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Background: For patient-oriented mobile health tools to contribute meaningfully to improving healthcare delivery, widespread acceptance and use of such tools by patients are critical. However, little is known about patients’ attitudes toward using health technology and their willingness to share health data with providers.

Aims: To investigate primary care patients’ comfort sharing health information through mobile devices, and patients’ awareness and use of patient portals.

Methods: Patients (n = 918) who visited one of 6 primary care clinics in the Northwest US completed a survey about health technology use, medical conditions, and demographics.

Results: More patients were comfortable sharing mobile health information with providers than having third parties store their information (62% vs 30%, Somers D = .33, p < 0.001). Patients older than 55 years were less likely to be comfortable sharing with providers (AORs 0.37-0.42, p < 0.01). Only 39% of patients knew if their clinic offered a patient portal; however, of these, 67% used it. Health literacy limitations were associated with lower portal awareness (AOR = 0.55, p < 0.005) but not use. Portal use was higher among patients with a chronic condition (AOR = 3.18, p < 0.004).

Conclusion: Comfort, awareness, and use of health technologies were variable. Practices introducing patient-facing health technologies should promote awareness, address concerns about data security, and provide education and training, especially to older adults and those with health literacy limitations. Patient-facing health technologies provide an opportunity for delivering scalable health education and self-management support, particularly for patients with chronic conditions who are already using patient portals.
Introduction
The potential for health information technologies (HIT) to play a transformative role in health service delivery has received considerable recent attention, with much enthusiasm focused on how patient-oriented technologies can improve care for chronic medical and behavioral health conditions. Such technologies include electronic patient portals, mobile health smartphone applications (apps), wearable biosensors, and other home-based systems allowing the collection, display, and transmission of patient-generated health data. Because smartphone adoption has been disproportionately high amongst racial and ethnic minorities, mobile health technologies may reach segments of the population that have been historically underserved in healthcare settings, thus representing a potential opportunity to address healthcare disparities for certain groups. The rapid growth of the consumer mobile health market into a multibillion dollar industry reveals strong consumer interest in using mobile health tools and recent industry reports suggest high levels of consumer trust in mobile health technologies. However, for patient-oriented technologies to have a substantial impact on the delivery of healthcare, it would be necessary for these tools to enable the straightforward transmission of patient-generated health data to healthcare providers, and it is unclear whether consumer interest and trust extend to such tools that facilitate data-sharing.

In contrast to the consumer market, the healthcare sector has been slow to adopt information technologies, and using such technologies to engage patients is a recent innovation. In 2008, less than 10% of hospital systems in the United States had any electronic medical record system, and by 2013 only 6% met Stage 2 Meaningful Use criteria, which include a basic patient portal. Privacy concerns and security breaches involving health information may present barriers to patient adoption of mobile health tools that communicate directly with healthcare providers or may discourage their disclosure of sensitive information. Furthermore, early reports have identified disparities in patients’ use of portals associated with sociodemographic characteristics including race/ethnicity and health literacy.

For patient-oriented mobile health tools to contribute meaningfully to improvements in healthcare delivery by facilitating patient education and engagement or enhancing patient-provider communication, widespread acceptance and use of such tools by patients are critical. However, little is known about patients’ attitudes toward using health technology and their willingness to share health data with providers. To address this gap in knowledge, this study aimed to assess the perspectives of primary care patients in community-based clinics in a practice-based research network in the 5-state WWAMI (Washington, Wyoming, Alaska, Montana, Idaho) region on the use of patient-oriented health technologies. We evaluated patients’ comfort using mobile health tools to share health information and their awareness of and use of patient health portals, hypothesizing that patients would be more comfortable sharing mobile health data with their healthcare providers than with third parties (i.e., companies that are not a part of the provider system). In addition, we examined demographic and clinical correlates of comfort, awareness, and use.

Methods
Study Sites
Study sites were six primary care clinics within the WWAMI region Practice and Research Network (WPRN) that chose to participate because they were interested in mobile health. Several sites had participated in a separate study with similar methods immediately prior to the current study. Participating clinics were located in four states (Washington, Wyoming, Alaska, Idaho) and included four hospital-associated outpatient practices, one office practice, and one Federally-Qualified Health Center. At the time of the study, five of the sites had an online patient portal available for patients. The clinics serve many low-income patients (22%-62% of patients uninsured or receiving Medicaid). Participating sites received an administrative stipend of $500. At each site, a champion was engaged throughout the project to assist in study design, coordination, and implementation.

Participants and Procedures
All adult patients (ages 18 and over) seen for a visit in any of the participating sites during a 2-week period in June 2013 were given a brief questionnaire (see Appendix) when they checked in for their appointment. The anonymous survey was designed to be completed in less than 5 minutes and returned to a collection box in the waiting area. Patients were informed that participation was voluntary and would not affect their healthcare. The surveys had unique tracking numbers used to facilitate estimation of the response rate. This study was considered minimal risk and was granted an exempt determination by the Institutional Review Board at the University of...
Measures

Participants reported their age, gender, self-reported ethnicity, and completed a 3-item measure of health literacy that has been validated in a variety of medical settings.\(^\text{17-19}\) Consistent with prior research, scores from each item were summed to yield a total score from 3 (poor health literacy) to 15 (no health literacy limitations) and coded dichotomously as having any health literacy limitation (scores 3–14) versus none (score = 15).\(^\text{11,20}\) As much of the enthusiasm for mobile health tools centers on their potential role for managing chronic medical and behavioral health conditions, participants were asked to report on depressive symptoms and the presence of chronic medical conditions. Participants completed the 2-item Patient Health Questionnaire (PHQ-2), a validated measure of depressive symptoms, scored from 0 to 6, with a cutpoint of 3 to identify patients with probable major depression.\(^\text{21,22}\) Participants also reported whether they had a history of depression or any of the following common chronic medical conditions: high blood pressure, diabetes, heart disease, asthma, chronic pain, or any other chronic condition not listed.

Mobile phone ownership and mobile health use.

Mobile and smartphone ownership were assessed by two questions adapted from the Pew Internet & American Life project.\(^\text{23}\) Mobile health use was assessed by asking participants if they have ever used their phone to “find health or medical information”; “download or use a health ‘app’”; or “track or manage a health issue (your diet or weight, activity, mood, blood pressure, etc.)”.

Attitudes about mobile health data-sharing.

Comfort with sharing mobile health data was assessed by asking participants “if you were using a patient portal or health app on your phone, how comfortable would you feel entering private information if (a) your doctor could see your information; (b) the information is stored by a third party (like a website or company that is not part of your doctor’s office)”. Responses were coded as “very comfortable”/“comfortable” versus “uncomfortable”/“very uncomfortable”.

Patient portal awareness.

Participants reported whether their doctor or clinic has a patient portal (like MyChart or E-care) for patients to communicate with their doctor or clinic, with responses “yes”, “no,” and “I don’t know”.

Patient portal use.

Participants who reported that their clinic has a patient portal were asked whether or not they use the patient portal.

Data Analysis

Data from the surveys are stored electronically on a secure server at the University of Washington. Because the survey was anonymous, no identifying information is contained in the data files. Descriptive statistics were used to characterize attitudes about mobile health data-sharing, patient portal knowledge and use. To assess whether attitudes differed for sharing mobile health data with providers versus third parties, a significance test of Somer’s D was performed. This Somer’s D statistic tested for the difference in proportion endorsing comfort sharing data with provider versus comfort sharing data with a third party accounting for person-level and site-level clustering of responses. To examine correlates of patients’ attitudes about mobile health data-sharing, separate mixed effects logistic regression models estimated the adjusted associations between patient characteristics (age, gender, race/ethnicity, health literacy, chronic conditions, and depression) and attitudes. Separate models were constructed for each item (comfort sharing with a healthcare provider and comfort with third-party storage). To the fully adjusted models, we assessed the associations between attitudes and mobile phone ownership by adding a term for mobile phone ownership. To assess the additional associations of attitudes with smartphone ownership and mobile health use, we conducted analyses on a subset of the patients. First, among patients who own mobile phones, we assessed the association between attitudes and smartphone ownership by adding a term for mobile phone ownership. To assess the additional associations of attitudes with smartphone ownership and mobile health use, we conducted analyses on a subset of the patients.
sharing with a healthcare provider and comfort with third-party storage). Similarly, separate models were constructed to assess correlates of patient portal awareness and patient portal use in a subset of the sample. Patients treated in the one clinic that did not offer a patient portal at the time of the study were excluded from both models. The model assessing portal use was restricted to only patients who endorsed awareness of their clinics’ portal. Multiple imputation (m = 40) was used to impute missing independent variables in multivariate models using Stata’s “mi” commands. All variables were included in the imputation and assumed to have a multivariate normal distribution. Multivariate regressions were performed on each imputed data set and results combined using Rubin’s rules.24

Results
As reported previously, 918 participants completed the survey for an estimated response rate of 67.4%.16 As is typical of primary care patients, a majority of participants were female (75%), and many had health literacy limitations (62%), chronic medical conditions (63%), and current depressive symptoms (21%). Participants spanned a range of ages (range: 18-94 years; 15% 18-24 years, 21% 25-34 years, 19% 35-44 years, 19% 45-54 years, 16% 55-64 years, 9% 65 years or greater; mean = 42.7 years; SD = 15.9 years) and ethnicities (80% non-Hispanic white, 5% Hispanic or Latino, 4% Asian American/Pacific Islander, 2% African American, 9% American Indian/Alaska Native or multiracial/other).

Attitudes about mobile health data-sharing.
Among 789 participants who responded to the survey items assessing attitudes about data-sharing, a majority (62%, n = 493) were comfortable or very comfortable sharing data with their healthcare provider, but most (70%, n = 550) were uncomfortable or very uncomfortable with third-party storage of mobile health data, a difference that is statistically significant (Somers D = .33, p < 0.001). Patients above the age of 55 years were significantly less likely to report comfort sharing mobile health data with providers than counterparts under 25 years (AORs 0.37-0.42, p < 0.01), whereas gender, race/ethnicity, health literacy, chronic conditions and depressive symptoms were not significantly associated with comfort (Table 1). In contrast, comfort with third-party storage of mobile health data was unrelated to patient characteristics (Table 1). Technology ownership and use were significantly associated with attitudes toward mobile health data-sharing. Specifically, mobile and smartphone ownership and mobile health use were each significantly associated with greater comfort sharing mobile health data with healthcare providers (AORs 1.77-3.04, p < 0.01), with similar but less pronounced patterns evident for comfort with third-party storage (Table 2). After accounting for mobile or smartphone

<table>
<thead>
<tr>
<th>Age (reference = 18–24)</th>
<th>Comfort sharing with provider</th>
<th>Comfort with third party storage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOR 95% CI</td>
<td>p</td>
</tr>
<tr>
<td>25–34</td>
<td>0.90 0.54, 1.52</td>
<td>0.70</td>
</tr>
<tr>
<td>35–44</td>
<td>0.88 0.51, 1.51</td>
<td>0.63</td>
</tr>
<tr>
<td>45–54</td>
<td>0.74 0.43, 1.26</td>
<td>0.27</td>
</tr>
<tr>
<td>55–64</td>
<td>0.42 0.24, 0.72</td>
<td>0.002</td>
</tr>
<tr>
<td>Age 65+</td>
<td>0.37 0.19, 0.72</td>
<td>0.003</td>
</tr>
<tr>
<td>Female (reference = male)</td>
<td>0.88 0.61, 1.25</td>
<td>0.46</td>
</tr>
<tr>
<td>Race/Ethnicity (reference = White)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian / Pacific Islander</td>
<td>0.83 0.35, 1.98</td>
<td>0.68</td>
</tr>
<tr>
<td>African American</td>
<td>0.72 0.28, 1.86</td>
<td>0.50</td>
</tr>
<tr>
<td>Latino</td>
<td>1.12 0.53, 2.36</td>
<td>0.77</td>
</tr>
<tr>
<td>Other / Multiracial / American Indian / Alaska Native</td>
<td>1.39 0.78, 2.46</td>
<td>0.26</td>
</tr>
<tr>
<td>Any health literacy limitation</td>
<td>0.86 0.63, 1.19</td>
<td>0.37</td>
</tr>
<tr>
<td>Any chronic medical condition</td>
<td>1.01 0.73, 1.39</td>
<td>0.96</td>
</tr>
<tr>
<td>Current depressive symptoms</td>
<td>0.82 0.56, 1.18</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Table 1: Associations between patient characteristics and attitudes about mobile health data-sharing. (n = 789)
ownership, the association between age and comfort sharing mobile health data with providers was unchanged (AORs 0.38-0.46, p < 0.05), however this association was attenuated in the model that included mobile health use (Age 55-64 years: AOR = 0.68, NS; Age > 65 years AOR = 1.85, NS; data not shown in Table).

Table 2: Associations between mobile technology ownership and use and attitudes about mobile health data-sharing.

<table>
<thead>
<tr>
<th>Ownership Type</th>
<th>n</th>
<th>AOR</th>
<th>95% CI</th>
<th>p</th>
<th>AOR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile Phone Owner a</td>
<td>789</td>
<td>2.58</td>
<td>1.51, 4.40</td>
<td>0.001</td>
<td>789</td>
<td>1.57</td>
<td>0.86, 2.87</td>
</tr>
<tr>
<td>Smartphone Owner b</td>
<td>681</td>
<td>1.77</td>
<td>1.22, 2.56</td>
<td>0.002</td>
<td>681</td>
<td>1.63</td>
<td>1.10, 2.40</td>
</tr>
<tr>
<td>Mobile Health User c</td>
<td>444</td>
<td>3.04</td>
<td>1.91, 4.85 &lt; 0.001</td>
<td>440</td>
<td>2.13</td>
<td>1.31, 3.47</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Models adjusted for age, gender, race/ethnicity, health literacy, chronic medical conditions, depression, and clustering within clinics.

aAmong all patients; reference group is non-mobile phone owners.
bAmong mobile phone owners; reference group is mobile owners who do not own smartphones.
cAmong smartphone owners; reference group is smartphone owners who are non-mHealth users. Patients were considered mobile health users if they endorsed any of the following activities on their mobile phone: finding health information, downloading or using a health “app”, or tracking or managing a health issue.

Patient portal awareness.

Among 815 participants who responded to questions about the patient portal, most did not know whether their clinic had an electronic patient portal (53%, n = 433) or responded incorrectly to the survey item (8%, n = 67). Specifically, 59 patients (12%) from the 5 clinics with a patient portal indicated that the clinic did not have a portal and 8 patients (2%) at the clinic without a portal reported that their clinic did have one. Among 481 participants from the 5 clinics with portals, patients with any health literacy limitations were significantly less likely to know about the portal than counterparts without health literacy limitations (AOR = 0.55, p = 0.005), whereas patient demographic variables, chronic medical conditions, and depressive symptoms were unrelated to awareness of the patient portal (Table 3).

Table 3: Correlates of patient portal awareness and use among patients at 5 sites with a patient portal.

<table>
<thead>
<tr>
<th></th>
<th>Patient portal awareness (n = 481)</th>
<th>Patient portal use (n = 186) a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOR</td>
<td>95% CI</td>
</tr>
<tr>
<td>Age (reference = 18-24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-34</td>
<td>0.92</td>
<td>0.44, 1.91</td>
</tr>
<tr>
<td>35-44</td>
<td>1.07</td>
<td>0.52, 2.21</td>
</tr>
<tr>
<td>45-54</td>
<td>0.88</td>
<td>0.42, 1.87</td>
</tr>
<tr>
<td>55-64</td>
<td>1.46</td>
<td>0.65, 3.28</td>
</tr>
<tr>
<td>Age 65+</td>
<td>0.71</td>
<td>0.29, 1.71</td>
</tr>
<tr>
<td>Female (reference = male)</td>
<td>1.18</td>
<td>0.75, 1.88</td>
</tr>
<tr>
<td>Race/Ethnicity (reference = White)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian / Pacific Islander</td>
<td>1.17</td>
<td>0.49, 2.80</td>
</tr>
<tr>
<td>African American</td>
<td>1.81</td>
<td>0.48, 6.85</td>
</tr>
<tr>
<td>Latino</td>
<td>1.15</td>
<td>0.45, 2.91</td>
</tr>
<tr>
<td>Other / Multiracial / American Indian / Alaska Native</td>
<td>0.83</td>
<td>0.41, 1.65</td>
</tr>
<tr>
<td>Any health literacy limitation</td>
<td>0.55</td>
<td>0.36, 0.83</td>
</tr>
<tr>
<td>Any chronic medical condition</td>
<td>1.18</td>
<td>0.76, 1.82</td>
</tr>
<tr>
<td>Current depressive symptoms</td>
<td>0.76</td>
<td>0.45, 1.27</td>
</tr>
</tbody>
</table>

Models adjusted for clustering within clinics.
aAmong patients who know about their site’s patient portal.
n = 125) reported that they had used the portal. Patients with chronic medical conditions were significantly more likely than healthy counterparts to use the portal (AOR = 3.18, p = 0.004; Table 3) and individuals ages 25 to 44 years were somewhat more likely to use the portal than counterparts between 18 and 24 years of age (AORs 2.94-2.95, p < 0.10). Gender, race/ethnicity, health literacy, and current depressive symptoms were unrelated to use of the patient portal among patients who knew about it. In addition, patients’ report of their comfort sharing mobile health data with providers was strongly associated with use of the patient portal (AOR = 3.67, 95% CI 1.66-8.13, p = 0.001, not shown in Table).

Discussion

Although patient-facing HIT has only recently been introduced into healthcare delivery in the United States, our results demonstrate high acceptance by most patient groups. A majority of patients were comfortable sharing patient-reported mobile health data with healthcare providers and most patients who were aware of their clinic’s patient portal used it. Use of an electronic patient portal was particularly high among individuals with chronic diseases for whom timely communication with healthcare providers may be particularly valuable. However, attitudes and awareness were not uniformly positive and our findings reveal characteristics of patients and technologies that are associated with acceptability and use.

Importantly, older adults reported significantly less comfort with sharing patient-generated health data with healthcare providers, a finding that held in models that accounted for technology ownership. Although lower comfort in older adults thus cannot be attributed solely to lower technology ownership, the association did not persist once actual use of mobile health tools was accounted for. Given the cross-sectional nature of the survey, we cannot determine causality as use of mobile health tools may increase comfort with mobile data sharing, or comfort may precede use. Interestingly, older adults were equally likely as younger counterparts to be aware of their clinic’s patient portal and to use it, suggesting that age-associated patterns in technology attitudes and use differ across types of health technologies and platforms. Future research should be directed at understanding the factors that facilitate adoption of health technologies by the subgroup of older adults who report both comfort sharing mobile health data and use of mobile health tools. This research will inform efforts to encourage health technology use more broadly among older populations. We also note that young adults between 18 and 24 years of age were somewhat less likely than those between 25 and 44 years to use a patient portal. We speculate that this could reflect a general tendency in that age range to be less engaged with the healthcare system and suggest that future research should have a specific focus on health technology use among older adolescents as they transition into young adulthood.

Our findings contribute greater understanding to associations between health literacy limitations and HIT use. We found that health literacy limitations were associated with lower awareness of a clinic’s patient health portal. Future research should examine whether clinic staff or providers may be less likely to offer patient-facing technologies to patients with health literacy limitations. In contrast, health literacy limitations were not associated with comfort with mobile health data-sharing or with actual use of the patient portal among those who were aware of their clinic’s portal. Together these findings illustrate important nuances in understanding associations between health literacy and HIT use that are directly relevant for potential interventions. Past studies have documented that low awareness of patient-facing HIT represents a major barrier to patients’ use25-27 and therefore efforts to increase awareness of health technologies should explicitly target patients with health literacy limitations to address this barrier and mitigate potential disparities in health technology use.

We found that more patients were comfortable sharing mobile health data with providers than with third-party storage. This discrepancy may suggest that patients are more willing to use HIT that is offered directly by their healthcare system than through external vendors. Our survey did not assess this directly; however, this interpretation would be consistent with prior findings that patient-provider communication and trust in providers are associated with patients’ use of electronic portals.28 Although reported attitudes may be more conservative than actual behavior,29,30 we did find that comfort sharing mobile health data was strongly associated with actual use of a patient portal and therefore the discrepancy in attitudes may have implications for adoption. Conversely, it is possible that the item wording and the hypothetical nature of the questions led to more negative attitudes
toward third-party involvement in mobile health data storage and that patients may be more willing to use third party tools when presented to them than their reported attitudes suggest. Future research should assess the robustness of these differences in patient preferences by including a more varied set of questions for comfort sharing with different recipients. Likewise, future research should assess how patients’ comfort may differ for different types of health data, particularly for information that may be considered sensitive, such as substance use, sexual behaviors, or mental health and to what extent individual differences exist in comfort for different types of information.

The present survey provides key information about patients’ attitudes and use of patient-facing health technologies, however certain limitations should be considered. The survey was conducted among individuals presenting for primary care appointments and therefore the sample may have been enriched in individuals who exhibit greater healthcare seeking. For example, depressed individuals use more primary care services than non-depressed counterparts, and therefore would have been more likely to be included in the sample. However, individuals with significant depression may have been less likely to participate due to low motivation. Notably, the percentage of individuals in our sample with significant depressive symptoms (21%) is similar to estimates of the prevalence of depression in primary care settings, suggesting minimal bias. The consumer market for mobile technologies has continued to evolve rapidly since the time that data collection occurred and it is likely that patients’ attitudes and use are also evolving, both as exposure to technologies increases and as reports of security concerns emerge.31,32 Our survey did not address patients’ use of wearable devices. Because these devices were less common when the survey was conducted and many such devices are connected to smartphone health apps, we suspect that the survey captured the majority of patients’ use of mobile health technologies at the time. The study was based on self-report measures of attitudes and use which may differ from observed use of health technologies. Finally, the survey did not assess patients’ beliefs about the value of HIT use for improving their health and well-being. Prior studies have suggested that evidence of efficacy is an important factor for patient adoption,26,33 yet studies to date have been inconsistent in identifying such benefits.27

This study highlights several practice implications. Efforts to disseminate patient-oriented technologies should include proactive patient education about new tools with a specific focus on increasing awareness among patients with health literacy limitations. Such efforts could also include components to educate patients regarding the privacy and security of their health data, particularly among older adults who endorse more concerns than younger counterparts. Past research has documented that healthcare providers play an important role in encouraging HIT use among their patients,26,27 and therefore efforts to promote patients’ use of HIT may also include education for providers to enhance providers’ “buy-in” and include strategies for providers to encourage patients’ adoption. Other strategies include providing hands-on guidance to patients to introduce them to the patient portal, for example by having a member of the clinic staff available to help patients enroll and learn to navigate it.

Healthcare is undergoing a significant transformation as patient portals are being deployed rapidly in the context of Meaningful Use incentives that require them and as integrating patient-reported outcomes into electronic health records is gaining momentum. Simultaneously, as more information technology companies develop and market health-related products and services, patients will have access to an expanding array of health technologies and may look to healthcare providers and systems for guidance in navigating these options. By increasing understanding of patient preferences, patterns of adoption, and barriers, healthcare systems will be better positioned to develop successful strategies to offer health technologies to their patients. Our results indicate a significant opportunity for increasing patient use of health information technologies by increasing awareness and educating patients about how systems protect the security of patient-reported health data. To mitigate disparities in care, such efforts should specifically target high priority groups such as older adults and those with health literacy limitations, while continuing to engage patients with chronic diseases.

Conflicts of Interest
The authors report no potential conflicts of interest.

Acknowledgements
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References


Appendix. Mobile Technology and Health Survey Instrument

The survey was printed on both sides and folded in half to distribute it as a “booklet”.

Mobile Technology and Health

This clinic is doing a research study with the University of Washington. This survey will ask you about how you may use a cell phone to manage your health. Your answers, taken with other responses, will help your clinic provide better care to patients.

- The survey should take less than 5 minutes to fill out.
- Your answers are anonymous, which means that they cannot be traced back to you in any way.
- Your doctors and nurses will not see your answers.
- Taking part in this survey is up to you. It is voluntary. You do not have to answer any questions you do not want to answer.

DO NOT FILL OUT THE FORM IF:
(1) You are 17 years old or younger
(2) You have already filled out this form

**PART 1: You and your phone**

1. Do you have a cell phone... or a BlackBerry, iPhone or other device that is also a cell phone? (Yes) (No) (Go to PART 2)

2. Some cell phones are called “smartphones” because of certain features they have. Is your cell phone a smartphone, such as an iPhone, Android, Blackberry or Windows phone? (Yes) (No) (Go to PART 2)

3. Have you ever used your phone to: Check all that apply.
   - Find health or medical information
   - Download or use a health “app” (Yes) (No) (Go to PART 3)
   - Track or manage a health issue (diet or weight, activity, mood, blood pressure, etc.) (Yes) (No) (Go to PART 3)

3a. How often do you use your phone for these health reasons?
   - Once a month or less
   - 2 or 3 times a month
   - 1 to 5 times a week
   - Once a day or more

**PART 2: How you use your phone**

4. How did you learn about the mobile health apps you have used?
   - My doctor or clinic
   - Friend or family
   - Website or Internet
   - Paper, mail or other ad
   - Other:

5. What is the name of the most useful health “app” you have used?

6. What does the app do that is useful for you?

**PART 3: Your use of other health technologies**

9. Doctors often give patients with information. With cell phones, doctors or nurses could give you a video to watch or an app to use instead of papers to read. How helpful would it be for your doctor to give you information through your phone? (Yes) (No) (Go to PART 4)

20a. Do you use the patient portal? (Yes) (No) (I don’t know (Go to 21))

21. If you were using a patient portal or health app on your phone, how comfortable would you feel entering private information?
   - Very comfortable
   - Comfortable
   - Uncomfortable
   - Very uncomfortable

E. The information is stored by a third party (like a website or company that is not part of your doctor’s office)?
   - Yes
   - No

**PART 4: Your use of other health technologies**

22. Some people communicate with their doctor or clinic through a “patient portal” on the internet (like MyChart or E-care). Does your clinic have a patient portal? (Yes) (No) (Go to 21)

23. If you were using your cell phone to communicate with your doctor, how comfortable would you feel communicating with your doctor?
   - Very comfortable
   - Comfortable
   - Uncomfortable
   - Very uncomfortable

24. How would the following features be for you to have on your phone?
   - Get feedback on how I’m doing
   - Tell me if my symptoms are normal
   - Help with stress management or coping
   - Help me change a habit (diet, smoking, etc.)
   - Tell me how many calories I’m eating
   - Support group / social network
   - Other feature (describe:)

**Mobile Technology and Health**

This clinic is doing a research study with the University of Washington. This survey will ask you about how you may use a cell phone to manage your health. Your answers, taken with other responses, will help your clinic provide better care to patients.

- The survey should take less than 5 minutes to fill out.
- Your answers are anonymous, which means that they cannot be traced back to you in any way.
- Your doctors and nurses will not see your answers.
- Taking part in this survey is up to you. It is voluntary. You do not have to answer any questions you do not want to answer.

DO NOT FILL OUT THE FORM IF:
(1) You are 17 years old or younger
(2) You have already filled out this form

**PART 1: You and your phone**

1. Do you have a cell phone... or a BlackBerry, iPhone or other device that is also a cell phone? (Yes) (No) (Go to PART 2)

2. Some cell phones are called “smartphones” because of certain features they have. Is your cell phone a smartphone, such as an iPhone, Android, Blackberry or Windows phone? (Yes) (No) (Go to PART 2)

3. Have you ever used your phone to: Check all that apply.
   - Find health or medical information
   - Download or use a health “app” (Yes) (No) (Go to PART 3)
   - Track or manage a health issue (diet or weight, activity, mood, blood pressure, etc.) (Yes) (No) (Go to PART 3)

3a. How often do you use your phone for these health reasons?
   - Once a month or less
   - 2 or 3 times a month
   - 1 to 5 times a week
   - Once a day or more

**PART 2: How you use your phone**

4. How did you learn about the mobile health apps you have used?
   - My doctor or clinic
   - Friend or family
   - Website or Internet
   - Paper, mail or other ad
   - Other:

5. What is the name of the most useful health “app” you have used?

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   - Very comfortable
   - Comfortable
   - Uncomfortable
   - Very uncomfortable

E. The information is stored by a third party (like a website or company that is not part of your doctor’s office)?
   - Yes
   - No

**PART 4: Your use of other health technologies**

22. Some people communicate with their doctor or clinic through a “patient portal” on the internet (like MyChart or E-care). Does your clinic have a patient portal? (Yes) (No) (Go to 21)

23. If you were using your cell phone to communicate with your doctor, how comfortable would you feel communicating with your doctor?
   - Very comfortable
   - Comfortable
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3a. How often do you use your phone for these health reasons?
   - Once a month or less
   - 2 or 3 times a month
   - 1 to 5 times a week
   - Once a day or more
PATIENT NAVIGATOR FACILITATED TEXT MESSAGING INTERVENTION IMPROVES LINKAGE TO CARE IN VIRAL HEPATITIS B: A PILOT STUDY

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1Center for Viral Hepatitis, United States; 2Korea Community Health Services, United States; 3W Medical Strategy Group, United States

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Background: Despite the high prevalence of chronic hepatitis B (CHB) in Asian Americans and other ethnic groups, a majority of these populations remains unscreened and unprotected. A large percentage of those who are chronically infected with hepatitis B virus (HBV) are not linked to care owing to a poor health care access. The purpose of this study was to evaluate the use of mobile text messaging in engaging individuals with hepatitis B or at risk for it, and to assess their acceptance of text messaging interventions.

Materials and Methods: A total of 32 individuals who were either chronically infected with HBV or non-immune to HBV were assigned to a patient navigator (PN), who subsequently arranged for the subjects to communicate through text messaging. The frequency and contents of messages between the subjects and the PN were evaluated. After the three month intervention period, results on linkage to care (LTC) were obtained. A self-report questionnaire was employed to assess the subjects’ feedback on the use of text messaging.

Results: All of 32 participants responded to the PNs with either text messaging or phone calls. The most frequent message themes were finding doctors and appointment reminders. Fourteen of 16 HBV infected subjects were linked to physicians, and all of 16 non-immune subjects received one or two vaccinations. The survey revealed strong receptivity to and acceptance of the use of text messaging.

Conclusions: Mobile text messaging intervention provides a platform for patients to engage with medical personnel, thereby improving their access to healthcare.
crucial, lack of health literacy associated with poor patient-physician communication are also formidable barriers affecting LTC in these minority populations. Improvements in patient education, counseling, and navigation may create an effective strategy to improve linkage from diagnosis to HBV-directed care.

Any effective patient-oriented communication tool that can provide linguistically and culturally accessible information necessary for health maintenance has potential to foster patients’ engagement in their care. mHealth tools as simple as smartphones may be good examples and have been utilized to increase access to healthcare. Smartphones can not only facilitate communication between patients and their physicians, but can also create new ways to provide patients with disease education, and connect them to a variety of resources in their communities. Smartphones and other mHealth tools also offer a unique advantage in that they can provide easy, anonymous, and comparatively inexpensive access to people irrespective of their cultures, languages, incomes, or geographical locations.

Certain ethnic minority groups are more likely to own mobile phones and to use them to access specific health information that would not otherwise be readily available to them, thereby tending to reduce health disparities. A recent Pew Internet Research Center survey, for instance, showed that English-speaking Asian Americans had a higher level of ownership of smartphones than any other ethnic group in the U.S. A striking 98% of Asian Americans own some type of cell phone, compared with 90% of whites, 92% of blacks and 93% of Hispanics.

Seventy-five percent of the 4.5 billion cellular phone users worldwide currently use text messaging, and 97% of Americans use it at least once per day. Thus, for Asian Americans and other minority ethnic groups, text messaging can provide patients with information on health care in their own languages, and can promote health literacy and preventive medicine, thereby combating the health disparities related to CHB care. Health-related text messaging via mobile phones started with routine appointment reminders. Text messaging has subsequently been tested as a tool to engage patients with a variety of medical conditions. Motivational text messages to young children with type 1 diabetes mellitus have demonstrated positive effects on diabetes control and adherence. Tailored text messaging has also been shown to have a positive impact on behavior changes in diabetic adults.

Text messaging has also been shown to improve treatment adherence and health outcomes in HIV patients. Other examples include Text4Health-Adolescents, a randomized text messaging intervention, which facilitated improved immunization rates in a low-income, urban population. Similarly, the Text4Baby campaign helped expectant mothers to receive prenatal information and other important resources. In addition, text messaging has been successfully implemented in smoking cessation, weight control, and treatment of tuberculosis.

In this study, we investigated the use of text messaging in facilitating the connection between subjects and physicians. We also examined subjects’ responses to the potential benefits of text messaging in health maintenance. The results suggest that in an ethnic minority population text messaging can effectively link patients to hepatitis care.

Methods

Participants

A group of 32 Korean Americans aged 18 to 69 was randomly selected from persons enrolled in a community-based hepatitis B screening campaign conducted in metropolitan New York between January 2015 and June 2015. All the participants were Korea-born immigrants, and preferred to communicate in Korean. They owned either smartphones or other cell phones with text messaging capability. A total of 16 individuals chronically infected with HBV, who were found to be hepatitis B surface antigen positive, was identified (CHB group). Another group of 16 people, who demonstrated a lack of immunity, was also identified (non-immune group). Both CHB and non-immune groups were assigned to a PN, who then initiated communication procedures. Hepatitis B screening results were initially provided by the PN to all the participants in person or by phone. This was immediately followed by a text message to each participant. Through text messaging, the non-immune group was sent initial messages advising them to receive free hepatitis B vaccination at one of the local health care facilities. The CHB group was also advised to see a physician for further evaluation and management. The members were asked to contact the PN with any questions. All communications between the participants and the PN took place during the three month period September 1, 2015 to November 30, 2015.
At the end of the three months, the PN called and/or texted each participant to determine the presence or absence of linkage.

**Patient Navigators**

The PN program provided all participants with specific information they needed to be adequately linked to a physician or a health care facility. The study employed two PNs. One had a Masters in public health and the other had a BS in nursing. Both PNs were employees of a non-profit community service organization. PNs were bilingual members of the subjects’ community who were familiar with clinicians and other health care resources within that community. PNs also had experience in advising CHB patients and were supervised by a group of gastroenterologists.

For further evaluation of CHB in this study, all 16 HBV infected individuals were given a list of community physicians with expertise in hepatitis B. The other group of 16 non-immune subjects was given a list of health care facilities where they could be vaccinated. All communications between subjects and PNs relied on text messaging except when communication took place through telephone calls. The PNs kept detailed records of all communications with the subjects.

**Data Collection and Measurement**

All the data were anonymized before they were reviewed and analyzed retrospectively.

**Text Messaging**

The number of messages between each participant and his or her PN ranged between 1 and greater than 20. All of the text messages sent by the PNs and those they received from the participants were recorded over the three-month study period. The degree of participant engagement was estimated by determining the frequency of text messaging. The contents of the text messages were also evaluated by classifying the messages under the following four different thematic categories: finding doctors/reminders; education; compliance/adherence; and “other.” Finding doctors referred to identifying community physicians whom subjects felt comfortable communicating with in their native language. Reminders referred to notifications to admonish the participants to make appointments for evaluations or vaccinations. Education included all messages providing explanations on further testing or on vaccination and any public health information on viral hepatitis. Messages related to regularly taking medications, getting tested periodically, and adhering to physicians’ instructions were assigned to the category of compliance. Messages that could not be assigned to any of the other three classes above were grouped under “other.”

**Survey**

The survey was designed to evaluate the acceptance of text messaging as a tool for communication between the subjects and health care personnel. The survey results consisted of responses to a questionnaire. Participants were asked to answer the questions: “Do you prefer text messaging to telephone calls?”, and “How much are you satisfied with text messaging as a communication method?”. To each question, subjects were instructed to assign ‘Levels of Importance,’ employing the following scale: 0=Disagree; 1=not sure; 2=Agree; 3=Strongly agree. In the second part of the survey, participants were asked about the specific need for and use of text messaging. Specifically, the following questions were asked: “How did text messaging help you with regard to the following five aspects?: a.) finding doctors, b.) appointment reminders, c.) education about diseases and conditions, d.) easy, faster access, and e.) fostering trust with medical personnel.”

**Results**

**Demographic Characteristics**

The sample of 32 subjects included 17 male and 15 female Korean American residents of metropolitan New York. Their age range was 18–69, with an average age of 48. Messages were sent to all 32 subjects, and 23 (72%) of them responded with at least one text message during the three-month study period (Table 1). Twelve of 17 men (71%) and 11 of 15 women (73%) responded, showing similar rates of response between the sexes. Subjects in all age groups responded without a significant difference among the groups. The nine participants who did not text back responded with phone calls. Thus, all of the 32 responded to the texts with either text messages or phone calls.

**Subject interactions through text messaging**

During the three months of intervention, 166 messages were sent to a total of 32 participants. In response, 23 participants (72%) responded with a
total of 133 text messages, averaging 5.8 messages per texting respondent. Figure 1 shows the details on the frequency of these messages. Each of the 32 participants received at least one message sent by the assigned PN at the beginning of the three-month period. The HBV-infected subjects received a message reminding them to visit a physician for additional tests, and the non-immune participants received reminder messages advising them to get vaccinated. The number of the messages sent by the participants to the PN, however, varied widely, ranging from 0 (among those relying solely on telephone) to more than 10 messages per respondent. Of note, the number of the messages in CHB group was significantly greater than the number of messages in non-immune group. Forty and 126 messages were sent and 26 and 107 test messages were received by the PN in non-immune and CHB groups, respectively.

Thus, the average number of messages per texting respondent in the CHB group was 6.7 as compared to 1.6 in the non-immune group.

Contents of the messages
We categorized the contents of the messages into the following four broad classes: finding doctors and reminders; health education; compliance/adherence; and other. As shown in figure 2, the greatest proportion of the messages was related to finding doctors and reminders. The majority of these messages belonged to the subjects in CHB group. The second most frequent theme was health education. Participants often asked about the benefits and potential side effects of vaccination, long-term complications of CHB, and use of antiviral medications.

Outcome Evaluation
At the end of the three-month study period, 30 participants altogether were linked to a physician or a health care facility for evaluation and vaccination, respectively. This represents a 94% linkage rate.

All of the participants from the non-immune group received at least one vaccination. In the HBV infected group of 16, a total of 14 went to see specialists within the community for further evaluation, demonstrating a linkage rate of 88%. Four of these 14 HBV infected individuals were started on antiviral medication during the three-month intervention period.

Acceptance of Text Messaging
Of 23 individuals who responded with texting, twenty subjects participated in the survey. There were 11 men and 9 women with an average age of 49. As shown in table 2, sixteen respondents preferred texting to phone calls, and 19 respondents expressed satisfaction with texting.

Table 1: Demographic Characteristics and Text messages sent and received during the three month intervention period

<table>
<thead>
<tr>
<th>Gender</th>
<th>Sent*</th>
<th>Received**</th>
</tr>
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<tbody>
<tr>
<td>Male</td>
<td>17</td>
<td>12</td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>23</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Sent*</th>
<th>Received**</th>
</tr>
</thead>
<tbody>
<tr>
<td>18–29</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>30–39</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>40–49</td>
<td>8</td>
<td>6</td>
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<tr>
<td>50–59</td>
<td>11</td>
<td>7</td>
</tr>
<tr>
<td>60–69</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>23</td>
</tr>
</tbody>
</table>

* refers to the number of participants PNs sent text messages to; ** refers to the number of participants who replied to the PN with at least one message

Figure 1: Number of messages sent and received by PN during the three month intervention period

Figure 2: Messages categorized under different themes
In the survey addressing specific needs and uses text messaging can serve, a majority of the respondents reported that text messaging provided easy access and saved time, and was useful for finding doctors and for appointment reminders (Table 3). Many also felt texting provided the additional advantage of storing the communication record for future reference. No subject indicated any disagreement with the statement that text messaging is useful.

**Discussion**

To our knowledge, this is the first study to demonstrate that text messaging can be successfully utilized to enhance patient engagement in hepatitis B care. Text messaging combined with the coordinating role of the PN program not only facilitated communication between the subjects and health care personnel, but it also helped to link the subjects to physicians.

**Text messaging— a tool for interactive communication with subjects**

Twenty-three of 32 participants actively communicated with PNs through text messaging during the three-month period. Since the remaining nine other participants, who did not reply with texting, responded with phone calls, mobile communication took place with all of the 32 subjects enrolled in the study. Thirty of 32 participants were linked to medical care, demonstrating a 94% linkage rate within a relatively short period: the three-month intervention. Especially in an era when irrational resistance to vaccination has become a serious public health problem, it is also remarkable to see that all 16 individuals in the non-immune group received hepatitis B vaccine, resulting in 100% linkage to care. In the CHB group, 14 out of 16 subjects were linked to physicians, representing a linkage rate of 88%.

The observed impressive rate of response and the high rate of LTC may be attributable to interactive communications between the subjects and the PN. During the first encounter between each subject and the PN, when the intervention began, the PN assessed each individual’s needs and characteristics. The text messages and the contents of the phone calls were subsequently tailored to fit each subject’s needs. A major benefit of mobile technology is its capacity for interactivity, which enables adapting messages according to a subject’s education, socio-economic background, needs, and other characteristics. It can facilitate interpersonal interactions between patients and health professionals. The use of individually tailored information has been shown to be effective in promoting beneficial health behavior changes in adults in other contexts as well.29,30,31

Although text messaging has been the most popular tool for facilitating behavioral interventions towards effective chronic disease self-care support, only a small percentage of American adults living with chronic diseases receives the benefits of text messaging for their health care support.32,33,34 With advances in mobile health services and the widespread use of mobile phones in the Asian American population and in other ethnic minority populations, text messaging may be a powerful, cost-effective way to facilitate communication between the patients and health care personnel, thereby improving health literacy and care disparity in ethnic minority populations.

**Role of the Patient Navigator in Linkage**

The success of linkage in this study would not have been possible without the PN program. The PN offered a culturally and linguistically tailored navigator program in coordinating access to clinical care by providing the subjects with the available healthcare resources in the community. The PN initially assessed each subject to determine his or her background and needs, and subsequently communicated with the subjects to direct them to meet

<table>
<thead>
<tr>
<th>Table 2: Text Messaging: Preference over the Phone and the Level of Satisfaction</th>
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<tbody>
<tr>
<td>Response</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Not Certain</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Very Certain</td>
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</tbody>
</table>

<table>
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<tr>
<th>Table 3: Specific Uses of Text Messaging in Communication with Medical Personnel</th>
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<tr>
<td>Text Messaging can help you with</td>
</tr>
<tr>
<td>Finding doctors</td>
</tr>
<tr>
<td>Appointment Reminders</td>
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<tr>
<td>Education</td>
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<tr>
<td>Easy access and saving time</td>
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<tr>
<td>Building trust with doctors</td>
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those needs. The PN system, reliant upon mid-level providers, is thus a healthcare service delivery model built around the patient, created to reduce barriers to care at comparatively modest cost.

The implementation of the PN system is especially helpful in hepatitis B care where LTC has been documented to be poor in various ethnic populations with high prevalence of CHB. Many patients chronically infected with HBV have been unable to access appropriate care for further evaluation and management. For instance, investigators have noted that only 40–66% of HBV infected patients are referred to appropriate care. Further, a large proportion of HBV-infected individuals do not follow up for further evaluation, suggesting a significant failure in sustaining LTC. Implementation of the PN program, however, has been shown to improve the linkage in CHB. We have previously demonstrated that, within one year, 42 of 45 individuals chronically infected with HBV were linked by a PN program to specialists for appropriate care. The high linkage rate of 88% from the CHB group in the current study also supports the critical role of the PN program in facilitating the linkage.

The successful LTC for CHB patients required significantly greater navigational effort than the LTC for the non-immune group. This is reflected in our data, which demonstrated that the number and frequency of messages per texting respondent in the CHB group was 6.7 as compared to only 1.6 in the non-immune group. These results indicate the value of continuous communication between patients and PNs to motivate patients to obtain further care.

**Diversity of Message Themes**

As shown in the varied contents of the messages, text messaging can convey a wide spectrum of information. Because of its interactive nature, text messaging caters to specific needs of individual patients. In this study, the most frequent theme of the messages was related to finding doctors and appointment reminders. In the CHB group, for instance, a large number of text messages inquired about locating Korean-speaking specialists within their community. Secondly, a substantial number of communications fell under ‘education’. The discussions related to potential use of antiviral medications in CHB and the need for vaccination in non-immune group, for instance, belonged to this category.

The survey from the text message users demonstrated a high degree of satisfaction with text messaging for communicating with the PN (Table 2). A majority of respondents also felt that text messaging allowed easy access, saved time, and helped with finding doctors and remembering appointments (Table 3). These results are congruent with the results of other studies on chronically ill patients, which have demonstrated high levels of receptivity and satisfaction.

**Limitations of the study**

We recognize that there are some limitations in our study. First, the sample size (n=32) is small, and the participants in this study may not be representative of the overall Korean American or other ethnic minority populations in the United States. Future studies investigating a larger number of subjects with a wider spectrum of ages and socio-economic classes would help to determine the need for and the efficacy of text messaging in engaging patients to obtain care. Secondly, further research is needed to determine if and how interactive communications through text messaging may actually serve to bring about changes in the patient’s health beliefs, which subsequently drive patients towards proper care. Third, studies with a longer intervention period would be required to assess more accurately the safety, sustainability, and effectiveness of text messaging intervention in promoting LTC. Fourth, the current study did not employ a control group receiving usual care without PN-facilitated text messaging, thus limiting a direct comparison between the PN-facilitated text messaging and control group. Nevertheless, the high rate of LTC noted in the current study with PN-facilitated text messaging intervention significantly contrasts with the lack of LTC documented in other previous studies without the use of text messaging.

Fifth, although none of the subjects lost his phone or complained about privacy, reliance on electronic communications entails inherent risks to privacy and security. Where HIPAA or analogous state statutes are applicable, and perhaps even where they are not, measures must be taken to protect privacy and security of text messages, which are often not encrypted and which may be stored by the telecommunication vendor or wireless carrier. Finally, given the critical role played by the PNs in the care of the study subjects, it is not possible to distinguish between the benefits arising from the utilization of text messaging and those attributable to the advice, skill, and culturally competent overall care of the PNs.
Conclusion
Mobile phone text message intervention in hepatitis B care may facilitate communication between patients and medical personnel, thereby helping patients to engage and access appropriate health care services within the community.

Declaration of Conflicting Interests
The authors declare they have no conflict of interest.

Ethics
All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee.

Competing Interests
The authors declare that they have no competing interests.

Authors’ Contributions
CSH conceived of the study, participated in the design of the study, and drafted the manuscript. SSK, SL and SY participated in the design of the study and performed statistical analysis. JM participated in its coordination and edited the manuscript. All authors read and approved the final manuscript.

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FINDING TIME FOR SLEEP: IDENTIFYING SLEEP CONCERNS IN NON-SLEEP SPECIALTY CLINICS USING THE MYSLEEPSCRIPT APP

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Corresponding Author: rsalas3@jhmi.edu

Background/Aims: To determine the utility and feasibility of implementing an mhealth tool into the clinical workflow of non-sleep specialists to assist in the evaluation, management, and education of patients with disrupted sleep.

Methods: MySleepScript is a clinical iPad® App developed by an interdisciplinary team of sleep experts that allow healthcare providers to screen and educate their patients who demonstrate symptoms concerning for unhealthy sleep behaviors and sleep-related difficulties. MySleepScript was conducted in 5 outpatient specialty clinics from 07/2014-9/2015. Patients were asked to answer questions regarding sleep habits, behaviors, and environment. Based on the patient responses, providers were provided a report regarding the “level of concern” for potential sleep disorders as well as customized sleep educational information for their patients. Patients were asked to complete satisfaction surveys.

Results: Of 120 patients, 66% completed the app within 15 minutes (87% within 20). Positive results were collapsed (strongly agree or agree). Ninety-four percent of patients found the app easy to use, 78% preferred the app platform to paper, 83% felt it enhanced communication with provider, 65% found the educational output helpful. Ninety-one percent recommend providers continue using MySleepScript. No significant differences across participant characteristics were observed for satisfaction survey responses regarding ease of use, preference over paper, or recommendation to continue using app. Degree of enthusiasm for MySleepScript was particularly high among non-Caucasian patients.

Conclusions: Our results demonstrate the feasibility of an mhealth sleep clinical tool conducted across a diverse patient population with uniform demonstration of increased overall patient satisfaction.

Introduction

Millions of Americans currently suffer with disrupted sleep, many of whom with undiagnosed and untreated sleep disorders. Sleep disturbances and disorders are a public health epidemic resulting in roughly 16 billion dollars in direct medical costs annually and 150 billion dollars in reduced workplace productivity in the United States alone. Poor sleep can negatively impact cognitive performance, mood, metabolism, quality of life, and life expectancy. Disrupted sleep is also significantly associated with several chronic conditions, including but not limited to diabetes mellitus, hypertension, cardiac disease, psychiatric disorders, obesity, and chronic pulmonary disease. Furthermore, sleep disturbances and disorders transcend demographic boundaries and can affect any patient, regardless of age, profession, socioeconomic status, education, race, or ethnicity, making the issue of sleep deprivation important for patient care across multiple medical specialties.

With a current membership of just under 6000 within the American Academy of Sleep Medicine and 1200 for Sleep Research Society, American Academy of Sleep Medicine, National Sleep Foundation, and Association of American Medical Colleges have predicted future physician shortages regardless of age, profession, socioeconomic status, education, race, or ethnicity, making the issue of sleep deprivation important for patient care across multiple medical specialties.

The introduction of mobile health (mhealth) serves as an untapped clinical resource tool for the non-sleep specialist caring for patients commonly at-risk for sleep conditions. Despite the potential benefit of mhealth tools in a clinical setting, few studies have investigated the use of the mobile platform to assist clinicians in clinical screening and diagnosis, facilitating communication and partnership with the patient, and improving patient outcomes. Thus, the need for a clinical (and educational) paradigm to address the sleep epidemic in healthcare is not only critical, but also time sensitive. To better equip clinicians managing patients with unmet sleep care needs, we developed an iPad app to be implemented in the clinical workflow of non-sleep specialist clinics. The main aim of our study was to evaluate the feasibility of implementing the MySleepScript mhealth clinical tool across various established clinical workflows. As such, we specifically assessed the amount of time patients needed to complete app, patients’ satisfaction with using the app, and whether satisfaction using the app varied by patients’ characteristics (e.g., age, race, education).

Method

Study Protocol

Our study with the MySleepScript iPad app was conducted from July 2014 to September 2015 across 5 non-sleep specialty Johns Hopkins outpatient clinics: neuro-Human Immunodeficiency Virus (HIV) clinic, movement disorders clinic, men's health clinic, and multiple sclerosis clinic. Certified trained student research assistants conducted the study in these clinics. Each patient was approached by a study team member and consented using a standardized Oral Consent Script approved by the Johns Hopkins Institutional Review Board.

Healthcare Provider Preparation

Prior to utilizing the MySleepScript app in clinic, the clinician completed an interactive sleep educational iPad app, MySleep101, created by our team. This app is made up of 10–15 minute interactive videos discussing the common presentations and treatment considerations for the following sleep disorders: Basic Sleep Concepts, Restless Legs Syndrome (RLS), Hypersomnia, Insomnia, Sleep Apnea, Circadian Rhythm Sleep Wake Disorders, Parasomnias, Post-traumatic Stress Disorder (PTSD) related sleep disturbances. MySleep101 was based on the Khan Academy approach to deliver brief, high yield and engaging lectures focused on the identification and management of common sleep disorders. Users of this app learn about risk factors and symptoms associated with sleep disorder(s) of concern as well as behavioral strategies for managing them, under the guidance of the healthcare team. After viewing of the educational material and achieving a minimum score on the MySleep101 post-test,
the MySleepScript app is “unlocked” for use by the provider.

Development of MySleepScript iPad® App

MySleepScript is an electronic clinical sleep app designed to assist non-sleep specialist clinicians in the evaluation and management in the outpatient setting. The MySleepScript clinical app encompasses a variety of standardized surveys mixed with other pertinent questions relating to sleep in an algorithm with built in logic depending on the entered responses. The validated surveys within the app include: The Pittsburgh Sleep Quality Index,20 Insomnia Severity Index,21 The Patient Health Questionnaire,22 Berlin,23 PTSD,24 RLS,25 and Perceived Neighborhood Disorder Scale Survey.26 Furthermore, questions developed by the sleep experts were included to target RLS, circadian rhythm disorders, parasomnias, and PTSD-related sleep disturbances. Questions from the JH Sleep Environment Inventory, created by the group to identify potential environmental contributors to poor sleep, were used as well. These surveys and questions were grouped and categorized into five sections accordingly: “Sleep Habits and Behaviors,” “Sleep Environment,” “Sleep and Neighborhood,” “Stress Level,” and “Sleep Attitudes.” Demographic information and “Sleep Habits and Behaviors” are mandatory for every patient to complete while the other sections are optional and completed depending on the provider’s prior selection of preferred questionnaires. For our study, patients completed the following three questionnaires - Demographics, “Sleep Habits and Behaviors,” and “Sleep Environment.”

Based on the patient’s responses, MySleepScript provides the clinician a “level of concern,” initiates an automated referral to the sleep specialist (if appropriate), and generates a customized educational PDF document (Figure 1) for the clinician/healthcare team to discuss and/or give to the patient to take home. Of note, MySleepScript does not diagnose patients with a sleep disorder, but rather identifies potential sleep concerns for particular sleep disorders so that clinicians already trained with MySleep101 educational app can explain the concern for a potential sleep disorder, refer or order tests (if decided by the clinician), and/or provide patient education. Clinicians have the opportunity to educate the patient regarding individual risk factors, discuss behavioral modifications, and provide a document stating these points as well.

Study Workflow

We allowed each clinician team leader to determine the integration of the app into the clinical workflow allowing for flexibility. In the movement disorders clinic and men’s health clinic, patients were asked to participate in the study before having been seen by their provider. In the HIV, headache, and multiple sclerosis clinics, patients were approached immediately after their clinic visit. In either case, the results of the MySleepScript app were reviewed with the clinician and patient upon completion of the app. Patients also had the opportunity to read and receive via email the customized educational script. After this experience, each patient was then asked to fill out the satisfaction survey on paper. The two models of the study protocol are illustrated in Figure 2.

Patient Satisfaction Survey

In order to assess feasibility of using this tool in the clinical setting, our team developed a short satisfaction survey that each patient completed after using the app. This satisfaction survey was administered on paper and was completely distinct from the questions in the app assessing sleep. The survey featured seven questions – six that used a five-level Likert scale (strongly disagree to strongly agree), and one that used a yes/no format question. The Likert survey asked the following questions: “I found the MySleepScript app easy to use,” “I prefer completing questionnaires like this rather than paper versions,” and “I am happy my healthcare provider is using this app.” The question “Compared to previous visits with this provider, I feel that MySleepScript enhanced the quality of this visit” was only completed by follow-up patients. The yes/no question asked, “Would you recommend that your provider continues to use this MySleepScript app.” The results of the satisfaction surveys were entered into a database. Answers to Likert scale questions were assigned a value one through five, with “strongly agree” as “1” and “strongly disagree” as “5,” while “yes” as “1” and “no” as “0.”

Data Analysis

The results from the satisfaction surveys, time to completion, and demographics were the primary outcome data analyzed in this study. Descriptive statistics were conducted to quantify whether or not a majority reported favorable responses to the MySleepScript satisfaction survey items.
This My Sleep Script was prepared for [blank].

You have some symptoms that may be indicative of poor sleep quality possibly due to your sleep environment. This form provides basic information on what it means to have a “healthy sleep environment” and what immediate steps you can take to create one in your home. If at any time in the future, you feel that your sleep quality has worsened or that you begin to experience symptoms during the day that you associate with declining sleep quality then please let your health provider know and we can consider a referral to the sleep clinic for a formal evaluation.

Common Causes for a Poor Sleep Environment

The environment in which people sleep (e.g., Bedroom) can impact their sleep quality. In many individuals, factors such as noise, light, sleep surface (e.g., Bed), temperature, and movement from bed partners can negatively affect their sleep. In fact, there is a recognized sleep disorder, ENVIRONMENTAL SLEEP DISORDER that occurs when conditions in the environment result in disrupted or poor quality sleep. Such a disorder may trigger other sleep disorders such as insomnia which can evolve into a chronic, and often, severe sleep disorder.

Just like maintaining a healthy diet, maintaining healthy sleep habits helps to promote good sleep quality and overall health. Examples of healthy sleep habits include:

- Limiting caffeine intake at least 8 hours before bedtime
- Cutting out smoke and all tobacco products before bedtime
- Not consuming large quantities of alcohol prior to bedtime
- Not using alcohol to help you sleep
- Getting up at the same time every day
- Not spending excessive amounts of time in bed
- Avoiding long naps
- Don’t do intense exercise close to bedtime
- Having a comfortable sleeping environment
- Getting into the sun when you have breakfast

Most people can always find room for improving their sleep habits. Unhealthy sleep behaviors and habits can cause problems with memory, job function, interactions with others and even mood. In addition, it can also eventually trigger or develop into other sleep disorders such as insomnia and circadian rhythm disorders.

Symptoms of Sleep Disruption

- Difficulty with attention and concentration
- Difficulty with learning and memory
- Depressed mood
- Anxious mood
- Trouble staying asleep
- Irritability
- Fatigue

Risks of Poor Sleep Quality Include:

- Hypertension
- Diabetes
- Depression
- Weight gain

Steps You Can Take to Improve Your Sleep Environment

People may have several risks that increase the likelihood of environmental sleep disorder. The good news is that many are modifiable so you have the power to change these from unhealthy to healthy habits. Here are some behavioral strategies you can consider to help create a more healthy sleep environment and adopt more healthy sleep behaviors/habits. While you have some risk for poor quality sleep as identified above, a referral to a sleep specialist is not warranted at this time.

1. AVOID A MESSY BEDROOM Messy rooms can lead to depressed and anxious moods, which can contribute to poor sleep quality.
   - Maintain a clean bedroom for a good night’s sleep

2. ROOM TEMPERATURE Having a too hot or too cold bedroom can negatively impact your sleep. Consider the following:
   - A fan or additional cooling system
   - A window AC
   - Cooling blanket
   - Sleep in cotton sheet pajamas
   - Taking a bath/shower 2-3 hours prior to bedtime
   - Changing into a fresh pair of socks at bedtime

3. AVOID HAVING TOO MANY PEOPLE IN THE BED/BEDROOM Having too many people in the bedroom increases the chances of sleep disruption and poor sleep quality throughout the night.
   - Consider reducing the number of people in your bed or bedroom or sleeping in another bedroom

4. REDUCE ALLERGENS Reducing allergens in the room may improve sleep quality.
   - Using an air purifier in your sleeping room
   - Changing bed sheets every week
   - Changing out pillows every year
   - Changing out mattress ~ every 5 years
   - Getting carpets cleaned regularly or even eliminating carpet

Figure 1: Customized sample educational sleep document.
Independent samples t-test was conducted to examine whether responses on the continuous satisfaction survey items differ between new and follow-up patients. For the dichotomous satisfaction survey item, a chi-square test was conducted. T-tests and chi-square tests were conducted to determine if there were demographic differences with respect to satisfaction survey answers.

**Results**

From July 2014 to September 2015, 120 patients were enrolled in the study across 5 clinics (see Table 1). The study included 64% follow-up patients and 36% new patients. The majority of our patients were male (80%). Most of the patients identified as White (62%), followed by Black (28%), Asian (3%), and Latino (2%). The average age was 57 ± 14. The majority of patients (87%) completed the app in less than 20 minutes, but a substantial percentage (66%) of patients completed the app in less than 15 minutes (Table 1).

**High Percentage of Patients Reported Satisfaction with MySleepScript**

Ninety-one percent of the patients recommended that their health provider continue to use the MySleepScript app in their clinic. A majority of patients strongly agreed/agreed that the app was easy to use (94%), preferred the app compared to paper formats (78%), felt the app improved communication with their practitioner (83%), and provided helpful output for them as patients (65%). Overall, 85% of patients reported that they were glad their health provider was using the app (see Table 2).

**MySleepScript Satisfaction Report Differences across Patient Characteristics**

No significant differences across patient characteristics (i.e., age, sex, race, education, and employment status) were observed for the satisfaction survey responses regarding ease of use, preference over paper, or recommendation to continue using app. No significant demographic differences were found between new and follow up patients. No significant differences across the patient characteristics (i.e., age, sex, race, education, and employment status) were observed for the time taken to complete MySleepScript.

More non-White patients (80%) than White patients (41%) (p = 0.009) reported that they strongly agreed that the MySleepScript was an easier form of communication. More non-White patients (60%) than White patients (16%) (p = 0.001) also reported that they strongly agreed the MySleepScript provided valuable output, and more non-White patients (76%) than White patients (35%) (p = 0.004) strongly agreed they were glad the provider was using the MySleepScript app.

Furthermore, more full-time working patients (74%) than unemployed (0%), retired (32%), or disabled patients (33%) (p = 0.008) reported that they strongly agreed the app was an easier form of communication. More patients 40-64 years of age (52%) compared to patients 20-39 years of age (29%) and ≥ 65 years of age (15%) (p = 0.018) reported that they strongly agreed the MySleepScript provided valuable output.

A significantly higher percentage of new patients (100%) than follow-up (88%) patients recommended that health practitioners should continue to use the MySleepScript app (X² (1) = 5.15, p = 0.02). As illustrated in Table 2, new patients were also significantly more likely than follow-up patients to report the app was easy to use (new patients mean = 1.12 (SD = 0.33) (follow-up patients mean = 1.43 (SD = 0.70); t (111) = 3.21, p = 0.002) and were glad the practitioner was using the app (new patients
mean \( \mu = 1.50 \) (SD = 0.67) (follow-up patients mean \( \mu = 1.82 \) (SD = 0.80); \( t (114) = 2.22, p = 0.028 \)). Among the follow-up patients, a high percentage reported they strongly agreed/agreed (66%) that the app enhanced the quality of their practitioner visit.

### Discussion

Our team developed the *MySleepScript* iPad© app to equip clinicians with a patient friendly, time-efficient clinical tool to help in the evaluation of patients experiencing sleep disturbances. With mhealth platforms improving communication and healthcare across a variety of specialties and benefitting clinicians,16,27,28 their use have already become quite ubiquitous. For example, 85% of faculty physicians and 90% of residents use their mobile phones in clinical settings.29 However, this mhealth utilization is generally limited to tools such as medical references, drug information, and calculators.29 *MySleepScript* represents an innovative utilization of the mhealth platform, especially from the standpoint of sleep healthcare, in its ability to equip the clinician with a resource to assist with the evaluation, management, and education of sleep disturbances/disorders.

Our goal was to assess patient satisfaction, patient characteristics, and time to completion across various established clinical workflows to evaluate the feasibility of implementing *MySleepScript*. With the increase in technology in recent years, many clinicians are cautious of introducing mhealth into their practice due to the fear of patient resistance, patients’ lack of experience with technology, and disruption of provider-patient communication.17,18,30 Supporting this, one study revealed that 20% of physicians reported “patients’ resistance to technologies” as a reason for their own skepticism.31 Thus, in order to for clinical mhealth technologies to be successful, it is imperative to demonstrate that patients are willing to use and can benefit from these technologies. Our data show that the majority of patients across a variety of demographics and clinical cohorts embraced the incorporation of mhealth tools into the clinical workflow, finding it easy to use and superior to the traditional format of filling out paper questionnaires. Furthermore, our results suggest that the degree of enthusiasm for mhealth tools was significantly higher among specific demographics, particularly middle aged, employed, and non-White patients. Such unique spikes in enthusiasm may warrant further
exploration since mhealth may serve as a targeted strategy to enhance patient outreach and close potential health disparity gaps that may exist.

Interestingly, 83% of patients in our study believed that using the app enhanced communication between the provider and patient. Many skeptics caution that new health technologies could erode the doctor-patient relationship and diminish personalized care. Some evidence suggests that the use of Electronic Health Records (EHRs) has impacted critical components of patient-provider interaction and communication. Since patients in our study completed the app prior to their face-to-face encounter with the clinician, the use of this app likely did not negatively impact communication in the same manner as EHR documentation during a clinic visit may. Though our survey did not describe how exactly the MySleepScript experience helped to enhance the communication between clinician and patient, our data show that patients using MySleepScript reported the improvement in communication.

Based on individual questionnaire responses, MySleepScript produces customized educational output in the form of a PDF handout to each patient depending upon their responses to the questionnaires. Our results show that 65% of patients found this customized material helpful. Empowering and partnering with the patient is a core principle of clinical care, and personalizing educational materials for each patient provides an opportunity for patients to be involved in their care. This approach contrasts with the “one-size-fits-all” educational method often used in brochures, online healthcare education websites, and pre-printed paper information sheets.

One advantage of an iPad app is that it can be completed at a variety of different time points and locations during the clinic visit, and including prior to being roomed for their visit while sitting in the waiting room. The waiting room has already been accepted as a medium for health education and patient engagement. Gilliam et al have successfully implemented an iPad app in waiting rooms on contraception education with initial positive results on satisfaction and effectiveness. Our results also showed that 66% of patients completed the app within 15 minutes and 87% completed within 20 minutes. No significant differences were observed across participant characteristics (i.e., age, sex, race, education, and employment status), suggesting that this app may be completed by a variety of patients in a timely manner. Considering the average waiting room time in 2014 was 23 minutes, implementing this app in waiting rooms may serve as a resourceful use of the patients’ time.

One of the main reasons physicians adopt new technologies is to use time more efficiently. This app’s ability to automatically calculate scores for a number of surveys instantaneously allows for real-time inclusion of the results into the patient visit and treatment plan. Furthermore, this app can improve record keeping for completed surveys and in the future could allow for further integration with patient medical records and health portfolios. For the two clinics where the app was administered preceding the patient’s scheduled clinic visit (i.e., Urology/Men’s Health; Movement Disorders), providers did not report any issues or concerns with respect to clinic flow. However, provider attitudes were not directly measured in this study and serves as a future direction for further analysis.

Our study is not without limitations. Though we had encouraging satisfaction scores, our results included 120 patients in only 5 subspecialty clinics. Furthermore, the majority of our patients were male (80%) with an average age of 57 years. With the large diversity in outpatient clinic types, locations, specialties, populations served, and workflow, our conclusions are not necessarily applicable to every outpatient clinic. Moreover, our study is subject to selection bias, as the 5 clinics were not randomized and were pre-selected based on opportunities to conduct the study. Thus, the observed patient satisfaction ratings with the MySleepScript may not be generalizable across adult communities and academic clinic settings. Though providers reported no issues with respect to clinical workflow, follow-up studies should be completed to truly assess the perspectives of clinicians and their clinical administrative healthcare team using this app. Obtaining provider satisfaction and perspectives is critical in assessing what value, if any, does the app add to the clinician. While patients provided high satisfaction scores in using this app, it is unclear what, if any, measurable direct benefit this app brings to patient care. Although this app has a built-in customized educational component and assists clinicians in the assessment and management of patients with sleep issues, the impact on patient outcomes and clinical follow-up rates as a result of this tool warrants further investigation.
Conclusion

MySleepScript is an electronic clinical tool designed to assist clinicians in the evaluation, management, and education of sleep disturbances. Further studies are warranted to determine the perspectives of providers and to investigate both the benefits and health outcomes of mhealth educational and sleep medicine clinical tools placed in the hands of a non-sleep trained specialist. Results of this study, however, demonstrate promise that this approach was well received by a diverse population of patients which serves as a fundamental step towards widespread application.

Conflict of interest

Authors report no conflict of interest.

Financial disclosure

Dr. Rachel Salas has entered into an agreement with UpToDate, Inc. and has been paid royalties for her contribution of medical articles for this publication. She has received less than $400.

She has received royalties from sales of the MySleep101 iPad app. She has received less than $75.

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She has received royalties from sales of the MySleep101 iPad app. She has received less than $75.

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References


COMPARING THE VALIDITY OF A GPS MONITOR AND A SMARTPHONE APPLICATION TO MEASURE PHYSICAL ACTIVITY

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Background: A recent approach to increasing physical activity levels, managing weight and improving health has been via technological advances, such as the Web 2.0 technologies, wearable activity trackers and smartphones. These approaches might be effective due to reduced cost, user-friendly environment and real-time feedback provided. Many of these monitors and smartphone applications are marketed to provide personal information on the level of physical activity, however little or no information is available regarding their validity.

Aims: The purpose of this study was to compare the criterion validity for distance travelled and total energy expenditure (TEE) between a commercially available GPS monitor, Garmin Forerunner 310XT, and a freeware GPS application for Android smartphones, Runkeeper, under semi-structured activity settings.

Methods: A single, healthy and physically active participant took part in all trials. The same protocol was repeated on 40 occasions (20 walking and 20 running sessions). The participant wore the Garmin GPS on the left wrist and a smartphone with the Runkeeper application activated on the left arm. Distance was compared against an objectively measured distance with three different methods and energy expenditure estimates for each monitor was evaluated relative to criterion values concurrently obtained from the portable metabolic system Cosmed K4b2. Differences from criterion measures were expressed as a mean absolute percent error and were evaluated using repeated measures ANOVA and Bland-Altman plots.

Results: For overall group comparisons, the mean absolute percent error values for distance were 0.30% and 0.74% for Garmin (walking and running), while higher values were calculated for Runkeeper (3.28% during running and 4.43% during walking), which significantly overestimated distance in both conditions. For energy expenditure estimation, significant differences were observed for both monitors (p<0.001). Garmin significantly underestimated energy expenditure compared to the criterion method in both conditions by 17%, while Runkeeper significantly overestimated it by 6.29% during running and 35.52% during walking.

Conclusions: The present study offers initial evidence for the validity of GPS technology of wearable activity monitors and smartphone applications for measuring distance travelled. However, estimates of energy expenditure were poor, except for Runkeeper during running which provided acceptable error.
Introduction
Every year approximately 3.2 million deaths and 32.1 million illnesses are associated with physical inactivity. In most western societies people between 18 and 35 years belong in the high-risk group of becoming either overweight or obese, due to lack of physical activity (PA). In order to reverse these statistics, individuals are recommended to accumulate at least 30 min/day, 5 days/week of moderate intensity PA or 15 min/day, 5 days/week of vigorous intensity PA (75 min/week), or a combination of both.

A recent approach to increasing PA levels, managing weight and improving health has been via technological advances, such as the Web 2.0 technologies, activity trackers and smartphones. Griffiths and colleagues proposed that these approaches might be effective due to reduced cost, user-friendly environment, real-time information and feedback provided. Sufficient evidence exists to support the positive effect of these programs with the use of new technologies, especially when these are combined with other research approaches, such as face to face interventions. For example, King and colleagues used three mobile applications to change the physical (in)activity and sedentary behavior of 95 underactive adults during an 8 week intervention program, and the results provided initial support for promoting PA and reducing sedentary behavior. Also Laurson, Welk and Eisenmann asked 111 children to wear pedometers over a seven day period and record their steps. Children who wore the pedometers longer appeared more active, with a significant increase of steps per minute.

Global Positioning System (GPS) technology, even though it is quite new in PA and exercise, is a low cost, objective and discreet way to track individuals’ movement. Most previous studies have concluded that it is a valid way to measure distance travelled. For example, Specht and Szot tested six GPS receivers and found that logging receivers, such as Garmin Forerunner 310XT, demonstrated the highest accuracy in determining positions. In another similar research, four wearable GPS monitors were compared while four adults walked a distance of 1.24 km and the most accurate device was Garmin Forerunner 205. Using a similar methodological approach, Lee et al. chose four low cost GPS minotors and found that all devices were valid for distance estimation, with Garmin 60 to be the most accurate.

Even though GPS monitors are accurate for distance estimation, commercially available applications that use the GPS sensor of the smartphones are sparsely tested for their accuracy. Bauer for example compared ten GPS applications over a 1 km distance, with the Adidas miCoach been the most accurate and Runkeeper having a divergence of 20 m.

Nowadays these monitors and applications have the ability to estimate, using anthropometric and GPS data, the energy expenditure (EE) of individuals during exercise. However, no published research, only a Master’s dissertation and a conference paper have validated these outcomes. Mallula compared a Garmin Forerunner 405CX with Nike+ application for iPod and found that the application was more accurate in EE, while the device had a more valid estimation of distance and speed. Furthermore, Adamakis and Zounia in a preliminary study compared a Garmin Forerunner 310XT with the Runkeeper application for Android smartphones, with the Garmin monitor having the best results in distance, speed and EE, while Runkeeper overestimated all exercise parameters. In conclusion, Bort-Roig and colleagues suggested that well designed studies are needed that comprehensively assess physical activity measurement accuracy, however till these days few researches have validated GPS monitors and smartphone GPS-enabled applications.

The purpose of this study was to compare the criterion validity for distance travelled and total energy expenditure (TEE) between a commercially available GPS monitor, Garmin Forerunner 310XT, and a freeware GPS application for Android smartphones, Runkeeper, under semi-structured activity settings.

Method
Research design
An experimental research design was used. The independent variable was the type of GPS monitor: Garmin Forerunner 310XT and freeware Runkeeper Android application. The primary outcome was distance and the secondary outcome was total energy expenditure (TEE), during walking and running.

Participant
One single, healthy and physically active individual, who could run at least 5 km continuously, took part in all trials. The same protocol was repeated on 40 occasions (20 walking and 20 running sessions)
during 40 consecutive days. Relevant characteristics such as height (190 cm), weight (80 kg), gender (male) and age (33 years) were entered into each monitor separately. The anthropometric measures were obtained at the beginning of the data collection session. Standing height was measured to the nearest 0.1 cm with the use of a wall mounted Harpenden Stadiometer (Harpenden, London, UK), using standard procedures. Body mass was measured by participants in light clothes and bare feet on an electronic platform scale (Tanita Corp., Tokyo, Japan) to the nearest 0.1 kg. Following anthropometric measurements, the participant was asked to lay down in bed for 10 minutes and then fitted with the portable indirect calorimeter (Cosmed K4b2) to measure resting energy expenditure (REE). REE was measured for 15 minutes with the subject quiet, but awake. The first 5 min as well as the last minute of measurement were eliminated and the REE was obtained from the average of 9 min. REE measurement was performed after a 10-hour fast, following previously published guidelines. The REE was expressed as kilocalories (kcal) per minute by dividing the TEE by 9 and the estimation was 1.05 kcal

**Instruments**

Smartphone - Samsung Galaxy S4 mini (Samsung Electronics Co., Ltd., Suwon, South Korea): The Samsung Galaxy S4 mini uses Google’s Android Jelly Beam 4.2.2 mobile operating system equipped with a built-in GPS receiver, accelerometer and gyroscope. This phone is small, 125 by 61 by 9 mm, and lightweight, 107 grams.

Runkeeper Android application: Runkeeper, software version 4.4.3 (FitnessKeeper, Inc.; http://Runkeeper.com/) is one of the most commercial applications for Android and iOS smartphones. Runkeeper is a free of charge application, which calculates average pace and speed, laps’ speed, route distance, elevation and estimated calorie burn for a variety of fitness activities, in high accuracy and real time, using the in-built GPS sensor of the Android phone. EE is calculated taking into account the user’s inputted variables including gender, height, weight and fitness class. It then combines the data with heart rate information from the heart rate strap. More specifically, it evaluates the time between heartbeats (beat to beat) to determine estimated Metabolic Equivalent (MET), which in turn is used to determine actual work expenditure. This method is inexpensive and with relatively high accuracy, with a marginal error of 7-10%. It is considered a reliable method for estimating the rate of oxygen consumption (VO₂) and EE, however it may underestimate these parameters by 6% to 13% respectively. Furthermore, this prediction method may be considered sufficiently accurate to determine the average VO₂ in field use, but it does not allow precise estimation of VO₂.

**Objective-criterion measurements**

Distance: The criterion distance was measured by: a. Leica DISTO™ D810 laser range finder, which provides typical measuring accuracy ±1 mm and has a range up to 200 m, b. Calibrated measuring

The program has full and efficient functionality after downloading, with no need for additional software download being necessary. Furthermore it can record and upload exercise data to a computer database after been registered to an online system. It has the ability to track running and walking sessions separately and calculate energy expenditure based on these activities. Additionally, we made sure from its description that the application relied solely on GPS for tracking the user. Finally, Runkeeper has been identified as the application with the most applied behavior changing techniques (eight in number) in the market.

Garmin Forerunner 310XT: Garmin, software version 4.50 (Garmin Ltd., USA; https://buy.garmin.com/en-US/US/into-sports/running/forerunner-310XT/prod27335.html), is a GPS-enabled training and heart rate monitor for multisport athletes. Its physical dimensions are 54 × 56 × 19 mm, with display size 33 × 20 mm and lightweight, 72 grams. It is water resistant up to 50 meters, with a 20-hour battery life and a memory history of 1000 laps. Forerunner tracks time, distance, average and lap speed and pace, heart rate with a premium heart rate monitor, on land and estimated calorie burn.

The main method for EE estimation on Garmin fitness monitors uses the Firstbeat algorithm. The calculation takes into account the user’s inputted variables including gender, height, weight and fitness class. It then combines the data with heart rate information from the heart rate strap. More specifically, it evaluates the time between heartbeats (beat to beat) to determine estimated Metabolic Equivalent (MET), which in turn is used to determine actual work expenditure. This method is inexpensive and with relatively high accuracy, with a marginal error of 7-10%. It is considered a reliable method for estimating the rate of oxygen consumption (VO₂) and EE, however it may underestimate these parameters by 6% to 13% respectively. Furthermore, this prediction method may be considered sufficiently accurate to determine the average VO₂ in field use, but it does not allow precise estimation of VO₂.
wheel, and c. Google Maps Distance Calculator (http://www.daftlogic.com/projects-google-maps-distance-calculator.htm). The three-way estimated distance course was 3.58 km.

Energy Expenditure: Indirect calorimetry was utilized in this study as the criterion method for TEE. The accuracy of estimated TEE by the two monitors was compared to that measured breath by breath with Cosmed K4b2 (Cosmed S.r.l., Rome, Italy) portable metabolic analyzer. Cosmed allows measurement of oxygen consumption under free-living conditions providing valid and reliable results in the general population. Previous research, in which Cosmed was compared with the Douglas airbag method and the traditional metabolic analyzer Medgraphics D-Series, showed that Cosmed provided comparable energy expenditure estimates in stable, submaximal exercise intensities and the results of oxygen consumed, carbon dioxide eliminated and respiratory quotient ranged within acceptable limits of agreement. It comprises an analyzer unit and a facemask. Volume and gas calibrations (4% CO₂, 16% O₂) were performed before each trial by following manufacturer recommendations.

**Experimental procedures**

The study was conducted at an urban outdoor environment, on a wooded paved trail with no grade (0%) around an Athens central park (Figure 1). This is an area of 49 acres, which formerly was hosting the military camp ‘Goudi’ and currently is used as a recreational and sports park. Before the start of every session, both GPS monitors were activated and the GPS signal was ensured to be acceptable for adequate measurement. The participant’s personal data were entered manually in the smartphone application and the GPS monitor prior to the start of the test. The chest strap for measuring heart rate for the GPS unit as well as the calorimeter was placed around the chest of the participant, while Garmin was placed on the left wrist and the smartphone on the left arm. The calorimeter was placed on a harness over the subject’s shoulders and strapped around the subject’s chest and back. The face mask was placed covering the subject’s mouth and nose so as to not allow air to escape.

The 3.58 km test began at the quarter mile mark (point A, depicted on Figure 1) and was run or walked on an out and back course ending at the measured ending line (point B, depicted on Figure 1: The 3.58 km park route.)
The calorimeter needed a brief calibration before being started. This was conducted on the trail prior to the start of the 3.58 km course. When the calibration was complete, the 3 devices (Garmin, Runkeeper and calorimeter) were started simultaneously (± 2 sec) and the participant began to walk or run. One researcher started the calorimeter and the GPS unit, and the participant started the Runkeeper. The participant walked, ran at a comfortable pace, and self-selected speed. At the end of the 3.58 km course all measuring devices were stopped simultaneously (± 2 sec) by the same researcher who started them. The data from all devices were collected and recorded on a data sheet and, afterwards, data were transferred to the online websites of each monitor.

In total, the participant conducted 20 running and 20 walking sessions. The average time needed in order to complete the 3.58 km course running was 21 min 5 sec ± 55 sec and walking 38 min 22 sec ± 52 sec. The average heart rate, as measured by Garmin’s heart rate strap, was 155.65 ± 3.95 bpm for running and 99.60 ± 7.91 bpm for walking.

Each monitor uses different outcomes measures to summarize EE data. The Runkeeper provides estimates of TEE, while the Garmin reports estimates of activity EE. In order to provide comparable estimates in the EE results, it was necessary to add REE to the activity EE values for the Garmin, adding the measured REE obtained prior to the activity protocol to the estimated EE. This ensured that we had comparable outcome measures of TEE for both monitors. This procedure was implemented in previous studies and ensured that we had comparable outcome measures of TEE for both monitors.

### Statistical analysis

The statistical analysis was conducted with the use of the statistical package SPSS version 21.0 (IBM SPSS Corp., Armonk, NY, USA) and the significance level was set at p < 0.05. Data analysis was based on Bruton, Conway and Holgate recommendations. Before the main procedures, variables were screened for accuracy of data entry, missing values, potential outliers and distribution (skewness and kurtosis) for running and walking separately. No missing values were observed and the box plots, skewness and kurtosis analysis indicated that no extreme values existed and data were approximately normally distributed.

Data were analysed using descriptive (mean, standard deviation) and inferential statistics. A two-way repeated measures ANOVA (measurement method × type of activity) was performed to detect differences in the dependent variables between methods at two intensity levels. Post-hoc analyses using paired t-tests with the Bonferroni correction were conducted to examine specific differences between the two GPS monitors and the criterion methods. Mean absolute percent errors (MAPE) were also calculated to provide an indicator of overall measurement error (MAPE = |(monitor measurement - actual measurement) / actual measurement| × 100) and was used as an outcome measure. A smaller MAPE represents better accuracy, and less than 3% is considered acceptable for distance and 10% for TEE. This method is a more conservative estimate of error that reflects the true error in estimation and provides the most appropriate indicator of overall error. Further analyses included Bland-Altman plots, which were calculated to examine the level of agreement between each monitor and the criterion methods across all dependent variables. Limits of agreement were calculated as ± 2 SD from the overall mean bias between the dependent variables and each GPS monitor.

### Results

#### Distance

Table 1 provides descriptive statistics (means, SD) for all of the different monitors compared with the measured values for distance in the two conditions, walking and running. Separate 3 (2 GPS monitors + criterion) × 2 (walking or running) repeated measures ANOVA were conducted to examine differences in distance obtained from Garmin and Runkeeper. There was no significant interaction effect between the 3 measurement methods and the 2 types of activities [F(1,21) = 1.58, p = 0.23, η² = 0.08] and no significant main effect between walking and running [F(1,19) = 2.94, p = 0.10, η² = 0.13]. However there was a significant main effect between the 3 measurement methods

<table>
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<tr>
<th></th>
<th>Walking</th>
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<tr>
<td>SD</td>
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<td>0.00</td>
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<tr>
<td>Runkeeper</td>
<td>3.74</td>
<td>3.70</td>
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<tr>
<td>SD</td>
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<td>0.11</td>
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<td>Garmin</td>
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<td>3.58</td>
</tr>
<tr>
<td>SD</td>
<td>0.04</td>
<td>0.02</td>
</tr>
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</table>

Table 1: Descriptive statistics for Distance (km)
[F(1,21) = 64.44, p < 0.001, η² = 0.77]. Post-hoc within-subjects contrasts with Bonferroni correction revealed that Runkeeper significantly overestimated distance [F(1,19) = 73.75, p < 0.001, η² = 0.80], while Garmin provided almost the same results as the measured distance [F(1,19) = 0.57, p = 0.46, η² = 0.03].

The MAPE (computed as the average absolute value of the errors relative to the measured distance) observed for Garmin during the running condition was 0.30% and for the walking condition was 0.74%. A larger MAPE was observed for Runkeeper during running (3.28%) and walking (4.43%) (Figure 2).

Bland-Altman plot analysis showed the distribution of error and assisted with testing for proportional systematic bias in the estimates. The plots show the residuals of the various estimates on the y-axis (measured distance – monitor) relative to the mean of two methods (x-axis). The plots (see Figure 3) revealed the narrowest 95% limits of agreement for Garmin during running (mean bias = 0.00; 95% CI = −0.01 to 0.01 km) and Garmin during walking (mean bias = −0.01 km; 95% CI = −0.02 to 0.01 km), while higher values for Runkeeper during running (mean bias = −0.12 km; 95% CI = −0.17 to −0.07 km) and walking (mean bias = −0.16 km; 95% CI = −0.20 to −0.12 km) were observed. The slopes for the fitted lines were significant for all measurements; Runkeeper walking (slope = −1.93, p < 0.001), Runkeeper running (slope = −1.96, p < 0.001), Garmin walking (slope = −1.78, p < 0.001) and Garmin running (slope = −1.05, p < 0.001), which suggests significant patterns of proportional systematic bias for these monitors.

### TEE

Table 2 provides descriptive statistics (means, SD) for all of the different monitors compared with the

<table>
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<th>Devices</th>
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<th>SD walking</th>
<th>Mean running</th>
<th>SD running</th>
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<td>4.51</td>
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<td>23.74</td>
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<tr>
<td>Garmin</td>
<td>184.60</td>
<td>38.26</td>
<td>259.30</td>
<td>21.95</td>
</tr>
</tbody>
</table>

Table 2: Descriptive statistics for estimated TEE (kcal), with added measured REE for Garmin
measured values from the Cosmed in the two conditions, walking and running. Separate 3 (two GPS monitors + criterion) × 2 (walking or running) repeated measures ANOVA were conducted to examine differences in TEE obtained from Garmin and Runkeeper application. There was a significant interaction effect between the 3 measurement methods and the 2 types of activities \[F(2,38) = 16.10, p < 0.001, \eta^2 = 0.46\], a significant main effect between walking and running \[F(1,19) = 267.47, p < 0.001, \eta^2 = 0.93\] and a significant main effect between the 3 measurement methods \[F(2,38) = 128.74, p < 0.001, \eta^2 = 0.87\]. Post-hoc within-subjects contrasts with Bonferroni correction revealed that Runkeeper significantly overestimated TEE for both conditions \[F(1,19) = 44.72, p < 0.001, \eta^2 = 0.70\], while Garmin significantly underestimated TEE for both conditions \[F(1,19) = 15.14, p = 0.001, \eta^2 = 0.44\].

The MAPE (computed as the average absolute value of the errors relative to the measured distance) observed for Garmin during the running condition was 17.39% and for the walking condition was 17.32%. A smaller MAPE was found for Runkeeper during running (6.29%) and larger for walking (35.52%) (Figure 4).

Bland-Altman plot analysis showed the distribution of error and assisted with testing for proportional systematic bias in the estimates. The plots (see Figure 5) revealed the narrowest 95% limits of agreement for Garmin during walking (mean bias = 13.95 kcal; 95% CI = -4.45 to 32.35 kcal) and for Runkeeper during running (mean bias = -19.65 kcal; 95% CI = -31.10 to -8.20 kcal), while higher values for Garmin during running (mean bias = 54.75 kcal; 95% CI = 43.78 to 65.72 kcal) and Runkeeper during walking (mean bias = -70.25 kcal; 95% CI = -81.77 to -58.73 kcal) were observed. The slopes for all fitted lines were significant; Runkeeper walking (slope = -1.73, p < 0.001), Runkeeper running (slope = -1.75, p < 0.001), Garmin walking (slope = -1.94, p < 0.001) and Garmin running (slope = -2.03, p < 0.001), which suggests significant patterns of proportional systematic bias with these monitors.

**Discussion**

The present study aimed to examine the criterion validity of Garmin Forerunner 310XT GPS monitor and freeware Android application Runkeeper for distance and TEE estimation, during walking and running. To our knowledge, this is the first study that has tried to compare the accuracy of a
commercially available GPS and a freeware smartphone application under semi-structured settings. Even though Garmin Forerunner 310XT and Runkeeper have been validated for distance estimation, the algorithms that they use for EE prediction have never been validated previously. Furthermore, studies, which compare wearable activity monitors and smartphone PA applications are scarce in the international literature and only recently some similar attempts have been conducted.\(^3\)\(^2\),\(^3\)\(^3\)

A unique feature of this study was the naturalistic design that sought to replicate free-living over-ground movement. In contrast with traditional validation studies,\(^3\)\(^4\) the participants were given the option to select the intensity of walking and running they preferred during exercise. The results of the present study support the accuracy of these methods for distance recording, however TEE estimates had large errors.

A further advancement, as indicated by Bai et al.,\(^3\)\(^5\) was that both individual-level and group-level accuracy in distance and TEE estimation were evaluated. MAPE values and 95% limits of agreement provided a useful indicator of individual-level validity and reflected the error that individuals could expect if they were tracking their personal activity estimates. Overall distance error estimates were similar to results from previous evaluations of wearable monitors and smartphone applications,\(^1\)\(^2\),\(^1\)\(^4\) with overall MAPE values typically ranging from 0.30% to 4.43% for both Garmin and Runkeeper. Garmin had the smallest MAPE in both conditions and was the most precise estimate based on the 95% limits of agreement. Runkeeper had higher errors, overestimating distance; however, these errors of 3% to 4% are acceptable. Taking into account the small difference between the lower and upper limit of agreement of 0.10 km, this application may also be considered valid for distance counting.

On the other hand, TEE error estimates were larger, ranging from 6.29% (Runkeeper during running) to 35.52% (Runkeeper during walking). Garmin underestimated TEE, whereas Runkeeper overestimated it. The slopes for the fitted lines in the Bland-Altman plots were all significant due to at least two outliers in each graph, which might have significantly biased the outcomes of these analyses. Since no previous study has validated the EE of

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**Figure 4:** Mean absolute percent error (± SD) for TEE estimation.
GPS devices and applications, no direct comparable results could be made. Most previous studies, which examined the validity of accelerometer-based wearable activity trackers (Fitbit, Jawbone, Nike +, etc.) came to similar conclusions. Runkeeper during running gave a MAPE less than 10%, making it accurate in TEE under this condition, while MAPE during walking was significantly higher. Garmin was more stable during the two conditions, with an overall medium to large MAPE of 17%.

Mean bias and repeated measure ANOVA provided alternative indicators of group-level accuracy. The mean bias and repeated measure ANOVA results favored only Garmin for distance estimation, which provided group-level validity. Both the monitor and the application had low group-level accuracy for TEE estimation, differing significantly from the criterion measurement.

A novel finding is that Garmin’s TEE estimation was less accurate than expected. Garmin, in order to estimate TEE, uses the Firstbeat algorithm, which combines the data obtained from the heart rate strap. Previous research showed that this might underestimate EE by 6% to 13%. In this study, the error was 17%. The accuracy of EE predictions was not improved with the addition of heart rate measures to traditional GPS device, in accordance with previous research findings in accelerometer-based monitors. A possible explanation for the limited accuracy of EE prediction could be that the algorithm used could not accurately compute EE based on distance and heart rate, even though these initial raw data were very accurate. Technical assistance was sought from the company to ascertain specific information regarding the algorithm used to determine EE, however this information was not disclosed.

The present study had some limitations. Only one healthy participant performed all activities and thus we did not account for different potential confounding factors such as BMI, monitor placement, gender and age, which could potentially influence accuracy. In addition, we examined the accuracy during walking and running in outdoor terrain, so the results cannot be generalized in other settings. Lastly, these estimates were obtained for a specific distance and may not reflect accuracy for longer distances, in example for a marathon race.

**Conclusion**

In conclusion, the present study offers initial evidence for the validity of GPS technology of PA.
monitors and smartphone applications for measuring distance travelled during walking and running. However, estimates of EE were low, except for Runkeeper during running which provided acceptable error. This limits their use for monitoring energy balance, and therefore as a weight management tool. These results can assist consumers, researchers and health care providers to make evidence-based choice for a GPS PA monitor to measure distance during exercise. People who own Android smartphones have a valid alternative for distance estimation during walking and running with this freeware GPS application. Caution should be made when mixing the results from different activities into one estimated measure, due to probable cancelling of overestimation and underestimation from these activities, which may lead to an illusion of improved accuracy.

No competing interests
All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

References


ASSESSING ELECTRONIC CAPTURE OF PATIENT REPORTED OUTCOMES IN PROSTATE CANCER POPULATIONS

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Note: This research was presented as a poster at the 2013 Annual Meeting of the American Urologic Association under the title “Assessing the Feasibility of Electronic Data Collection for Men with Prostate Cancer”.

Background: In prostate cancer patients, the commonly-used patient-reported outcome tool to assess quality of life is the EPIC-CP (Expanded Prostate Cancer Index Composite for Clinical Practice).

Aims: To evaluate the feasibility of administering an electronic version of the EPIC-CP and determine preference in providing data by either electronic or pencil-and-paper instrument (PAPI) formats.

Methods: Patients with known prostate cancer who had previously completed a PAPI EPIC-CP were asked to choose between the traditional PAPI version of the EPIC-CP and an electronic version on an iPad. After completing the questionnaire, participants were given a satisfaction questionnaire regarding their experience. At the end of the study, physicians and office staff also completed a satisfaction questionnaire.

Results: Of the 225 men enrolled, 104 chose to complete the PAPI version and 121 chose the electronic version. Patients in the electronic group were younger (63.6 vs. 68.9 years) and rated themselves more computer savvy (7.6/10 vs. 4.8/10). The electronic questionnaire took longer to complete (5.4 vs. 4.0 minutes). Patients found both versions easy to use but reported higher satisfaction with the electronic version (8.5/10 vs. 7.8/10). Number of omitted questions was similar between groups. Physicians and office staff were highly satisfied with the electronic version but cited wireless coverage as a limiting factor.

Conclusion: Patients who chose the electronic EPIC-CP found it easy to use and were highly satisfied with their choice. Randomized-controlled trials are necessary to examine the effects of a computerized questionnaire on patients who would otherwise prefer the PAPI.
Introduction

With an estimated 220,800 cases diagnosed in 2015 alone, prostate cancer is by far the most commonly diagnosed malignancy in males in the United States. Prior to treatment and through continued management of prostate cancer patients, informed discussion of functional outcomes and quality-of-life (QOL) has become standard of care. Physician engagement with QOL issues is considered so fundamental to effective management that consistent assessment of QOL before and after primary therapy has been proposed as a national quality-of-care metric.

In this context, a number of patient-reported outcome (PRO) tools have been developed to help clinicians evaluate QOL rapidly and systematically. These tools, which traditionally employ the use of a paper-and-pencil instrument (PAPI), are filled out prior to the patient interview. Several studies have shown improved patient-physician communication and patient satisfaction using these PRO tools compared to traditional interviewing techniques alone.

In prostate cancer patients, the commonly-used PRO tool to assess QOL is the EPIC-CP (Expanded Prostate Cancer Index Composite for Clinical Practice).

Unfortunately, adoption of these tools in the clinical setting remains poor, especially outside of large academic centers. One proposed explanation for poor adoption is the time and effort required for patients and office staff to complete the PAPI questionnaires, calculate results, present these results to the clinician, and transfer all of the obtained data to the patient record. Electronic collection of patient data offers potential solutions to these issues by facilitating rapid analysis, advanced graphical presentation, and effortless incorporation into research databases. Previous studies in populations of cancer patients have shown that clinical use of such computerized PRO tools is feasible, valid, and generally well-received by patients and physicians. However, concerns regarding the implementation of computerized PRO tools in outpatient urology clinics remain, as no study has directly addressed patient preference in the adoption of electronic PRO tools over traditional PAPI assessment methods.

In our study, we evaluated the feasibility of implementing an electronic option for completing EPIC-CP during routine office visits in an outpatient setting with a prostate-cancer-specific population. We specifically assessed patient preference when given a choice between electronic and PAPI input methods and identified features, such as age and self-reported technical proficiency, that made patients more likely to select the electronic PRO tool. We also reported patient and physician satisfaction achieved with both survey delivery methods as well as benefits and challenges encountered during implementation of the electronic method.

Methods

We identified patients with prostate cancer who presented for follow-up to three outpatient urology clinics of a single institution. The dates of inclusion were August 2012 to May 2013. Patients were required to be proficient in English and between the ages of 18 and 89. To ensure familiarity with the questionnaire, eligible patients were required to have completed the EPIC-CP during a previous visit. During initial contact in the examination room, patients were approached by a research nurse coordinator for enrollment in the study. All participants were given a choice between the traditional PAPI EPIC-CP (Figure 1) and an electronic version. The patient’s medical record number, date of birth, and first name linked questionnaire responses to demographic information within the medical record. Response times were recorded based on time to complete all survey items and time until data were available in the research database. Surveys were considered incomplete and excluded from further analysis if the patient completed fewer than half of the questions. After completing the EPIC-CP, patients provided anonymous feedback on their experience through a separate satisfaction survey.

<table>
<thead>
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<th>Your assessment</th>
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<td>Urinary Incontinence Symptom Score = 4</td>
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<tr>
<td>Urinary Irritation/Obsstructive Symptom Score = 4</td>
</tr>
<tr>
<td>Bowel Symptom Score = 2</td>
</tr>
<tr>
<td>Sexual Functioning 1 = 3</td>
</tr>
<tr>
<td>Sexual Functioning 2 = 3</td>
</tr>
<tr>
<td>Vitality/Hormonal Symptom Score = 2</td>
</tr>
</tbody>
</table>

Overall Prostate Cancer Quality of Life Score = 17

Thank you for completing this survey. Please return the iPad to the nurse or physician.

Figure 1: Paper and Pencil Instrument Version of the EPIC-CP
Our primary outcomes were patient preferences for data entry methods, time to patient survey completion, number of questions omitted, number of men requiring assistance to complete the questionnaire, self-reported satisfaction, and ease of completion with the method chosen. These were evaluated using the Wilcoxon rank-sum tests and Student’s t-tests using the R software environment. Secondary outcomes included qualitative physician and office staff feedback regarding electronic survey implementation, time to entry of results into the research database, questions omitted, and staff error in calculating EPIC-CP section totals. Time to entry of results was compared between groups using a t-test; number of questions omitted was compared using both t-tests and chi-squared tests.

EPIC-CP
The Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) is a validated questionnaire completed by the patient providing health-related quality-of-life (HRQOL) measures regarding prostate cancer and its treatment. It consists of three multiple choice questions in each of five domains (urinary incontinence, urinary irritative/obstructive, bowel function, sexual function, and vitality/hormonal) plus a summary item regarding urinary bother for a total of 16 items. Patients are asked to provide responses based on their health over the preceding four weeks. All items have four to five possible responses ranging from least to most symptomatic, and all responses except the summary urinary bother item are assigned an integer score ranging from 0 (best) to 4 (worst). Overall scores may be calculated for each domain by adding the scores of the component questions, resulting in possible domain scores ranging from 0 (best) to 12 (worst). Similarly, an overall EPIC-CP score may be calculated by adding scores from the five domains with the response of the summary urinary bother item reported separately.

Paper and Pencil Instrument (PAPI)
The PAPI EPIC-CP used in this study has been fully described elsewhere. Briefly, it consisted of a one-page, single-sided presentation of the EPIC-CP questionnaire. The summary urinary bother item was presented first, followed by the scored items, which were grouped by domain. Each item is visually grouped with a list of possible responses, which patients select by circling or checking corresponding boxes. Corresponding numerical scores were provided next to each response, and blank spaces were left at the end of each domain and at the end of the overall questionnaire with instructions for nursing staff to calculate and fill in the appropriate totals.

PAPI questionnaires were completed by patients in the examining room prior to contact with the physician and response times were measured with a stopwatch. Completed PAPI questionnaires were returned to administrative staff. EPIC-CP section and total scores were calculated and written on the completed PAPI EPIC-CP questionnaires, which were subsequently scanned for the patient record and presented to the physician with the patient’s standard chart. Once scanned, the PAPI EPIC-CP forms were collected by a research coordinator and abstracted into the database in batches.

Electronic Questionnaire
The electronic version was developed at WUSM using LimeSurvey, a free and open-source survey application. Electronic questionnaires were administered on a tablet computer (iPad [Apple, Cupertino, CA]) via a secure wireless connection. Questions were presented one at a time in landscape view only, although the size of the text could be modified using pinch-to-zoom gestures. Upon clicking a saved icon on the iPad, an initial screen appeared for the research coordinator, who then completed five items: patient first name (free-text), medical record number (eight-digit numeric entry), patient date of birth (date format), treating physician (radio-button with urology physicians’ names), and survey completion method (single selection item of electronic, paper, or refused). After completing these, the research coordinator would hand the iPad to the participant, who would see a text-display with the survey title and instructions to select ‘Next’ to begin the survey. Upon completion of the survey, EPIC-CP section totals were automatically calculated, which appeared to the participant and research coordinator on the final screen (Figure 1). All information was available to the clinician via a separate web interface, and data from patients who elected to participate in the study were automatically logged in the research database.

Satisfaction Surveys
Upon completion of the EPIC-CP questionnaire, participants were asked to complete an anonymous PAPI questionnaire examining their satisfaction
with the questionnaire format, their comfort in completing the questionnaire, and their self-assessed computer literacy. Scores were expressed on a 1-10 scale, with 10 indicating high satisfaction or proficiency. At the conclusion of the study, physicians and office staff were asked to complete a brief questionnaire regarding their experience with the study and both input methods.

Ethics Statement
The protocol for this research project was approved by the Institutional Review Board (201208089) and the Protocol Review Monitoring Committee (12-X135) of our institution. Our study conforms to the provisions of the Declaration of Helsinki (as revised in Tokyo 2008). Informed consent was obtained from all individual participants included in the study.

Results
Two hundred twenty-five men were enrolled in the study. One hundred twenty-one (54%) chose the electronic version of the EPIC-CP questionnaire, and 104 (46%) chose the PAPI version. Three patients who chose the electronic version had incomplete surveys due to technical issues, such as dropped internet access; these were excluded from further analysis. Patients who chose the electronic version were significantly younger than those who chose the PAPI version (mean age 63.6 vs. 68.9, respectively, \( p < 0.0001 \), Table 1). Those who chose the electronic questionnaire also rated their computer skills more highly (mean 7.6 vs 4.8, respectively, \( p < 0.0001 \)). Additionally, patients who completed the electronic questionnaire were less likely have a relative, friend, or office staff member complete the questionnaire for them (total 1 vs. 8 patients, respectively, \( p = 0.0354 \)). The overall score for the PAPI questionnaire was tallied by hand 34 times, and 13 of these were inaccurate for an error rate of 38.2%. Automatic calculation of section totals for the electronic survey gave accurate results.

Participants took longer to complete the electronic survey (mean 5.4 vs. 4.0 minutes, respectively, \( p = 0.0025 \)). However, responses from the electronic questionnaire were uploaded to the research database instantaneously compared to the mean 9.6 days taken to input the PAPI responses (95% CI 8.1–11.1 days). While patients found both formats easy to use (electronic mean 9.1 vs. PAPI mean 8.8, \( p = 0.0612 \)), satisfaction was significantly higher in patients who completed the electronic version (mean 8.5 vs. 7.8, respectively, \( p = 0.0148 \)).

Overall, there was no significant difference between the input methods and the number of questions omitted (electronic mean 0.38 vs. PAPI mean 0.27 questions skipped, \( p = 0.382 \)). For questions 7 to 9, which deal with sexual functioning, there was no significant difference in questions skipped (electronic mean 0.09 vs. PAPI mean 0.20 questions skipped, \( p = 0.14 \)). We did find that patients who took the electronic version may have been more likely to have skipped one item related to sexual functioning while patients completing the PAPI version skipped two or three items, but this did not reach statistical significance (Table 2).

There were 7 respondents for the separate satisfaction survey for physicians and office staff to take after the study. All considered both the electronic and PAPI versions easy to use (mean 9.2 vs 8.4, respectively, \( p = 0.62 \)). The most frequent complaint regarding the electronic version was that the office wireless internet coverage was insufficient (n = 2).

Discussion
In this study, we describe the introduction of an electronic version of the EPIC-CP questionnaire for men being followed for prostate cancer in

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<th>P-value</th>
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<td>104</td>
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<td>Age (years)</td>
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<td>68.9 ± 8.6</td>
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<td>Time to Complete</td>
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<tr>
<td>Time Until Results in Database (days)</td>
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<tr>
<td></td>
<td>(95% CI: 8.1–11.1)</td>
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</tbody>
</table>

Table 1: Number of patients, patient age, completion time, and time until EPIC-CP results in research database separated by questionnaire version.

<table>
<thead>
<tr>
<th>Questions Skipped</th>
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<th>PAPI</th>
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<tbody>
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<td>0</td>
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<td>94</td>
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Table 2: Number of questions related to sexual functioning skipped by patients separated by questionnaire version.
**Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP)**

**Prostate Cancer Quality of Life (QOL)**

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Date of Birth:</th>
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<tbody>
<tr>
<td>Physician:</td>
<td>Date of Visit:</td>
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</table>

**Patients:** Please answer the following questions by circling the appropriate answer. All questions are about your health and symptoms in the **LAST FOUR WEEKS.**

**Select ONE answer for each question:**

1. **Overall, how much of a problem has your urinary function been for you?**
   - No Problem
   - Very small problem
   - Small problem
   - Moderate problem
   - Big problem

2. **Which of the following best describes your urinary control?**
   - Total control
   - Occasional dribbling
   - Frequent dribbling
   - No urinary control

3. **How many pads or adult diapers per day have you been using for urinary leakage?**
   - None
   - One pad per day
   - Two pads per day
   - Three or more pads

4. **How big a problem, if any, has urinary dripping or leakage been for you?**
   - No problem
   - Very small problem
   - Small problem
   - Moderate problem
   - Big problem

**CLINICIANS: Add the answers from questions 2-4 to calculate the Urinary Incontinence Symptom Score (out of 12)**

5. **How big a problem, if any, has each of the following been for you?**
   - Pain or burning with urination
   - Weak urine stream/incomplete bladder emptying
   - Need to urinate frequently

**CLINICIANS: Add the answers from questions 5a-5c to calculate the Urinary Irritation/OBSTuctive Symptom Score (out of 12)**

6. **How big a problem, if any, has each of the following been for you?**
   - Rectal pain or urgency of bowel movements
   - Increased frequency of your bowel movements
   - Overall problems with your bowel movements

**CLINICIANS: Add the answers from questions 6a-6c to calculate the Bowel Symptom Score (out of 12)**

7. **How do you rate your ability to reach orgasm (climax)?**
   - Very good
   - Good
   - Fair
   - Poor
   - Very poor to none

8. **How would you describe the usual quality of your erections?**
   - Firm enough for intercourse
   - Firm enough for masturbation and foreplay
   - Not firm enough for any sexual activity
   - None at all

9. **Overall, how much of a problem has your sexual function or lack of sexual function been for you?**
   - No problem
   - Very small problem
   - Small problem
   - Moderate problem
   - Big problem

10. **How big a problem, if any, has each of the following been for you?**
    - Hot flashes or breast tenderness/enlargement
    - Feeling depressed
    - Lack of energy

**CLINICIANS: Add the answers from questions 10a-10c to calculate the Vitality/Hormonal Symptom Score (out of 12)**

**CLINICIANS: Add the five domain summary scores to calculate the Overall Prostate Cancer QOL Score (out of 60)**

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**Figure 2:** iPad Summary Screen
outpatient urology clinics. Approximately half of the men enrolled chose the electronic questionnaire. As expected, those who chose the electronic version were slightly younger and perceived themselves as more skilled with computer technology. These men found the electronic questionnaire easy to use, completed it quickly, and were highly satisfied with their choice. Our study also suggests that patients who express a preference for electronic input methods are capable of using them and ultimately satisfied with their choices regardless of their age or self-reported technical proficiency. Our data demonstrates the feasibility of introducing a successful electronic data collection method for the EPIC-CP questionnaire in urology offices. This is consistent with the literature in other fields of medicine, which shows that electronic questionnaires yield increased user satisfaction and comparable data collection. Examples include questionnaires on pelvic floor dysfunction, general health, pain, and disease-specific quality of life.20–26

Physicians and office staff were also highly satisfied with the electronic surveys. This is especially notable given that accessing the results of the questionnaire on a website separate from the normal medical record required a deviation from the normal workflow. The fact that questionnaire and assessment results could be quickly displayed on a tablet computer and then carried into the examining room was cited as a significant improvement over the presentation of other pieces of clinical data in the EMR, which must be accessed at static workstations in our clinic. The deviation in workflow for office staff may have been offset by the automatic calculation of EPIC-CP section totals in the electronic survey.

The advantage of accurate calculations of section totals merits special attention, as inaccurate section total calculations represents a clear breakdown in communication, leading clinicians to make decisions based on faulty information. However, proper functioning of the electronic questionnaire was contingent on adequate wireless coverage. Because wireless networks at many outpatient clinics are not currently treated as mission-critical resources like the wired connection to the electronic EMR, sites adopting electronic PRO tool options should strongly consider ensuring the availability of a back-up entry method or asynchronous survey collection, so the data will be uploaded as soon as an internet connection is again available.

Those who completed the electronic survey were significantly more satisfied with their experience than those who filled out the PAPI form. Our results may be biased by self-selection by those who are comfortable with computer technology. It also may be reflective of a correlation between affinity for technology and another confounder that could make these patients more satisfied, such as appreciation of quantitative PRO questionnaires themselves. Similar statements can be made about the increased speed and decreased frequency of omitting questions regarding sexual health demonstrated by those choosing the electronic questionnaire. We have begun work on a randomized-controlled trial to examine the effects of a computerized questionnaire on patients who would have otherwise preferred the PAPI.

Conclusions

Both PAPI and electronic EPIC-CP questionnaires were associated with high levels of patient satisfaction regardless of age and self-reported computer skills. The electronic questionnaire may help address potential barriers to adoption of PRO tools. Qualitative assessment by staff highlighted the electronic system’s advantages in data entry and access; however, these were dependent on local wireless infrastructure.

Conflicts of Interest

Financial support was provided by the Midwest Stone Institute. Otherwise, all authors declare no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years and no other relationships or activities that could appear to have influenced the submitted work.

Acknowledgements

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References


ADOLESCENTS’ PERCEPTIONS ON SMARTPHONE APPLICATIONS (APPS) FOR HEALTH MANAGEMENT

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Background: Despite the growth in smartphone use among adolescents, few mobile health applications (apps) – apps designed to support general health management – are designed specifically with this population in mind.

Aims: To explore adolescents’ perceptions regarding the use of smartphone apps for health management using qualitative methods.

Methods: Inductive thematic analysis of 20 individual semi-structured interviews exploring 1) experience with health-related smartphone apps, 2) perceived barriers to, and 3) facilitators to app use.

Results: Of the 20 participants, 55% were male, 40% Latino, and 50% Black, with mean age of 15.1 years (SD = 1.7). Forty percent had used health apps for tasks such as managing a medical condition or achieving a fitness goal. The overall “look and feel” of apps impacted adoption. Barriers to use included low awareness, competing priorities, and negative impressions, including the perception that health apps were designed primarily for adults. Facilitators to use included general features of the app (interface design, multimedia content, customizability, and rewards) and social influence.

Conclusion: The experiences, attitudes, and preferences regarding health apps uncovered from this study may inform future mobile health interventions targeting adolescents.

Introduction

Mobile technology usage has grown exponentially since the introduction of smartphones, fueling an explosive proliferation of companion applications (apps).1 Smartphone penetration is high among younger demographic groups, with 73% of adolescents aged 13–17 years in the United States having access to a smartphone and 58% having downloaded apps.2,3 Mobile health interventions using smartphones are increasingly deployed in clinical settings to augment patient education, communication, monitoring, and chronic disease management,4 and there are currently thousands of commercial smartphone “health apps”— apps designed to support health management.

The advantage of smartphone apps over traditional approaches to health management, particularly among the younger, tech-savvy generation, is that they provide an interactive, social, and personalized...
platform to help users modify their own behaviors with minimal professional contact. Since devices accompany users at almost all times of day, users can seamlessly integrate health monitoring into their daily schedules. Because apps can be widely disseminated across socio-demographic groups, they may address barriers that have historically impeded health change among teens, such as time constraints, convenience, social factors, motivation, and access to care, thus filling gaps in addressing disadvantage or diversity. Apps can also tackle various aspects of health, including diet, exercise and various modes of behavior change through motivation via role models (stages of change) and addiction theories. An individual can therefore find an app that applies to their specific health needs.

Despite a growing body of research on health-related smartphone applications, there is a gap in understanding how this technology pertains to adolescents. The majority of studies to date has targeted adult populations, and as a result, may not be relevant to adolescents, who could have distinct technology usage patterns. In addition, research has focused primarily on efficacy under ideal “laboratory” situations rather than effectiveness in real-world settings, and may overestimate users’ “natural tendency” to adopt smartphone apps. Even under optimal conditions, studies have demonstrated low user engagement and poor adherence. A fundamental flaw underlying poor uptake in health app interventions may rest at the core of the design process; a systematic review discovered that only 22.5% of studies involved target users or relevant stakeholders prior to the development of apps. Further studies that have attempted to understand adolescent usage patterns of mobile apps for health have found that on a broader scale, it is important to understand how social media can affect adoption of health apps, emphasizing the need for clearer understanding of the factors that influence long term uptake.

Eliciting adolescents’ motivations for using an app is important because that determines how to tailor an app to the user to promote continued usage. Since few studies have focused on teenagers’ pre-existing attitudes towards health apps, we collected qualitative data to better inform app developers and healthcare professionals about adolescents’ perspectives and biases towards using smartphone apps for health management in general. Specifically, we wanted to learn about 1) teens’ experiences with health apps, 2) barriers to, and 3) facilitators to health app use. Gained insight may inform future strategies involving this promising technology.

Methods

Setting

This study was performed during well-care visits at the Boston Children’s Hospital Primary Care Center at Longwood (PCC-Longwood) from February to April 2015. The PCC-Longwood is an urban academic practice that annually serves 15,000 children predominantly from diverse Boston neighborhoods; 67% are insured through Medicaid, the US health insurance program for low-income individuals and those with disabilities.

Participants

Participants were English-speaking adolescents between the ages of 13 and 18 years who owned a smartphone with Internet access, recruited by convenience sampling. Researchers identified potential candidates from the electronic medical record and invited them to participate in the study during a break in their appointment.

Interviews

Two researchers obtained written informed consent from parents and assent from adolescents, and then conducted individual semi-structured interviews using a guide developed by the research team (Table 1). The interview guide included a list of questions and topics to be covered during each session; however, conversations were allowed to stray from the guide if appropriate and relevant. The use of the semi-structured guide ensured that collected data was reliable and comparable between sessions.

Survey question domains included: 1) prior experience using health apps, 2) perceived barriers to, and 3) facilitators to adopting smart phone apps for health management. To elicit responses to questions in each domain, the research assistants began with general open-ended questions (“What do you generally use your cell phone for?”) then followed with open-ended probing questions (“how, when, where, why?”) or specific prompts to encourage participants to provide additional clarifying details when needed. Interviews lasted 10–20 minutes. There was no remuneration for the study, but participants and parents were thanked for their time. Health apps were broadly defined as mobile applications that were aimed towards health promotion, including
apps for fitness, diet (nutrition recommendations, calorie counting), behavioral regulation, or carbohydrate counting for diabetes. Adolescents were invited to share their experiences about the various types of apps they had used, thus contributing to a broad inclusion of both health and fitness apps.

The Boston Children’s Hospital Institutional Review Board approved the study procedures.

Data Analysis

All interviews were audio recorded and transcribed verbatim. De-identified data was analyzed using inductive thematic analysis.12 After generating initial codes, in which text segments were attached with labels in order to sort out the data in relation to the research questions; emerging themes or patterns were determined, first independently by two researchers, then collaboratively to establish consistency and validity of findings. As a group, themes were then refined and reviewed to ensure they formed coherent patterns and connected back to the data set. This process was repeated until both researchers were satisfied with the thematic map. Throughout the entire data analysis, any discrepancies were consulted with a third researcher.

Results

Participant Characteristics

Twenty-four candidates were approached, but two were not interested and two did not own a smartphone. The mean age of the 20 study participants was 15.1 years (SD 1.7 years) and 11 were males (55%). Race/ethnicity was divided among 8 Hispanics/Latinos (40%), 10 Blacks/African Americans (50%), 1 White/Caucasian (5%), and 1 Native Hawaiian/Pacific Islander (5%), reflecting the population served by the hospital.

Overview

The group of participants as a whole had some familiarity with health-related smartphone apps. Individually, they identified considerable opportunities, barriers, and facilitators related to health app use. These findings were grouped into three major domains—experiences with health apps, barriers to, and facilitators to using health apps—and recurrent concepts were further classified into themes (Table 2).

Experiences with health apps

Eight participants (40%) had previously used health apps, with six reporting consistent use for at least 1 month. App users reported utilizing them to manage disease, reach a desired fitness goal, or improve health behaviors, such as physical activity or mindful eating. As a matter of fact, one patient with diabetes mellitus and another with attention deficit hyperactivity disorder (ADHD) considered health apps to be essential, medically necessary tools for tracking health conditions. The teen with diabetes mellitus, for example, used an app to...
calculate the amount of carbohydrates he consumed with each meal, while the participant with ADHD used an app to practice relaxation techniques. Several health conscious users felt that apps aided their inner drive to achieve a certain fitness level. Other individuals found apps to be helpful reminders to stay on track with their health goals. "Everyone has those days when you don’t want to do things. I think baby steps is what it takes, you know, to reach that, you know, just to get used to doing it consistently, and I think that’s when an app can help."

Out of the eight participants who had tried a health app, two experimented with the app only once before abandoning it. One felt that the app did not enhance her running experience, while the other no longer thought the app relevant to her.

**Barriers to using health apps**

*Lack of Awareness*

Among the most frequently cited barriers to smartphone health app use was lack of awareness. Three participants had never heard of health apps, and out of the 17 participants who had heard of them, more than half were unaware of their functionalities. Even among owners of phones that came preloaded with a health app, few had opened them. An iPhone owner explained that there were not enough advertisements, promotions, or hype around health apps to stimulate his interest in this type of service. "It [Apple’s Health app] is automatically on my phone, and it was never introduced when I set up my phone... I think if there was more exposure to it, more assistance with it, I think that would encourage users to click on it and actually use it."

**Competing Priorities**

Many adolescents viewed health management as a low priority relative to other interests. One participant attributed this to "all the distractions in the world, on TV, just if we’re just on social media, we get distracted on people’s posts, people’s pictures, people’s comments, celebrities, reality TV." Many participants reported that they would rather play games, surf the web, or go on social media than monitor their health on a smartphone. Even in the app store, their attention is drawn towards entertainment apps. "I mean, cuz on the app store, all you really look for are music, games, cuz like, I mean, I have a bunch of games there, so that’s really all I look at, unless you’re like in something health, they’re not going to look at anything else."

Paradoxically, a group of high school athletes interested in physical well-being felt that tracking physical activity on an app was extraneous because they were already exercising. "What I don’t understand is why would you need an app that tell you..."

<table>
<thead>
<tr>
<th>Domain</th>
<th>Theme</th>
<th>Description</th>
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<tbody>
<tr>
<td>Prior Experiences</td>
<td>1. Medical necessity</td>
<td>Common reasons to download and use health apps were management of a medical condition, reaching a certain fitness goal, and improving health behaviors.</td>
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<tr>
<td></td>
<td>2. Inner drive</td>
<td>Only a minority of adolescents used health apps because most were unaware of the specific features and capabilities of this technology.</td>
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<tr>
<td>Barriers to use</td>
<td>1. Lack of awareness</td>
<td>There was a perception that health apps were meant only for adults as well as a social stigma attached to apps that caused some adolescents to dismiss this technology. Because of competing interests, adolescents tend not to use their smartphones for health.</td>
</tr>
<tr>
<td></td>
<td>2. Competing Priorities</td>
<td>Positive predictors for health app use included personalized data tracking and coaching, combination of different media forms (images, music, video), and rewards to sustain interest. Adolescents were more likely to pick up health apps if they knew others who used them.</td>
</tr>
<tr>
<td></td>
<td>3. Negative perceptions</td>
<td>Social networking sites were seen as a promising platform to share accomplishments and foster collaboration and support, but also a potential avenue for cyber-bullying.</td>
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<tr>
<td>Facilitators to use</td>
<td>1. Features: Interface design, multimedia content, customization, rewards</td>
<td>Positive predictors for health app use included personalized data tracking and coaching, combination of different media forms (images, music, video), and rewards to sustain interest. Adolescents were more likely to pick up health apps if they knew others who used them.</td>
</tr>
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<td></td>
<td>2. Social influence</td>
<td>Social networking sites were seen as a promising platform to share accomplishments and foster collaboration and support, but also a potential avenue for cyber-bullying.</td>
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Table 2: Key themes clustered within domains that were identified through inductive thematic analysis of 20 adolescent interviews
you’re on a diet if you know that you’re on a diet. Why would you look at the phone every day if you know what you have to do.” These individuals seemed to perceive health apps as a last resort for staying healthy. “If I was to stop playing basketball, then I have no other choice but to work out on the phone.”

Negative Perception of Health Apps
Several participants described a social stigma surrounding the use of health apps. One participant thought that using health apps could make teenagers unpopular among their peers. “Some don’t do it cuz they feel other people won’t like it. Some people don’t think it’s cool. That’s why they don’t use it. They’re afraid if they use it, someone might make fun of them.” Strategies suggested by participants to combat these negative perceptions included using celebrity endorsements and marketing through social media.

A commonly held belief was that health apps were meant only for adults. “Well, like more so adults that like to work out a lot they may use this app to help them.” Negative comments about health apps included “it wasn’t physically appealing” and “this thing, like is boring and dull for a teenager’s use [and] is really complex. One participant was dissuaded by how difficult it was to navigate the app. “I looked at it and one, I didn’t know how to use it so I just didn’t bother with it.”

Facilitators to Using Health Apps
Features of Apps
Interface Design and Multimedia Content
Several participants were enticed by an app because of its “look and feel.” “Well it looks really, I dunno, it looks really cool. It looks pretty modern, sleek, so that’s why I like using it.” Apps that were simple to use and visually appealing with vibrant colors, bold graphics, animation, and videos piqued some health app users’ initial interest. Various participants recommended adding music features and game components to the app, such as giving prizes or points for achieving certain tasks, creating exercise competitions between friends, and incorporating virtual adventures that require exercise.

Customization
Apps that enabled customization, such as goal setting, personal data tracking, and tailored messaging, were universally deemed important by participants. An adolescent who used an app with a step counting feature said it motivated him to work harder each day. “I actually want to exercise more. Like before, I’ll stick around and play video games. Now, I want to get my steps more than yesterday or the day before. I want to progress more.” Others mentioned that real-time feedback on biometric data, like heart rate and calories expended, encouraged them to increase physical activity in their day. “I like that it like could tell you what is going on with your heart. . . It’s a cool app because it encourages me to do exercise more.”

Some participants wanted calorie counting so they would know how many calories they were consuming and burning so that they could adjust their portion sizes, diets, and physical activity levels. However, not everyone felt that calorie counting was a desirable feature because weight was a sensitive issue that adolescents might not be ready to tackle on a smartphone app. “I think like telling you your weight, that’s something. Don’t do that. Don’t do that. I think that’s the biggest one, the weight thing.” Such strong emphasis on weight could lead to stigma and weight shaming from fellow adolescents, as noted by a participant, “I don’t think they should post online how many calories they burned or something since some of that can get bad cuz then it could start cyber-bullying online.”

Several participants felt that a “virtual health coach” app would push them towards achieving their personal health goals. For example, participants wanted apps to give them diet and exercise recommendations. “Um, like just letting me know how much I can do. Just lose weight, how fast I can get it done. How much time it would take to get to the goal. Uh like certain number of calories per week.”

Rewards
Intrinsic motivation appeared to be an important factor among teen app users. One adopter said he used health apps to achieve a desired, pre-set goal. “Cuz I would wanna know everything I can do possible, so give me all that you can tell me how to help me reach my goal, cuz that’s where I wanna get.” For several others, this intrinsic motivation appeared rooted in a desire to keep a medical condition under control. The participant who had ADHD, for example, used an app to guide him through breathing and relaxation techniques whenever he felt agitated. If he did not use the app, he “got kinda cranky.”
To help engage those with lower intrinsic motivation, participants suggested incorporating tangible rewards such as gift certificates, food baskets, or workout equipment, to externally motivate the completion of targeted health behaviors. Others suggested rewards in the form of app store credit or virtual points that could lead to actual, physical prizes to reinforce the completion of positive health behaviors.

Social Influence
Participants reported that seeing or hearing other individuals use health apps would influence their own decision to adopt them. Celebrity endorsements could garner interest among teens, which one participant noted, “I know kids are influenced if a lot of people using it are like famous or popular.” For example, “if Kobe Bryant or Lebron James were using it, I think that would encourage more teenagers to use it.” Physicians could also play an influential role. Some participants reported they would start using a health app if their doctor recommended it. Certainly, peer pressure could affect teens’ decisions to pick up new habits, like using health apps. One participant explained how he convinced his baseball teammates to start using a health app, and this subsequently led to a fun competition between them during practice. “I actually got four friends download it the other day. Yeah, cuz it tells you how many steps, we were on a run in baseball, so like, look, I took more steps than you.”

Social media sites, like Facebook and Twitter, were also viewed as practical platforms to bring awareness to apps. “You have to get something that’s going to catch a kid’s eye and then it will be word of mouth. One kid loves it, they tell their friends about it. Then that’s when it becomes on social media.” Social media can also showcase individual achievements, which in turn might generate healthy competition and collaboration among peers. Two participants found that posting their fitness accomplishments on social media instilled a sense of personal accomplishment and motivation to keep exercising. Additionally, social media could be used to share health information with others as well as promote unique features of the apps. “I think that if, let’s say you achieve a task, achieve walking a mile, if you can share that with your page or your friends online, that can encourage others to use the app. It could encourage them to want to do something more active and eat healthier =.” However, despite its various suggested benefits, some participants feared that linking social media to health apps could contribute to cyber-bullying or promote excessive exercise.

Discussion
In this qualitative study, we examine prevailing beliefs regarding the use of smartphone applications for managing health among adolescent patients seen for routine care at a large urban pediatrics clinic in Boston. Our findings suggest that, despite the rapid proliferation of mobile health technology, uptake of smartphone health apps remains low among youth. Nearly two-thirds of teens in our study had never used a health app, and one-fourth of them had not even heard of health apps. Our results are consistent with recent statistics showing that only 21% of teenage smartphone users aged 13 to 18 years downloaded mobile health apps and of those, only 8% used them regularly.13

In our study, we found that lack of awareness, even among owners of sophisticated smartphones, was an important deterrent to using health apps. Additional adoption barriers included the widely held perceptions that health apps were “boring,” “meant for adults,” or “a last resort to staying healthy.” Participants were particularly concerned about the opinions of their peers and worried that they would be branded as “losers” for using health apps. Competing priorities were a further obstacle to sustained health app use. Youth said they had better uses for their time and preferred using their phone to text friends, play games, or watch videos. However, adolescents diagnosed with chronic medical problems presented a notable counterpoint and perceived health apps as indispensable tools to help them manage their conditions.

We also learned that engaging app features, such as user-friendly interfaces and multimedia content, were important facilitators of health app adoption among teens, while personalized tracking and tangible rewards sustained usage to reinforce desired behaviors. Social influence was another major facilitator of health app adoption and use among adolescents. Adolescents reported being more likely to try a particular health app if a friend, doctor, celebrity, or networks on social media recommended it to them.

In consideration of these findings, we synthesized potential strategies to promote the use of health apps among adolescents: 1) incorporate features that appeal to adolescents and 2) use social media to build awareness and a community of users.
Incorporating features that appeal to adolescents

In a digital age when teenagers are spending substantial amounts of time using media—texting, social-networking, watching videos, and gaming—health apps need to be fun and entertaining for teenagers to use them.

“Gamification” or the integration of game elements into apps was embraced by many of our respondents as a strategy to counteract the negative perceptions surrounding health apps. With nearly three-quarters of teens playing games online or on their phones, the integration of game elements, such as virtual badges, leaderboards, points, and challenges, into health apps could draw interest from a wide adolescent audience. Furthermore, research already suggests that electronic games can improve physical activity, health education, and disease self-management outcomes.

Beyond entertainment, games may also promote intrinsic motivation. According to self-determination theory, people are naturally driven to pursue new experiences for personal growth and fulfillment. Since gamification can integrate new challenges or health tasks into apps, users’ innate desire to conquer them could be harnessed. Tangible, extrinsic rewards in the form of gift cards and app store credit, as suggested by our participants, could also be linked to games, which studies have shown, may help attain health outcomes that would not ordinarily be achieved with intrinsic motivation alone.

As our study further suggests, the “look and feel” of an app can pique teens’ initial interest. Colorful images, animation, and popular culture references may increase appeal to teens. Multimedia content with videos (e.g. instructional videos for exercise or cooking) and music (e.g. music that syncs to workouts, platform for free music) could keep apps entertaining.

Personalized features, such as having a “virtual trainer” that provides individualized exercises, diets, and advice could inspire healthier habits as it caters to users’ specific goals and lifestyle. While counting calories may be desirable by some users, a strict focus on body weight could have detrimental consequences. Studies show that the stigma, excessive exercise, and teasing resulting from weight preoccupation can contribute to depressive symptoms. Additionally, a strong emphasis on weight may propel teenagers who are weight-conscious to attempt extraneous exercise or dieting with potential serious risks. Therefore, we recommend that health apps steer away from a narrow weight-focus and instead target lifestyle behaviors conducive to optimal health.

In summary, health apps should be entertaining, visually appealing, user-friendly, and customizable to suit personal interests and preferences. Because teenagers are at a pivotal time of development as they begin making their own health decisions, apps that enable goal setting and health tracking could provide teens with more autonomy over their health.

Using social media to build awareness and a community of users

Given that lack of awareness appears to be a primary reason why few teens use health apps, social media could bring widespread awareness and interest to this novel technology. According to a recent poll, 41% of consumers said social media would affect their choice of a specific doctor, hospital, or medical facility. With 76% of teens on social media, platforms like Facebook and Twitter have potential to reach a broad adolescent audience while addressing misperceptions about health apps.

Social media also provides a vehicle to integrate marketing strategies, such as audience segmentation, to target populations that are traditionally not reached by the medical system. Since teens prefer visuals, music, comedy, and popular culture; marketing health apps with these interests in mind could potentially entice naïve users and reshape any preconceived attitudes about apps.

Connecting social media with health apps can also foster a sense of community among users. A prior study illustrated how creation of a mobile virtual community in overweight individuals allowed them to gain increased social support because they could seek out one another for advice and encouragement. Social media can also provide easier platforms to share information and words of encouragement, which our interviews noted. Further evidence shows that peer driven information exchange can create empowered patients who learn how to manage their health from others sharing the same conditions. The fitness tracker, Fitbit, is a prime example of how social media conversations can breed success. According to a report by Kantar
Media, one of the primary reasons for Fitbit’s unmatched success in the wearable fitness device market is its high volume of users who share their achievements on Twitter.27

**Strengths and Limitations**

A major strength of this study was its qualitative research approach. Conducting individual interviews allowed participants to openly share and elaborate their thoughts. As a result, we were able to capture insightful and nuanced perspectives from a diverse adolescent population representative of the demographic served by many safety-net health care institutions. Although a reasonable number of interviews were conducted, two-thirds of participants had not had meaningful experiences with a health app; as a result, these discussions were limited to hypothetical situations, so their input may not accurately portray how apps are actually used. In the future, trigger materials or prototypical apps can be provided to prompt further discussion. Future studies can also capture a broader adolescent population to gain unique perspectives towards health apps in relation to weight and health status.

**Conclusion**

Over the past several years, there has been an explosion in mobile apps for health, yet the majority of apps are not tailored to the younger, tech-focused generation. The insights gathered in this study can aid diverse stakeholders involved in adolescent health. Developers can incorporate app features proposed in this study to design apps that are practical and desired by their target audience. App designers can also assist in the overall design of health apps to make them “hook” people in the same way that entertainment does. Pediatricians and other healthcare professionals can use their influence to promote tried and tested apps to patients, while also helping them understand how this technology may pertain to their lives. Adolescents have a responsibility to start learning how to take care of themselves—health apps give them the opportunity to put health into their own hands. As research for mobile health apps continues to grow, we believe that they will one day be part of standard care.

**Author Contributions**

AC and RK equally contributed to the conception and design of the study, acquisition of data, analysis and drafting of the manuscript. JC is the Principal Investigator and assisted in the interpretation of the data and provided substantial guidance and input during the revision of the manuscript. All authors approved the final version of the manuscript.

**Disclosures**

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**References**


METHODOLOGICAL ISSUES OF USING PLACEBOS IN INTERVENTIONS BASED ON DIGITAL TECHNOLOGY

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Background/Aims: Use of placebo is the ideal for comparison in clinical trials to reduce biases. With digital technology being used more frequently in healthcare interventions, how do we determine the placebo effect where interventions exploit technology? If placebo in medicine is traditionally defined by a lack of pharmacological agents, how might we begin to move towards controlling for effects of digital technology?

Method: This paper explores the traditional placebo effect and discusses its impact in healthcare contexts with digital technology with reference to a particular trial. Different meanings of placebo in the context of evaluating technology suggest new challenges and positive consequences.

Results: Methodological considerations are discussed, which enabled the development of a placebo-controlled evaluation of a digital technology in healthcare and rehabilitation.

Conclusion: Digital placebo was controlled in our trial by employing technology across all groups in the absence of evidence-based practice and shows how to control for unknown and hidden effects of technology.


Introduction
As digital technology becomes more personalized¹,² and is able to record and represent richer information about the body, the demands we place upon it in trials and in medicine will increase. Digital technology in health care settings is already set to increase in three ways: a) wireless sensing b) sequencing the genome and c) imaging and printing organs.³ These will enable further capture and investigation of individual data such as blood glucose or blood pressure, or capturing responses to therapy in real-time.³ As the volume of research with digital technology and mobiles increases, methodology will need to adapt and become more robust.

Where possible, interventions evaluated using the gold standard of double blind randomized controlled trials often employ placebos as an effective countermeasure to context and subjectivity. Placebo is the purposeful null effect of an intervention and is usually employed in opposition to an active technology e.g. therapy, within a clinical trial. However, use of placebo in interventional trials where digital technologies such as mobiles are used, requires evaluation, and as yet there is no clearly established methodology. In complex interventions with digital technology, rigorous evaluation is needed, and traditional placebo alters due to demands placed on trial fidelity.
This paper is based on our experiences and reflections from our own evaluation of placebo during the development of an NIHR feasibility trial using a commercial device for children with cerebral palsy (ISRCTN17624388; IRAS ethics approval 14 NW 1499). Our study, just completed, explored the potential of utilising a widely available commercial games console (the Nintendo Wii Fit) within the home to deliver regular, tailored physiotherapy schedules of Virtual Reality Therapy (VRT) for children with cerebral palsy in comparison to free play usage. Participating families completed an online questionnaire regarding children’s current use of computer games such as Nintendo Wii Fit within the home. They were then randomised into either a supported or unsupported (control) participant group. Supported participants followed a therapist prescribed schedule over a 12-week period, utilising only specified Nintendo Wii Fit games for designated amounts of time per session. Sessions lasted 30 minutes, undertaken three times a week with games selected for specific physiotherapy purposes, such as core stability or balance. During this 12-week period, bi-weekly telephone contact to families oversaw the child’s progress, updated game selection and responded to any queries. Parent, carers, and children were required to keep a simple daily diary to rate sessions. Unsupported (control) participants used the Nintendo Wii Fit for 30-minute sessions, 3 times a week, over a 12-week period. However, they had a free choice over which games they chose and the duration of each game played within the session. Bi-weekly phone contact was also made during the 12-week period. Parents and children were also requested to keep a simple daily diary to rate sessions. Assessments of balance and functional mobility were taken at three time-points: before commencing the trial, halfway through, and on completion. An exit questionnaire asked parents and children to report on factors such as engagement, ease of use and fatigue.

In each section of this article we return to our study to provide grounded examples. First we discuss our study as a context for where the placebo effect fits into complex interventions incorporating digital technology. Second, we discuss placebo, its history and use in clinical trials is discussed. Placebo constraints are made up of four factors: a) the placebo effect, b) the placebo delivery c) the placebo object, and d) the way in which placebo controlled trials measure output. Last, we give further examples of where the placebo with digital technology has been tried and could have a medical application. There are as yet few examples of this type of intervention trial, but given the potential for growth with digital technology, especially with mobiles, this is set to increase. Our examples show different contexts and types of research incorporating digital technology where placebo effects are tackled or controlled. We conclude by conjecturing as to whether complex interventions using digital technology will enable the appropriate construction of placebos and enable fair comparisons.

A Complex Intervention and Placebo

Complex interventions require careful planning around the practical effectiveness of an intervention, how the intervention exerts its effect and how interactions between components change across intervention groups. An effective intervention that produces meaningful outcomes may change completely if there is additional impact of technology on placebo.

For our study, a traditional control group of “best pre-existing current treatment” (most likely standard physiotherapy) therefore was considered a difficult option due to the current lack of understanding of a placebo effect with technology. For example, other factors e.g. the Hawthorne effect or observational bias may occur as a result of simply being watched during an intervention. The actual impact of using digital technology is not as yet known, comparing a virtual reality group with a group without virtual reality is an option but could have overstated benefits. A comparison group considered children standing on a wobble board, whilst watching a video of the sports/activities that would be played on the gaming system on a large screen. This option was close to the digital version, but was comparing a digital with a non-digital version.

However it was decided that both groups would have to be given the digital technology but with subtle differences between groups, as there was no way to control for hidden effects of the digital technology. Group ‘A’ became a supported therapy group, with a prescribed programme of therapeutically oriented games for targeted skeletal-muscle groups, a suggested number of times per week for activity, and bi-weekly phone calls by a physiotherapist. Group ‘B’ became an unsupported group with un-prescribed access to the console, with suggested number of times per week for activity on the console, and bi-weekly phone calls from research staff to see how the
participants were progressing, but without offering structured or scaffolded learning support.

Our choices regarding trial groups were altered because of the possibility of hidden and unforeseen effects of technology that led us to ask: What constitutes placebo? What are the wider implications for placebo with complex interventions when digital technology is incorporated? What implications does this have on fair comparison in complex interventions? We now address these questions by looking at the constituent parts of the placebo effect, its delivery, the object that is the focus of the placebo, and how hidden effects get measured or are controlled.

What is a placebo?

A placebo is often used to find out whether a treatment has real or just perceived benefits. Placebo has been shown to be in some cases as powerful as an active intervention or drug and “conveys meaning, influences expectations and possibly triggers conditioned responses or behaviour changes”11, so that “[t]he simple act of receiving any treatment (active or not) may in itself, be efficacious because of expectation of benefit”.10,12 This meaning has gradually been extended to include receiving, or simply seeking medical attention, and can sometimes be enough to help patients recover.13

Doctors have often realised that illness can be self-limiting, and so may give an inactive treatment, with the outcome being that a patient might benefit psychologically. Medically the term has been in use from as early as 1772, with the term entering the medical lexicon increasingly in the 19th century.

Placebo can account for as much as 30-40% of patient relief for ailments such as pain, blood pressure, asthma, and coughs.14 What is unclear is how placebo actually works. Factors as strange as drug packaging can impact on effectiveness.4 The placebo effect is a conglomeration of effects rather than any single entity. Brissonnet15, suggests that literature on the subject of placebo prior to 1996 may even be faulty, as our understanding of placebo was incomplete, and whilst Brissonet is concerned with medical placebo the observation is appropriate given the subsequent growth of mobile and digital technology. Yet, the significance of placebo is such that Curie et al (2015) report that even for individuals with an intellectual disability they are still effective, warning of dangers “when testing novel treatments” due to contextual factors.31 Curie et al also suggest limits to the impact of placebo as individuals with co-morbid dementia showed no placebo response, whilst the higher an intelligence quotient score the greater the likelihood of response.

For our Virtual Reality feasibility study, the simple act of using a commercial console by children may well have been enough to obtain functional improvement but this is further complicated by benefits of the therapeutic programme or natural development with age. Further, if individuals and families are biased toward the benefits of digital technology or mobile smartphone use, this may change attitudes, opinions, perceptions, and outcomes with technological intervention, even if there is no actual benefit. The use of digital technology makes it difficult to identify those causal factors that can cause positive change.

Placebo is an umbrella term

Placebo in healthcare evaluations is complex, and can be thought to comprise three key elements: the effect, the delivery and the object.

1) The Placebo Effect.

Placebo effects occur because of the feeling or perception that an intervention is working and has associated wellbeing, which is produced by the placebo, pure or pseudo.15 Homeopathic treatments are a good example of pure placebo, as described in Ben Goldacre’s book Bad Science4, as the chemicals are on the whole dummy treatments. A placebo effect is problematic however, as a lack of active ingredient somehow causes physical change.16 Placebo is inert, so the placebo effect is also rather referred to as a meaning response.16 For example, studies where there is an effect of the placebo such as blue pills being judged as depressants, and red pills being seen as dangerous, subsequently participants experience exactly that - a blue pill depressing a participant, a red pill judged as danger, it is highly likely that the same effects may occur with company names, or the colour of mobile phones.16 Meaning response permeates all interactions between clinician and patient, such as manner, language, dress, diagnosis, and prognosis.16 Therefore, ‘placebo effect’ refers to the meaning response from the participant that is desirable and is under investigation. Meaning response that is undesirable and not under investigation is now commonly referred to as the “nocebo effect”.17 For example, inert treatments
not under investigation and that produce endogenous opiates in participants would be nocebo.\(^\text{16}\)

Complex interventions that incorporate digital technology may result in a potential meaning response with associated wellbeing. For example, the simple presence of a commercial console (e.g. Wii Fit) may change beliefs and attitudes about its effectiveness as a therapeutic device, producing a desired outcome based on feelings or perceptions that the technology is going to have an effect. But it would be vital to know what element of meaning response is under investigation, especially when the active elements of digital technology are still unclear.

2) The Placebo Delivery.

If placebo effect is constructed from wanted and unwanted meaning response constructed through interaction, how placebo is given or delivered to the participant or patient is also important. This is the who, where, and when of the placebo, and not only includes the meaning response generated by the doctor or health professional, but also includes the context in which the placebo is given, the immediate timing of the placebo, and the perception of interventions over time. Context effects and impacts in medicine, so-called ‘optimal healing environments’ are well researched, and include factors such as expectations to treatment and empathy.\(^\text{11,16}\) For example, delivery tends to work better if a drug is subcutaneously injected as opposed to taken orally, it is also better if given with empathy rather than neutral manner.\(^\text{11,16}\) Placebo effects are also larger when the mode of delivery is physical (see the placebo object below), as opposed to pharmacological or psychological.\(^\text{19}\) Placebo delivery with digital technology is as much to do with rituals, or activities that routinely occur in a set order, as well as ideas surrounding computers and mobile technology during interaction that surrounds patient consultation.\(^\text{13}\) Delivery is not limited to a clinical setting, as seen by advances in tele-health care, as mobile delivered interventions are more likely to occur in the home, which may or may not be considered an optimal healing environment for complex interventions incorporating digital technology. The place, timing, and delivery of therapy with a commercial console or piece of equipment for example will therefore further complicate the impact of technology. Recent evidence on the impact of mobile phone screens on melatonin and sleep levels shows how physical response is genuinely affected, linking the bluer end of the light spectrum used in screen devices to common alert states of behavior.\(^\text{33,34}\)

In our study we were using the commercial console in the home. Use in the home may change the clinical effect of the console, as the clinical relationship of patient-health professional has been removed, as has the time of day when the technology may be used, creating further possible positive or negative effects.

3) The Placebo Object.

Placebo effect is the ‘meaning response’ (see section 1 above) under investigation; the delivery is the manner in which the agent causing change is transferred to the participant. The placebo object is the focus of the intervention i.e. the drug, therapeutic intervention (e.g. needle in acupuncture), packaging, smartphone, or machine that might be used in a clinical trial. This overlaps somewhat with the meaning response but focuses on the physicality of an object, referring to the attributes and expectations given to a particular object. The object at the heart of the intervention can be vested with a wide variety of meaning response, from a needle – potentially negative – to positive such as the colour of packaging on a headache or smartphone tablet box implying cleanliness, purity or relief from symptoms. The physical object that is the focus of the placebo may well alter with the type of digital technology. If a placebo object is a computer or mobile phone, then the type, (e.g. familiar, novel, bespoke, ‘off-the-shelf’, old) of computer becomes important. Computers such as a desktop, a smartphone, a tablet, a Radio Frequency Identification (RFID) tag, or a smart-object all change the dynamics of interaction. If a patient-clinician relationship alone improves outcomes,\(^\text{18}\) a patient-object (e.g. the computer) relationship may also improve or worsen outcomes similar to how tools like stethoscopes are considered an important part of clinical rituals.\(^\text{15}\) The object, when presented in the right clinical way, vested with important attributes such as validated tests, becomes imbied with clinical meaning.\(^\text{20–22}\)

For digital technology such as smartphones, the value of placebo as an object, exposes the importance of what Gibson called object affordance, or the perceptual cues and clues that imply how the object will be used.\(^\text{22}\) For our feasibility study it may be that positive outcomes could be explained away simply because we made the console the subject of a health study.
Once the placebo is delivered through an object like a smartphone we have then selection of criteria applicable to establish a placebo:

1. Placebo effect or meaning response i.e. the feelings and perceptions that individuals have of the placebo/intervention
2. Placebo delivery: The interaction that occurs during the delivery of the placebo/intervention
3. The physical object itself e.g. the mobile element such as a smart phone

All three need careful consideration if mobile technology delivers a medical intervention. It may be prudent to survey participant’s attitudes and perceptions toward mobile technology itself prior to data collection, or have attitudes specified as confounding factors in analysis plans. Internet and mobile addiction could for example confound results if as recently found, individuals who have lower working memory capacity and poorer attentional control are more prone to problematic mobile phone use, and are less resilient to digital media distraction. The type of mobile e.g. branding, aesthetic factors may also need to be carefully planned. How the intervention is delivered will also matter, for example whether the intervention is to be delivered via software at home or whilst at a clinic.

There is however, further complication when considering placebo use, and that is how placebo effects are measured.

The Placebo Effect measured

This is the output caused by the apparent action of the placebo. This is greatly complicated by factors that can influence measurement. The placebo effect is often confused with other confounding factors in experiments. Measured outcomes as a result of a placebo trial may in fact be due to a multiplicity of unintended factors.

For example, the Hawthorne or observer effect occurs where individuals change their behaviour simply because they believe they are being observed. A positive interpretation by participants of the Hawthorne effect is known as the Demand effect; participants think they know what experimenters are looking for. If participants are presented with information differently, e.g. positive or negative delivery by an individual, this becomes the Halo Effect. Where an intervention is out of the ordinary, an occurrence that is common in the mobile and digital technology field, behavior may change simply because of the Novelty effect. The Will Rogers phenomenon occurs where changes in diagnostic criteria seemingly produce improvements in prognosis for individuals, especially when diagnosis improves early detection and so patients appear to live longer. Simpson’s Paradox occurs where trends in experimental findings can be completely changed if sub-groups are analyzed separately or together, such as trends in data can also completely disappear.

What we can see is that not only do treatment or intervention protocols need to be carefully designed, but that with the introduction of digital technology additional confounders of attitudes, objects and delivery potentially require further planning before trials get underway.

Placebo in Complex Interventions Using Digital Technology

Traditional placebo effects are based on an individual ingesting a drug, or taking part in an intervention that is believed to be effective as a treatment. For example, the participant agrees that they may be getting absolutely nothing within a clinical trial, but they may be willing to take that risk (e.g. new phone based method of delivering cognitive behavioural therapy) if the risks are offset by increased life expectancy. However, if hidden factors surrounds a digital object e.g. through a screen, a monitor or a mobile, this makes placebo additionally complex, and may not carry the same weight in terms of life and death decisions. For example, the ‘on’ and ‘off’-ness of digital technology is problematic; dummy technology cannot be ‘on’, deliver therapeutic effects, and deliver bogus therapy at the same time. Some research has attempted to do exactly that, replicate digital technology, yet give dummy feedback to the participant.

Heywood and Beale used EEG to look at the difference between the delivery of a biofeedback tool for children with Attention Deficit/Hyperactivity disorder (ADHD). In the experimental condition children with ADHD were given a standard EEG biofeedback treatment that reflected their affective state, designed to alter behaviours synonymous with ADHD. This was alternated with a placebo protocol identical to the treatment but with averaged EEG feedback from all participants and so not linked to the individual’s real affective state, with
the hypothesis that having real-time information would enable individuals to recognize when they were becoming hyperactive, or likely to lose interest. The result was that the live EEG feedback produced no difference to the placebo compared to baseline levels and as a result reinforces the need to test out the salient ingredients of any given intervention when using digital technology. However, as is discussed below, the use of a placebo without a control condition lessens the power of findings.

Chittaro and Sioni^{25} developed a game that detects a user’s level of stress and depression and then feeds that back to the individual in the form of a 3D virtual character which embodies the state of the person, with the aim of influencing the person’s affective state. In their placebo condition the user’s stress level was measured by pseudo-randomly taking into account real time readings from physiological sensors. The experiment used two further types of sensor, a single physiological sensor, which measured skin conductance, and a second sensor that detected four types of affective information, skin conductance, heart rate, and the muscular response of two muscle receptors. Their findings showed that only the single physiological sensor was better than the placebo condition, therefore the placebo was the same as the multiple sensor in allowing individuals to alter their affective state based on biofeedback. In both of these experiments the use of a placebo condition, or a dummy treatment showed that digital treatment was not effective.

Some work within tangible computing, and the ‘internet of things’^{26}, a branch of computer science that uses digital tags embedded within objects, has attempted to use a control condition not as treatment as usual, but as an experimental condition but with digital technology simply turned off. Obviously for screen-based digital technologies e.g. mobile, tablet, multi-touch surfaces, technology being off is problematic, however for technology that is within the ‘internet of things’ this may have less impact. In a number of novel experiments Hinske et al^{27,28} looked at a child’s play environment which was augmented with RFID antennae and Dolby stereo. In these experiments a toy, a Playmobil knight’s castle was either used with digital augmentation turned on or off. Both play environments were therefore valid as they were using the same object, but with only one augmented with digital feedback. When comparing children’s play with the augmented knight’s castle and with the knight’s castle, it was found that the augmentation promoted more talking and more interaction. In the augmented knight’s castle there is a problem if a placebo condition was tried in that there is no way the technology could deliver the same effects experienced with the digital technology in a bogus way, as children’s activity with toys caused digital feedback to occur. In this instance, activity dependent differences in digital feedback confounded comparison between placebo and real conditions.

More recently, Denisova and Cairns (2015)^{33} have shown that a placebo effect can occur in digital games when users are primed to expect certain features of a game, which in due course resulted in deeper immersion. When users thought artificial intelligence was switched on during game use, even though it was not, deeper immersion was reported.

In certain circumstances it is impossible to construct a placebo using digital technology because the technology is either on or off. Further, placebos with digital technology are currently never ingested, invasive, or part of the human body. A true digital placebo might begin to have a place in experimentation when digital tags are placed under the skin of workers. This could be used in clinical settings with slow-release drugs, controlled by digital technology, or to investigate further the patient-clinician relationship if clinicians were tagged and then factors affecting measurement such as the Hawthorne effect were purposefully manipulated. The placebo object may be useful if wearable technology is being used to gather data about user head motion or stability, eye gaze, gross motor function, especially if it is impossible to tell if the technology is switched on or not.

Conclusions

Whilst medicine still debates the impact of placebo, it appears that there is a multi-faceted definition of what constitutes placebo. Further, investigation into cumulative effects of individuals receiving placebos over time does not as yet show effective ways of estimating the effect of placebo.\textsuperscript{11} Whilst the best use of placebo employs RCT double blind methodology (e.g. BOTXN versus saline injections) with a no-treatment control group, even this complicates methodology by introducing a third group.\textsuperscript{11} There is as yet mixed evidence for the placebo effects in clinical trials, but evidence is growing for placebo interventions being now statistically (but not necessarily clinically) significant for “patient and observer-reported continuous outcomes”.\textsuperscript{19}
A placebo paradigm using digital technology may only be useful in healthcare settings only if all sub-factors are taken into consideration; the feelings and perceptions of individuals, the measurements being taken, the participant group, the interaction and delivery of the placebo and the placebo object itself. Mobile technology in medicine is bound to bring with it a new type of meaning response, which will require careful adjustment to counterbalance effects. Surveying a population may be one way to begin to understand hidden factors if a study is at risk, prior biases could therefore be carefully considered before beginning a trial. Checking the acceptability of a new intervention through patient and public involvement before trial may also reveal any hidden effects that may occur. The uses of new methods of data capture e.g. mini-RCTs where participants may be in more than one experimental group depending on activity, offers novel ways of accounting for individual variance. It is conceivable that groups could and should be constructed within a trial based on prior average daily smartphone use, age, demographics, or whether their preferred mode of delivery is tablet over smartphone. Ultimately the impact of hidden effects of digital technology will come down to the efficacy, method and planning of the trial, and as long as software, human computer interaction experts, and clinical teams work together closely the “more hype than hope” accusation aimed at digital technology should not arise.

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