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Dear Readers,

7th July, 2016

It is with great pleasure that we present the second issue of the *Journal of Mobile Technology in Medicine* for 2016 with excellent examples of translational mHealth research. One of the great challenges confronting global health care is accessibility and affordability to diagnostic technologies and timely referral to specialist services.

In this issue, Ludwig et al provide a brief overview of the existing technologies available to aid automated diagnostic and referral in the field of the ophthalmology. The authors provide a summary of a potential pathway for automated ophthalmic care through the use of mobile diagnostic devices that can facilitate image collection. The first step in the clinical algorithm is safe and accurate image capturing technologies. The authors highlight examples of mobile diagnostic adapters developed by the Peek Vision group (UK), D-eye system (Italy), and iExaminer (Welch Allyn) which convert the modern smartphone into an anterior and posterior segment image capturing device. These images can then be collated, filtered for quality, and interpreted by automated software and results can, in theory, be graded in real-time to provide risk stratification and triaging of patients.

Whilst the concept of automated diagnostics in ophthalmic care is not new, the challenge over the last 20 years has been to develop algorithms that meet sensitivity and specificity criteria to be safe for day to day real world clinical practice. Ludwig et al succinctly illustrate examples whereby the two common modes of automated image analysis, neural networks and deep learning are now meeting the level of reliability and reproducibility for safe clinical practice. Importantly, Ludwig et al highlight examples of the utility of automated grading technologies developed for two of the most common, yet insidious causes of global vision loss, glaucoma and diabetic retinopathy.

The evolution of automated diagnostic technologies now truly positions health care in the 21st century to reach and provide care to a greater population breadth than ever before. The benefits of such technologies will always be balanced by the caveats of the necessity for clinical correlation by a specialist or appropriately trained medical professional, the costs of equipment, and the need for further evidence in larger population based studies. This is particularly poignant for automated software based learning. Nevertheless, there is a clear value in ability of these technologies to facilitate early diagnosis, triaging and timely referral of patients in rural and remote and low-resourced settings, where the greatest burden of global morbidity exists.

Reference
MOBILE AND WEARABLE DEVICE FEATURES THAT MATTER IN PROMOTING PHYSICAL ACTIVITY

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Background: As wearable sensors/devices become increasingly popular to promote physical activity (PA), research is needed to examine how and which components of these devices people use to increase their PA levels.

Aims: (1) To assess usability and level of engagement with the Fitbit One and daily SMS-based prompts in a 6-week PA intervention, and (2) to examine whether use/level of engagement with specific intervention components were associated with PA change.

Methods: Data were analyzed from a randomized controlled trial that compared (1) a wearable sensor/device (Fitbit One) plus SMS-based PA prompts, and (2) Fitbit One only, among overweight/obese adults (N = 67). We calculated average scores from Likert-type response items that assessed usability and level of engagement with device features (e.g., tracker, website, mobile app, and SMS-based prompts), and assessed whether such factors were associated with change in steps/day (using Actigraph GT3X+).

Results: Participants reported the Fitbit One was easy to use and the tracker helped to be more active. Those who used the Fitbit mobile app (36%) vs. those who did not (64%) had an increase in steps at 6-week follow-up, even after adjusting for previous web/app use: +545 steps/day (SE = 265) vs. −28 steps/day (SE = 242) (p = .04).

Conclusions: Level of engagement with the Fitbit One, particularly the mobile app, was associated with increased steps. Mobile apps can instantly display summaries of PA performance and could optimize self-regulation to activate change. More research is needed to determine whether such modalities might be cost-effective in future intervention research and practice.
Introduction
In the U.S., the growing and linked epidemics of obesity and physical inactivity have severe health consequences, and there is a need to develop cost-effective health behavior interventions to increase physical activity (PA) at the population level. Past PA interventions that have been successful have focused on self-regulatory skills whereby people were encouraged to manage their own behavior change by setting goals and self-monitoring. For example, pedometer and/or web-based interventions have shown that providing participants with feedback on PA performance and asking them to record their steps can increase motivation and PA levels. Advancements in technology provide increasingly more opportunities to facilitate users to build self-regulatory skills including self-monitoring of PA. The Fitbit One is a commercially available device that measures PA with a small wearable tracker (accelerometer) and displays instant PA readings. These data such as total number of steps per day can be uploaded to a personal website (Fitbit.com) or mobile application software (app) on a smartphone or tablet for comprehensive summaries of PA data across time – through which individuals can assess their self-regulatory change processes.

Process evaluations of health behavior interventions often make the distinction between the amount of program components delivered or provided to participants (“dose delivered”) vs. the extent to which participants actively engage in those prescribed activities (“dose received”). Although devices like the Fitbit One possess the technology to help build self-regulatory skills for PA, the level of engagement with the device is ultimately up to the individual. In other words, the simple act of making the device accessible does not necessarily guarantee that people will actively engage with the technology and benefit from the technology. There is a dearth of information about the level of engagement with a PA monitoring device (e.g., Fitbit One) and the impact of engagement level on self-regulatory skills and behavior change. The purpose of this study was to evaluate users’ actual level of engagement with the Fitbit One (particularly its various components) to determine the potential effects of this technology for increasing PA.

In our previous work, we tested the effects of the Fitbit One with and without SMS-based prompts to promote physical activity in a 6-week randomized controlled trial (N=67). All participants were provided a Fitbit One to monitor their activity levels. Overall, the combined intervention (Fitbit One with SMS-based PA prompts) was not successful in increasing PA levels for more than one week. A possible explanation for the loss of these study effects in PA change could be in part due to a lack of engagement with the intervention components. In this current study, we hypothesized participants’ level of engagement with the intervention components, specifically the (1) Fitbit tracker, (2) Fitbit website, (3) Fitbit mobile app, (4) and/or text messages, would be positively associated with objectively measured change in number of steps at 6-weeks follow-up (as measured by the Actigraph GT3X+).

Methods
Study Design & Population
The study consisted of a two-arm design where half the participants were randomized to receive daily SMS-based PA prompts and all participants received the Fitbit One. The study employed convenience sampling for recruitment in San Diego from January 2013 – January 2014, mostly among a pool of women from a mammography registry at the University of California, San Diego (UCSD), Moores Cancer Center, who had consented to being contacted for research opportunities. Additionally, participants were recruited via word-of-mouth and flyers that were posted throughout the community including the UCSD and San Diego State University campuses. Initial study eligibility was assessed over the telephone and the criteria included being a non-smoker, 19–69 years of age, overweight or obese (calculated BMI of >25 kg/m² using height and weight), and not meeting recommended PA guidelines for adults (<150 min/wk moderate-to-vigorous intensity physical activity, or MVPA). Additionally, the eligibility criteria included self-reported motivation to increase PA levels within a month from screening assessed using a 1-item question, physical fitness to increase PA levels assessed by self-reported responses from the “Physical Activity Readiness Questionnaire” (PAR-Q), ability to use SMS text messaging on a personal mobile phone, and access to a personal computer that was capable of running the Fitbit One software. The UCSD institutional review board approved the study protocol and all participants provided written informed consent.

Study Procedures
Participants who met the initial telephone eligibility criteria were invited to the UCSD Moores Cancer Center for a 1-hour clinic visit for further
assessments were collected at baseline and a 6-week follow-up. Details on study procedures are published elsewhere. 

Study Intervention Groups

Fitbit One for Self-Monitoring
All participants in both intervention and control groups were asked to wear a Fitbit One tracker every day and to upload PA data from their tracker to the website (Fitbit.com) and/or mobile app. The tracker allowed participants to receive instant feedback on their PA performance and the uploaded data from the tracker to the website or mobile app provided more detailed summaries of their daily PA data in their personal Fitbit accounts. Study personnel emphasized the importance of uploading and charging the Fitbit One daily in an effort to minimize missing data.

Fitbit One plus SMS-Based PA Prompts as Simple Reminders
Participants randomly assigned to the intervention group were contacted by either telephone and/or email to indicate three preferred times of the day (for each day of the week) to receive text message reminders to engage in PA. They were informed that they could contact the study at any time if they wanted to change their pre-set schedules. Study personnel constructed 42 text message reminders (<150 characters) and used a commercially available website (Eztexting.com) to program and schedule automatic delivery of all text messages. The full set of text messages was delivered over a 2-week period and repeated throughout the 6-week study period. The content of the messages were basic reminders to engage in PA (e.g., “Good morning [name]! This is your 9AM reminder to do at least a 10-minute bout of moderate-to-vigorous intensity physical activity.”).

Measures

Baseline Questionnaire
At baseline clinic visit (prior to randomization), participants completed a self-administered questionnaire which included sections on demographic variables (i.e., age, gender, education level, and ethnicity), text messaging use, previous web or app use to monitor PA (yes or no), and confidence in their ability to increase their PA levels (very confident or confident/somewhat confident). We also collected weight and height measurements to calculate baseline body mass index (BMI). A detailed description of these items and response options are published elsewhere.

Follow-Up Questionnaire
A brief follow-up questionnaire was conducted over the telephone at the end of the 6-week study period. Items asked participants about their experience with the Fitbit One (i.e., tracker, website, and mobile app), and in the intervention group only, the SMS-based PA prompts. Specifically, these items assessed participants’ attitudes on the usability of the Fitbit One and SMS text messages in addition to whether they thought these intervention components were useful in helping them to increase their activity levels. Questionnaire items on the Fitbit One were: “The Fitbit tracker was easy to use,” “Overall, the Fitbit tracker helped me to be more physically active,” “The Fitbit website was easy to use,” and “Overall, the Fitbit website helped me to be more physically active” [Ratings: 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, or 1 = strongly disagree]. Items on the SMS-based PA prompts were: “Daily text messages that prompted me to be physically active helped me to be more physically active” [Ratings: 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, or 1 = strongly disagree] and “The 3 daily text messages that prompted me to be physically active were…” [Response options: 3 = too many, 2 = just right, or 1 = too few].

Participants were asked to assess their actual use and responses, or their level of engagement, with each intervention component. Items on using the Fitbit tracker were: “On a typical day, I checked the Fitbit tracker to see… (1) how many steps I’ve taken, (2) how much distance I’ve travelled, and (3) if the tracker to see...
flower grew taller (for PA intensity) [Ratings: 5 = very often, 4 = often, 3 = sometimes, 2 = rarely, or 1 = never]. Item on the Fitbit website (fitbit.com) was: “In a typical week, I logged onto my Fitbit.com account…” [Ratings: 5 = every day (7 days/week), 4 = most days (5 days/week), 3 = some days (3–5 days/week), 2 = rarely (1–2 days/week), and 1 = never (0 days/week)]. Items on the Fitbit mobile app were: “Did you use the Fitbit mobile app?” [Ratings: 1 = yes or 0 = no]. If yes, “How often did you use the Fitbit mobile app?” [Ratings: 6 = more than once a day, 5 = about once a day, 4 = few times per week, 3 = couple times per week, 2 = about once per week, or 1 = less than once per week]. Items on SMS-based PA prompts were: “Overall, did you engage in at least a 10-minute bout of physical activity after receiving a text message from the study? Would you say…” [Ratings: 5 = always, 4 = usually, 3 = about half the time, 2 = rarely = 2, or 1 = never] and “How soon after receiving a text message did you engage in at least a 10-minute bout of physical activity?” On average, would you say…” [Ratings: 7 = 1–30 minutes, 6 = 31–59 minutes, 5 = 1–2 hours, 4 = 3–6 hours, 3 = 7–9 hours, 2 = 10–12 hours, or 1 = more than 12 hours]. Higher response scores indicated a higher level of engagement.

Objective Measures of Physical Activity – Steps

The primary dependent variable for measure of physical activity was steps that was objectively measured using a tri-axial accelerometer (Actigraph GT3X+), which is a valid and reliable measure of PA in adults, at baseline and 6-week follow-up. ActiLife 6.10 software was used to process Actigraph GT3X+ data to flag invalid data or those collected when the device was not worn for exclusion in the final analysis. Details on processing Actigraph GT3X+ accelerometer data using ActiLife 6 Data Analysis Software including how to conduct wear time validation is available elsewhere. In brief, the Troiano technique was used to set parameters to detect non-wear periods for wear time validation, specifically: a “minimum length” of 90 minutes of consecutive zeros to define a “non-wear” period; a “spike tolerance” (or “spurious count” tolerance) of 2 minutes to continue counting non-wear periods as non-wear until this threshold was met; “wear periods” of less than 10 minutes were ignored; “minimum wear time per day” was set to 600 minutes per day; and “minimum days of valid wear time” was at least 5 days per week including a weekend day.

Statistical Analysis

Descriptive statistics were conducted for all variables. Mean (SD) or frequencies (N, %) were calculated for demographic variables including age, gender, education level, and ethnicity in addition to baseline BMI, physical activity (from Actigraph GT3X+), technology use, and confidence to change PA. Mean (SD) Likert-type response scores and frequencies (N, %) of yes/no responses were also calculated to assess self-reported usability and level of engagement for each Fitbit One and SMS-based intervention component. A mixed-model repeated measures analysis was conducted to test and compare weekly changes in steps between those who responded higher vs. lower level of engagement for each assessment item using 5–7 aggregated steps/day at follow-up with the Actigraph GT3X+. For example, Likert-type responses that described a participant’s level of engagement as “very often” and “often” were collapsed into one category (higher level of engagement) and “sometimes,” “rarely,” and “never” to another category (lower level of engagement). A random subject-specific intercept was included to model between subject variability. Fixed effects included in the models were time (i.e., pre-, and post-intervention), group (i.e., high vs. low engagement), and the group-by-time interactions. All models were adjusted for daily wear-time minutes of the Actigraph GT3X+ accelerometer. Adherence to modeling assumptions was tested using residual plots (e.g., qqpplots to examine if residuals followed a Gaussian distribution). All analyses were conducted using SAS software, version 9.3 (SAS Institute Inc., Cary, North Carolina).

Results

Study Sample

The study sample (N = 67) was 91% female, 61% college graduates, and 67% non-Hispanic White with a mean age (SD) of 48.2 (11.7) years, BMI (kg/m²) of 31.0 (3.7) (category = “obese”), and an average baseline of 6,819 (415) steps per day (Table 1). In a typical week, participants reported that they used text messaging about four days, and on those days, sent and received approximately three text messages. Forty percent of participants indicated that they had previously used either a website or mobile app to track and/or monitor their physical activity levels, and all participants indicated some level of confidence in their ability to increase their PA levels (Table 1). Sample characteristics stratified by study group are reported elsewhere.
Fitbit One: Usability & Level of Engagement

A total of 61 participants completed the follow-up questionnaire. Mean (SD) response scores indicated that overall participants “strongly agreed” that the Fitbit tracker (4.7; SD = 0.6) and “agreed” the Fitbit website (4.3; SD = 0.8) were easy to use (Table 2). Participants also “agreed” that the Fitbit tracker (4.0; SD = 0.8) was helpful for being more physically active, and somewhat “neutral” that the Fitbit website (3.8; SD = 0.8) was helpful for increasing activity levels. Participants reported checking their Fitbit trackers “often” to view their steps (4.2; SD = 0.8), and “sometimes” to view their distance (3.7; SD = 1.1) and the intensity of their activity (3.4; SD = 1.1). Overall, participants logged onto their personal Fitbit.com web accounts “at least 5 days/week” (4.0; SD = 1.0). A total of 22 participants (36%) reported that they used the Fitbit mobile app, of which they also indicated that they used the app a “few times per week” (4.2; SD = 2.0).

SMS-Based PA Prompts: Usability & Level of Engagement

Only intervention group participants were asked items about the text messaging intervention. A total of 31 participants completed these items (Table 3). Mean (SD) response scores indicated that overall participants were “neutral” about whether the text messages were helpful in being more physically active.

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Table 1: Participants’ baseline characteristics (N = 67)

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Mean (SD) or N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>48.2 (11.7)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>61 (91%)</td>
</tr>
<tr>
<td>Male</td>
<td>6 (9%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>&lt; College</td>
<td>26 (39%)</td>
</tr>
<tr>
<td>≥ College</td>
<td>41 (61%)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic White</td>
<td>45 (67%)</td>
</tr>
<tr>
<td>Other</td>
<td>22 (33%)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
</tr>
<tr>
<td>Overweight (25–29)</td>
<td>33 (49%)</td>
</tr>
<tr>
<td>Obese (≥ 30)</td>
<td>34 (51%)</td>
</tr>
<tr>
<td>PA (Actigraph GT3X+)</td>
<td></td>
</tr>
<tr>
<td>Steps (n/day)</td>
<td>6,819 (415)</td>
</tr>
<tr>
<td>MVPA (min/week)</td>
<td>33.6 (3.1)</td>
</tr>
<tr>
<td>Total PA (min/week)</td>
<td>152.2 (6.5)</td>
</tr>
<tr>
<td>Wear time (min/day)</td>
<td>841.3 (119.9)</td>
</tr>
<tr>
<td>Technology Use</td>
<td></td>
</tr>
<tr>
<td>In a typical week, approximately how many days do you text message? (Range 1–5)†</td>
<td>4.4 (1.1)</td>
</tr>
<tr>
<td>On those days, approximately how many text messages do you receive? (Range 1–4)§</td>
<td>2.7 (0.9)</td>
</tr>
<tr>
<td>On those days, approximately how many text messages do you send? (Range 1–4)§</td>
<td>2.7 (1.0)</td>
</tr>
<tr>
<td>Previous Web or App Use for PA</td>
<td></td>
</tr>
<tr>
<td>Have you ever used a website or app on your mobile phone or tablet to track and/or monitor PA levels? (Yes)</td>
<td>27 (40%)</td>
</tr>
<tr>
<td>Confidence PA Change</td>
<td></td>
</tr>
<tr>
<td>Very confident</td>
<td>31 (46%)</td>
</tr>
<tr>
<td>Confident/ somewhat confident</td>
<td>36 (54%)</td>
</tr>
</tbody>
</table>

† Abbreviation: PA = “physical activity”
§ Response options: 4 = Everyday (7 days/week); 3 = Most days (5 days/week); 2 = Some days (3–5 days/week); 1 = Rarely (1–2 days/week); 0 = Never
active (3.0; SD = 1.0). Participants’ reported that the frequency of three PA prompts per day were “just right” (2.5; SD = 0.6). Overall, participants “rarely” engaged in a 10-minute bout of PA after receiving a text message (2.5; SD = 0.6). If they did engage in a 10-minute bout of PA, the activity was performed approximately “3–6 hours” after receiving the text message (4.7; SD = 1.2).

Change in Steps by Level of Engagement with Intervention Components
Generally, participants who were more engaged with the Fitbit One and/or SMS-based PA prompts were associated with greater mean (SE) change in steps per day at 6-week follow-up (Table 4). However, between-group differences were not statistically significant; specifically, participants who responded to

<table>
<thead>
<tr>
<th>Mean (SD) or N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usability</strong></td>
</tr>
<tr>
<td>The Fitbit tracker was easy to use (Range: 1–5)†</td>
</tr>
<tr>
<td>The Fitbit website was easy to use (Range: 1–5)†</td>
</tr>
<tr>
<td>Overall, the Fitbit tracker helped me to be more physically active (Range: 1–5)†</td>
</tr>
<tr>
<td>Overall, the Fitbit website helped me to be more physically active (Range: 1–5)†</td>
</tr>
<tr>
<td><strong>Level of Engagement</strong></td>
</tr>
<tr>
<td>Fitbit tracker</td>
</tr>
<tr>
<td>On a typical day, I checked the Fitbit tracker to see how many steps I’ve taken (Range: 1–5)‡</td>
</tr>
<tr>
<td>On a typical day, I checked the Fitbit tracker to see how much distance I’ve travelled (Range: 1–5)‡</td>
</tr>
<tr>
<td>On a typical day, I checked the Fitbit tracker to see if the flower grew taller (Range: 1–5)‡</td>
</tr>
<tr>
<td>Fitbit website: In a typical week, I logged onto my Fitbit account... “every day” to “never” (Range: 1–5)§</td>
</tr>
<tr>
<td>Fitbit mobile app</td>
</tr>
<tr>
<td>Did you use the Fitbit mobile app? (Yes)</td>
</tr>
<tr>
<td>(If yes) How often did you use the Fitbit mobile app? (Range 1–6)§</td>
</tr>
</tbody>
</table>

Table 2: Usability and level of engagement with the Fitbit One (N = 61)

<table>
<thead>
<tr>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usability</strong></td>
</tr>
<tr>
<td>Daily text messages that prompted me to be physically active helped me to be more physically active (Range: 1–5)†</td>
</tr>
<tr>
<td>The three daily text messages that prompted me to be physically active were... “Too Many,” “Just Right,” or “Too Few” (Range: 1–3)‡</td>
</tr>
<tr>
<td><strong>Level of Engagement</strong></td>
</tr>
<tr>
<td>Overall, did you engage in at least a 10-minute bout of physical activity after receiving a text message from the study? Would you say... “Always” to “Never” (Range: 1–5)§</td>
</tr>
<tr>
<td>How soon after receiving a text message did you engage in at least a 10-minute bout of physical activity? On average, would you say... “1–30 minutes” to “More than 12 hours” (Range: 1–7)¶</td>
</tr>
</tbody>
</table>

Table 3: Usability and level of engagement with SMS-based PA prompts (N = 31)
frequently using the Fitbit One’s tracker to check their steps count were associated with greater increases in steps (SE): +280 (224) steps/week in those who responded “very often” or “often” vs. −135 (243) steps/week for “sometimes,” “rarely,” or “never”; and (2) distance travelled: 349 (214) steps/week in those who responded “very often” or “often” vs. 135 (243) steps/week for “sometimes,” “rarely,” or “never.” Similarly, more frequent use of the Fitbit website (5–7 days vs. 5 days per week) was also associated with increases in steps (SE): +266 (227) steps/week vs. −43 (264) steps/week. As mentioned, in this study, we did not find group differences in changes in steps. However, there was a statistically significant within-group difference among those who responded “yes” vs. “no” to using the Fitbit mobile app: +545 (265) steps/week vs. −28 (264) steps/week, respectively, even after adjusting for previous web and/or app use for PA (p = .04). This finding warrants further investigation on the utility of mobile apps to keep participants engaged with a given device for self-regulation of their physical activity levels.

Only about half the participants who received SMS-based PA prompts responded that they engaged in PA “always,” “usually,” or “half the time” (vs. “rarely” or “never”) after receiving a text message, and this was associated with only a small increase of +8 (454) steps/day (vs. −66, SE = 336). Among those who engaged in a 10-minute bout of PA <2 hours (vs. ≥2 hours), there was also an increase of +172 (442) steps/day (vs. −211, SE = 1). Again, group differences were not statistically significant.

**Discussion**

In a sample of mostly overweight and obese middle-aged women, these data indicate that the Fitbit tracker was easy to use. Most participants reported that the Fitbit tracker was helpful in increasing their PA levels, more so compared to the Fitbit website.
A comparison among the Fitbit tracker, website, and mobile app indicated that the mobile app was objectively useful in increasing PA levels from baseline to 6-week follow-up as measured by change in steps using an Actigraph GT3X+. Overall, participants who received the SMS-based PA prompts showed minimal engagement and change in physical activity levels. Overall, results from this study suggest that use and/or how much an individual engages with various intervention components could have an impact on PA change. Studies with larger samples are needed to reexamine and further elucidate the impact of participants’ level of engagement with specific mobile health intervention components.

**FitBit One Tracker, Website, and Mobile App**
In this study, about a third of participants used the Fitbit mobile app and they had a significant increase in number of steps at follow-up. The Fitbit mobile app is a fusion of the tracker and website in that it is easily accessible, provides instant feedback on performance, and is capable of providing more in-depth PA data such as minutes of activity by intensity level (i.e., light, fairly, and very active minutes). Previous pedometer- and/or web-based interventions that have featured self-monitoring components involving PA records and logs on calendar or web pages have been shown to be efficacious in increasing PA levels.7–12,21–25 In this study, participants who used the tracker and website also increased their steps at follow-up and these data support a non-significant trend to suggest self-monitoring activities can be useful to promote changes in PA. Studies are needed to investigate whether these devices enhance the user’s ability to monitor their PA levels compared to traditional methods and also identify factors associated with what motivates individuals to use and engage with these devices for behavior change.

Research on mobile app interventions is scarce despite their increasing popularity as devices like the iPhone include built-in sensors including accelerometers that allow even more opportunities for users to self-monitor their own health behavior. Results from this study provide data to indicate a significant positive association between using a PA mobile app and an increase in steps at follow-up. In this sample of overweight/obese adults, these results were stable even after adjusting for factors such as baseline motivation. Still, there are probably segments of the general population that might be more receptive to such technologies in monitoring their own PA levels – an area of research that remains to be examined and that could aid in more effective targeting of mHealth interventions. Overall, participants self-reported that the Fitbit One helped them to be more physically active but this was not supported by the objective measures of steps at follow-up that was recorded by the Actigraph GT3X+ accelerometer. This observation highlights a (1) strength of this study, namely, the use of a validated objective measure of PA and (2) discrepancy in participants’ perceptions about the utility of the Fitbit One to promote PA and actual outcomes. Therefore, studies that examine user experience of direct-to-consumer wearable devices like the Fitbit require rigorous trials in real-world settings over an adequate amount of time for measure of sustained long-term change.

**SMS-Based Physical Activity Prompts**
Overall, SMS-based PA prompts were not successful in promoting PA. More than half of the participants who received text messages indicated that they “rarely” or “never” did a bout of PA after receiving a text message. In the primary outcome study,15 we reported that these text messages as simple reminders to prompt PA were only able to achieve short-term effects that did not last more than one week. However, other text messaging PA interventions, with comparatively more content and intensity, have also reported short-term effects.26,27 In consideration of these findings, we recommend that future studies examine the utility of text messages to prompt self-monitoring rather than prompt the specific outcome behavior (e.g., physical activity). Studies have shown that it is possible to effectively train or coach participants, including those who were overweight, to self-monitor their PA by keeping records/logs in a diary, webpage, or PDA.12,19,28,29 Future studies could examine how SMS-based prompts can be used to prompt self-monitoring, and thus increase their level of engagement with the device, to promote PA.

**Limitations**
This study consisted of a convenience sample of overweight and obese adults who were inactive prior to the start of the 6-week trial. Results are therefore not representative of other populations who may require less help to increase their PA. A large proportion of the sample were middle-aged women from the UCSD mammography registry, who had consented to be contacted for research opportunities and therefore could have been more...
compliant and/or motivated to improve their health behavior compared to the general population. Also, it might be possible that a small sample size resulted in some of the large standard errors and did not provide adequate power to detect statistically significant group differences. The study relied on self-reported measures of participants’ level of engagement with the Fitbit One and text messages, which is prone to measurement biases including social desirability that can result in errors. However, the nature of the problem created challenges in obtaining objective measures of participants’ level of engagement primarily because the researchers did not have access to these data such as number of times participants logged onto the Fitbit website and duration of time actively spent on the website. It is recommended that researchers collaborate with companies like Fitbit Inc. to develop ways to obtain objective measures of these activities for future research purposes (with permission from study participants) to enhance the effectiveness of these devices in changing PA.

Conclusions
As wearable sensors/devices and other technologies including mobile apps become increasingly popular, there is a need to examine how and how much people use these devices for self-monitoring and changing PA behavior. In this study, greater use of self-monitoring components, particularly the use of the Fitbit mobile app, was associated with more PA. Mobile apps are accessible, instantaneous, and comprehensive having the potential to optimize people’s self-regulatory skills in setting and reaching their PA goals. More research is needed to examine people’s level of engagement with new technologies including mobile apps to determine whether these modalities might be cost-effective strategies in future intervention research and practice.

Conflicts of Interest
None declared.

Acknowledgements
This research was supported by a gift from the Carol Vassiliadis family; and manuscript preparation in part by the National Cancer Institute Grant CA-113710. The study would like to acknowledge UCSD undergraduate interns Quynh Nguyen and Amy Nham for their assistance in study implementation.

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A Qualitative Study Exploring Stakeholder Perceptions of Video Directly Observed Therapy for Monitoring Tuberculosis Treatment in the US-Mexico Border Region

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Background: Tuberculosis (TB) incidence in the U.S.-Mexico border region exceeds both countries’ national rates. The four U.S. states bordering Mexico account for nearly 40% of total U.S. TB cases. TB treatment monitoring using directly observed therapy (DOT) is a globally-accepted practice; however, it is resource intensive for providers and patients.

Aims: To determine whether Video DOT (VDOT)—a process whereby patients record themselves taking their medication by mobile phone and sending the videos to their TB care provider for observation—could be used to remotely monitor TB treatment adherence.

Methods: We conducted five focus groups with TB patients and four with TB care providers in San Diego, California, U.S. and Tijuana, B.C., Mexico.

Results: VDOT consistently received broad support: U.S. patients valued greater autonomy and Mexican patients valued improved privacy. Groups agreed technology would not be a barrier, but emphasized need for adequate patient training.

Conclusion: Patients and providers in both countries found VDOT conceptually feasible and acceptable.

Introduction
Tuberculosis (TB) now surpasses HIV as the leading cause death from an infectious disease and is also the number one killer of HIV-infected persons.1-3 TB occurs in both developing and developed countries and remains a persistent problem among populations living in the United States (U.S.)-Mexico border region.4,5 In 2012, there were 9,951 new reported cases of TB in the U.S. (3.2/100,000 population).6 However, the U.S. border states—California, Arizona, New Mexico, and Texas—account for almost 3,700 TB cases (~40% of total U.S. cases), with incidence rates of 5.8, 3.2, 1.9 and 4.7 per 100,000 pop., respectively.7 TB incidence in
Mexico’s northern border states is also substantially higher than Mexico’s overall incidence (16.8/100,000 pop.), with Baja California (California’s sister state) bearing the greatest burden in all of Mexico (58.5/100,000 pop.).

While TB can be effectively treated with antibiotics, treatment typically takes 6 months and may extend to 24 months for patients with drug resistant TB. Moreover, adherence to medication regimens is critical to avoid prolonged periods of infectiousness, relapse, and the emergence of drug resistant strains. The U.S. Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and Mexico’s National Center for Preventive Programs and Disease Control (CENAPRECE) all recommend Directly Observed Therapy (DOT) as an essential component of patient care for TB in order to ensure adherence and stem TB transmission and drug resistance. DOT is a patient-centered approach to treatment in which patients are observed ingesting each dose of anti-TB medication and is intended to maximize the likelihood that patients will complete therapy. It can be provided in the patient’s home, a clinic, or other mutually agreed upon location.

In Mexico, as in the U.S., local health jurisdictions dictate the allocation of resources for DOT. Since cities such as Tijuana have limited resources for TB services, DOT is not possible for all TB patients. Although, studies have shown that DOT is highly effective in achieving high TB treatment adherence, especially when combined with individualized care; DOT can limit patient mobility and privacy, involves travel costs and may be especially difficult for patients who live far from health clinics. Traditional DOT is poorly suited for patients who are highly mobile or have limited availability during traditional clinic hours (e.g., work or school), or travel out of the country, which happens frequently in U.S.-Mexico border cities. DOT modalities that are responsive to the needs of these patients are needed to improve adherence and completion of TB treatment, especially among patients who may require binational care coordination, as offered through the San Diego County CURE TB Referral Program.

Use of mobile health (mHealth) technology to improve patient care continuity, including DOT, has captured the interest and imagination of researchers and clinicians who envision how technology can promote medication adherence through improved self-care practices. Prior work applying technology to ease the time- and resource-intensive demands of traditional DOT includes using landline phones with video monitors to allow health department staff to remotely observe patients taking their medications. Little data are available on this form of “Video DOT” (VDOT), because this approach has been used only in small pilot studies or adopted by TB programs without a research component. Studies evaluating VDOT using mobile phones, instead of landline phone, are currently underway, but few have been published to date. These include a feasibility study in Kenya and work completed by members of our own team to pilot test VDOT involving videos recorded by TB patients using smartphones, which are subsequently observed by a healthcare provider through a secure website. Interventions that make use of video capabilities available on most cell phones, however, have been largely unexplored for TB medication adherence and pose a promising application for TB patients in both low- and high-resource settings.

The current binational qualitative study was undertaken to assess the acceptability and feasibility of cell phone-based VDOT for monitoring TB treatment adherence in the U.S.-Mexico border region prior to developing and pilot-testing the application. This paper presents the results of a qualitative study conducted to inform the design and implementation of a subsequent binational pilot study of a VDOT application for TB treatment monitoring.

Methods

Study Population

This qualitative study was conducted collaboratively by the University of California San Diego and the TB control programs of San Diego County and Tijuana. In San Diego, care for active TB cases is centralized through the county’s Tuberculosis Control Program. In Tijuana, TB control is overseen by the Secretary of Health of Baja California at the state level and is managed by the local sanitary jurisdiction in conjunction with care delivery through local health centers.

Recruitment and enrollment

A convenience sample of TB patients, care providers (e.g., physicians, nurses and DOT workers) and local TB public health officials were invited to participate in focus groups. TB patients who had completed treatment within the past six months or were still on treatment but non-infectious, and had received...
traditional in-person DOT (hereafter referred to as “patients’”) were invited by TB control program staff in each city to participate. Patient eligibility criteria included: age ≥ 18, completed at least three months of TB treatment and tested smear or culture negative for *M. tuberculosis*, and able to speak English or Spanish. TB providers (nurses and physicians) and DOT workers on both sides were invited to participate in the focus groups through their respective TB control programs. Eligibility criteria included: age ≥ 18 years, able to speak English or Spanish, and currently providing TB clinical care, DOT, case management or outreach to TB patients.

Focus groups were conducted in the participants’ native language (English/Spanish) by facilitators who were members of our study research team (MZ, KC, JCM, JLB and RSG). Written informed consent including permission to tape-record the sessions for transcription and coding purposes was obtained from all participants. Participants completed a brief demographic questionnaire. San Diego patient participants were offered a gift card worth $20.00 USD and Mexican participants were offered a comparable amount of $200 Mexican pesos as remuneration for their time and travel.

**Ethics Statement**

The study was approved by the Institutional Review Board at the University of California, San Diego and the Bioethics Committee of El Colegio de la Frontera Norte (COLEF) in Tijuana.

**Focus group procedures**

Separate focus groups were held for patients and providers. The facilitator briefly described VDOT as a method of monitoring medication intake by using a smartphone to capture a video of someone (patient) taking their TB medication and then automatically sending the video in an encrypted manner to their care provider for observation (Figure 1). Facilitators informed the participants that videos could not be viewed on the cell phone and only health department personnel would have access to the videos. Each focus group started with a facilitator reading aloud the study purpose and voluntary nature of participation. Following the introduction, the facilitator used a semi-structured focus group interview guide (see Appendix 1 patient guide, Appendix 2 provider guide) to elicit participant reactions to VDOT and obtain participant perceptions of the overall feasibility and acceptability of VDOT, as well as advantages/disadvantages of VDOT versus traditional in-person DOT. Participants were also asked to identify patient characteristics that could make VDOT better suited for some patients than others, and to provide recommendations for overcoming possible technological barriers to using VDOT.

*Figure 1*: Informing a binational video cell phone directly observed therapy trial for Tuberculosis.¹⁷
Provider focus group questions elicited feedback on intervention procedures, preferred patient characteristics and possible enhancements to maximize adherence or lower cost. Participants were also asked to comment on the potential barriers and facilitators of using smartphones to record and send videos of patients ingesting their medications.

Analysis of Qualitative Data

Constant Comparative Analysis Methods—"a structured data coding process that allows for jointly coding data to explore the breadth of responses within primary themes—were used to analyze the focus group transcripts."22-24 We applied theoretical thematic analysis procedures based on Braun and Clarke's work25 to identify patterns within our focus group data based on our interest to understand participant perspectives on the proposed VDOT intervention. Our a priori themes for this qualitative study followed recommendations for conducting feasibility studies described by Bowen and colleagues,26 particularly when there was a lack of prior studies on a specific intervention among a population of interest that may have distinct needs or interests. Drawing on Bowen and colleagues' work, we applied the following general focus areas to guide our exploratory work and understand the feasibility of VDOT in a binational context: Acceptability (reaction to the proposed intervention), Demand (estimated use of the intervention) and Practicality (evidence of potential efficacy amidst individual, time, commitment or other constraints). Our major a priori themes were: 1) perceived intervention feasibility and acceptability; 2) technical recommendations; 3) patient-provider relationship and interactions; and 4) characteristics of good VDOT candidates.

Focus group data were audio-recorded and discussions were summarized. Spanish-language focus group summaries were translated into English by a bilingual/bicultural study team member (JCM). Two study team members (MLZ and KC) developed initial categories and a coding scheme based on the a priori themes and conducted a detailed review of patient focus group summaries (i.e., open coding). The two study team members independently reviewed and coded the transcripts by hand using the coding scheme. The coders then met to discuss and refine categories, resolve coding discrepancies, refine coding interpretation and assign new codes as needed. Final coded transcripts included patient and provider recommendations and concerns surrounding implementation and perceived feasibility and acceptability of VDOT. The analytic process considered potential differences and similarities between patient and provider perspectives, as well as indicators of cross-cultural or binational differences between them. Demographic data were described using SPSS 16.0.

Results

Participant Characteristics

In total, nine focus groups were conducted—six in San Diego (four with patients; two with DOT workers and providers together) and three in Tijuana (one each with patients, providers and DOT workers separately). Overall, 22 patients and 47 staff took part in the groups. Sessions ranged from 46 to 103 minutes (mean = 82 minutes). San Diego's 14 patient respondents were ethnically diverse, including 8 Latinos (57%). Racial background (including Latinos) was as follows: 4 (29%) Asian, 2 (14%) Caucasian/White, 2 (14%) African American, 3 (21%) other, and 3 (21%) who preferred not to respond. Detailed demographic information provided in Table 1 show that study participants were diverse in terms of age, gender, race/ethnicity and socio-economic status. Patients spent an average of 7.4 months having their treatment monitored through in-person DOT in San Diego and average of 8 months in Tijuana. Owning a cell phone was reported by 8 (57%) patients in San Diego and 7 (88%) patients in Tijuana. Overall, 9 patients (41%) (5 [37.5%] in San Diego and 4 [50%] in Tijuana) reported prior experience sending a picture from their cell phone and 4 patients (2 [14.3%] in San Diego and 2 [25%] in Tijuana) reported prior experience sending a video from a cell phone.

Theme 1: Perceived implementation feasibility and acceptability of VDOT

Both patients and providers felt that VDOT was a feasible and acceptable alternative to in-person DOT. Overwhelmingly, patients from Tijuana and San Diego stated that VDOT could be a convenient way to receive DOT for TB treatment. They felt that it would make their lives easier and that VDOT would improve patient acceptability of DOT in general, as one patient described:

“With the demonstration that has been shown, I think it's really easy to use.” (Female patient, San Diego)
A DOT worker noted:

“...I feel like I was being babysat, I’m an adult…”
(Male patient, San Diego) and

“It’s upsetting in the initial stages. I was upset because, like these people don’t trust me. I am an adult. I am responsible. I want to be cured.”
(Female patient, San Diego).

The notion of in-person DOT as paternalistic was not evident among Tijuana patients who focused more on VDOT allowing greater flexibility of daily mobility. Patients in both cities felt that VDOT could help alleviate privacy concerns associated with DOT because a clinician or DOT worker would not be required to routinely visit the patient’s home or work place. Clinic staff from Tijuana felt that VDOT had the potential to save time and money for their patients:

“It’s a bit of work that we will have to do with this program, but I see it as 10 fewer trips during the day . . . .”

San Diego patients reported that VDOT could provide a sense of independence, trustworthiness, freedom of mobility and convenience (e.g., not needing to wait at home for the DOT worker to arrive). They also mentioned that with in-person DOT they sometimes felt patronized and untrusted:

“A DOT worker noted:

‘Promotores’ the benefit here [Tijuana] would be for the patients, especially during these times of rain we don’t have access to them and it would also benefit those who live far. I believe that those are the benefits for us.’”
(Male DOT worker, Tijuana)

San Diego patients reported that VDOT could provide a sense of independence, trustworthiness, freedom of mobility and convenience (e.g., not needing to wait at home for the DOT worker to arrive). They also mentioned that with in-person DOT they sometimes felt patronized and untrusted:

“...I feel like I was being babysat, I’m an adult ...”
(Male patient, San Diego)

Table 1: Participant demographic and technology experience profile by study site

<table>
<thead>
<tr>
<th>Demographics</th>
<th>San Diego Patients (n = 14)</th>
<th>San Diego Providers (n = 14)</th>
<th>Tijuana Patients (n = 8)</th>
<th>Tijuana Providers (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of DOT Experience (months)</td>
<td>Mean (SD) 7.4 (7.1)</td>
<td>N/A</td>
<td>8.0 (1.6)</td>
<td>N/A</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Range (1–22)</td>
<td>(24–76)</td>
<td>(24–88)</td>
<td>(24–71)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 9 (64.3)</td>
<td>5 (35.7)</td>
<td>4 (50.0)</td>
<td>15 (45.5)</td>
</tr>
<tr>
<td>8 (57.1)</td>
<td>Female 5 (35.7)</td>
<td>9 (64.3)</td>
<td>4 (50.0)</td>
<td>16 (54.5)</td>
</tr>
<tr>
<td>2 (6.1)</td>
<td>No Response</td>
<td>6 (42.9)</td>
<td>2 (100)</td>
<td>33 (100)</td>
</tr>
<tr>
<td>Hispanic/Latino Ethnicity</td>
<td>8 (57.1)</td>
<td>6 (42.9)</td>
<td>8 (100)</td>
<td>33 (100)</td>
</tr>
<tr>
<td>Cultural Background</td>
<td>Asian 4 (28.6)</td>
<td>3 (21.4)</td>
<td>–</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Caucasian/White</td>
<td>2 (14.3)</td>
<td>6 (42.9)</td>
<td>–</td>
<td>6 (18.2)</td>
</tr>
<tr>
<td>African American/Black</td>
<td>2 (14.3)</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Native American /Alaskan Native</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (21.4)</td>
<td>1 (7.1)</td>
<td>6 (75.0)</td>
<td>8 (24.3)</td>
</tr>
<tr>
<td>No Response</td>
<td>3 (21.4)</td>
<td>4 (28.6)</td>
<td>2 (25.0)</td>
<td>17 (51.5)</td>
</tr>
<tr>
<td>Housing (past 3 months)</td>
<td>Live in own home 4 (28.6)</td>
<td>7 (50.0)</td>
<td>4 (50.0)</td>
<td>15 (45.5)</td>
</tr>
<tr>
<td>Live in parent’s home 3 (21.4)</td>
<td>1 (7.1)</td>
<td>6 (42.9)</td>
<td>1 (12.5)</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Live in someone else’s home 1 (7.1)</td>
<td>–</td>
<td>3 (37.5)</td>
<td>–</td>
<td>1 (3.0)</td>
</tr>
<tr>
<td>Live in hotel or rooming house 4 (28.6)</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Other/No Response 2 (14.2)</td>
<td>6 (42.9)</td>
<td>–</td>
<td>16 (48.5)</td>
<td>–</td>
</tr>
<tr>
<td>Cell Phone Experience</td>
<td>Owns a cell phone 8 (57.1)</td>
<td>13 (92.9)</td>
<td>7 (87.5)</td>
<td>30 (90.9)</td>
</tr>
<tr>
<td>Used camera on cell phone 5 (35.7)</td>
<td>13 (92.3)</td>
<td>4 (50.0)</td>
<td>22 (66.7)</td>
<td>–</td>
</tr>
<tr>
<td>Sent photos using a cell phone 5 (35.7)</td>
<td>7 (50.0)</td>
<td>4 (50.0)</td>
<td>22 (66.7)</td>
<td>–</td>
</tr>
<tr>
<td>Sent videos using a cell phone 2 (14.3)</td>
<td>4 (28.6)</td>
<td>2 (25.0)</td>
<td>13 (39.4)</td>
<td>–</td>
</tr>
</tbody>
</table>
It will avoid having to go out in the unit/vehicle.” (Male DOT worker, Tijuana)

It also reduced the burden on patients who received clinic-based DOT as noted by this patient:

“As a TB patient, it would be great not having to show up at the clinic every day.” (Female patient, Tijuana)

**Theme 2: Technical support and recommendations**

Sufficient patient training and technical support to use VDOT were the major concerns in all groups. Patients in both cities expressed concern that the technology might be hard for some individuals to learn and use, but also stated that adequate preparation and training could help to overcome potential problems. Patients and providers offered specific technical recommendations to facilitate successful uptake of VDOT. San Diego patients focused on the need for understanding their TB disease first before attempting to initiate VDOT. Tijuana patients expressed concern about cellular coverage while traveling outside the region and whether the proposed VDOT program included sufficient training on how to perform the procedures. As one participant mentioned:

“I do not know how to operate this type of device, but if I get a good phone and someone to tell me everything on [how] to use it, I can do it.” (Female patient, Tijuana)

Providers in both cities also emphasized the need for sufficient patient and staff training and ongoing technical support. San Diego providers focused on adequacy of the VDOT training protocol, how to tailor VDOT to the needs of patients (e.g., Spanish-language dominant patients), maintaining patient confidentiality (e.g., during recording and after transmission of videos), and liability of sending video information. Tijuana clinic staff were more focused on number of hours of patient and staff training. As one provider noted:

“…we also have to consider how confident the patient is handling a camera. Many of them are illiterate; many of them are patients who don’t have greater resources other than their family who tells them how to do things or does them for them.” (Male provider, Tijuana)

**Theme 3: Patient-provider relationship and interactions**

A theme across focus groups in both cities was concern over how the patient-provider relationship might change with VDOT. Patients in both cities indicated some concern over losing contact with the DOT worker, as one participant noted:

“You would lose that personal touch … the worker comes to you, smiling and says, ’hey, how are you?’ and everything. It helps boost your ego right, because somebody cares for you.” (Female patient, San Diego)

A second participant alluded to the expanded role of the promotor in supporting individual patient’s health:

“My promotor helped me out a lot. She would bring me the cup for my bacilloscopy [sputum smear], she would remind me of certain things, an important date, etc. Truthfully, it really is necessary for the promotor to come to our homes.” (Male patient, Tijuana)

San Diego patients felt that this would be less problematic if prior interaction with the DOT worker included instruction on how to use VDOT, and educating the patient to help them become less reliant on the DOT worker and more confident on how to use VDOT. The reduction in patient-provider contact was noted, but it was less important among San Diego patients who placed greater value on the opportunity to gain independence.

San Diego providers mentioned concerns over potential loss of face-to-face communication with patients, but this was not as prominent as technical and training concerns. Not surprisingly, loss of interpersonal communication or interaction was expressed most strongly among Tijuana DOT workers. They felt that the trust and personal relationship with patients could be jeopardized by VDOT, because the time they spent with patients was important for building trust.

“There is something to be said about having that face-to-face interaction at the beginning … So, that’s where things like reliability and you know, being able to trust them to begin with, that they are actually going to [take their medication] in a way that is going to benefit them in the long run is concerning to us …” (Female provider, San Diego)

Another provider commented:

“When we go and give them their medication and watch them take it, it’s not just watching them and thinking they already took and it I’m leaving … We stay with them, talk to them, ask how things are going, how they’re feeling, etc. That’s how we gain their trust and we appreciate that. Hence, that would be lost.” (Female provider from Tijuana)
During the course of the focus group discussion, Tijuana DOT workers identified a positive potential impact of VDOT on the patient-provider relationship. They considered that VDOT may free up some of their time with patients who are doing well and allow them to focus efforts and time with those patients who need closer follow-up and more direct contact.

**Theme 4: Characteristics of “good candidates” for VDOT**

Patients and providers in both cities offered recommendations about the profiles of patients who would and would not be good candidates for VDOT. For example, patients recommended that individuals who lacked familiarity with technology might be poor candidates, citing older patients as an example. Patients felt that some older patients might lack experience or comfort needed to use technology to record their treatment and would be unsuccessful and/or non-adherent to their medication if they were enrolled in VDOT. Patients felt that to participate, VDOT candidates needed to be willing to adhere to VDOT protocols. Tijuana patients specifically mentioned that persons who inject drugs and/or who are homeless may not be good VDOT candidates because their lifestyle could adversely affect their willingness or ability to be adherent. Tijuana patients and clinic staff commented about how some may try to make it look like they swallowed the pills but had not.

Providers in both cities felt that individuals with complicated disease such as multi-drug resistant TB or co-morbid conditions (e.g., HIV or diabetes) may also not be good candidates for VDOT. Tijuana providers were more specific about their perceptions of which patient circumstances would make them less desirable candidates for VDOT, including patients who were hospitalized, in drug abuse treatment, or undergoing other treatments.

Patients in both cities also indicated that certain patients may be more likely to lose, break, or sell the mobile phone loaned to them for VDOT. They reported that patients whose environments pose increased risk for phone theft might be poor candidates. Participants recommended contingencies for these cases, including mandated penalties for losing the VDOT phone and signing contractual agreements for patients to cover the cost of lost/stolen/broken cell phones. Participants explained:

*“I think that if a patient will put a deposit until it’s finished, then they will take care of it…”* (Female patient, San Diego)

*“Maybe a written agreement, with terms and conditions [would help to get the phones back]…”* (Female patient, San Diego)

**Discussion**

To our knowledge, this is the first study to qualitatively assess patient and provider perspectives about the use of mHealth interventions for TB treatment adherence monitoring, as well as the first to be conducted in a binational setting. This study explored patient and provider perceptions on a novel VDOT intervention to monitor and improve adherence to TB treatment. We found that overall, patients and providers on both sides of the border believed that the proposed intervention was feasible and acceptable, especially if the research team addressed specific areas of concern and considered participant recommendations. Participants also provided concrete and useful advisement that informed a subsequent VDOT pilot study.19

Patient and provider insights into VDOT feasibility and acceptability indicated that VDOT could play an important role in supplementing the array of TB care continuity approaches currently used in San Diego and Tijuana. Patient acceptability was demonstrated by interest in how VDOT could promote medication adherence autonomy and patient privacy. Providers saw VDOT as an additional tool for assuring TB treatment adherence. Patient literacy and comfort with technology, adequate training and technical support were among the recommendations for implementing VDOT.

An important finding was that patients and clinic staff from San Diego and Tijuana shared some priorities and perspectives on VDOT, while differing on others. Subtleties in patient and provider focus group discussions indicate that commonalities in perspectives may have different underlying reasons. For example, San Diego patient concerns about adequate training were in the context of having sufficient self-efficacy to use VDOT independently. Conversely, San Diego provider concerns about adequate patient training were more related to ensuring that clinicians could rely on VDOT to effectively monitor patient adherence. This difference in perspectives is not new, as members of our research team have documented in earlier studies that physician and patient agreement on specific barriers to health care, may in fact be due to vastly
different underlying reasons. For example, in a study conducted by Zuñiga and colleagues on barriers to HIV clinical trials participation in San Diego, patients and providers agreed that lack of transportation to the clinic was a barrier. Qualitative study findings revealed, however, that Latino participants were apprehensive about taking public transportation due to immigration concerns, while providers perceived it as a lack of transportation.

Cultural differences between San Diego and Tijuana patients were revealed in perspectives about the patient-provider relationship. Tijuana patients expressed concern that VDOT might jeopardize face-to-face contact with their providers. This was also a concern mentioned by San Diego patients; however, patient independence in managing their treatment was of greater relative importance.

In comparison to the U.S. health care system, the Mexican health care system generally has a more paternalistic approach to care delivery where patients are expected to comply unquestioningly with medical directives. We saw this reflected in Tijuana patient expectations for receiving sufficient training and support, and when referring to consequences when they do not adhere to the VDOT protocol. Members of our study team (FM, MLZ) have identified similar patient perspectives where patients living with HIV felt scolded by providers when they were unable to adhere to medication. San Diego patients were oriented more towards how VDOT could promote greater independence in health care management. These findings underscore the need for clinicians and researchers to understand and manage expectations of patient self-reliance to participate in VDOT.

Limitations and feasibility issues of implementing the VDOT intervention merit attention. Since the purpose of this study was to inform the development of a VDOT application that was previously non-existent, costs related to the mobile devices, cellular service, and program implementation were not assessed. Costs, as well as actual feasibility and acceptability of the resulting VDOT system were assessed in a subsequent pilot study conducted in San Diego and Tijuana.

Other limitations inherent to small qualitative studies are that we relied on a convenience sample of participants who may not represent other TB patient or provider perspectives in other communities. Since patient eligibility criteria limited the number of potential participants, and clinic staff participation was limited by availability, study findings might not be representative of all TB patients and providers. However, obtaining patient and provider perspectives in high- and low-resource communities allowed for enhanced sensitivity to city-specific opinions and expectations to inform the development and subsequent evaluation of the VDOT system. In addition, the broad-scale, binational engagement of health departments provides critical information about how patients and providers perceive TB treatment monitoring and how it affects their lives, not as patients but as individuals. Finally, the opinions of the focus group participants were based on a hypothetical example of how VDOT would be used; however, it is unknown how these opinions would differ if the patients were shown a working example of VDOT or were given an opportunity to use it.

Conclusion
Results of this study indicate that TB patients and providers in San Diego and Tijuana considered VDOT to be feasible and acceptable for monitoring patients ingesting their TB medications. Participants generally thought this approach would make adherence monitoring less burdensome and more confidential than in-person DOT. Detailed patient technical training and ongoing support for both patients and providers appeared to be essential for successful implementation of a VDOT program. Findings from this study underscore important considerations about differences in the culture of health care delivery context (U.S. versus Mexico). Country-specific considerations regarding patient and provider expectations about the patient role in their care, patient health outcomes, and patient satisfaction with care are especially important given the great potential for mHealth interventions to be applied transnationally.

Our work highlights the role that the culture of health care delivery can play in perceived risks and benefits of VDOT and future mHealth applications. Importantly, the binational nature of this study allowed us to identify overt and nuanced differences and similarities in concerns and preferences of TB patients and providers around the use of mHealth globally. Study findings were used to inform the subsequent development and implementation of VDOT pilot study for TB treatment monitoring. This study contributes much needed empirical data to guide mHealth innovation for addressing TB, as
well as other diseases regions where scarce health care and manpower resources must be more strategically managed.

Acknowledgements
The authors wish to thank Deborah McIntosh, Gabriela Escalante, Cristhian Colin, Dr. José Guadalupe Bustamante, and Dr. Rafael Laniado-Laborín. For their efforts and for sharing insights that were crucial for developing the VDOT System. The authors also thank the study participants for the feedback they provided to help develop the system.

This study was funded by grants from the National Institutes of Health (R21-AI088326). JLB was also supported by NIMH grant K01-MH095680. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

References


Appendix 1

University of California, San Diego (UCSD)

VCP-DOT Pilot Program Focus Groups

Dr. Richard Garfein

**PATIENT FOCUS GROUP FACILITATOR GUIDE**

**Introduction**

I appreciate your help with the consent forms and the brief survey. A few notes about our session today. This session will be recorded, but your name will not appear in any report or summary of the session. All of your comments are very important and we would like to give each person the opportunity to talk about their experiences or express their views. It is also important to remember that what is talked about here is confidential and that we respect everyone’s privacy and keep our conversation in this room.

Ok, now let’s get started …

People who work in health care know it is important to be able to help TB patients take their medications. Directly observing patients taking their medications has been shown to significantly improve adherence to treatment, but we are aware that this can be time-consuming and inconvenient for patients. We want to understand better whether we can use cell phone technology to remotely watch patients taking their medications.

I will now explain how face-to-face DOT is currently done and then I’ll explain how we think VCP-DOT can be done. (EXPLAIN FLOW DIAGRAM BRIEFLY TO PARTICIPANTS).

**VCP-DOT Procedures: Are they appropriate?**

Let’s start by getting an idea of how familiar the members of our group are with using cell phones …

Q1. How often each day do you use your cell phone (for calls, texting, or other reasons)?

Q1.1 What experiences have you had using a cell phone to take a picture or video and send it to someone? Have you seen someone else do this?

Q2. If you were to receive a cell phone that can record video, what problems do you think you might have with using cell phones to send a video?

Q3. How do you think such problems could be overcome?

Q4. In what situations do you think VCP-DOT would not be good to use?

Q5. Will standard or VCP-DOT be more effective in helping patients to take all of their medications? Why? Why not?

Q6. If you were going to use the VCP-DOT what would make it easier for you?

Q6.1. Let’s say that you were instructed to take your TB medication at 1:00 in the afternoon, how hard would it be for you to find a place to record this process and send it to the nurse (by “hard” I mean finding a private place, finding the time to do it, etc)
Q6.2 Now what do you think would make it easier for you to do this?

VCP-DOT Advantages/Disadvantages

Q7. Let’s think about comparing the two kind of directly observed therapy, the standard way and then using cell phone video … In your opinion what advantages do cell phones have over standard DOT?

Q8. What disadvantages does VCP-DOT have compared with standard DOT?

Technical Advantages and Disadvantages of VCP-DOT

Q9. What cell phone features (display size, camera quality, keyboard size and layout, memory capacity, sound quality, unlimited minutes, etc.) would you like to see if you were going to try out this new process to send video information?

Q10. Are cell phones acceptable and a good option for patients?

Q11. Would it help patients remember to take their medication and send their video recordings if they received a reminder message on their phone everyday?

Final Thoughts - End of the Session

Q12. What other ideas do you think could help people use the cell phone for taking their TB meds? Perhaps something that we have not talked about yet, that may improve our ability to use this technology for medications?

End of Session

Conclusion: This concludes our focus group session. I very much appreciate your participation today. What we have learned from you is very important in order to know how to best implement the VCP-DOT Pilot program in our community.

Once again, thanks.

Appendix 2

University of California, San Diego (UCSD)
VCP-DOT Pilot Program Focus Groups
Dr. Richard Garfein

PROVIDER FOCUS GROUP FACILITATOR GUIDE

Introduction

I appreciate your help with the consent forms and the brief survey. Now we can begin the focus group discussion.

Our discussion will focus on the potential barriers and facilitators of using cell phones to record and send videos of patients self-administering their TB medications. Our purpose is to ask clinicians about their opinions on methods to overcome barriers with Video Cell Phone-Direct Observed Therapy (VCP-DOT) and to develop optimal procedures for delivering VCP-DOT. We are also asking patients in separate focus group discussions.

This session will be recorded, but your name will not appear in any report or summary of the session. All comments are very important and we would like to give each person the opportunity to talk about their experiences or express their views. It is also important to remember that what is talked about here is confidential and that we respect everyone’s privacy and keep our conversation in this room.

I will now compare how face-to-face DOT is currently done with how we think VCP-DOT can be done. (EXPLAIN FLOW DIAGRAM BRIEFLY TO PARTICPANTS).

VCP-DOT Procedures: Are they appropriate?

Q1. Which of these procedures do you think are appropriate? Which are inappropriate?

Q2. Do you see any procedures that will be difficult for the patient to follow?

Q3. Do you see any procedures that will be difficult for the TB Control staff to implement?

Q4. What modifications would you recommend to offset these difficulties?

Q5. What aspects of VCP-DOT are considered improvements/deficits compared to standard DOT?

Q6. What VCP-DOT procedures that I described would you change and how?

Adherence To VCP-DOT Treatment

Q7. Are there additional enhancements that can be made to the VCP-DOT protocol to improve the patients’ or TB Control staff’s ability to maximize treatment adherence or lower cost?

Q8. What other features (e.g., reminder messages, FAQs, live support) should be included to improve adherence and patient satisfaction?

Q9. What type of patient characteristics would make a patient a poor candidate for VCP-DOT?

Technical Issues

Q10. What are some of the technical problems you think may arise and what do you think we would need to address these?

Q11. Do you have any thoughts about cell phone devices and service providers features that will be necessary for the intervention to function effectively?

Q12. How much training do patients need to use video cell phones?

Cost

Q13. Do you think VCP-DOT will cost more or less than standard DOT and why?
Use in Other Countries

Q14. In your opinion, do you think this intervention could be adapted for use in a resource-limited country, such as Mexico?

Final Thoughts - End of the Session

Q15. What else comes to mind, perhaps something that we have not talked about yet, that may improve the VCP-DOT Pilot Program?

Conclusion: This concludes our focus group session. I very much appreciate your participation today. What we have learned from you is very important in order to know how to best implement the VCP-DOT Pilot program in our community.

Once again, thanks.
AN INTEGRATED mHEALTH MODEL FOR TYPE 2 DIABETES PATIENTS USING MOBILE TABLET DEVICES

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Background: Ease of use, proximity to the user and various health maintenance applications enable mobile tablet devices to improve patient self-management. With mobile phones becoming prevalent, various mobile health (mHealth) programs have been devised, to improve patient care and strengthen healthcare systems.

Aims: This study explored how mHealth programs can be developed for type 2 diabetes patients through a co-design participatory workshop between practitioners and researchers. The aim was to design a mHealth pilot program from the input.

Methods: A co-design workshop was conducted with 15 participants, including general practitioners, specialists, nurses and a multidisciplinary research team. Participants generated 31 statements in response to a trigger question and engaged in a structured discussion. Thematic cluster analysis was conducted on the statements and discussions.

Results: Through the analysis, patients’ self-management and health system integration emerged as the main topics. Further analysis revealed that there were two distinct areas of patient self-management; ‘compelled’ and ‘empowered’.

Conclusion: With the results, a loose-knit mHealth pilot program was developed wherein patients with various levels of conditions and digital skills could be incorporated. In order to encourage sustainable changes, practitioners proposed that mobile devices must be situated in the patients’ everyday settings and that digital training should be provided.


Introduction

According to the World Health Organization, the number of diabetes patients worldwide will have reached 366 million by 2030.1 In Australia, diabetes is the sixth leading cause of death and the death rate continues to rise.2 The diagnosis and treatment of diabetes are crucial, as the condition may pose other risks such as heart disease, stroke, blindness, and kidney failure. Type 2 diabetes results from the body’s ineffective use of insulin and accounts for approximately 90% of all diabetes diagnoses. Simple lifestyle changes such as maintaining an optimal
body weight, engaging in physical activity and adopting a healthy diet are essential to the management of type 2 diabetes.1

Diabetes is a chronic condition that needs special attention to diet and exercise that involves patients’ active self-management.3 Self-management of an illness requires a considerable level of knowledge, discipline and self-regulation. For this reason, prescribed activities are not solely determined by medical factors. For example, the health outcomes of blood glucose self-testing among type 2 diabetes patients have not been clearly established. Nevertheless, the practice is beneficial because it can contribute to the patients’ self-management strategies by giving patients the opportunity to reflect on their condition.4 Characteristics of successful patients include accountability, motivation for change and active participation. Peer support and community resources are also effective methods of engaging patients. A longitudinal study on relationship between the patients’ social networks and their self-management of chronic illness shows that social involvement with wider resources supports not only the day-to-day tasks but also helps manage long-term conditions and the patients’ emotional well-being.5

With mobile phones becoming prevalent, various mobile health (mHealth) programs have been devised to improve patient care and strengthen healthcare systems. Ease of use, portability and ubiquity all point to the potential of mobile devices for use in preventing, diagnosing and treating illnesses, as well as increasing access to health services and lowering costs. The benefits of using mobile devices are in the continuous access they provide and their proximity to users. Mobile devices are both ‘always on’ and ‘always with’ the user.7 This enables seamless healthcare service delivery, while requiring active participation and control by the users.

There are many potential benefits of mHealth programs. Mobile applications (apps) may be used for positive health promotion, physical fitness, treatment adherence and disease management. Mobile technologies can also be used for diagnosis, complying with treatment, obtaining patient information and increasing administrative efficiency.8 As part of the DC Chronic Care Initiative, Katz, Mesfin and Barr conducted a mobile phone-assisted diabetes self-management project.9 Thirty-two type 2 diabetes patients were given mobile phones with subscription and were connected to an interactive platform for patients and health care providers to track blood glucose and receive real-time feedback and diabetes information. Although half of the patients dropped out in the middle of the study, among those who remained hospital emergency room visits and hospitalization were reduced. Technology can support patients’ self-management, for example, by enabling self-monitoring of blood glucose levels. However, it is difficult to sustain the behaviour.10

An important element of diabetes care is the patients’ active involvement in their self-management.11-13 The ability varies from person to person and evolves over time.14 The contextual nature of health behavior influences an individual’s level of engagement.15

The digital environment that affects the user’s engagement and the sustainability of the patient’s behavioural change must be taken into consideration. However, it has not been established whether behavioural change techniques provided by digital devices are effective in the long run.16 A meta-analysis of 85 internet intervention programs concludes that they were mostly effective especially if they were based on the theory of planned behaviour. Including more techniques and using additional communication methods were found to enhance the effects.17 Effective health interventions need to be based on theories of behavioural change that incorporate specific techniques. Intervention programs usually entail a controlled experiment where subjects are randomly assigned to a trial. The changes in behaviour are measured after the trial and the effectiveness of the program is evaluated. While such models provide efficient ways to implement medical treatments, the limits of such experiments are that they cannot explain the broader link to other socio-cultural factors that come into play when patients are dealing with their health conditions. A more holistic examination of the multitude of factors that influence patients’ engagement with digital technologies is necessary.

Most mHealth studies examine the effectiveness of interventions delivered via mobile devices, using controlled trials where variables can be observed in isolation.18 Such models offer limited means for the observation of patients’ long-term behavioural changes. Digital devices are used within the user’s socio-cultural context and mHealth programs cannot be separated from other uses of the devices. However, little is known about the process of how patients adapt to the devices used in mHealth programs. In order to implement a sustainable program, we
need to carefully examine how mHealth tools are adopted and utilized by users within the broader social context.

It is crucial to know the affordances as well as how users engage with digital technologies.

Easy and instantaneous access to information is one of the strengths of mobile devices. The internet is known to be effective in providing dietary information, accessing electronic medical records, education and visualising data. Mobile phones are good for uploading glucose levels, receiving text messages from clinicians and running self-management applications.19

Mobile tablet devices are not as widely used as smartphones or computers. They are positioned in-between computers and phones in that they afford large enough screens for users to engage in lengthy information seeking but are also highly portable.7 The portability within a designated area such as the home or office, differentiate them from computers.20 The proximity to the user, continuous Internet access and ease of use can be used advantageously when devising self-management programs.

Research questions
This study adopted an exploratory approach because little research has been conducted specifically on mobile tablet devices in mHealth. Mobile tablet devices can be positioned between mobile phones and computers and offer a unique experience to users.20 However, like any other technologies, the adoption is complex because it does not occur in a vacuum, and it involves interaction with the user over time.21 Technologies are constantly advancing; therefore, implementation of new programs should be flexible and contextual.22 How users – practitioners and patients - perceive of and interact with the technologies is crucial to implementing a successful digital health program. As a first step towards developing a sustainable mHealth program, the aim of this paper was to identify ways in which these devices can be situated within mHealth from the practitioners’ viewpoint. This will set the initial frame for further investigation into how mHealth programs can be embedded into the overall management of chronic illness, in this case, type 2 diabetes.

The following research questions were established:

RQ1. According to practitioners what are the potential uses of mobile tablet devices in managing type 2 diabetes?
RQ2. What areas do practitioners perceive to be particularly beneficial to patients in their uses of mobile tablet devices to manage type 2 diabetes?

Methods
In order to facilitate an environment where the new technologies are embraced by users and benefit them, a co-design method was adopted as a first step in developing a mHealth pilot program for diabetes patients. Using a qualitative approach, this study commenced with a broadly defined concept of mHealth in order to explore the elements of a successful technology adoption in self-management and health care.

A practitioner co-design workshop (N = 15) involving GPs, nurses, and the research team was held at a local GP Super Clinic# on July 22, 2014. The aim of the workshop was to develop a framework of a year-long mHealth pilot program. This paper reports on the practitioners’ perspectives on how mHealth may be enabled in primary care settings. We initially invited all of the GPs and nurses at the Clinic (N = 16) of which 11 attended.

The workshop was carefully structured so that all participants could fully contribute regardless of their role in the discussion. Too much or too little information may lead to premature decision-making and poorly conceptualised designs.23 Structured dialogue methods are suitable for use in complex situations where the group cannot meet regularly to discuss the project and have not collaborated before, but share a common goal. A workshop facilitating a structured dialogue was optimal for the purposes of this study, because of the complexity of the prevailing issue and also due to the diverse expertise of participants.

Prior to the workshop, a trigger question was posed in order to ensure efficient management of the discourse; the participants were required to respond with up to two statements. The trigger question, “how could you and your diabetes type 2 patients use a mobile tablet to manage this health condition?” was sent out to the practitioner participants and they were asked to bring their draft statements to the workshop. During the fairly open discussion, the facilitator deliberately asked all participants to

#GP Super Clinic is an initiative of Australia’s Department of Health and is a government funded program intended to bring together general practitioners, practice nurses, allied health professionals, visiting medical specialists and other health care providers to deliver primary health care services, with a patient-centric model of health care delivery.
present and explain their responses. This method enabled participants not only to engage in the discourse equally but also to appreciate the diversity in the responses given.

A total of 31 statements were collected and categorized by themes. Eleven practitioners participated in the discussion, including seven GPs, one specialist, and three nurses. Throughout this paper, pseudonyms are used for anonymity. Six research team members participated in the dialogue to ensure diversity in the viewpoints presented and to maintain focus on the research goal. Two practitioners were also research team members, but are indicated as practitioners in this paper. In the analysis, the non-practitioner research team members are identified as R1-R4. These researchers are scholars with expertise in communication, health, information studies and technology.

During the first round of discussion, participants were given the opportunity to clarify and elaborate on their statements that they supplied before open discussion. The written statements that the participants and the discussions that followed during the workshop were both taken into account when identifying the themes. The written statements were collected and compiled together. Participants had the opportunity to clarify or modify their statements during the discussion. The research team took notes during the discussion and added the text to the list of statements. The statements and notes were qualitatively analysed by two research team members initially. Statements were grouped into themes during several iterations. The recurring themes were then categorized into items that reflect different aspects of a mHealth program. The themes and subcategories were shared with the team members for validation. The research was approved by the Human Ethics Committee at the lead researcher’s organization.

Results
Fifteen participants generated 31 statements (see Appendix for the list) in response to the trigger question. Using qualitative thematic clustering, two broad topics were identified: patient engagement and health system integration (Table 1). Practitioners viewed mobile tablet devices to be mainly used by the patient in their self-management but also envisioned a scope for mobile technologies to provide seamless access to the existing digital health systems.

The patient self-management topic comprised the majority of the statements, with 24 of 31 statements related to the devices’ use for patient self-management. Self-management, then, was divided into two sub-topics depending on patients’ level of engagement, which was named as ‘compelled’ and ‘empowered’. Participants differentiated activities that are required by the doctors such as recording blood glucose levels, which patients often find burdensome. We labelled such routine activities as ‘compelled’. Other activities which patients are more engaged with we labelled as ‘empowered’. The general consensus was that active information seeking, communication, self-reflection, and education can empower patients to engage in sustainable self-management activities. On the other hand, healthcare system integration implies a broader policy that facilitates a shift to a digitalised healthcare delivery. Statements for each category are summarised in Table 1.

Patients’ use of mobile tablet devices for self-management can be understood within a broad context of their overall digital engagement. Identification of diversified uses of mobile tablet devices is an important step towards the design of effective mHealth programs. Mobile devices are intended to serve many purposes, including self-management. Two sub-topics related to self-management activities emerged from the discussions, namely, assistance with day-to-day activities required for routine diabetes management, and patient empowerment aimed at enhancing autonomous self-management. The two sub-topics – ‘compelled’ and ‘empowered’ - were identified as related, yet conceptually distinct.

Mobile devices as tools for compelled self-management
Mobile devices can be effectively used by patients to facilitate the management program prescribed for diabetes patients, such as keeping record of blood glucose levels (BGL) and other biometric data. It can also be used as a tool to provide easy access to authoritative information. When first diagnosed, patients receive basic information from health practitioners, such as what to do, avoid, and not eat. In a mHealth program, basic knowledge and record keeping should be readily accessible to patients via the devices (R1).

However, simple recording and obtaining knowledge do not automatically constitute effective self-management. Patients must constantly track, look back on, and adjust their behaviour. Mobile devices
have the potential to bridge the gap between knowledge and behavioural change by improved tracking and recording, compared to the pen-and-paper method. Use of mobile apps as constant reminders and feedback on dietary information about the food intake is an immediate benefit. The devices can also be used to “coordinate reminders for multiple appointments” (R2).

Among the compelled activities, checking and recording blood glucose levels and getting access to authoritative information online were suggested as activities that could be conducted on a mobile tablet device.

Mobile devices as patient empowerment tools

Nevertheless, several challenges must be addressed prior to the implementation of mHealth programs. While it is important “to respond to prompts [for] correct treatment times” (Alyssa) and use the “built-in reminders such as when to take pills or exercise” (Cooper), “there has to be something in it for them (as far as outcomes are concerned); they have to be doing it for themselves” (Declan). Beyond the immediate benefits, patients must want to continue to use the device after the novelty phase (Mason). For the device to be empowering, practitioners suggested a need for various activities that are
more than simple day-to-day self-management. For example, patients may engage more meaningfully with their self-management when participating in educational activities, keeping reflective journals, and managing customised exercise or diet routines. Empowerment can also occur when patients share information or receive social support. By using the device, patients may have “time to realize what effect their food and diet can have” (Declan). The mHealth program can enable patients to exercise “autonomy with their health and be more proactive, which will help us (staff) tend better to the patients” (Kira). The devices can also be used to coordinate activities or support planning (Peter).

The device can be utilized as an “educational package” (Colin) providing general information on type 2 diabetes, what it is, and why it must be controlled and managed. It can serve as a preventive measure to screen further complications. Accessing information through online resources could also facilitate autonomous management. Patients often need to “get information on what to do in any situation” (Kaitlin) or “communicate with others to share information and experience” (R3). On-screen availability of the information was considered a “better format to help them understand their condition” (Daniel).

Managing diabetes can be challenging because it requires a certain level of self-discipline and consistency. Patients have to constantly monitor their activities or record their BGL just to maintain their daily lives. They have to learn to live with their health conditions. The practitioners acknowledged the importance of patients’ autonomy. Patients can address the daily challenges by learning more about the relevant health condition, sharing information, reflecting on the difficulties, and learning new coping mechanisms. In general, acquisition of new knowledge and learning new ways to manage a condition are successful pathways to self-care. When designing or evaluating an mHealth diabetes management program, it is crucial to incorporate patients’ sense of autonomy and independence (Colin) and instil a sense of “owning their disease” (Kira), by allowing them to “turn into their own researcher, with the device constantly giving them feedback” (R4).

Patients’ varying digital skills and attitudes towards the technology also need to be taken into account. Possible attrition during the pilot program must also be considered (Kaitlin).

The ultimate question is whether mHealth self-management programs can change patients’ behaviour. Many patients experience fatigue in their self-care and often “cannot maintain or control their lifestyles” (Emma). One of the aims of this project is to “identify the types of people whom mHealth would appeal to” (Peter).

Four additional empowerment activities—diet and nutrition, exercise, keeping a journal, and communicating—were suggested as activities that are essential to sustainable self-management that could be conducted with mobile tablet devices.

**Incorporating mobile tablet devices seamlessly into the current healthcare delivery system**

By connecting patients via mobile devices to online health systems, practitioners can keep track of patients records closely (Audrey). The devices can fill the void between doctors’ visits and provide patients with “a sense of access and care in-between consultations” (R2).

The addition of the device to patients’ various health management options could, over time, enhance the overall digital environment, if both doctors and patients are tolerant of digital health systems. “There is a national e-record system, but only about one third of patients have signed up and nobody really uses it. For this to be effective, practitioners have to use it first” (Declan). Seamless introduction of digital technologies via easy accessible mobile devices into the healthcare delivery system could encourage the online system. Furthermore, if mobile devices are used prevalently among patients and they increasingly demand access to e-records, this could be a trigger for a wider adoption (R2). Potentially, mobile devices may serve as a gateway to other digital health systems (R3).

**Discussion**

As outlined in Table 1, a mHealth model of patient self-management was suggested. And for mHealth programs to be effective, patients must perceive the technologies to be beneficial to their daily diabetes management as well as have the capability to utilise the tools on these devices. Patients need to be comfortable in using the digital tools available to them. The practitioners proposed an open and loose-knit pilot program where patients can learn, explore, and make use of the devices in long term. Positioning the devices within the context of the patients’ every day context was viewed as a
precondition for effective engagement with the devices, and eventually successful mHealth program outcomes.

Among the uses of the devices, practitioners’ suggestions were grouped into six activities. Of these, measurement of biometric information (e.g., BGL) through mobile apps and getting access to credible websites are named as “compelled” activities. These activities are necessitated by the patients’ diabetes condition and often required by their GPs. Four additional activities—diet and nutrition, exercise, keeping a journal, and communicating—are labelled as “empowered” activities. These are activities that are essential to maintaining the patients’ health but need further engagement from the patient in order to be effective. The concept, “patient empowerment,” that emerged from the discussions is an important element of sustaining self-management which can be a challenge to diabetes patients.

When implementing a mHealth program the following needs to be considered. First, due to the complexity of adopting digital technologies, instead of applying a clinical intervention model in short term, a looser model of self-management that is embedded into the patients’ everyday lives should be designed. To date, theoretical causal inferences about emerging technologies are often limited. Second, technology adoption does not occur in a vacuum; it is usually intertwined with other aspects of life and users’ needs. A broader approach is needed to understand how people engage with new technologies. When technology adoption is required in the program, the user’s context needs to be considered. Third, when appropriated by users, technologies result in divergent outcomes. What is meaningful and effective for one user is not necessarily so for another. Thus, a diversified approach, rather than a one-size-fits-all strategy, is necessary during implementation of mHealth programs. This is particularly the case if the patients’ levels of digital literacy are varied.

At the co-design workshop, practitioner participants agreed that the pilot program should allow patients sufficient autonomy and encourage them to try new tools independently. Rather than implementing a highly structured intervention program, discussions at the workshop suggest that an initial exploratory program, where patients are invited to engage in various digital activities relating to their health management, that includes sufficient digital literacy training and technical support, would be more likely to induce behavioural changes among diabetes patients in the long term.

A limitation of this paper is that only the practitioners were involved in the design of the program. A fuller picture of how patients engage with mobile devices for their self-management can be painted after observing the patient participants for a year in the next step of the project. Nevertheless, this paper contributes to the body of literature in mHealth where new technologies are constantly introduced into health care. It emphasises the importance of interaction between technology and user (patient) during the implementation of an mHealth program. The integration of digital technologies, appropriate programs of lifestyle changes, and active engagement of patients into the model was suggested as crucial elements of a sustainable mHealth program. New technological systems must be accompanied by a shift that occurs at all levels, including technical and organizational systems, patient participation, and practitioner support.

The next step of the research is to conduct a pilot program with type 2 diabetes patients where participants are to be given iPads preinstalled with mobile apps to help manage their health condition. Mobile tablet devices have larger screens which may be favourably accepted by novice users of digital technologies. Compared to iPads, mobile phones are more portable but the uses may be limiting due to the small screen size.

**Conclusion**

This paper reports findings from a co-design workshop involving healthcare practitioners and a multidisciplinary research team. The first research question asked what practitioners perceived to be potential uses of mobile tablet devices in managing type 2 diabetes. Broadly, integration into the existing healthcare delivery system was identified as an important function of mobile tablet devices. More importantly, most practitioners suggested that mobile tablet devices will benefit the patient if used as the patients’ motivational and self-management tools. The second research question was related to how patients could use the device to self-manage their condition. In this, practitioners suggested measurement and recording activities as an alternative to paper-based method. Empowering the patient by transferring a sense of ownership and autonomy was also regarded as an important role of mHealth.
From this result, we proposed a co-design model where an open mHealth program can be explored. In the proposed mHealth program, patients with various levels of digital skills are to be given adequate time to adapt to the devices and applications, ultimately giving them an opportunity to learn and appropriate the technology independently. Since patients come with different levels of digital literacy, the approach should be individualized where each user can learn at their own pace. During the implementation of the mHealth pilot program, adequate training and support must be provided in addition to the access to devices and digital tools. Such efforts to enable digital engagement should be seamlessly integrated into the mHealth program of self-management, whereby patients can comfortably engage in both ‘compelled’ and ‘empowered’ activities in order to find effective ways of managing their diabetes condition.

References


Interact with GP visually and sharing information
Allow the patient a little time to **realise** what effect their food and diet *has* regarding diabetes evolution
As a gateway to other digital health systems
As a tool for co-ordination - journal
As a tool to support planning (diary, calendar, cycle of care)
Better access to dietary information
Better format to help them understand their condition, better way to monitor their progress
Built in reminders for tasks, able to use tablet for own purpose as long as used for diabetes management
Clarity in written form
Communicate with other patients to share information and experience
Diabetes glucometer data, questions to specialist, HbAlc and advise to patient
Education package - general information about type 2 diabetes, what is it, why control it and how to manage it
Exercise feedback ("fitbit")
Get info on what to do in any situation, log BGLs
Identify important, comprehensive and authoritative online information for diabetes type 2 and pin to the tablet screen before distribution
Information on quality of food items, with respect to glycaemic control
Monitoring their daily BSLs which will then guide the course of treatment
Monitoring trends regarding their BSL within certain periods of time to assist guiding their lifestyle habits e.g. diet changes
Patient management in greater detail
Patient to investigate, plan and monitor a suitable diet for diabetes type 2
Patients will have autonomy with their health and be more proactive which will help us (staff) to better care for the patients as well
Positive feedback for results and as a resource for diet advice, exercise medication reminders, updates, visits, resource of effects
Provide “sense” of access and care between physical interventions, coordinate reminders for multiple appointments
The tablet facilitates the recording necessary + eases the realisation if the figures define a state of diabetes
This will be a good method for researchers to do their work and further improve the future of diabetes possibly.
- Monitors all conditions including stress
- Tips on diets, recipes, planner
- To monitor BSL and BP
- To record BSL, engaging with their condition themselves
- To respond to prompts ie correct treatment time. Diet advise for when and what to eat
- To take regular sugar readings and HbAlc and record them on a mobile tablet instead of a book
- To track compliance with lifestyle goals - physical activity, food preparation, psychological goals (Hawthorne effect)

**Appendix 1**: List of statements
Introduction: Mobile apps are used as an aid in the mental health services in many high income countries. The present study was conducted to assess frequency of mobile phone use amongst patients with mental illness.

Methods: Patients attending psychiatric outpatient department of a public funded tertiary care hospital in India were assessed for use of mobile phone and its possible utility in mental health service delivery using a semi structured questionnaire.

Results: The study had 350 subjects, out of whom 307 (87.7%) reported using mobile phone on a regular basis. Mobile phone was used for phone calls, sending and receiving short text messages (SMS) recreation, and accessing social networking sites. Most of the users agreed that the mobile phone could be used as an aid in mental health service delivery, and expressed willingness to receive educational messages.

Conclusion: Patients with mental illness attending psychiatric outpatient services in India use mobile phones and are willing to use as a treatment aid.

Introduction
In the last few years, there has been a remarkable spread of mobile technology in low and middle-income (LAMI) countries, with its penetration being much higher than the general infrastructure. For example, in India, there are 943.9 million wireless telephones with a teledensity of about 75%, and the mobile phones constitute about 97% of the total telephones. Mobile technologies, with an easy and wider availability, portability, being self powered, increasingly better computational capacities and decreasing costs, user familiarity and internet connectivity, have opened up new alternatives for health care delivery that can be delivered through the existing infrastructure, as people carry mobiles with them all the time.

Recent studies from high-income (HI) countries have reported that a number of people use mobile phones to search for health related information. Most patients with mental illness own mobile phones, use it for activities other than spoken conversations like sending emails, web browsing and social networking, and mobile phones have been explored as a potential aid in mental health services. Studies from HI countries have demonstrated the use of mobile phones in delivering psychosocial interventions (crucial for recovery) like provision of health information, prompts for medications, reminders,
self-monitoring, and practice of skills in real world situations.\textsuperscript{4}

In India, mental health resources for psychosocial interventions are meagre and are not commonly applied in the care of patients with mental disorders\textsuperscript{5} as there is a gross deficiency of mental health resources (0.2 psychiatrists, 0.03 clinical psychologists, 0.05 psychiatric nurses, and 0.03 social workers per 100,000 of the population).\textsuperscript{6,7}

In this context, mobile technologies have a potential to become an important mental health care service link between the meagre mental health services and the unfulfilled mental health care needs of the vast majority of unreached patients and caregivers, and can be used for a range of indications in mental health like increasing awareness, training, linkages between services, clinical services and research.

We are planning to develop a mobile based intervention framework for imparting psychosocial interventions to the patients attending psychiatric services. Before making mobile based interventions suitable for the needs of the patients, it is important to know whether the patients with mental illness are using mobile phones as there is absence of research in this field from India. The present study was conducted to find out the frequency of mobile phone use among patients with mental illnesses, and to assess feasibility of using mobile phones in improving service delivery and delivering educational messages in them.

**Methodology**

The study was conducted in psychiatry outpatient services at the All India Institute of Medical Sciences, New Delhi, India. The service runs a walk-in clinic, where all the first contact patients are seen, and a follow up clinic where the old patients already on treatment from the service are seen. Every fifth patient aged 18–60 years, visiting the walk-in clinic, and every fifth patient visiting the follow up clinic over a period of three months (from February – April, 2015) were recruited for the study.

The subjects were explained the purpose of the study. A written informed consent was taken. In patients with psychotic disorders, who were unable to give consent, consent was taken from the accompanying relative. The data was collected using a semi-structured questionnaire (attached as Appendix), prepared for the study by the investigators. The study was approved by the Institute ethics committee.

The data was analysed using descriptive statistics, reported as mean and standard deviation for continuous variables and percentages for discrete variables.

**Results**

A total of 350 subjects were recruited for the study, 205 (58.6%) males and 145 (41.4%) females. Two hundred and thirty five (77.1%) subjects were from the follow up clinic and 115 (32.9%) were from the walk in clinic. Mean age of the subjects was 33.3 (±11.5) years. About 40% of the subjects had received 10 years of formal education, one fifth had studied upto 12\textsuperscript{th} standard, and about 30% were graduate. Mean duration of illness was 6.2 (±7.6) years, and mean duration of treatment was 1.5 (±3.5) years. Common diagnosis included neurotic, stress related and somatoform disorders (47.0%), mood disorders (32.0%), schizophrenia and related disorders (14.3%), and disorders due to psychoactive substance use (4.0%).

Three hundred and seven (87.7%) subjects reported using mobile phones regularly. Most of the subjects used mobile phone for making and receiving phone calls, and about two third also used it for sending and receiving short text messages (SMS). About half of them used clock and alarm functionalities, two fifth also used it for recreational activities, and around 30% used for accessing social network sites (Table 1).

Most of the subjects reported that mobile phones could be used as an aid to treatment for psychiatric disorders. This included use as a reminder for appointments (90.4%), and to take medications (72.3%). About half of the subjects suggested that mobile phones could be used for recording and reporting of side effects. Forty two percent of the subjects reported that mobile phones could be used for receiving educational information related to their mental illness. Only 17% of the subjects felt that these could be used for imparting psychological treatments (Table 1).

More than 70% of the mobile phone using subjects expressed that the phones could be used to receive educational messages regarding any precautions to be taken (70.5%), activities and exercises (55.4%), information about their mental illness (36.5%), dietary advice (26.9%) and information about stress reduction techniques (24.7%) (Table 1).
In a single open-ended question about any other use of mobile phone related to psychiatric treatment, about 11% of the subjects provided a suggestion. Sixteen subjects felt that mobile phones can be used to give feedback regarding treatment. Fifteen subjects felt that these can be used for sharing experience regarding treatment through specific patient groups on social networking sites.

**Discussion**

More than 85% of the patients with mental health problems in our study were using a mobile phone. The mobile phones were being used for a range of activities besides making phone calls. Most subjects opined that it could also be used as an aid in the treatment.

All of our subjects used mobile phone for making and receiving phone calls, but over two third also used it for sending and receiving SMS. The phone was also used for other functions like clock and alarm by about half of the subjects, for recreation by about two fifths, and for accessing social network sites by 30% of the subjects. Earlier studies have also reported the most common uses of mobile phones in patients with severe mental illnesses as for making phone calls, texting, and internet.3

Regarding the potential usage of mobile phones in treatment, most (90%) of the subjects reported that these can be used to remind them for appointments. Majority of the subjects indicated use of mobile phones in pharmacological treatment as reminder for taking medications and reporting side effects. However, only less than half of the subjects indicated that mobile phones can be used for receiving educational information related to their mental illness, and even fewer subjects felt that these can be used for imparting psychological treatments. The finding is not unusual as majority of the patients with mental illnesses receive pharmacological treatment with minimal psychosocial interventions due to lack of resources for the latter.5 However, when asked specifically about the kind of educational messages they wanted to receive, majority of them listed only psychosocial interventions. About three fourth of the subjects wanted to receive messages regarding any precautions to be taken regarding illness or medications. Other areas of requested information included messages regarding activities and exercises, information about their illness, dietary advice and stress reduction techniques. This shows that the mobile phones appear to have a high potential of use in the mental health care settings.

Our results are in line with the studies from HI countries which have reported that 72%–97% of

<table>
<thead>
<tr>
<th>Purpose</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of application (n = 307)</td>
<td></td>
</tr>
<tr>
<td>Making and receiving calls</td>
<td>301 (98.1)</td>
</tr>
<tr>
<td>Sending &amp; receiving SMS</td>
<td>210 (68.4)</td>
</tr>
<tr>
<td>Clock &amp; Alarm</td>
<td>153 (49.8)</td>
</tr>
<tr>
<td>Recreational activities</td>
<td>121 (39.4)</td>
</tr>
<tr>
<td>Use of social networking sites</td>
<td>93 (30.3)</td>
</tr>
<tr>
<td>Utility of mobile phones in treatment as an aid (n = 271)</td>
<td></td>
</tr>
<tr>
<td>As Reminder</td>
<td></td>
</tr>
<tr>
<td>Reminder for appointment</td>
<td>245 (90.4)</td>
</tr>
<tr>
<td>Reminder to take medicines</td>
<td>196 (72.3)</td>
</tr>
<tr>
<td>Recording and reporting of side effects</td>
<td>142 (52.4)</td>
</tr>
<tr>
<td>Receiving information about mental illness</td>
<td>115 (42.4)</td>
</tr>
<tr>
<td>Psychological treatment</td>
<td>46 (16.97)</td>
</tr>
<tr>
<td>Kind of Educational messages</td>
<td></td>
</tr>
<tr>
<td>Any precautions to be taken</td>
<td>191 (70.5)</td>
</tr>
<tr>
<td>Activities or exercises</td>
<td>150 (55.4)</td>
</tr>
<tr>
<td>Knowledge about their mental illness</td>
<td>99 (36.5)</td>
</tr>
<tr>
<td>Dietary advice</td>
<td>73 (26.9)</td>
</tr>
<tr>
<td>Information about stress reduction techniques</td>
<td>67 (24.7)</td>
</tr>
</tbody>
</table>

Table 1: Mobile phone use and its utility as aid to psychiatric treatment. Application of mobile phone in day-to-day life (n = 307)
patients with mental illnesses and substance use disorders own a mobile phone. The results are not surprising since compared to an average 2008–2012 growth rate of mobile subscriptions of just 10.15% in the HI countries, the growth rate was much higher (75.07%) in South Asia driven mainly by growth in India.

The study had a limitation of being conducted in a tertiary care setting in a big city and hence the findings may not be generalizable to other settings. We did not screen specifically for the use of smartphones, since most of our subjects use ordinary phones.

**Conclusion**

The study concludes that most of the patients with psychiatric disorders attending outpatient services in India use mobile phones, and welcome its use as a treatment aid. Mobile phones offer a potential to be utilised in India with limited human resources in mental health and a potential use in psychosocial treatment.

**References**


**Appendix A:**

Feasibility of using mobile phones in improving service delivery and creating health awareness in patients with mental disorders

(Please tick mark the answers)

1. Date  Regn No.  Name

2. Age  Gender  Education

3. Address:

4. Mobile:  E mail (if any):

5. Diagnosis

6. Duration of Illness:

7. Duration of treatment at AIIMS:

<table>
<thead>
<tr>
<th>1. Do you have a mobile phone?</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. For what all functions do you use mobile phone? (Kindly mark as many as applicable)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Making &amp; receiving calls</td>
</tr>
<tr>
<td></td>
<td>Sending &amp; receiving messages</td>
</tr>
<tr>
<td></td>
<td>Clock &amp; alarm</td>
</tr>
<tr>
<td></td>
<td>Contact list</td>
</tr>
<tr>
<td></td>
<td>Any other</td>
</tr>
</tbody>
</table>

3. Do you think that it can be used as a helping aid in your treatment?  Yes/No
4. If yes, kindly tell, how? (Kindly mark as many as applicable)
   - Reminder for appointment
   - Reminder to take medicines
   - Recording & reporting of side effects
   - Receiving education messages related to your illness
   - Psychological treatment
   - Any other

5. What kind of educational messages you would like to receive?
   - Any precautions to be taken
   - Activities or exercises
   - Dietary advice
   - Any other

Any suggestions, you would like to make
PRETESTING mHEALTH: IMPLICATIONS FOR CAMPAIGNS AMONG UNDERSERVED PATIENTS

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Background: For health campaigns, pretesting the channel of message delivery and process evaluation is important to eventual campaign effectiveness. We conducted a pilot study to pretest text messaging as a mHealth channel for traditionally underserved patients.

Aims: The primary objectives of the research were to assess 1) successful recruitment of these patients for a text message study and 2) whether recruited patients would engage in a process evaluation after receiving the text message.

Methods: Recruited patients were sent a text message and then called a few hours later to assess whether they had received, read, and remembered the sent text message.

Results: We approached twenty patients, of whom fifteen consented to participate. Of these consented participants, ten (67%) engaged in the process evaluation and eight (53%) were confirmed as receiving, reading, and remembering the text message.

Conclusion: We found that traditionally underserved and under-researched patients can be recruited to participate in a text message study, and that recruited patients would engage in a process evaluation after receiving the text message.

Introduction

In the U.S., 90% of adults own a mobile phone and 81% of mobile phone owners use text messaging. Notably, Americans send or receive on average 41.5 texts each day, making text messaging a potent tool for communication. With the growing prevalence of text messaging, the uses of text messaging have broadened beyond everyday conversation. In fact, several research studies have already capitalized on the ubiquity and advantages of text messaging to encourage health behavior changes.2–7 Notably, text messaging can readily reach patients of demographics that are traditionally underserved: racial and ethnic minorities, low-income, and low education level. These demographics use text messaging more often compared to other demographics (Table 1).1
The NIH Making Health Communication Programs Work, commonly called “The Pink Book”, has emphasized the importance of pretesting messages to ensure that messages resonate with the target audience and can influence behavior change. Given the emergence of new media for health campaigns, pretesting the channel of message delivery is equally important. The Pink Book has also emphasized process evaluation; this step is often overlooked in health campaign design. Process evaluation assesses the effectiveness of project management and each step of campaign development.

In preparation for a mHealth campaign, we conducted a pilot study to pretest a mHealth channel and pretest a process evaluation among a subset of predominantly racial and ethnic, low-income patients. These populations are traditionally hard-to-reach and suffer from worse health outcomes. The primary objectives were to assess 1) successful recruitment of these patients for a text message study and 2) whether recruited patients would engage in a process evaluation after receiving the text message. A secondary objective of this study was to assess whether patients were able to remember the text message that we sent.

**Methods**

**Setting and Participants**

This study was conducted in February 2015 in a community clinic affiliated with the Baylor College of Medicine in Houston, Texas. The clinic serves a predominantly low-income population, many of whom are racial and ethnic minorities and do not have health insurance. Among the health system’s patients, 60% are Hispanic, 25% are African-American, 64% self-pay for their health care, 21% are on Medicaid and Children’s Health Insurance Program, and 10% are on Medicare. The study was approved by the Baylor College of Medicine Institutional Review Board.

Participants were eligible if they 1) were a patient at the clinic, 2) were 35–55 years of age, and 3) owned a mobile phone. The age group of the participants was selected using audience segmentation to ensure participant demographics corresponded with those for a future mHealth campaign. For recruitment, a research assistant approached patients in the waiting room of the study site.

During the consent process, participants were informed that the research team would send them a simple text message such as “Have a great day.” A research assistant would then call them to evaluate whether the participant received, read, and remembered the text message – the process evaluation. Participants verbally consented and a member of the research team noted their first name and phone number. Demographic information was not collected.

**Text Message Delivery**

The research team used Google Voice® to send the text messages. The Google email server, Gmail®, was used to access Google Voice®. A study Gmail® account was created and a Google Voice® phone number was selected. Google Voice® was chosen because a non-personal phone number given by Google could be used to send the text messages. Additionally, Google Voice® offers a free text

<table>
<thead>
<tr>
<th>Average Number of Text Messages Sent and Received Each Day</th>
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<tbody>
<tr>
<td>All text messaging users</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Men</td>
</tr>
<tr>
<td>Women</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>18–29</td>
</tr>
<tr>
<td>30–49</td>
</tr>
<tr>
<td>50–64</td>
</tr>
<tr>
<td>65+</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Household Income</td>
</tr>
<tr>
<td>Less than $30,000</td>
</tr>
<tr>
<td>$30,000–$49,999</td>
</tr>
<tr>
<td>$50,000–$74,999</td>
</tr>
<tr>
<td>$75,000+</td>
</tr>
<tr>
<td>Education level</td>
</tr>
<tr>
<td>Less than high school</td>
</tr>
<tr>
<td>High school diploma</td>
</tr>
<tr>
<td>Some college</td>
</tr>
<tr>
<td>College+</td>
</tr>
</tbody>
</table>

Table 1: Pew Research Report: The average number of text messages sent and received each day by demographic group (1)
message service. Google Voice® also allows the same text message to be sent to up to five participants at a time. Text messages can easily be sent from a computer and remain secure, only available to members of the research team with the username and password to the Google Voice® account. Participants were texted through the Google Voice® platform within 24 hours of consenting to participate. The message said, “Houston is a great city to live in! From Alex at Baylor College of Medicine.”

**Process Evaluation**

Process evaluation phone calls were conducted within three hours of sending the text message. The phone used to make the evaluation call was an office phone, and thus did not use the Google Voice® phone number. During the phone call, the research assistant verified that the person who answered the phone was the study participant. Then, the research assistant asked if the participant had received the text message. Of those who said yes, to confirm that the participant had actually received the text message, the research assistant asked if the message was either A) “Houston is a great city to live in! From Alex at Baylor College of Medicine.” or B) “The weather outside is lovely. From Alex at Baylor College of Medicine.” Participants who selected message “A” were designated as having received, read, and remembered the message.

**Results**

We approached twenty patients to participate, of whom fifteen consented to participate (75% response rate). Factors affecting the response rate included the eligibility requirement of English and the 35–55 year age range. Additionally, the clinic was busy during times of recruitment, limiting the amount of time patients had to talk to the research team. We texted all fifteen participants with message “A” and then called all participants. See Figure 1 for the study process. Of the fifteen participants who consented and were texted, 3 did not answer the phone, and one number was disconnected. The research team spoke to eleven participants, of which one person who answered said the research team had dialed the wrong phone number. Overall, ten participants (67%) retained in the study protocol and engaged in the process evaluation. Two participants said they had received and read the text message; however, they chose “B” – the incorrect text message – as the message we sent. We designated

![Flow Diagram of Study](image_url)

Figure 1: Flow Diagram of Study. Participants who consented were texted and called to evaluate receipt, reading, and memory of the text message.
messages. Similarly, another study aimed at low-income pregnant women excluded 172 patients out of 44 recruited potential participants due to lack of cell phone number. Additionally, 10 participants dropped out during the study by declining further text messages. Finally, a text message study aimed at improving diabetes self-management found that 42 (95%) participants consented out of 44 recruited potential participants. Additionally, two (5%) participants requested to drop out of the study and three (7%) were lost to follow-up. In addition to participant retention, whether participants respond to actionable text messages has been studied. A pilot study evaluating text message reminders to improve adherence to antiretroviral therapy found that 48% of 7110 messages requesting a response were responded to by participants. Another study found that 74% of participants in the intervention group viewed at least half of text messages sent by the research team and 30% of participants viewed most or all of sent text messages. A study looking at whether people would pay for text messaging health reminders asked their participants to respond to three questions; three out of fifty-one participants (6%) did not answer the first question, two (4%) did not answer the second question, and zero did not answer the third question. While these studies described process outcomes that were obtained during text message interventions, the study goal of these studies was not to determine how these process outcomes can be improved. We hope to do that with the following.

While our study objectives were met, we note study design areas that could be improved for future mHealth campaigns. At the first drop-off point in the study, 75% of approached patients consented to participate. Although this is a high proportion, the sample size of the study could have been improved by approaching more patients. Additionally, recruitment and consent for minimal risk studies could be conducted via text message to improve study sample sizes. At the second drop-off point, several people did not answer the phone call. This may be because they did not recognize the research team’s phone number. It is also possible that the participant was busy and could not answer their phone. The phone call was made for the process evaluation. A more convenient method to communicate with participants for mHealth campaigns may be asking them to reply to the original text message. At the third drop-off point – patient recall of the text message – several factors may have influenced participants’ memory of the text message. It is possible that participants had not yet received or read the text message at the time of the phone call. Alternatively, due to social desirability bias, they may have guessed text message “A” or “B” to gratify the research assistant. Additionally, participants may not have remembered the text message because they had received too many texts that day. It is also...
possible that participants had seen the text message, but did not process the message to recall what it had said a few hours later. Notably, both text message choices had similar tones, which may have complicated the participant’s memory of the message. In addition, the time delay between the time of text and phone evaluation may have been too great. Finally, the participants who do not frequently receive text messages may not have been familiar with reading and remembering text messages.

To streamline a text message study protocol, we recommend the following measures. If possible, the same phone number should be used to both text and call participants. The research assistant should also read back to the participant the participant’s mobile phone number to ensure that the number was correctly recorded and no wrong numbers are called during the evaluation. Additionally, a research assistant should ask the participant to input the study phone number as a contact into their mobile phones. Finally, the research assistant should call participants at varying times and outside of business hours to ensure that participants are contacted at a time that is convenient for them.

The major limitation of this study is its small sample size. However, we wanted to prove feasibility of a text message study for traditionally underserved patients. Our results may not be extrapolated across the wider population. However, our study will be useful for researchers intending to evaluate the effectiveness of text messaging for health promotion among a target population of low-income patients. Notably, our relatively high retention rate of 67% was obtained in the setting of a very short (i.e., 1–2 days) study protocol. Text message studies of longer duration may find lower retention rates. An additional limitation is response bias in the evaluation phone call. Participants who answered “A” as the text message may have lied about receiving, reading, and remembering the text message and simply guessed the correct choice. Finally, some patients may have been reluctant to join the study because the benefit of receiving a generic, non-health-related text message may not have been clear to the patients. Studies that involve text messages with more relevant health messages may encourage greater participation.

Our findings thus contribute to the limited literature on process outcomes in developing mHealth campaigns. Further investigation on process outcomes of text message studies is needed, especially for traditionally underserved and under-researched patient populations who may have limited knowledge and use of mHealth. As a relatively new medium of communication in healthcare and research, text messaging should be further studied to ensure patients of differing demographics can receive, read, remember, and ultimately benefit from the text message.

Conclusions
Text messaging can be a potent research tool. This study’s findings support a future mHealth text message intervention for patients who are predominately racial and ethnic minorities and have low-income. We found that patients can be adequately recruited to participate in a text message study, and that recruited patients would engage in a process evaluation to confirm receipt of the text message.

Acknowledgements
This work was supported by the National Institute of Mental Health of the National Institutes of Health under Award Number K23MH094235 (PI: Arya). This work was supported in part by the Center for Innovations in Quality, Effectiveness and Safety (#CIN 13-413). The views expressed in this article are those of the authors and do not necessarily represent the views of the National Institutes of Health, the Department of Veterans Affairs, Rice University, or Baylor College of Medicine.

The authors would like to thank Dr. Thomas P. Giordano for his help in conceptualizing the study and Ms. Alexandra Trenary and Ms. Hannah Chen for their help in conducting this study. The authors would also like to thank Ms. Sajani Patel and Ms. Ashley Phillips for their thoughtful comments on the manuscript.

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: M. Arya reports grant from the National Institutes of Health/National Institute of Mental Health; 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


The current model of ophthalmic care requires the ophthalmologist’s involvement in data collection, diagnosis, treatment planning, and treatment execution. We hypothesize that ophthalmic data collection and diagnosis will be automated through mobile devices while the education, treatment planning, and fine dexterity tasks will continue to be performed at clinic visits and in the operating room by humans. Comprehensive automated mobile eye diagnosis includes the following steps: mobile diagnostic tests, image collection, image recognition and interpretation, integrative diagnostics, and user-friendly, mobile platforms. Completely automated mobile eye diagnosis will require improvements in each of these components, particularly image recognition and interpretation and integrative diagnostics. Once polished and integrated into greater medical practice, automated mobile eye diagnosis has the potential to increase access to ophthalmic care with reduced costs, increased efficiency, and increased accuracy of diagnosis.
algorithms that formulate patient-specific, actionable recommendations. Comprehensive automated mobile eye diagnosis includes the following: mobile diagnostic tests, mobile image collection, image recognition and interpretation, integrative diagnostics, and user-friendly mobile platforms (Figure 1).

**Mobile Diagnostic Tests**

Mobile software applications that test visual acuity and visual fields include Peek Vision and SightBook. Refraction testing can be done on a computer screen through Opternative and Eye Netra. Peek Vision is also developing software capable of color and contrast testing. However, a comprehensive mobile exam is still limited by the lack of accurate mobile software and/or hardware that detect necessary values such as pupillary response, extraocular movements, and iridocorneal angle.

**Mobile Image Collection**

Direct visualization of eye pathology through slit lamp examination with or without additional fundoscopic imaging can be critical in narrowing the differential diagnosis. Ophthalmologists have already developed several methods of visualizing both the anterior and posterior chambers with mobile phones. A simple method of fundus imaging described by Haddock et al. involves the use of a smartphone and 20D lens with or without the Filmic Pro application to control the camera’s illumination (Cinegenix LLC, Seattle, WA, USA).

Supplemental hardware that facilitates image capture from mobile devices includes the PAXOS scope (Digisight Technologies, Portola Valley, CA, USA; licensed from inventors of the EyeGo Smartphone imaging adapter), Peek Vision, D-EYE (D-EYE, Padova, Italy), and the iExaminer System (Welch Allyn, Doral, FL, USA). The PAXOS scope is a combined anterior and posterior segment mobile imaging system with a built-in variable intensity light source and posterior adapter that can accommodate various indirect lenses. It provides a 56-degree static field of view. Similarly, Peek Vision includes a low-cost adapter clip with optics blanks that re-route light from the flash to the retina. The same adapter, coupled with supporting Peek Vision software, allows for grading of cataract severity and retinal imaging. D-EYE provides a 5 to 8-degree field of view in an undilated pupil, and up to a 20-degree field of view if moved as close to the anterior segment as possible. The iExaminer System provides a 25-degree field of view in an undilated eye. The system requires the Welch Allyn PanOptic Ophthalmoscope, iExaminer Adapter fit to an iPhone 4 or 4S (Apple Inc., Cupertino, CA, USA), and the iExaminer App.

Images taken by these devices are limited by mobile phone camera resolution and field of view, the latter being affected by the presence or absence of pupil dilation. Additionally, images that are unable to be graded due to user error or patient pathology (e.g., cataracts obscuring views of the posterior chamber) could be detrimental to the care of patients in systems that rely solely on mobile imaging. A recent study comparing the iExaminer System to standard fundus photography devices found lower image resolution and longer time required to take
images using the smartphone setup.\textsuperscript{14} However, a study comparing smartphone ophthalmoscopy with the D-EYE device to dilated retinal slit-lamp examination found exact agreement between the two methods in 204 of 240 eyes on grade of diabetic retinopathy.\textsuperscript{15} Notably the latter study was performed with an iPhone 5 (8-megapixel iSight camera) and the former with an iPhone 4 (5-megapixel still camera). Enhanced mobile imaging hardware will continue to improve the resolution,\textsuperscript{16} and wider-field imaging can be provided by pupil dilation (requiring a technician or nurse), laser scan imaging (Optos PLC, Marlborough, MA) or by integration with software that patches retina images together into a mosaic, such as i2k Retina software (DualAlign LLC, Clifton Park, New York, USA).\textsuperscript{17} User error can be overcome with increasing experience with mobile imaging. However, patient pathology that obscures views of the posterior chamber will ultimately limit mobile diagnosis.

Furthermore, current mobile imaging does not replace the scleral depressed indirect ophthalmoscopic exam that allows stereoscopic views of the indented retina anteriorly beyond the peripheral retina to the ora serrata and pars plana. This capability would be needed for evaluation of flashes or floaters—a common presentation in which the diagnosis of retinal tear, hole, or detachment must be ruled out over multiple visits.

Another limitation in mobile image capture is the lack of a slit-lamp device for assessing individual corneal layers and the anterior chamber, limiting the precision of diagnosis of corneal pathology and of cell and flare diagnostic of uveitis. Automated mobile eye diagnosis will require hardware or software that allows for large-field image capture of the fundus and visualization of the corneal layers and the anterior chamber.

Image Recognition and Interpretation
Following image capture, automated mobile diagnosis requires an interpretation system that detects multiple features of the anterior and posterior segments. The ideal system would recognize atypical color, contrast, shape, and size of all visible components of the eye. Anteriorly, it would be able to distinguish the lids from the lashes, sclera, conjunctiva, limbus, iris, cornea, pupil, and lens, and posteriorly, it should be able to distinguish between the optic disc, macula, vascular arcades, and peripheral retina. After recognizing the component parts of the eye, so called “segmentation”, the system should then be able to label the type of abnormality and its location within the anatomy of the eye. Lastly, for a system to expand healthcare delivery and access, it would need to provide some level of instruction. On the simplest level, this could involve determining if a patient should be referred to an ophthalmologist or screened again at a later date. As we will discuss, significant progress has already been made in accomplishing this.

One method of expanding access to specialty care is to build tools that enable primary care providers to make decisions that typically require training in a medical specialty. One strategy is creating systems that eliminate prior knowledge as a prerequisite for diagnosis. For example, the identification of a skin lesion usually requires the clinician to have studied the presentation, shape, color, texture and location of various skin lesions as well as have a sense of disease variation and overlap. VisualDx is a subscription-based website that walks users through step-by-step visual diagnosis of dermatologic conditions, including some overlap with ophthalmologic diagnoses. Three other similar sites include gonioscopy.org, oculonco.com, and ophthalmicedge.org.\textsuperscript{18–20}

Peek Vision’s software automates one component of image recognition, optic cup:disc ratio calculation, important for diagnosis of glaucomatous optic neuropathy.\textsuperscript{19} Additionally, a team has automated the quantification of the number, morphology, and reflective properties of drusen based on spectral domain-optical coherence tomography.\textsuperscript{21}

An alternative solution is crowdsourcing. In two studies, researchers demonstrated the utility of crowdsourcing of untrained people looking at retina images in automated diagnosis.\textsuperscript{22–24} However, variation in human interpretation, the number and experience of reviewers prevent its application.

Several research groups are developing algorithms for automated diagnosis. The most developed application of these algorithms is in the area of diabetic retinopathy screening in which many proposed algorithms reach sensitivity and specificity percentiles in the 90s.\textsuperscript{25} One of the most published algorithms is the Iowa Detection System, that has as its input a retina color photograph, and as its output, a number between 0 and 1. The closer the output is to 1, the more likely the patient has a stage of diabetic retinopathy that should be referred to an ophthalmologist or that the photograph is of
insufficient quality to determine stage of diabetic retinopathy. It database includes numerous retinal images of racially diverse individuals taken using different camera types, and the Iowa Detection System been found to perform comparably to retina specialists. The best algorithm, however, remains a debatable issue as the algorithms are tested against human interpreters and with limited datasets where the gold standard is determined by another human interpreter or consensus of interpreters. Development of an algorithm capable of classifying disease outside of one spectrum of disease or of identifying the clinical significance of retinal findings remain an area of active research. We are living amidst a turning point in computing that has already revolutionized the field of computer vision and is set to change medical imaging.

Neural networks improve upon the algorithms for automated image recognition and interpretation. Neural networks are biologically inspired algorithms that learn to approximate a function (Figure 2). Their inputs can be composed of text, numbers or images. They contain interconnected layers of functions called “neurons” that receive inputs from neurons in the layer adjacent to themselves and pass their outputs to the next layer of neurons. The ultimate function that the neural network approximates is encoded in the strength of connection between neurons. These connections are fine tuned by training the neural network with correct inputs and outputs. For example, a retinal photograph with the correct diagnosis as the output. Neural networks have been in development since the 1940s, and many research groups have already applied these algorithms to interpretation of ophthalmic images. However recent advances in the availability of high performance computing hardware has made feasible the construction and training of neural networks that contain several layers, various schemes of interconnectedness, and several neurons in each layer. Due to the repeated stacking of many layers of neurons, this form of computation has been termed “deep learning” and lies at the core of artificial intelligence software such as Google self driving cars (Google Inc., Mountain View, CA, USA), voice recognition in phones, and Facebook facial recognition (Facebook Inc., Palo Alto, CA, USA).

Most algorithms proposed thus far for image diagnosis, even those that use neural networks, are composed of specific, coded features used in combination for image recognition. Ophthalmic diagnosis, however, is a complex task that takes into account the location of lesions, macroscopic and microscopic structural changes, and textures difficult to describe even by ophthalmologists. Deep learning, although flawed by drawbacks such as overfitting and need for large training sets, makes few prior assumptions about the features needed to recognize

![Figure 2: General Architecture of Neural Network](image)

General architecture of neural network with arbitrary number of neurons in each layer, number of layers, different schemes of interconnection between neurons in one layer and neurons in adjacent layer. It is fully connected, meaning that every neuron in a layer is connected to every neuron in its adjacent layer. Inputs are values such as pixel values from an image, and layers can be a one-dimensional row of neurons such as in the example or a three-dimensional volume such as in convolutional neural networks.
images. Deep learning learns features from the data with which it is trained. In the next five years, there will be a wave of literature describing the complex tasks these algorithms can perform in automated ophthalmic diagnosis.\textsuperscript{30,31}

**Integrative Diagnostics**

Ultimately, all data points gathered need to be integrated into one mobile system for diagnosis, such as with artificial intelligence software. IBM Watson, made famous by its Jeopardy! win, is an example of software that can integrate evidence-based medical knowledge accurately and consistently for automated diagnosis.\textsuperscript{32} IBM Watson's servers can process 500 gigabytes of information per second—the equivalent of 1 million books.\textsuperscript{32} IBM Watson's conversion of this information into evidence-based algorithms for diagnosis would provide the most up-to-date diagnostic programming possible.

**User-Friendly Mobile Platform**

To deliver the final information to the patient and/or physician, a user-friendly interface between the mobile phone and user will be necessary. An example of such an interface is Modernizing Medicine's electronic medical assistant (EMA) iPad application for ophthalmology, which integrates published healthcare information and provides physicians with treatment options and outcome measures.\textsuperscript{33,34} While a physician-mobile device interface may be useful in guiding treatment plans, a patient-directed interface may ultimately provide actionable steps for the patient to take before ever seeing a physician for treatment.

**Discussion**

The future of automated mobile eye diagnosis lies in improvements in each of the above components, particularly image recognition and interpretation and integrative diagnostics. With automated mobile eye diagnosis, patients will have faster access to information about their conditions to guide their next steps. Automated diagnosis will be a reliable, cost-effective, and accessible tool for individuals across demographics to gather ophthalmologic information necessary to understand and manage their conditions.

**Benefits of Automated Eye Diagnosis**

Given the increased availability of wireless networks and advancements in technology, automated eye diagnosis will prove to be more cost-effective, accessible, and reliable than specialist diagnoses.\textsuperscript{35,36} Automated diagnosis will have the highest yield in low-resource settings where both physical and economic barriers limit access to specialist diagnosis. In a 2007 study, researchers in Scotland found that automated grading of images for diabetic retinopathy reduced both the workload and associated costs of care.\textsuperscript{37} Automated grading for a cohort of 160,000 patients lowered the total cost of grading by 47% as compared to manual grading, a saving of US $0.25 per patient. Similar studies on automated diabetic retinopathy and cataracts services in Canada, US, and rural South Africa have also shown that early screening programs save programs between $1,206 and $3,900 per sight per year in diagnosis, treatment, and referrals.\textsuperscript{38-41} With this decrease in cost of automated eye diagnosis, the service can more easily spread to smaller clinics in rural areas for early detection and triage of eye pathology.

Additionally, unlike humans, computers can rapidly incorporate new scientific information into their algorithms. The processing power of IBM Watson, for example, is inevitably impossible for any human specialist.\textsuperscript{32} Furthermore, humans maintain various biases during diagnosis, such as anchoring bias (relying too heavily on the first piece of information given) and framing bias (being prejudiced based on the way a statement is phrased).\textsuperscript{36} Automated eye diagnostic programs can continuously add new information to their database and algorithms while avoiding biases to make decisions.

**Drawbacks to Automated Eye Diagnosis**

Potential drawbacks to automated eye diagnosis include initial costs as well as concerns about its reliability and sensitivity. The design phase involves initial investment in hardware for image capture, programming software, and program developers. Implementation requires distribution of hardware and software to the appropriate users. Maintenance entails ongoing costs for the programmers and personnel running the service. However, as mentioned previously with automated diabetic retinopathy and cataracts diagnosis, the savings can eventually trump the initial costs as screening services expand to more patients.\textsuperscript{37-41}

The accuracy of every step of automated eye diagnosis is critical to its success. In the Scotland diabetic retinopathy study, automated grading of 14,406 images from 6,722 patients missed three more cases of referable disease compared with manual grading.\textsuperscript{37} However, these were non-sight-threatening
maculopathy instead of referable or proliferative retinopathy. Additionally, in 2010, researchers found that the algorithm for automated detection of diabetic retinopathy lagged only slightly behind the sensitivity and specificity of retinal specialists. As algorithms improve and are conducted on larger datasets, we believe that automation will outperform experts in sensitivity and specificity.

Lastly, the transmission of patient information over mobile devices necessitates strict and established protocols in patient consent and personal health information security. Software developers must always consider the security of patient information.

Next Steps
The first step in shifting the roles of ophthalmologists away from data collection will be training ancillary providers to collect the data necessary for diagnosis. These providers can then submit a digital representation of the information to software that gives instructions on treatment options and further testing, shifting the focus of ophthalmologists towards education, treatment planning, and treatment implementation.

Conclusion
We believe that automated mobile eye diagnosis using evidence-based algorithms will increase patient safety, improve access to ophthalmic services, and facilitate timely referrals. However, completely automated eye diagnosis will require improvements in image capture and recognition as well as automated integrative diagnostics. Once polished and integrated into greater medical practice, automated eye diagnosis has the potential to become a powerful tool to increase access to ophthalmic services worldwide.

Acknowledgements
The project described herein was conducted with support for Cassie A. Ludwig from the TL1 component of the Stanford Clinical and Translational Science Award to Spectrum (NIH TL1 TR 001084).

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Although mobile technologies, devices and software have enriched our lives in many ways, including medical applications, the potential negative effects are often overlooked. A growing amount of evidence suggests that there are potential negative impacts of smartphones on biophysiological processes, especially on sleep. Studies have shown that blue lights, especially the short-wavelength light (380 ~ 495 nm) emitted from smartphone monitors, disrupts circadian rhythm by retarding nocturnal melatonin production.

Previously, we conducted a survey to examine the use of mobile phones among 398 nursing students. We found that 339 (85.2%) of them utilized mobile phones every night before sleep, and that 267 of them (67.1%) used mobile phones even after they turned off the room lights. In addition, we found that using mobile phones after turning off the room lights was associated with sleepiness during the daytime. While we found that such smartphone usage can disrupt sleep, we did not clarify the usage habits in detail, such as duration of phone usage, posture while using phones, and where phones are kept during sleep. We thought that by understanding such habits in detail we would be able to disentangle the factors that are playing roles in sleep disruption. Therefore we conducted a survey focusing on the factors mentioned above and tried to picture the habits of pre-sleep smartphone usage. The study was approved by the Institutional Review Board of Aino University Junior College.

A total of 141 nursing students were asked to participate in the survey after their classes and informed that the participation was voluntary and would not affect their grades. 138 of them (22 male, 116 female, 21.7 ± 5.2 years old) gave their consent and provided information about their phone usage habits. The students answered that they use phones before sleeping nearly every day (6.65 ± 1.13 days/week), for 35.0 ± 18.5 minutes. Regarding their body position, they used phones while lying in bed for 5.9 days/week, whereas they used phones while sitting in a chair for 3.5 days/week. Moreover, the time spent in the lying position was significantly longer than in the sitting position (12.52 ± 1.36 vs 18.22 ± 23.06 minutes, F(1,274) = 5.71, p < .05).

When we asked about their phone use habits after they turned off the room lights, it was also found that they used phones 5.14 ± 2.85 days/week even after they turned off the room lights. In terms of the lying position before and after they turned off the room lights, the time in the lateral position was significantly longer than the other lying positions (Before bedtime: F(2,274) = 17.79, p < .01; After lights out: F(2,274) = 8.66, p < .01).

Regarding the storage of mobile phones, 98.5% of participants kept phones within hand's reach. With regard to the power state of mobile phones while sleeping, more than half of the participants (50.7%) had their phone's ringtone on, 25.4% had their phone set to vibrate, and 21.7% had their phone's ringtone and vibrate off.

In addition to our previous report, there are other studies that showed negative impacts from smartphones on sleep; however, they did not provide details on the smartphone usage, including the duration, posture and/or storage, which are factors we consider important: e.g. posture can moderate the distance of the phone which directly affects the intensity of the light, and not only exposure to the
phone’s light before sleep but also the sounds of email receipt, etc. can directly interrupt their sleep. Thus many factors have to be taken into consideration when understanding sleep disruption. To the best of our knowledge, this is the first report which closely gathered such information.

As this is a survey, the results of the study must be interpreted in the context of the following limitations. First, the participants’ responses were based on their memory recall, and so bias will naturally exist in their answers. This is an inherent difficulty of surveys of this kind, and we could have eliminated this problem only by monitoring their sleeping habits every night. However this was not practical, and would not necessarily provide accurate results, as such monitoring can alter participants’ habits. Second, we targeted only nursing students who were in their early twenties, and therefore we cannot generalize the results of the survey in regards to other age groups. However, we consider that a similar usage pattern can be found to a certain degree, at least among youth. Third, we did not have questions regarding sleep quality, therefore we could not correlate smartphone habits to sleep disruption. Forth, questions regarding when not using smartphone were not included in the survey either; which made it difficult to study how people’s lives have been altered by smartphone usage.

In summary, a vast majority of the students who participated in the survey answered that they use their phone almost every night before sleep, even after they turned off the lights, and they favor doing so in a lateral laying position. Moreover, they do not turn off the power during sleep, and, keep their phone easily accessible within hand’s reach. Further study is needed to better understand what factors are playing major roles in sleep disruption caused by smartphone usage in order for us to recommend the proper use of smartphones.

Conflicts of Interest
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 organization for the submitted work; Taishiro Kishimoto has received consultant fees from Dainippon Sumitomo, Novartis, Otsuka, speaker’s honoraria from Banyu, Eli Lilly, Dainippon Sumitomo, Janssen, Novartis, Otsuka, Pfizer, grant support from the Pfizer Health Research, Takeda, Tanabe-Mitsubishi, Dainippon-Sumitomo, Otsuka and Mochida; Masaru Mimura has received grants and/or speaker’s honoraria from Asahi Kasei Pharma, Astellas Pharmaceutical, Daiichi Sankyo, Dainippon-Sumitomo Pharma, Eisai, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceutical, Meiji-Seika Pharma, Mochida Pharmaceutical, MSD, Novartis Pharma, Otsuka Pharmaceutical, Pfizer, Tsumura, Shionogi, Takeda, Tanabe Mitsubishi Pharma, and Yoshitomi Yakuhin within the past three years. Michitaka Yoshimura, Momoko Kitazawa and Kazuo Tsubota have nothing to disclose; no other relationships or activities that could appear to have influenced the submitted work.

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**p < .01, *p < .05.

Table 1: Smartphone Usage Habit among Youth (n = 138)
Acknowledgement
No funding has been received to conduct this study.

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