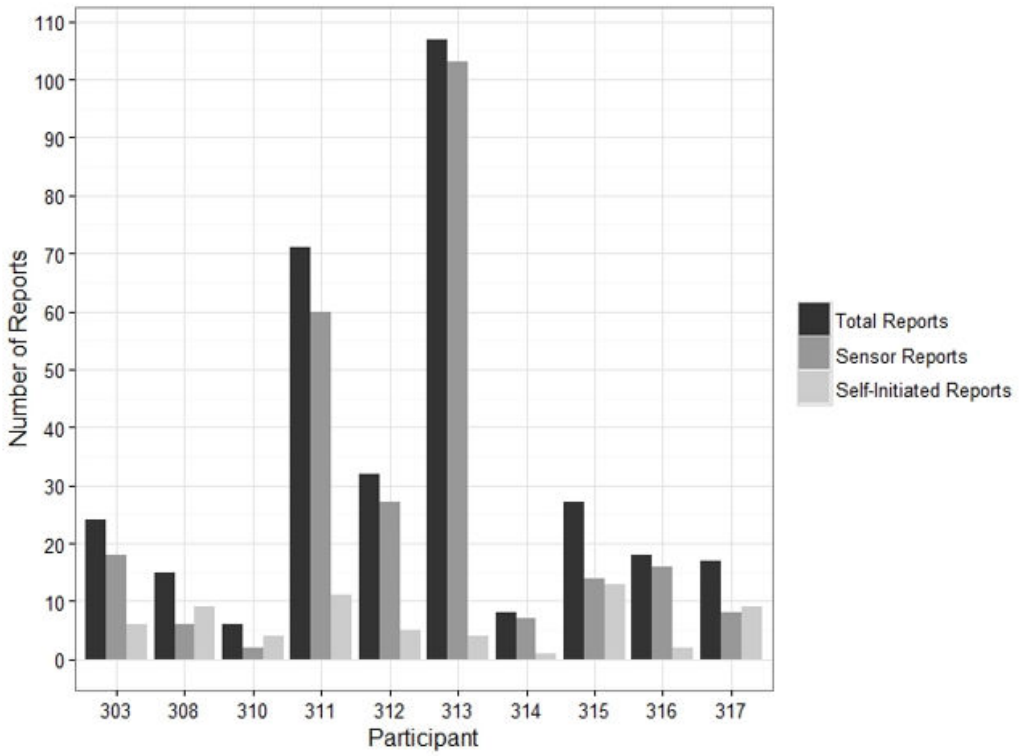
In light of the large number of sensor-trigged reports by participants 311 and 313, we examined the activity in each report for accuracy in reporting.

We calculated the total amount of time participants spent using the app by summing the amount of time they spent on each screen. On average, participants spent 17.50 min (SD 9.37) using the app, either in response to sensorband prompts or making a self-report. Reports that were not completed, that is, when participants did not get to the final screen, were not included.

By design, reporting a negative emotion generated a greater number of app screens for sensor-initiated and self-initiated reports. Thus, in Table 5, we examined the total number of negative emotion reports and the average amount of time

participants spent on the app when responding to a sensor-initiated or self-initiated report. With the exception of P315 who made 12 self-reports, most participants completed less than 6 (total=35), in contrast with the larger number of sensor-initiated negative emotion reports (total=170).

**Figure 4.** Number of completed reports by participants for each type of response (sensorband or self-initiated). The number of reports includes positive and negatively valenced emotions and personalized emotions ("other").




## Qualitative Findings

### *Perceived Advantages of MtM*

#### Prompting Awareness of Current Feelings

The predominant theme that emerged from the qualitative data focused on how MtM helped students access and identify their feelings and the intensity of those feelings. With one exception, all participants expressed that being notified of an increase in stress and responding to sensorband alerts through the app made them "think," "be aware of," "reflect," "identify," or "gauge" feelings and emotional states. This sentiment was expressed by participants regardless of the type of report and frequency of use. For example, as seen in Table 4, P316 received 15 sensorband alerts, whereas P317 received only 4. However, both participants remarked that MtM compelled them to reflect on their feelings. P317 noted, "I liked being forced to step back and assess my emotions," whereas P316 indicated, "it allowed me to check in with myself and forced me to be mindful about my behavior and feelings."

P314 received 7 sensorband alerts and initiated 1 self-report. She reported, "the band messages were helpful first when I was drinking and kind of depressed. It helped to put in what I was feeling." P303 noted that, "It made me realize how my body reacts to mood change." Others noted that the technology assisted them in coping with their feelings in situations not necessarily related to drinking. P308 found that, "the band reminds me that I can handle this, I can cope." Moreover, she said that, "the band made me less anxious about tests."

Finally, using the technology, particularly the messages on the app, made several participants feel emotionally supported. "...it was good to have the app to soothe me," noted P317.

#### Increased Awareness of Alcohol Use

Of the 10 participants, 9 reported that one or both components of the intervention increased their awareness of their drinking behaviors to varying degrees.

For many, the technology components were instrumental in helping them adhere to the alcohol risk reduction plan they formulated during the first in-person session with the clinician. P303, for example, rated the sensorband and app as, "somewhat dissatisfying" on the quantitative acceptability measure. However, in her qualitative interview, she expressed that simply wearing the band was a reminder that, "I was on the plan." She also noted that the screen which asked, "Drinking or Planning to Drink?" was a "really useful prompt and raised a question

for me about drinking and reminded me of the options that I had." Similarly, while P313 received the overwhelming majority of sensorband alerts and was "mostly satisfied" with the sensorband in her quantitative rating, she also indicated that, "the notifications of increased stress levels" helped her to engage in "reflective thinking" about what was causing her stress and how it related to her drinking, noting that it "helped me follow my plan to only drink once a week."

For several participants, wearing the sensorband seemed to increase their consciousness of the amount of alcohol they were consuming. For example, P316 recounted that during the first phase of using the sensorband with the Empatica app, "I got a cider and watched the EDA number go up. Seeing an immediate congruence was really helpful." She went on to explain that when using the MtM app, "Drinking with the band on was different...it made me think about the amount. I was surprised..."

Several participants recounted that the sensorband and MtM app helped them use protective behavioral strategies for alcohol use such as, "it restricted my purchases (of alcohol)" and "I decided not to go to a party" (P316). P310 found that, "I was able to drinker slower when using the band and slowing down worked well (to stick to my plan)."

For a minority of participants (3/10), the alerts sometimes increased their anxiety or level of stress. As described above, P303 felt that the alerts had positive effects, but also indicated that, "While I am dealing with stress I do not have to be reminded of the stress."

### Perceived Challenges Associated With the MtM Intervention

#### *Form and Functionality Issues*

##### Issues Related to Form

Two primary issues related to the form of the band emerged in the qualitative data. Approximately half of the participants indicated that the band was "uncomfortable," "bulky," or "too large." As a result, several participants felt "self-conscious" or "awkward" when wearing it, particularly if someone commented on it. Two participants indicated that using the technology in class was challenging. For example, P310 noted that while in class, "my professor commented on it which made me feel awkward," whereas a few other participants related that they would not wear the band "with a nice outfit" (P312) or "going out with friends" (P308).

##### Charging Issues

The main complaint raised by the vast majority of participants was that they kept forgetting to charge the phone and sensorband. This problem mainly stemmed from the fact that for most participants, the study phone was not their main personal phone. "The phone and band were too cumbersome to carry around," P313 recounted. Several participants related ways that they attempted to keep the study phone and band charged (eg, "I kept it near my daily jewelry").

##### Connectivity Issues

Many participants indicated that the band and phone disconnected frequently, which was "a deterrent to using" as explained by P310. P317 noted that, "it was hard to tell when it was or was not connected." Many participants understood that the connection problems were related to the Bluetooth technology that required constant proximity between the phone and the band. Several participants suggested that an alert be sent when the sensorband is not connected.

##### Inopportune Alerts and Attention

P314 indicated that, "it was annoying when it went off during class," and other participants mentioned feeling self-conscious needing to explain the sensorband and their participation in the study when questioned by peers and professors.

## Discussion

### Principal Findings

We found a high level of acceptability for a wearable sensorband integrated with an EMI on a smartphone app for ambulatory physiological monitoring and alerting of heightened emotion among college-age women with drinking problems. Combined with 2 in-person, brief-counseling sessions, this blended intervention was feasible to deliver and demonstrates promise for individualizing mobile health (mHealth) interventions and adding potency to provider-delivered health and clinical interventions. Importantly, quantitative and qualitative data indicated that overall, participants found that the sensorband alerts were valid indicators of heightened emotion. For many, the alerts promoted an increase in their awareness of thoughts, feelings, and behaviors related to their environmental stressors and drinking behaviors, consistent with the theoretical model of the intervention and with other studies of EMIs [65]. To our knowledge, this is the first intervention developed using wearable mHealth technology for addressing drinking problems among college-age women.

Participants demonstrated a high degree of engagement with the technology regarding the number of days using the sensorband and app, the number of sensorband triggered reports, and the overall amount of time spent on the app. As expected, there was significant variability in the number of sensor-triggered reports made by participants. While sensor-triggered reports constituted the vast majority of responses on the app, all participants engaged in at least one self-report, indicating that participants seem to feel that the app was helpful.

### Barriers to Use of the Technology

As is typical with new technologies, participants encountered several challenges to consistent use of the technology components. For some, determining their individual EDA threshold required adjustment over the course of the first few days, but once adjusted, most participants continued to utilize the sensorband and the app throughout the duration of this brief pilot. In future research, we will examine more nuanced strategies for assessing and determining individuals' EDA threshold. The primary barrier participants encountered involved carrying 2 phones (study phone and personal phone), resulting in participants forgetting to use the MtM technology, as well as frequent loss of the Bluetooth connection due to the distance between the study phone and the sensorband. Since the Empatica

sensorband can also be used with iPhones, in future studies we will be able to program and install the MtM app on participants' personal phones. Participants also provided instructive feedback regarding reducing the bulkiness of the sensorband and developing simple ways of turning off the alerts in particular contexts or at particular times. Future refinement of the timing of alerts is vital so that support is congruent with moments of need rather than at inopportune periods of time or when individuals are not experiencing the internal or contextual challenges that are the target of intervention [26]. For example, context sensing programs using global positioning systems (GPS) [66] or inputting students' class schedules for example, can be incorporated into the app in order to prevent alerting in specific environments. Additionally, as wearable devices have become more mainstream, incorporating the measurement of EDA and other physiological markers of emotion into these devices may reduce participant burden, and increase their utilization and scalability.

### Emotions and Related Contexts Elicited by the Technology

Issues related to school or work emerged as the predominant context reported by our college student participants in response to sensor-triggered alerts. Consistent with the literature [67], within these contexts, stress, anxiety, and fatigue constituted the primary feelings associated with these challenging situations. Surprisingly, "tired" emerged as a frequently endorsed emotion associated with increase in participants' EDA. Placing "tired" on the app was suggested by students in the target population in our development of the app, and we assumed that this emotion would be chosen by students while self-reporting rather than in response to increases in EDA. While in future research we will explore this emotional label in more depth, our qualitative interviews suggest that participants' ability to cope with stressful academic or other situations was dampened by their level of fatigue, thus endorsing "tired" felt as if it was an appropriate choice.

We also noted that there was little variability in the responses of emotions by participants, as stress, anxiety, and fatigue were the most frequently reported feelings on the MtM app. The serial positions of stress and anxiety as first and second on the first screen of the MtM app may have influenced this reporting, thus in future research, we will explore other ways of presenting choices such as the circumplex model [54] or allowing participants to write in their specific emotion, which may limit this potential bias.

### Theoretically Based Behavior Change

Our qualitative findings indicated that the use of CBT strategies in participants' real-world contexts promoted reflection of the type and nature of their individual stressors and the strategies they use to deal with them, including drinking. Although in this brief feasibility pilot we were unable to determine any intervention effects on drinking behaviors, these findings provide evidence that participants successfully enacted—in real-life, stressful situations—some of the key ingredients of empirically validated strategies for reducing problem drinking, specifically, identifying specific emotions and concomitant triggers related to stress and drinking as well as developing strategies for managing emotions and adhering to drinking-related goals. In future research, we will examine drinking outcomes over a longer duration to capture changes in alcohol consumption, frequency, and drinking patterns, including the contexts where participants utilize the sensorband and where they receive alerts. As academic or work issues constituted the vast majority of the issues participants chose when receiving an alert, we will be able to explore ways in which successfully managing stress by using the sensorband outside of drinking contexts assists students to reduce problem drinking.

We were particularly interested in understanding acceptability as measured by the amount of time participants spent on the app, particularly when responding to a sensor-triggered alert. Few studies of mHealth apps measure the amount of time participants spend on specific screens. Future research may entail examining how the amount of time spent on specific screens might mediate intervention effects, as well as understanding how contextual variables such as location or time of day effect the amount of time participants spend on their screen. We will examine patterns of screen time and how they relate to usability and outcomes with a larger sample. An important additional area of research entails specifying and individualizing the length of time individuals may need to use the technology in order to see changes in behavioral health patterns.

### Limitations

The major limitation of this pilot study is the very small sample size. Moreover, a limited number of sensorbands necessitated providing the sensorband to participants successively, restricting the amount of time participants' could use the sensorband. Despite these limitations, results of this study demonstrate the potential to enhance mHealth interventions and help individuals adopt and sustain behavioral change. Delivering intervention material "just-in-time," in the places and at the moment participants need to utilize behavioral change strategies learned in provider-delivered sessions has implications for deterring the drop-off typical of behavioral interventions and in particular, mHealth interventions [68]. Moreover, the results of this study have the potential to individualize treatment for patients in clinical settings where clinicians can review patients' patterns of activities, and associated feelings and triggers, and discuss how these may change over time, relative to their environment, time of year, and developmental level, for example.

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## Conflicts of Interest

None declared.

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## Abbreviations

**API:** Application Programming Interface
**AUDIT-C:** Alcohol Use Disorder Identification Test-C
**CBT:** Cognitive Behavioral Therapy
**CSQ:** Client Satisfaction Questionnaire
**EDA:** Electrodermal activity
**EMI:** Ecological momentary interventions
**GPS:** Global Positioning System
**MI:** Motivational Interviewing
**MtM:** Mind the Moment

**RA:** Research Assistant
**SECSAT:** Southeastern Consortium for Substance Abuse Training
**SNS:** Sympathetic nervous system
**TLFB:** Time Line Follow Back
**UHC:** University health center
**UTUAT:** Unified Theory of Use and Acceptance of Technology

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Original Paper

# Estimating Heart Rate, Energy Expenditure, and Physical Performance With a Wrist Photoplethysmographic Device During Running

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## Abstract

**Background:** Wearable sensors enable long-term monitoring of health and wellbeing indicators. An objective evaluation of sensors' accuracy is important, especially for their use in health care.

**Objective:** The aim of this study was to use a wrist-worn optical heart rate (OHR) device to estimate heart rate (HR), energy expenditure (EE), and maximal oxygen intake capacity ($VO_{2Max}$) during running and to evaluate the accuracy of the estimated parameters (HR, EE, and $VO_{2Max}$) against golden reference methods.

**Methods:** A total of 24 healthy volunteers, of whom 11 were female, with a mean age of 36.2 years (SD 8.2 years) participated in a submaximal self-paced outdoor running test and maximal voluntary exercise test in a sports laboratory. OHR was monitored with a PulseOn wrist-worn photoplethysmographic device and the running speed with a phone GPS sensor. A physiological model based on HR, running speed, and personal characteristics (age, gender, weight, and height) was used to estimate EE during the maximal voluntary exercise test and $VO_{2Max}$ during the submaximal outdoor running test. ECG-based HR and respiratory gas analysis based estimates were used as golden references.

**Results:** OHR was able to measure HR during running with a 1.9% mean absolute percentage error (MAPE). $VO_{2Max}$ estimated during the submaximal outdoor running test was closely similar to the sports laboratory estimate (MAPE 5.2%). The energy expenditure estimate (n=23) was quite accurate when HR was above the aerobic threshold (MAPE 6.7%), but MAPE increased to 16.5% during a lighter intensity of exercise.

**Conclusions:** The results suggest that wrist-worn OHR may accurately estimate HR during running up to maximal HR. When combined with physiological modeling, wrist-worn OHR may be used for an estimation of EE, especially during higher intensity running, and $VO_{2Max,}$ even during submaximal self-paced outdoor recreational running.

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**KEYWORDS**

fitness trackers; photoplethysmography; heart rate; heart rate determination; exercise test; oxygen consumption; energy metabolism

## Introduction

Advances in wearable sensors enable long-term monitoring of health and wellbeing indicators in various conditions and activities in both consumers and patients. Recently, significant progress in the size, power consumption, and accuracy of various different sensing technologies has led to an introduction of affordable wearable sensors with a reasonable battery life and

capability to monitor, for example, physical activity, sleep, heart function, and so on. However, the reliability and accuracy of the produced information has been questioned and significant differences between different brands have been found [1]. Therefore, an objective scientific evaluation of available wearable sensors is essential for the progress of their use, especially for health applications such as chronic disease prevention and management.

Heart rate (HR) monitoring provides valuable information on physiology and health status during sports, daily life, and sleep. Chest strap HR monitors have been used during sports to quantify and control training loads since the late 1980s. The main limitation for the wide and long-term use of chest strap HR monitors, especially in female users, is the discomfort that is caused by the tightness of the chest strap and possible skin irritations. Therefore, their application has remained relatively limited, especially in real-life wearable monitoring.

Wearable optical HR (OHR) monitoring technology based on photoplethysmography (PPG) has been significantly improved recently because of miniaturized low-power hardware and improved embedded algorithms. OHR technology can be applied on almost any part of the body, such as on the wrist, and can hence overcome some challenges of chest strap HR monitors in their usability and long-term use. However, relatively few scientific studies have reported OHR technology performance and accuracy in laboratory or real-life conditions. Olenick et al evaluated a Mio Alpha wrist OHR device during a graded treadmill exercise test until volitional fatigue and found a strong correlation between OHR and ECG-based HR [2]. In a study by Parak and Korhonen [3], wrist and forearm OHR devices were evaluated during multiple physical activities (walking, running, and biking) with a 5% agreement ranging from 76% to 78%. Delgado-Gonzalo et al evaluated the accuracy and reliability of two different wrist OHR devices (PulseOn and Mio Alpha) against ECG-derived HR in laboratory conditions during a wide range of physical activities and found the mean absolute error of PulseOn to be 3% and Mio Alpha to be 6% during laboratory protocol [4]. Similar or better accuracy was seen during normal outdoor sports activities [4]. In general, wrist-worn OHR devices seem to provide good accuracy during running, but less so in some other activities, such as biking and weight lifting [5-7]. These studies suggest that the currently available high-end OHR devices are reaching acceptable accuracy for HR monitoring during cardiovascular sports such as running, while different brands and devices may experience significant differences in their performance.

Exercise HR is itself a valuable parameter. For example, it allows a real time control of training loads. However, exercise HR alone is challenging to interpret for users, and an estimation of more advanced physiological parameters during exercise would be beneficial to allow a more insightful analysis of the training. An estimation of momentary oxygen consumption and total energy expenditure (EE) for each training session and an estimation of changes in physical performance achieved by regular training are examples of these insightful parameters. An indirect calorimeter is one of the most accurate reference methods for estimating EE. This method is based on the analysis of respiratory gases and is commonly used in laboratory settings. HR has also been used for estimating oxygen consumption. Montgomery et al [8] evaluated the accuracy of oxygen consumption and EE estimation based on chest strap HR monitors and found a slight underestimation with a 6% coefficient of a variation of 6% for oxygen consumption and 13% for EE. Keytel et al [9] reported a correlation coefficient of .913 between the chest strap HR-based method and indirect calorimeter-based EE. Running speed can also be used to estimate oxygen consumption; in runners, a strong correlation (>.99) has been reported [10,11]. Robertson et al [12] found a significant correlation between EE estimates based on indirect calorimetry and a HR chest strap based method during low intensity exercise and maximum intensity exercise. However, Wallen et al observed poor accuracy in an EE estimation of four OHR smart watches as compared with indirect calorimetry [13].

Physical performance may be estimated by the maximal oxygen consumption ($VO_{2Max}$) of a person. $VO_{2Max}$ can be measured directly with an expiratory gas analyzer during a maximal voluntary exercise test. Running speed may also be used to estimate $VO_{2Max}$ [14]. By estimating the oxygen consumption and speed during submaximal exercise, it is possible to estimate $VO_{2Max}$ without maximal exercise testing [15]. LeBoeuf et al found good accuracy of an OHR sensor placed in the ear in the assessment of EE and $VO_{2Max}$: −0.7 (SD 7.4%) and −3.2 (SD 7.3%) [16]. However, to our knowledge, the accuracy of a wrist-worn OHR on the estimation of EE, oxygen consumption, or $VO_{2Max}$ has not been widely studied.

The objectives of the current study were to use OHR to estimate HR, EE, and $VO_{2Max}$ during running and to evaluate the accuracy of the estimated parameters (HR, EE, and $VO_{2Max}$) against a chest strap HR and respiratory gas analysis derived from golden reference values.

## Methods

### Subjects

Twenty-four healthy adults (13 males and 11 females) participated in the study (Table 1). The inclusion criteria were age (18-55 years), BMI (18-30), normal self-reported health status, experience in treadmill running, and a self-estimated ability and willingness to continue the exercise protocol with an increasing load until exhaustion. The health status of the subjects was evaluated in advance through a self-reporting questionnaire and a verbal interview by a trained sports laboratory physiologist about the subjects' capabilities to reach maximum performance. The subjects provided signed informed consent to participate in the study and they were told that they could withdraw from the study or protocol at any time, if they so desired. The study followed the ethical guidelines of the Helsinki declaration.

**Table 1.** Demographics of the participants.

| Parameter | All | Male | Female |
|---|---|---|---|
| No. of participants | 24 | 13 | 11 |
| Age in years, mean (SD) | 36.2 (8.2) | 36.8 (9.1) | 35.4 (7.2) |
| Height in cm, mean (SD) | 174.1 (8.0) | 180.0 (5.6) | 167.2 (3.5) |
| Weight in kg, mean (SD) | 69.2 (10.6) | 76.1 (9.0) | 61.1 (5.2) |
| BMI[a] in kg/m$^2$, mean (SD) | 22.7 (1.9) | 23.4 (1.8) | 21.8 (1.7) |

[a]BMI: body mass index.

## Study Protocol

The study protocol included two parts: (1) a submaximal outdoor running test and (2) a maximal voluntary exercise test in the sports laboratory. The submaximal outdoor running test was performed in regular outdoor conditions in Finland with the aim of providing data from uncontrolled and sometimes challenging conditions, where subjects would train and perform their fitness tests when provided with self-testing equipment, such as a PPG wrist device and a mobile phone. The data from the submaximal outdoor running tests was used to estimate $VO_{2Max,}$ based on wrist PPG and mobile phone GPS data. The maximal voluntary exercise was performed to provide a standardized reference ("ground truth") for $VO_{2Max}$ for each individual and to compare EE from a wrist PPG against a standard respiratory gas analysis-based EE reference during running. The order of the tests was randomized with a maximal time difference of 7 days.

The submaximal outdoor running test was performed on a pre-defined outdoor track with a flat surface. The subjects were instructed to run at a self-determined pace for at least 20 min, targeting moderate to vigorous subjectively assessed intensity, and to run 5 km. HR was monitored with an optical wrist worn heart rate monitor (PulseOn, Espoo, Finland) and GPS data with a mobile phone (Samsung S3 Galaxy Trend). A Polar V800 HR monitor (Polar Electro, Kempele, Finland) with a built-in GPS sensor was used as a reference for the distance. The GPS reference for the distance was necessary, as the subjects performed the actual running test without continuous supervision and, hence, had a possibility to vary their running route to some extent. The PulseOn mobile app was used to track and store HR and running speed during the test. Field tests were performed outdoors between November 2014 and January 2015 in Finland in regular winter training conditions, that is, during days when it was not raining or snowing, the testing track was not too slippery to cause health risks, and the temperature was above -10 °C. The subjects were instructed to wear their own outdoor sports clothing as appropriate for the current weather during the test. These conditions are typical outdoor training conditions in Finland and, hence, provide a good benchmark for challenging real outdoor training conditions that are faced by ordinary citizens while training.

The maximal voluntary exercise test was performed in a sports testing laboratory with a treadmill (OJK-2, Telineyhtymä, Kotka, Finland). The indoor temperature during the tests was 20 °C. During the test, the subjects wore a face mask from the respiratory gas analyzer (Metalyzer 3B, Metasoft Studio 4.8, Cortex Biophysik GmbH, Leipzig, Germany), the PulseOn wrist HR device, and a chest strap HR device (RS800CX, Polar Electro, Kempele, Finland). The treadmill inclination was set to 0.6°. After setting up the measurement devices and instructing the user about the study protocol and the use of the treadmill, the subject performed a warm-up run at 8 km/h for 6 min. Then, the subject stood still for 6 min and the first blood sample was taken, after which the actual test started. The running speed was increased by 1 km/h, which was maintained for 3 min to reach a stable metabolism at each load. The initial running speed was set so that the predicted number of loads that the subject would be able to complete would be between 8 and 10. Between transitions, the treadmill was stopped for 20-30 s, during which a blood sample was drawn from the subject's finger to estimate the blood lactate (Biosen C_Line, EKF Diagnostic, 42 Barleben/Magdeburg, Germany). The test was continued until the subject wanted to stop (a stop signal was agreed upon in advance) or the following end criteria, based on recommendations by the Finnish Sports Testing Society, were met: (1) predicted maximum heart rate was reached, (2) measured $VO_2$ was stabilized or started to decrease, (3) blood lactate level increased above a threshold, or (4) respiratory exchange ratio was >1.1. After the test, the subject was allowed to recover for 3 min, which was followed by a 7 min cool down jog at a self-selected speed. After this, the final blood sample was taken.

## Energy Expenditure and Maximal Oxygen Intake Capacity Estimation From Optical Heart Rate

PulseOn OHRs recorded during submaximal and maximal tests were re-analyzed offline because of the randomized order of the field and laboratory tests. $VO_{2Max}$ was calculated from the submaximal test and EE was calculated from the maximal exercise test. HR, GPS data, and personal subject information (height, weight, gender, and age) were used for calculations. Both maximal HR estimated during the maximal exercise test and maximal HR estimated from the subject's age (208 − 0.7 × age [17]) were used for the $VO_{2Max}$ calculation. $VO_{2Max}$ estimated offline from the submaximal test was used for the EE estimation during the maximal exercise test.

The estimation of total EE was based on a method developed earlier [18]. Neural networks were used to derive momentary oxygen consumption ($VO_2$) from HR. Differences in the HR-$VO_2$ relationship during the different exercise phases (on and off phases) were included in the model. Personal maximal HR and estimated $VO_{2Max}$ were used for the calculation of the

momentary $VO_2$ value. EE was then estimated from $VO_2$, respiratory quotient (RQ), and caloric equivalent [18]. RQ describes the ratio between carbon dioxide produced and oxygen consumed in metabolism, varying from 0.70 to 1.00. RQ has a well-established deterministic relationship with the caloric equivalent, which describes the amount of energy expended per one liter of consumed oxygen, varying from 4.69 to 5.05 kcal/l $O_2$ [19]. Both exercise intensity and duration affect the RQ and caloric equivalent. An increase in exercise intensity results in an increased RQ and caloric equivalent, due to the increased oxidation of carbohydrate and decreased oxidation of fat. A prolonged exercise duration has an opposite effect, due to the increased oxidation of fat and decreased oxidation of carbohydrate. When the momentary $VO_2$ and caloric equivalent are known, it is possible to calculate the momentary EE. The total EE can be calculated by summing up the momentary EE values.

$VO_{2Max}$ was estimated from OHR and GPS speed recorded during the self-paced running test by a company (Firstbeat, Jyväskylä, Finland) [20]. The method is based on a linear relationship between $VO_2$ and the running speed. First, speed and OHR data are segmented to different HR ranges and the reliability of different data segments is estimated by calculating the correlation between HR and speed and comparing that to the variance of the data in that segment. In case of a wide variance and low correlation, the segment is discarded as being unreliable. Then, the most reliable data segments are used to estimate $VO_{2Max}$ by utilizing the relationship between HR and speed. Finally, $VO_{2Max}$ is estimated as the reliability weighted average of the segments.

### Data Analysis

A maximal voluntary exercise test was used to determine the reference ("ground truth") $VO_{2Max,}$ as well as measure EE during the test. EE was measured by averaging the measured EE, based on a respiratory gas analysis for each minute. Equations defined by Weir [21] were used to calculate EE, based on respiratory gas measurements. $VO_{2Max}$ was determined by using criteria defined by the Finnish Society of Sport Sciences [22].

HR data from a chest belt acquired during the laboratory test was analyzed with Firstbeat Sports software (Firstbeat, Jyväskylä, Finland, version 4.5). After applying an artifact correction algorithm to the signals, the maximum HR value was observed. A second-by-second chest strap HR was used as a reference for the OHR signal during the maximal voluntary test, and the acquired maximum HR value was used as the measured maximum HR in the further analysis.

### Statistical Analyses

The HR estimation accuracy of the wrist PPG device was estimated during the maximum exercise test by comparing HR from the wrist PPG device with chest strap-based HR. First, the data were re-sampled at 1.5 s sampling intervals. HR signals were synchronized in time by maximizing the cross-correlation between the signals at $t$=0. Then, the HR data was averaged over 5 s non-overlapping windows. HR accuracy was estimated by the following parameters [3,4].

Reliability: The percentage of time that the absolute error is smaller than 10 bpm.

Accuracy: The complement of the relative error (ie, 100% mean absolute percentage error).

The difference between $VO_{2Max}$ estimated with a wrist PPG device and GPS data during a submaximal test and with a gas analyzer during a maximal exercise test was compared by calculating the bias, mean absolute error (MAE), mean absolute percentage error (MAPE), and correlation coefficient (either Pearson when data was normally distributed or Spearman when this was not the case) between the estimates. Bland-Altman plots were constructed to allow a visual presentation of the agreement between the two estimation methods and their average error (bias), as well as 95% confidence limits of agreement.

The difference between EE estimated from the wrist PPG device and respiratory gas analysis was calculated during the maximum exercise test. The analysis was carried out separately for light intensity (below aerobic threshold) and medium heavy intensity (between aerobic and anaerobic thresholds). The estimation was only performed from light to medium heavy intensity levels, as higher intensity levels can change the body acid-base balance, which can distort the indirect calorimetry method [23]. The aerobic and anaerobic thresholds of the subjects were determined by the guidelines of the Finnish Society of Sport Sciences [22,24]. Bland-Altman plots were generated for a visual analysis of the error, and bias, MAE, MAPE, and correlation coefficients were calculated for the data.

The normal distribution of data was examined by the Shapiro-Wilk test. The difference between the methods was tested with a paired $t$ test in case normal distribution was confirmed and with the Wilcoxon signed rank test when normal distribution could not be confirmed. Pearson correlation coefficient was computed between normally distributed parameters, while Spearman rank correlation coefficient was used for the other parameters not meeting the normal distribution assumption. The strength of the correlation coefficients was interpreted based on the following definitions: weak ($r \leq .5$), moderate ($r$=.5–.7) and strong ($r \geq .7$). All statistical tests were performed as two-sided and the level of significance was set at $P$<.05.

All data analysis was carried out with MathWorks Matlab (version 8.5). All statistical testing was carried out with IBM SPSS statistics (version 22).

## Results

### Heart Rate Accuracy During Treadmill Running

HR estimated with a wrist PPG device appeared to closely follow HR monitored with a chest strap (Table 2). In most cases, wrist PPG HR estimated HR accurately over the entire protocol, even up to maximum HR and running speeds, as shown in Figure 1 (parts A and B). In a few cases, there were occasional outliers, as shown in Figure 1 (part C: in the worst case, OHR artifacts during the beginning of the recording are likely related to poor perfusion before fully warming up, while at the end, the

subject was struggling to maintain the running speed, resulting in non-rhythmic hand motions because the subject was aiming to gain support from the treadmill handles.). This can also be seen in Figure 2, which presents the Bland-Altman plot of the HR during the entire laboratory protocol from a wrist OHR device and chest strap HR.

**Figure 1.** Comparison of HR from chest strap (black line) and wrist PPG device (red line) during maximum exercise test: (A) best accuracy, (B) average accuracy, and (C) worst case.

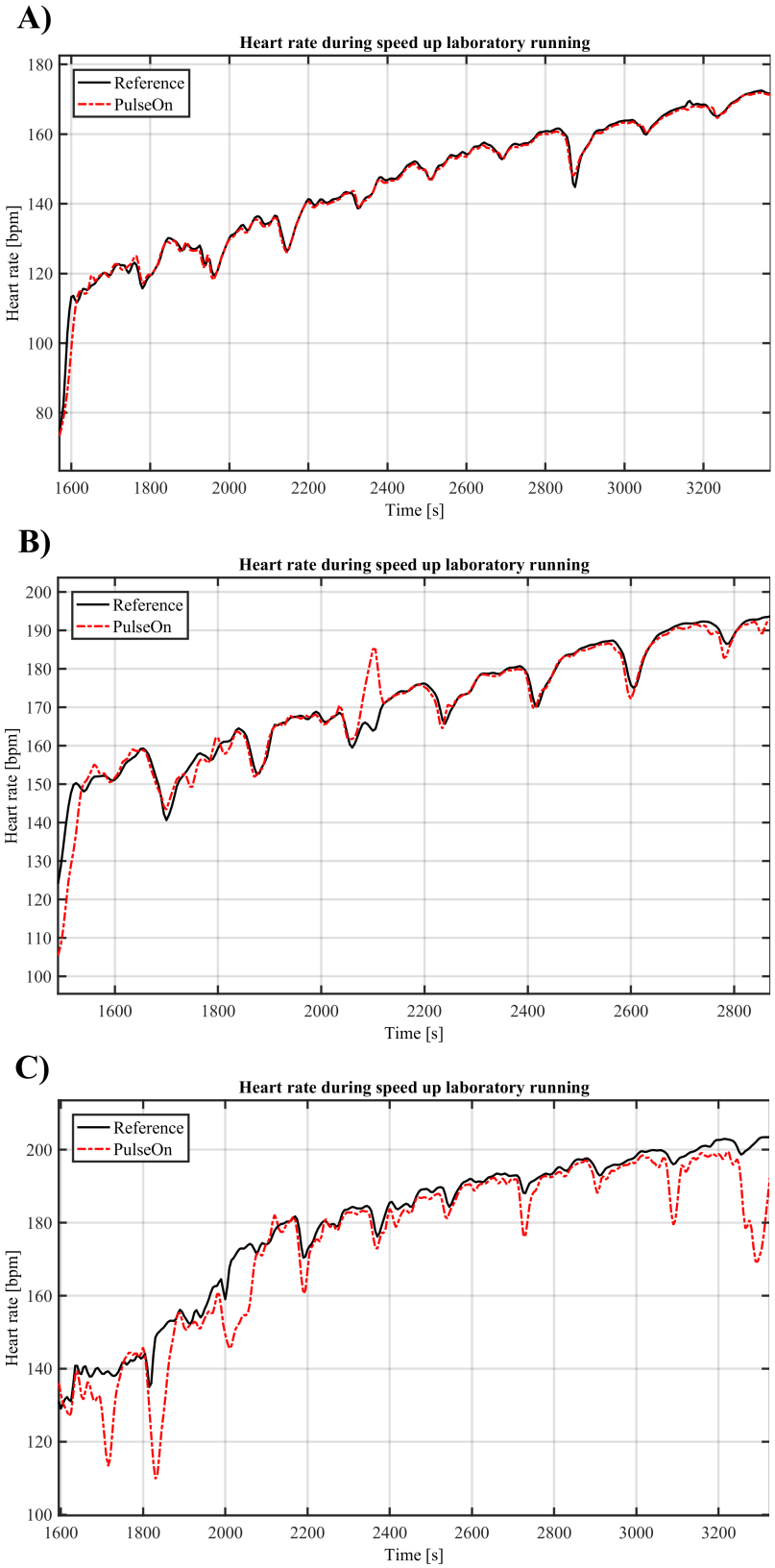


**Figure 2.** Bland−Altman plot comparing the wrist PPG device and chest strap HR device during maximum exercise protocol in all 24 subjects (solid horizontal line: bias, dashed lines: 95% confidence limits of agreement).

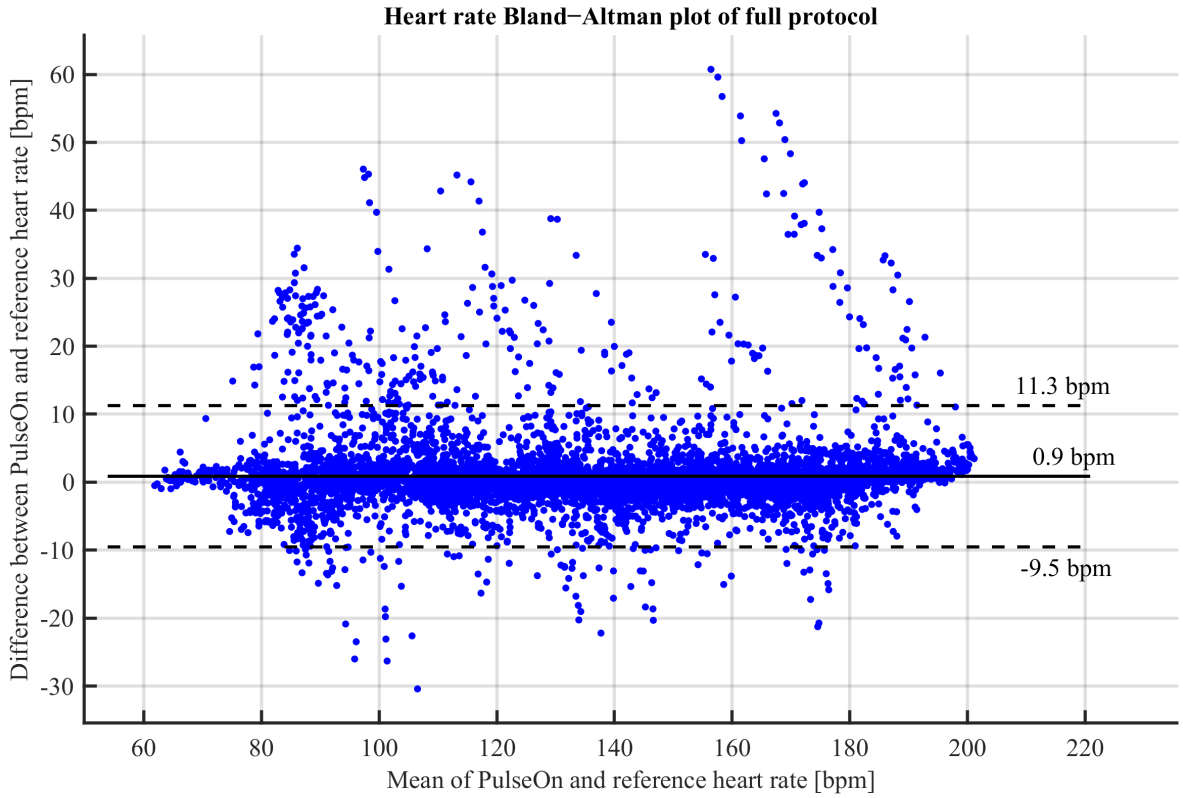
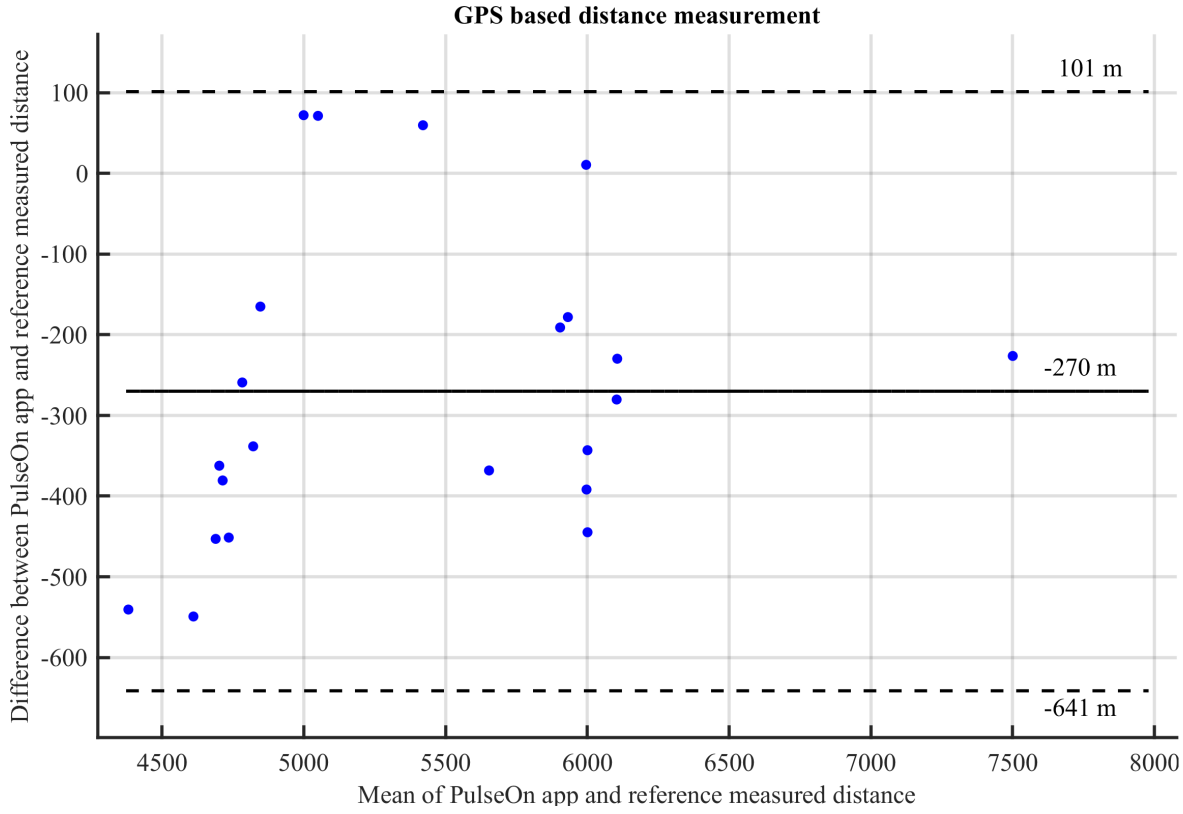



**Figure 3.** Bland−Altman plot comparing the phone GPS distance measured by the PulseOn app and a reference tracker distance estimation during outdoor running protocol (solid horizontal line: bias, dashed lines: 95% confidence limits of agreement).



### Maximal Oxygen Intake Capacity Estimation

$VO_{2Max}$ estimated with a wrist PPG device and phone GPS data with a PulseOn app was close to $VO_{2Max}$ measured during maximum exercise tests in laboratory conditions (Tables 3 and 4). $VO_{2Max}$ estimates were slightly underestimated with the submaximal test with the PulseOn app with a MAPE of 5.2% (4.7% for males and 5.8% for females), when measured maximum HR was used in the estimation. The distance estimated by a phone GPS was underestimated on average by 5.0% (−270m) (Figure 3). However, this error did not correlate with the $VO_{2Max}$ error. When an age-based maximum HR estimate was used, the error slightly increased (Table 4). There was no statistically significant difference between the estimates when the measured maximum HR was used in the estimation. Figure 4 presents the Bland-Altman plot of the $VO_{2Max}$ estimates, which shows a tendency towards larger errors with lower $VO_{2Max}$ values.

**Table 2.** Accuracy of wrist optical heart rate device during treadmill running up to maximum speed.

| Activity | Reliability, % | Accuracy, % |
|---|---|---|
| Rest when standing | 96.9 | 97.1 |
| Ramp-up running | 95.3 | 98.3 |
| Entire protocol | 95.4 | 98.1 |

**Table 3.** Maximal oxygen uptake ($VO_{2Max}$) estimated from optical heart rate data and based on measured maximum heart rate value.

| Performance metric | All (N=24) | Male (n=13) | Female (n=11) |
|---|---|---|---|
| Bias (ml ·kg$^{-1}$·min$^{-1}$) | −1.07 | −1.28 | −0.82 |
| SD[a] (ml ·kg$^{-1}$ ·min$^{-1}$) | 2.75 | 2.42 | 3.19 |
| MAE[b] (ml ·kg$^{-1}$·min$^{-1}$) | 2.39 | 2.29 | 2.51 |
| MAPE[c] | 5.2 | 4.7 | 5.8 |
| Statistical test (*P* value) | .06(W[d]) | .08(T[e]) | .42(T[e]) |
| Correlation coefficient | ρ=0.86, (*P*<.01)(Sp[f]) | *r*=.77, (*P*<.01) (Pe[g]) | *r*=.69, (*P*<.05) (Pe[g]) |

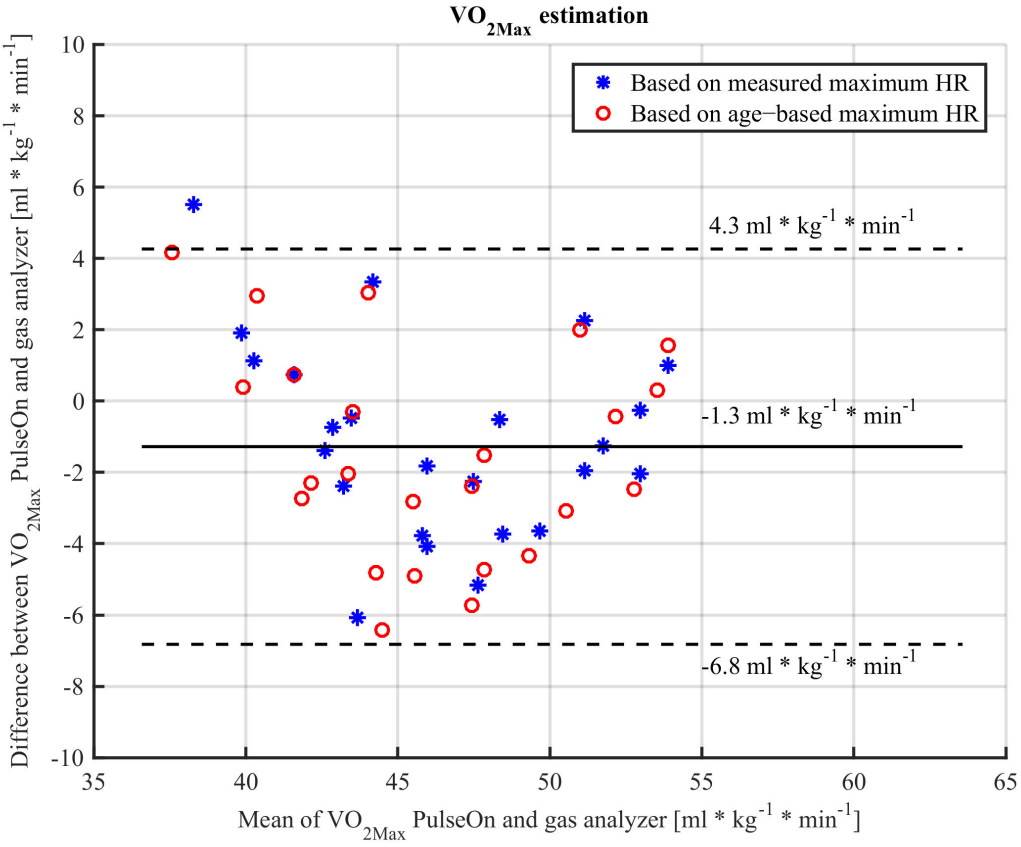
[a]SD: Standard deviation.
[b]MAE: Mean absolute error.
[c]MAPE: Mean absolute percentage error.
[d]W: Wilcoxon test.
[e]T: Paired *t* test.
[f]Sp: Spearman correlation coefficient.
[g]Pe: Pearson correlation coefficient.

**Table 4.** Maximal oxygen uptake ($VO_{2Max}$) estimated from optical heart rate data and based on an age-based maximum heart rate estimate.

| Performance metric | All (N=24) | Male (n=13) | Female (n=11) |
|---|---|---|---|
| Bias (ml ·kg$^{-1}$ ·min$^{-1}$) | −1.49 | −1.52 | −1.46 |
| SD[a] (ml ·kg$^{-1}$ ·min$^{-1}$) | 2.95 | 2.70 | 3.35 |
| MAE[b] (ml ·kg$^{-1}$ ·min$^{-1}$) | 2.76 | 2.58 | 2.96 |
| MAPE[c], % | 5.9 | 5.2 | 6.8 |
| Statistical test (*P* value) | .03(W[d]) | .07(T[e]) | .18(T[e]) |
| Correlation coefficient | ρ=0.87, (*P*<.01)(Sp[f]) | *r*=.73, (*P*<.01) (Pe[g]) | *r*=.63, (*P*<.05) (Pe[g]) |

[a]SD: Standard deviation.
[b]MAE: Mean absolute error.
[c]MAPE: Mean absolute percentage error.
[d]W: Wilcoxon test.
[e]T: Paired *t* test.
[f]Sp: Spearman correlation coefficient.
[g]Pe: Pearson correlation coefficient.

**Figure 4.** Bland−Altman plot of VO2Max estimates from the PulseOn app (wrist PPG device + phone GPS) during a submaximal exercise test versus gas analyzer based estimate during maximal exercise tests−dots represent data when age−based maximum HR is used for an estimation, while an asterix represents estimations based on true measured maximum HR (solid horizontal line: bias, dashed lines: 95% confidence limits of agreement).




## Energy Expenditure

Data from one male subject was excluded from the EE estimation analysis due do failure in respiratory gas analysis data acquisition, and results are reported for the remaining 23 subjects. Error in the EE estimation was lower (MAPE 6.7%) in the higher intensity exercise (above the aerobic threshold, but below the anaerobic threshold), but increased in lower intensities (Tables 5 and 6, and Figure 5). A wrist PPG device tended to underestimate the EE during treadmill running. The correlation with respiratory gas estimated EE was high (>.93) during higher intensity exercise, especially in females.

**Table 5.** Statistical error analysis of energy expenditure during light intensity.

| Performance metric | All (N=23) | Male (n=12) | Female (n=11) |
|---|---|---|---|
| Bias (kcal) | −11.93 | −14.24 | −9.41 |
| SD[a] (kcal) | 13.99 | 16.45 | 10.95 |
| MAE[b] (kcal) | 13.05 | 15.28 | 10.65 |
| MAPE[c], % | 16.5 | 16.6 | 16.3 |
| Statistical test (*P* value) | <.001 (W[d]) | .01 (T[e]) | .02 (T[e]) |
| Correlation coefficient[e] | ρ=0.77, (*P*<.01) (Sp[f]) | *r*=.88, (*P*<.01) (Pe[g]) | *r*=.79, (*P*<.01) (Pe[g]) |

[a]SD: Standard deviation.

[b]MAE: Mean absolute error.

[c]MAPE: Mean absolute percentage error.

[d]W: Wilcoxon test.

[e]T: Paired *t* test.

[f]Sp: Spearman correlation coefficient.

[g]Pe: Pearson correlation coefficient.

**Figure 5.** Bland−Altman plot comparing an energy expenditure estimation with a wrist PPG device and gas analyzer during a maximum exercise test−the asterisk denotes data before the aerobic threshold, while dots represent data between aerobic and anaerobic thresholds (solid horizontal line: bias, dashed lines: 95% confidence limits of agreement).

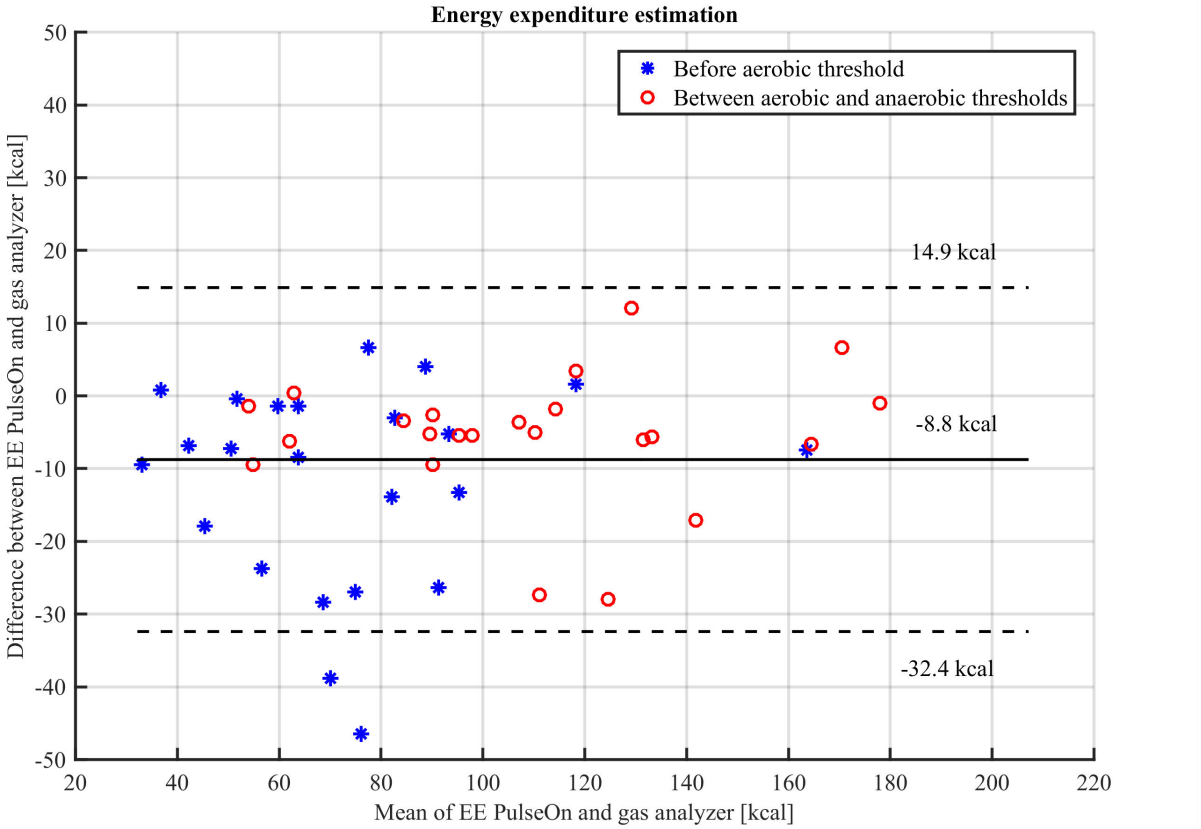



**Table 6.** Statistical error analysis of energy expenditure during medium heavy intensity.

| Performance metric | All (N=23) | Male (n=12) | Female (n=11) |
|---|---|---|---|
| Bias (kcal) | −5.58 | −6.78 | −4.28 |
| SD[a] (kcal) | 9.00 | 12.24 | 3.10 |
| MAE[b] (kcal) | 7.52 | 10.43 | 4.34 |
| MAPE[c], % | 6.7 | 8.2 | 5.1 |
| Statistical test (*P* value) | .007 (T[d]) | .08(T[d]) | .001(T[d]) |
| Correlation coefficient | *r*=.97, (*P*<.01) (Pe[e]) | *r*=.93, (*P*<.01) (Pe[e]) | *r*=.99, (*P*<.01) (Pe[e]) |

[a]SD: Standard deviation.

[b]MAE: Mean absolute error.

[c]MAPE: Mean absolute percentage error.

[d]T: Paired *t* test.

[e]Pe: Pearson correlation coefficient.

# Discussion

## Principal Findings

We estimated HR, EE, and $VO_{2Max}$ based on wrist PPG and phone GPS speed and evaluated their accuracy during running based on golden reference methods. OHR appeared to be accurate during running; the MAPE was 1.9% and reliability 95.4% during a maximal voluntary exercise test. This is well in line with the earlier results [4] and suggests that high-end consumer-grade OHR devices are capable of accurately monitoring HR during running, even up to a maximum HR.

The accuracy of more advanced parameters estimated from OHR is dependent, both on the accuracy of the OHR and on the validity of the analytical models. We used an HR-based estimation of the EE, and an HR and running speed-based estimation of the $VO_{2Max}$ developed earlier by a company (Firstbeat, Jyväskylä, Finland), which is widely available in various sports products. EE estimation with this method has been validated earlier [8], suggesting a slight underestimation

of EE by 13% when a chest strap HR was used. In our study, the overall EE estimation accuracy is well in line with this. EE estimation was the most accurate during medium or hard intensity with a MAPE of 6.7% (males 8.2% and females 5.1%). During light intensity, the error increased to 16.5% (males 16.6% and females 16.3%). Differences in the EE estimation based on HR may be related to individual differences in the basic metabolism, a thermogenesis effect due to diet or metabolic effect, which affects the body mass ratio [25]. For comparison, 10.1-18.2% MAE has been reported for EE estimation by activity trackers [26]. The EE estimates based on OHR and indirect calorimetry had strong correlations for all (N=23) subjects during light intensity (ρ=0.77), while at a higher intensity their correlation was close to 1 ($r$=.97). The results are comparable to a similar study by Robertson et al [12], who used a chest strap HR with the same EE estimation method [18] and reported moderate ($r$=.57) to strong ($r$=.85) correlations during low and high intensity exercise, respectively. However, significant differences between different OHR devices have been reported. Recently, Wallen et al studied the EE estimation accuracy of four different OHR devices against indirect calorimetry and found only one device (Samsung Gear S) to have a strong correlation ($r$=.86) with the reference, while the other three devices exhibited only a weak correlation to reference EE [13]. Our results suggest that a wrist-worn OHR may offer a similar estimation of true EE during running to chest strap HR based methods when a high quality OHR device and proper physiological model are applied in EE estimation.

The level of fitness may be quantified by the estimation of $VO_{2Max}$. We used OHR and a mobile-based speed estimation to estimate $VO_{2Max}$ during self-paced outdoor running in real and challenging outdoor conditions during winter in Finland. These conditions may be considered the "worst case" training conditions and, for example, the temperature difference may increase the observed estimation error for $VO_{2Max}$. The analytical method was based on the well-known HR versus speed relationship and on detecting the most reliable data periods for $VO_{2Max}$ estimation during the exercise [20]. We compared this estimate with the golden standard of the $VO_{2Max}$ estimation, that is, respiratory gas analysis acquired during a maximal voluntary exercise test in a sports laboratory. The results suggest that OHR and speed-based $VO_{2Max}$ estimation during self-paced running are able to quite accurately estimate $VO_{2Max}$, even in these challenging outdoor conditions; we found a MAPE of 5.2% (males 4.7% and females 5.8%) for $VO_{2Max}$ when an individually measured HR maximum was used in the estimation. When age-estimated maximum HR was used, the error increased slightly. A significant contribution to the inaccuracy originated from phone GPS tracking, which underestimated the distance by 5% on average and led to a corresponding underestimation of the $VO_{2Max}$. In addition, during the outdoor testing, there were challenging weather conditions (cold and winter), which posed challenges for PPG HR estimation because of potentially poor perfusion, increasing the potential error for the OHR during field conditions. These weather conditions may also have affected the real $VO_{2Max}$. Also, differences in running efficiency affect the correspondence between the running speed and the true physical load, and, hence, increase the error in HR and speed-based $VO_{2Max}$ estimation. There was also a tendency for the OHR and speed-based analysis to overestimate the $VO_{2Max}$ in individuals with a lower real $VO_{2Max}$. In summary, the results suggest that the method may be used to estimate $VO_{2Max}$ relatively accurately during self-paced running, even in challenging outdoor conditions.

## Limitations and Strengths

This study has several strengths, but also weaknesses. To our knowledge, this is the first study to report both EE and $VO_{2Max}$ estimation accuracy, based on OHR data. We used a realistic or even challenging setting (self-paced outdoor running in winter) to estimate $VO_{2Max}$. This is a setting that can be applied by an ordinary user, and as such, the method can be directly applied by healthy users to estimate their fitness levels. We used the golden standard (gas analyzer and controlled sports laboratory with maximal voluntary exercise) as a reference for EE and $VO_{2Max}$. The main weakness of the study is that it had a relatively small study population; however, despite this, the results can be considered to be at least indicative. In addition, the outdoor tests were carried out in a challenging environment (winter, cold, and sometimes potentially slightly slippery roads), increasing the error of the outdoor $VO_{2Max}$ estimation. On the other hand, this provides the worst case scenario, and the results were still within an acceptable error margin. Finally, the study included only one wrist OHR device, which limits the generalizability of the results. Only a single device was used for practical reasons—wearing several devices in both laboratory and outdoor conditions would have complicated the study implementation. The PulseOn device was chosen for the study because, at the time of data collection, to our knowledge, other available wrist OHR devices did not support estimation of $VO_{2Max}$ together with accurate data logging capability. However, the results are not without generalizability. The applied $VO_{2Max}$ and EE estimation algorithm [18,20] has been validated with a chest strap HR monitor [12], is commercially widely available, and could be applied with other accurate OHR devices as well. Hence, we do not consider the results of the study to be specific to applied wrist devices only, but to OHR technology in general.

## Conclusions

We applied a commercially available OHR device to estimate HR, EE, and $VO_{2Max}$ during running and evaluated their accuracy against golden standard methods. The results show that current high-end wrist OHR devices may provide accurate HR that can be compared with a chest strap HR, during running, up to a maximum HR. When combined with proper analytics, OHR may be used to quite accurately estimate EE, especially during moderate to medium heavy intensity activities. An estimation of $VO_{2Max}$ during self-paced outdoor running using OHR and a mobile phone's GPS data and proper HR analytics also allows a relatively accurate estimation of a fitness level ($VO_{2Max}$). Wrist PPG devices accompanied by phone apps provide a reliable alternative for training monitoring in realistic conditions.

## Acknowledgments

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## Conflicts of Interest

JP and IK are employees of PulseOn, Finland. PulseOn employed MU and JM during the period when the evaluation study was conducted.

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## Abbreviations

**HR:** Heart rate
**PPG:** Photoplethysmography
**OHR:** Optical heart rate
**BPM:** Beats per minute
**MAE:** Mean absolute error
**MAPE:** Mean absolute percentage error
**SD:** Standard deviation
**EE:** Energy expenditure
**VO2Max:** maximal oxygen consumption


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Original Paper

# A Bit of Fit: Minimalist Intervention in Adolescents Based on a Physical Activity Tracker

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## Abstract

**Background:** Only 5% of Canadian youth meet the recommended 60 minutes of moderate to vigorous physical activity (MVPA) per day, with leisure time being increasingly allocated to technology usage. Direct-to-consumer mHealth devices that promote physical activity, such as wrist-worn physical activity trackers, have features with potential appeal to youth.

**Objective:** The primary purpose of this study was to determine whether a minimalist physical activity tracker-based intervention would lead to an increase in physical activity in young adolescents. A secondary aim of this study was to assess change in physical activity across a 7-week intervention, as measured by the tracker.

**Methods:** Using a quasi-experimental crossover design, two groups of 23 young adolescents (aged 13-14 years) were randomly assigned to immediate intervention or delayed intervention. The intervention consisted of wearing a Fitbit-Charge-HR physical activity tracker over a 7-week period. Actical accelerometers were used to measure participants' levels of MVPA before and at the end of intervention periods for each group. Covariates such as age, sex, stage of change for physical activity behavior, and goal commitment were also measured.

**Results:** There was an increase in physical activity over the course of the study period, though it was not related to overall physical activity tracker use. An intervention response did, however, occur in a subset of participants. Specifically, exposure to the physical activity tracker was associated with an average daily increase in MVPA by more than 15 minutes ($P$=.01) among participants who reported being in the action and maintenance stages of behavior change in relation to participation in physical activity. Participants in the precontemplation, contemplation, and preparation stages of behavior change had no change in their level of MVPA ($P$=.81).

**Conclusions:** These results suggest that physical activity trackers may elicit improved physical activity related behavior in young adolescents demonstrating a readiness to be active. Future studies should seek to investigate if integrating physical activity trackers as part of more intensive interventions leads to greater increases in physical activity across different levels of stages of behavior change and if these changes can be sustained over longer periods of time.

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**KEYWORDS**

health behavior; health promotion; mHealth; physical activity tracker

## Introduction

Despite the documented benefits of physical activity on the physical, psychological, and social well-being of young people [1,2], only 5% of Canadian youth between the ages of 12 and 17 meet the recommended guidelines of 60 minutes of moderate to vigorous physical activity (MVPA) per day [3]. This is worrisome as physical inactivity during youth has been shown

to track into adulthood [4] and lead to an increased risk for multiple chronic conditions [5]. The need to identify successful interventions aimed at increasing physical activity among youth is warranted, given that results from previous intervention studies have shown room for improvement [6].

As youth are allocating increasingly more time to technology [7], technological platforms have concurrently gained popularity as a means to target health behavior [8]. mHealth technologies, including wearable physical activity trackers and mobile apps could be promising components of interventions aimed at reducing physical inactivity [9,10]. Past research has shown that interventions centered on the use of simple wearable devices, such as uniaxial pedometers, can lead to increases in physical activity participation and reductions in body mass index and blood pressure [11,12]. However, the strongest intervention effects have generally occurred when technological platforms were combined with at least one theoretically-based behavior change component [11]. Given that the newest accelerometer-based physical activity tracking devices are equipped with user-friendly features that relate to behavior change theory such as goal setting, review of past goals, and frequent feedback, it is possible that their effects on adhering to healthy physical activity levels is stronger [13]. The effects of such devices may also be more important in some sub-groups, for example, based on the stages of readiness to change. Past research has suggested that there is greater potential for intervention effectiveness in increasing physical activity among people who demonstrate the highest levels of readiness to get active as compared with those closed to the idea of being more physically active [14,15].

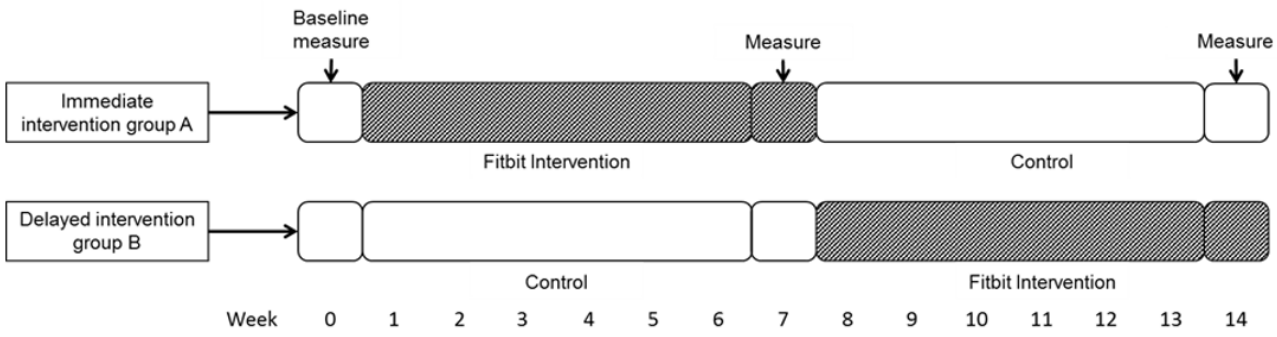
The use of commercially available accelerometer-based physical activity trackers as a means to target behavior change has been linked to increases in daily steps and time spent in MVPA in various adult populations [16-18]. Studies involving youth have, however, been limited to patients living with disease [19-21], eight-year-old children [22], and urban youth living in an under-resourced community [23]. Thus, the primary purpose of this study was to determine if a minimalist physical activity tracker-based intervention would lead to an increase in physical activity in young adolescents. Secondary aims of this study were to assess change in physical activity across a 7-week intervention, as measured by the physical activity tracker, and to assess differences in change in physical activity based on individuals' goal commitment and stage of behavior change.

## Methods

### Participants and Procedures

All students in the two Grade 8 (13-14 years old) classes in one school were invited to participate in this study. To participate, students had to obtain written informed consent from parents or legal guardians and provide assent as approved by the Centre Hospitalier de l'Université de Sherbrooke ethics committee. This study employed a quasi-experimental crossover design with a 7-week physical activity tracker-based physical activity intervention and a control period. Participants in one class (group A) were randomly assigned to the immediate intervention group and participants in the other class (group B) were assigned to the delayed intervention group (Figure 1). The crossover design was used to allow participants from both groups to have a chance to experiment with the physical activity tracker. This design also allowed controlling for individual-level covariates as participants served as their own control. Baseline measurements were obtained before the first week of intervention. Physical activity measurements for all participants were also obtained at the end of both intervention periods: weeks 7 and 14. This study took place between February and June, 2016.

**Figure 1.** Crossover design of the physical activity tracker-based intervention study.




### Intervention

The intervention focused on increasing physical activity via self-monitoring and self-regulation. During the intervention period, each participant was provided a wrist-worn physical activity tracker (Fitbit, model Charge HR; FitBit Inc. San Francisco, USA) that was equipped with a small screen displaying real-time summary data for steps, heart rate, distance, calories, and stairs climbed. Physical activity intensity minutes and temporal patterns were also available to participants through the accompanying Web-based Fitbit user account. Individual Fitbit user accounts were prepared by the study coordinator for each participant before the distribution of the devices. The study coordinator was also responsible for demonstrating how to use the Fitbit device and Web-based Fitbit user account. The intervention was similar to that used in previous studies [10,16] and was based on Behavior Change Technique research [24]. Empirical research shows that self-monitoring, in combination with at least one other self-regulation skill, can lead to positive physical activity related behavior change [24]. An individualized

goal that can be tracked using measures provided by the physical activity tracker was set by each participant, following a brief researcher-led presentation of the SMART (specific, measurable, attainable, realistic, and timely) principles of goal-setting [25]. Beyond receiving physical activity trackers during the intervention period and being asked to select a goal, participants did not receive other interventions. During the control period, participants received no intervention.

### Measures

Actical accelerometers (Philips - Respironics, Oregon, USA) were worn on the hip for seven days at baseline, week 7, and week 14. This lightweight omnidirectional accelerometer has been validated as an objective measure of physical activity in youth aged 10 to 15 years [26]. Accelerometer data were recorded in 15-second intervals, then cleaned and managed using procedures recommended by Statistics Canada [27] through a series of publicly available SAS codes adapted for this type of study [28]. Time spent in different physical activity intensities were determined by using cut-points established in previous research involving Actical accelerometers in children [29]. Sedentary activity corresponded to count values below 100, light physical activity to counts between 100 and 1500, moderate physical activity to counts between 1500 and 6500, and vigorous physical activity to counts greater than 6500. Only data for valid days, defined as 10 hours or more of wear time, were retained for analyses. Daily averages for MVPA were calculated from valid days.

Using the Fitabase analytics system (Small Steps Labs, San Diego, CA, USA), data from all physical activity trackers were remotely collected and aggregated whenever data were transmitted to users' personal Fitbit dashboards. Data captured included heart rate, daily steps, and minutes of intensity-specific physical activity. Wear time was calculated by subtracting non-wear time from 24 hours and non-wear time was defined as any interval with at least 60 consecutive seconds of zero recording of heart rate. As heart rate was recorded at variable time periods by the physical activity tracker, allowing for 60 consecutive seconds of zero recording of heart rate was sufficient to distinguish non-wear from wear time. Indeed, identification of valid days remained stable across use of higher thresholds, for example 5, 15, 30, and 60 minutes, whereas significant information was lost with a threshold set under 60 seconds.

A baseline questionnaire was used to collect information regarding age, sex, stage of change for physical activity behavior, and goal commitment. Specifically, participants indicated whether they participated in at least 60 minutes of physical activity per day, using an item corresponding to the five stages of behavior change (precontemplation, "No, I do not participate in physical activity and I do not intend to in the next 6 months;" contemplation, "No, I do not participate in physical activity regularly but I intend to in the next 6 months;" preparation, "No, I do not participate in physical activity regularly but I intend to in the next 30 days;" action, "Yes, I have been participating in physical activity regularly, but for less than 6 months;" maintenance, "Yes, I have been participating in physical activity regularly for more than 6 months") [30,31]. For analyses, these five stages of behavior change were grouped into two categories representing adoption (ie, action and maintenance) and preadoption (ie, precontemplation, contemplation, and preparation) as done by De Bourdeaudhuij et al [32]. Goal commitment, defined as determination to attain an objective, was assessed using a five-item scale refined and validated by Klein et al [33]. In this scale, participants indicated their level of commitment to the personal goal they had set with the following items using a 5-point Likert scale: (1) It's hard to take this goal seriously; (2) Quite frankly, I don't care if I achieve this goal or not; (3) I am strongly committed to pursuing this goal; (4) It wouldn't take much to make me abandon this goal; (5) I think this is a good goal to shoot for. Items 1, 2, and 4 were reverse-scored before calculating a mean of the five items meant to represent the construct of goal commitment [33].

### Statistical Power Calculation

Based on previous research, which showed that a similar Fitbit-based physical activity tracker intervention induced a 36% increase in MVPA (pre-post change mean=172, SD=83 to mean=234, SD=119), albeit in a sample of adult women [16], we estimated that 22 participants per group would provide 80% power with 95% CIs.

### Data Analysis

Wilcoxon rank-sum tests were used to compare between group differences at baseline and following both intervention periods. Wilcoxon signed-rank tests were used to compare within group difference at different time points. A multiple linear regression model was used to assess pre-post change in physical activity while controlling for the effects of time, goal commitment, and stage of behavior change. Physical activity data, from both physical activity trackers and accelerometers, were adjusted for valid wear days. A valid wear day was defined as at least 10 hours of wear time. Repeated measures analysis and Tukey post-hoc tests were used to assess changes in physical activity tracker-measured physical activity throughout the intervention period. All analyses were conducted using SAS 9.4 (SAS Institute, Inc., Cary, North Carolina, USA).

## Results

We recruited 46 of the 52 students eligible for this study. On average, the participants (52% girls, 24/46) were 13 years (SD=0.34) old and age and gender were distributed equally in both groups. There were no apparent or statistical (at Cronbach alpha<.05 with Fisher's exact test or independent *t* tests) differences in baseline characteristics between the two study groups (Table 1). At baseline, participants wore the accelerometer for an average of 13.0 (SD=1.3) hours per day and performed a mean of 35.5 (SD=19.0) minutes of MVPA per day. Accelerometer data were available for analyses for 43 participants at baseline, 32 at the end of the first intervention period (week 7), and 27 at the end of the second intervention period (week 14).

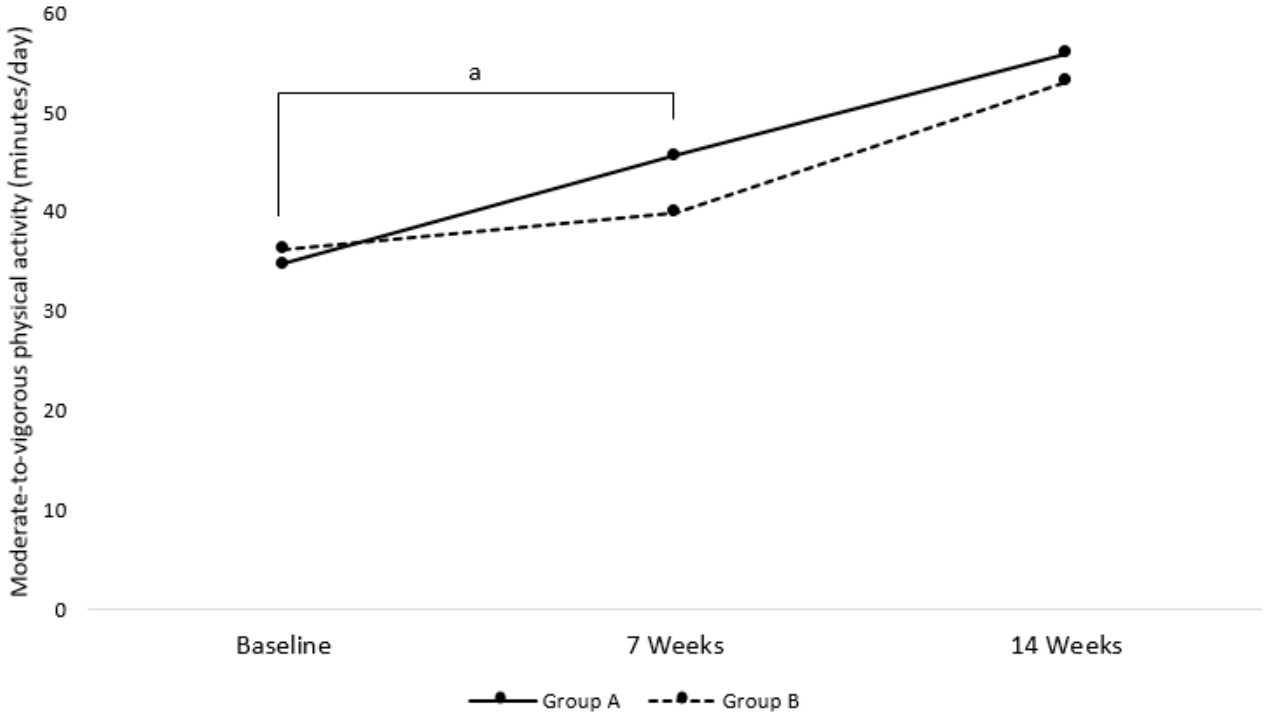
**Table 1.** Baseline characteristics of study participants.

| Characetristics | Group A (n=23) | Group B (n=23) |
|---|---|---|
| Age in years, mean (SD) | 13 (0.3) | 13 (0.4) |
| Females, n (%) | 12 (52) | 12 (52) |
| Accelerometer Valid Days, mean (SD) | 4.7 (1.7) | 3.1 (2.1) |
| Accelerometer Wear Time in hours, mean (SD) | 13.4 (1.2) | 12.6 (1.3) |
| MVPA[a] in minutes, mean (SD) | 34.7 (19.1) | 36.2 (19.2) |
| Sedentary Time in minutes, mean (SD) | 623.6 (82.6) | 587.5 (67.1) |
| Goal commitment score from 1 to 5, mean (SD) | 4.1 (0.6) | 3.7 (0.9) |
| **Stage of behavior change, n (%)** | | |
| Precontemplation | 3 (13) | 1 (4) |
| Contemplation | 1 (4) | 4 (17) |
| Preparation | 2 (9) | 4 (17) |
| Action | 3 (13) | 5 (22) |
| Maintenance | 14 (61) | 9 (38) |

[a]MVPA: Moderate to vigorous physical activity.

In the main analysis, the multiple regression model showed no overall effect of wearing the physical activity tracker on MVPA levels; however, a positive effect of time was found (*P*=.008). However, relative to baseline, the first group to receive the physical activity tracker intervention, group A, increased MVPA by 10.9 minutes/day (*P*=.03) over the first 7-week period, whereas the increase in MVPA for the delayed intervention group, group B, corresponded to 3.7 minutes/day (*P*=.56) during the same period (Figure 2). During weeks 8 to 14, group B was exposed to the intervention and displayed an average increase of MVPA of 13.2 minutes/day (*P*=.49), while the increase in MVPA represented 10.3 minutes/day (*P*=.64) in group A for this second period. There was no significance between group differences at the baseline or at the 7 weeks or 14 weeks assessments.

**Figure 2.** Baseline to 14-week changes in objectively measured physical activity from Actical accelerometers (group A was exposed to Fitbit from week 1 to 7 and group B was exposed to Fitbit from week 8 to 14, and "a" indicates significant difference between pre and post measurements within group A: *P*=.03).



After combining the pre and post intervention scores of both groups (group A pre-intervention at week 0 and post-intervention at 7 weeks, and group B pre-intervention at 7 weeks and post-intervention at 14 weeks), Wilcoxon tests suggested that changes in mean MVPA were related to differences in stages of behavior change (Figure 3). Participants in the adoption stages had a significant increase in MVPA from pre to post-intervention (*P*=.01), whereas participants in the preadoption stages did not change (*P*=.81). Whereas both groups had similar levels of MVPA at the pre-intervention time point, the post-intervention difference between the adoption and preadoption group was over 23 minutes of MVPA (*P*=.02). Moreover, physical activity tracker data showed that participants in the adoption stages averaged 2900 more steps and 20 more minutes of daily physical activity during the intervention phase than those in the preadoption stages. No association was found between goal commitment and MVPA.

The median participant in this study wore the physical activity tracker device for at least 10 hours per day on 67.3% of intervention days (33/49). Mean valid wear period was 30 days (SD=13), with a range of 6 to 49 days. Tukey post-hoc investigations suggest that wearing of the physical activity tracker peaked during the first two weeks of the intervention period and then dropped abruptly at the third week (Figure 4). The mean number of valid wear days during weeks 3 to 7 was significantly lower than in the first two weeks (*P*<.001). Physical activity tracker measured physical activity time and step count also showed similar decline after week 2 (*P*=.04) and week 3 (*P*=.01), respectively.

**Figure 3.** Moderate-to-vigorous physical activity among preadoption (precontemplation, contemplation, and preparation) and adoption (action and maintenance) participants before and after a 7-week minimalist physical activity tracker intervention: data are means and standard deviations (SD), “a” indicates significant differences between pre and post measurements within group (P=.01) based on the Wilcoxon signed-rank test, and “b” indicates significant difference between groups at the post-intervention measurement (P=.02) based on the Wilcoxon sum-rank test.

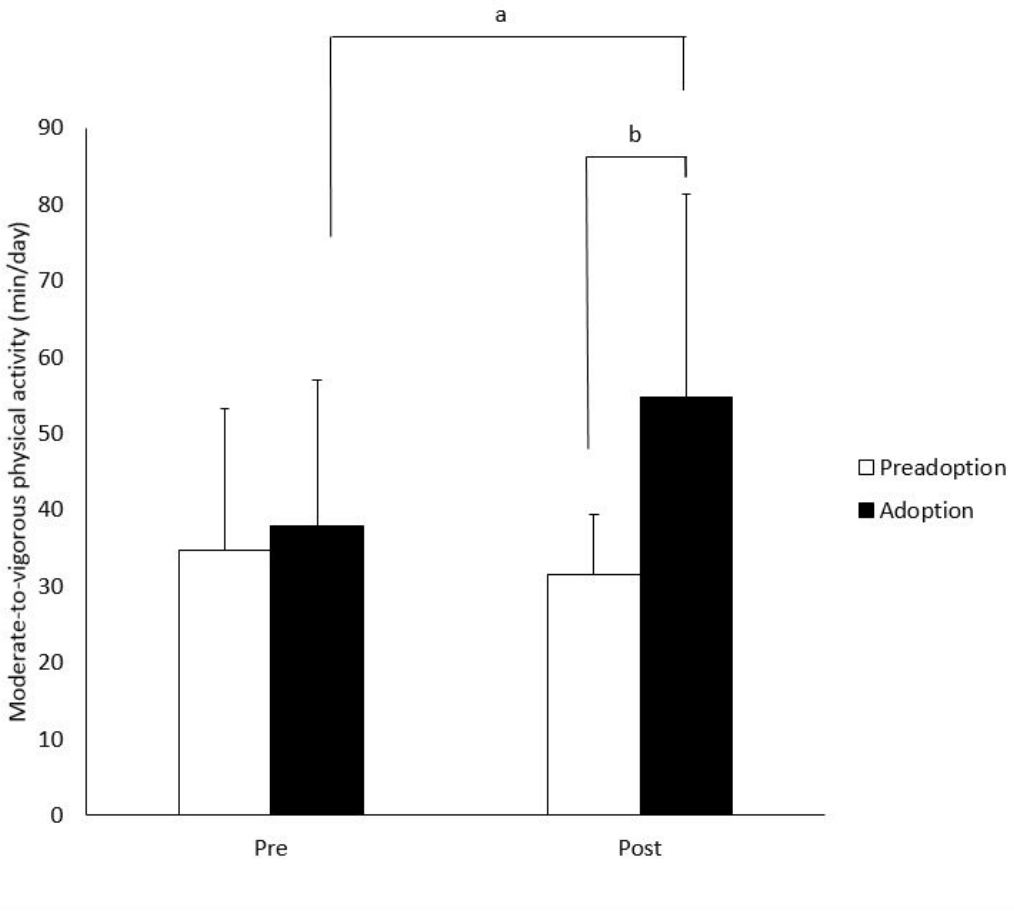
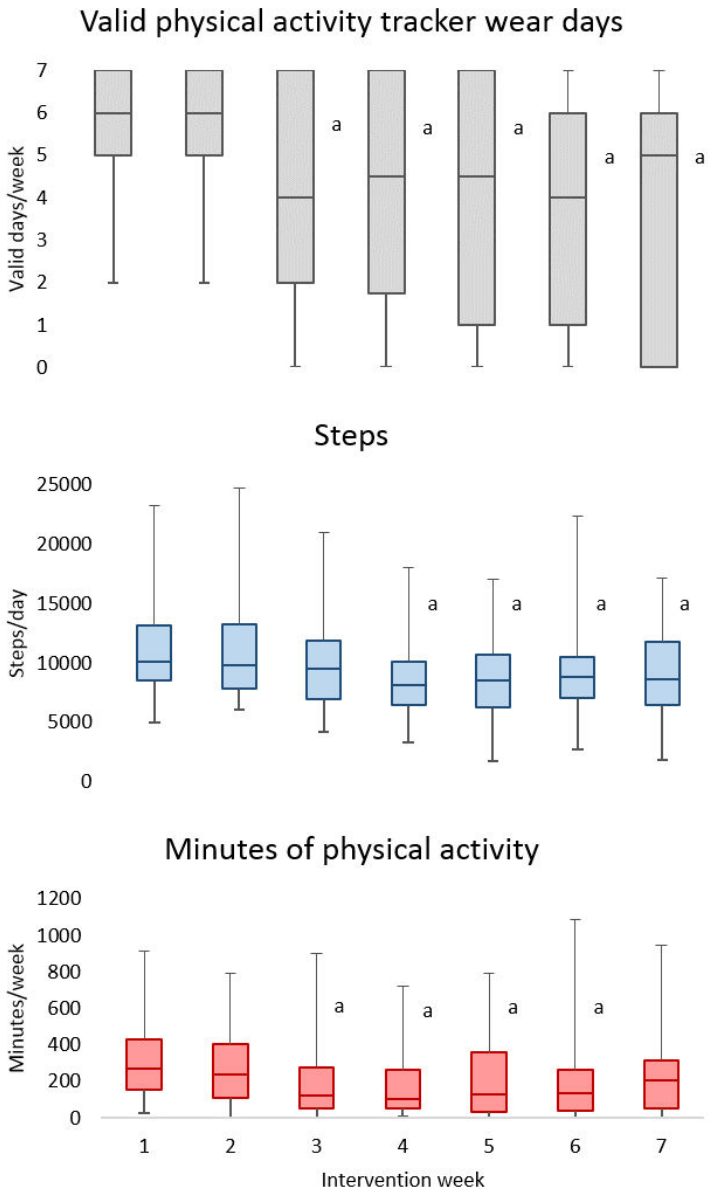


**Figure 4.** Changes in physical activity tracker measures during the 7-week intervention period (Valid days are defined as those with 10 hours or more of wear time, minutes of physical activity are Fitbit-defined minutes of "fairly to very active" physical activity, median and quartiles are represented in box plots, and "a" indicates significant differences from initial week).




## Discussion

### Principal Findings

With little research to date on the effects of using direct-to-consumer mHealth trackers as behavior change tools, the current study sought to examine the effectiveness of using a minimalist physical activity tracker-based intervention as a means of encouraging increased physical activity in adolescents. Although the main results suggested no change in MVPA as a result of having been exposed to a physical activity tracker, secondary analyses suggest that the interventions may have had beneficial effects for some sub-groups. For example, an intervention response occurred in a subset of participants who reported being in the action and maintenance stages of behavior change (adopters) in relation to participation in physical activity. Whereas these participants increased their daily average of MVPA by more than 15 minutes during the intervention period, those in the precontemplation, contemplation, and preparation stages (preadopters) had no change in their level of MVPA. This distinction manifested itself without the intervention being intentionally tailored to any specific stage of behavior change. Nevertheless, previous studies show that psychosocial determinants positively associated with physical activity generally increase across the stages of behavior change [32,34]. Adolescents in the adoption stages typically perceive fewer barriers, more benefits and have a better attitude and more self-efficacy in relation to physical activity participation [32]. Such underlying conditions likely predisposed these participants to be more receptive and to respond favorably to the exposure to a physical activity tracker. Although minimalist in nature, the introduction of a physical activity tracker may therefore represent a sufficient trigger for youth in the adoption stages to increase their level of physical activity. However, the

intervention was likely too simple to induce a behavior change among youth in the preadoption stages. Stage-specific intervention research suggests that in order to successfully motivate individuals in the preadoption stages, it is necessary to consider cognitive aspects of behavior change such as raising consciousness, social liberation, self-re-evaluation, self-liberation and counter-conditioning, helping relationships, and reward management [35,36].

The increase in physical activity among adopters may also be attributable to the fact that there was room for growth. Despite perceiving themselves as being active, objective measures suggested that participants in the adoption stages were not more active than those in the preadoption stages at baseline. This is similar to results from another study, which found little to no difference among levels of objectively measured MVPA of adolescents at different stages of behavior change [30]. Our results therefore point to the potential usefulness of assessing readiness to change before intervening. Although preadoption and adoption adolescents presenting similar objectively measured physical activity at baseline, the simple one-item questionnaire used to assess stages of change behavior change in this study correctly pre-identified participants who would best respond to the introduction of a minimalist physical activity tracker-based intervention.

This study was initiated during the middle of winter and extended to the end of spring. Thus, the start and end points of the study coincide with the typical periods of lowest and highest annual levels of physical activity in this age group, respectively [37-39]. This is noteworthy as the physical activity tracker-based intervention elicited an increase in physical activity during the study phase that corresponded to winter. Although it needs to be corroborated by other studies, it is possible that the introduction of physical activity trackers during this season could help some adolescents increase physical activity during the colder winter months. This is in support of findings from Dean et al [19] who observed, among a sample of adolescents with congenital heart disease, that wearing a physical activity tracker, as compared with not wearing one, was associated with a less abrupt decline of physical activity during winter months.

Continuous objective measurements obtained from physical activity trackers provided information suggesting that there was an acute effect of receiving the physical activity tracker. Specifically, compliance to wearing the physical activity tracker was at its highest during the first weeks of intervention. This would suggest that the device had a novelty effect, as demonstrated by others [23,40,41]. For instance, Shih et al [40] measured 50% attrition rates after the 2 week mark in a 6-week study in undergraduate students, while Schaefer et al [23], had only 2 participants (8%) use their physical activity trackers for a 4 month follow-up study. Beyond a decrease in compliance, it was noted that the average number of daily steps and minutes of physical activity were also at their peaks early in the intervention period. During the first three weeks, participants averaged between 9800 and 12,000 steps per day, which is close to the 10,000 to 12,000 steps per day recommended for this age group [42-44]. After the third week, however, this number declined to less than 9000 steps per day. Whereas normative data indicate that the majority of adolescents do not meet the step count recommendation [44], our findings suggest that there may be potential for physical activity trackers to encourage adolescents to perform near recommended levels of physical activity, at least over a short period of time.

It is possible that accompanying the distribution of physical activity trackers with a more intensive intervention would have led to greater compliance in wearing the device and greater increases in physical activity. The participants in our study, nevertheless, wore physical activity trackers to a greater extent than adolescents from under-resourced communities in another study [23], but also considerably less than post-menopausal women in another study [16]. Direct comparison to wear time during intervention in other studies involving adolescents is not possible as this kind of information tends not to be reported [41,45].

## Limitations

Limitations of this study need to be considered when interpreting the results. First, even though none of the participants was lost during the study, there was an unanticipated decline in compliance in wearing accelerometers at both post-intervention periods. This contributed to a loss of power to detect meaningful differences in physical activity, despite having initially recruited enough participants for adequate power. This drop in compliance may also have contributed to selection bias, wherein participants least likely to become more active did not wear the device at follow-up periods. Research is warranted to better understand adolescent engagement toward physical activity trackers to develop tailored interventions aimed at increasing compliance in this population [41,46]. Comparison between participants who completed all three evaluation periods and those who did not revealed no significant differences in physical activity level at baseline or distribution in stages of behavior change. Second, it needs to be considered that some activities were not measured because the accelerometer or physical activity tracker could not be worn (eg, swimming). Third, caution must be taken in interpreting physical activity tracker measured physical activity data as the proprietary algorithms used to calculate minutes of physical activity at different intensities are not publicly available. Fourth, although our results revealed a difference in intervention response between adolescents in the preadoption and adoptions stages, the small sample did not allow for in-depth analyses between each stage. Given the theoretical and empirical evidence of psychosocial and processes of change differences between each of the stages, future research with a larger sample is warranted to help elucidate which stages benefit the most from mHealth devices such as physical activity trackers. Future research should also assess whether similar physical activity tracker-based interventions lead to progressions in the stages of behavior change even among individuals who do not change their level of MVPA. Finally, although this study benefited from the strengths of randomization and crossover, having more randomization units in future studies would help attain group similarities even among unmeasured potentially confounding variables.

## Conclusions

In summary, although no overall effect was found, the secondary results of this study suggest that there is potential value in using

physical activity trackers to increase physical activity among adolescents in adoption stages of behavior change related to participation in physical activity. Adolescents in the adoption stages of behavior change may benefit from simply gaining access to a direct-to-consumer mHealth device designed to track physical activity. Future research is needed to better understand what additional strategies could be paired with physical activity trackers to lead to improvements in physical activity levels of adolescents in all stages of behavior change. This study also has implications for research as it demonstrates the feasibility of continuously and objectively measuring physical activity during an intervention involving adolescents.

## Authors' Contributions

MB and JG conceived the objectives of the analysis; JG collected and analyzed the data. All the authors participated in the interpretation of the data. JG and FG wrote the manuscript, while MB provided support.

## Conflicts of Interest

None declared.

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## Abbreviations

**MVPA:** moderate to vigorous physical activity
**SMART:** specific, measurable, attainable, realistic, and timely


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