Patient preferences for using mobile technologies in clinical trials

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\textbf{A B S T R A C T}

The use of mobile technologies to collect participant data in clinical trials offers a number of scientific and logistical advantages. However, little is known about potential research participant preferences about how to incorporate mobile technologies into the design and conduct of a trial. Using a web-based survey which described hypothetical mobile clinical trial and traditional clinical trial scenarios, we explored patients’ perceptions of and willingness to participate in mobile and traditional clinical trials, their preferred trial procedures related to the use of mobile technologies, and the preferred attributes of mobile technologies. The majority of survey respondents reported that they would prefer participating in a clinical trial that used mobile technology over the traditional trial that relied on standard in-clinic assessments. They expressed that mobile clinical trials offered greater convenience, a reduction of in-person clinic visits, and greater data collection accuracy. Respondents also reported preferences for the frequency of in-clinic visits during mobile clinical trials, device training and troubleshooting, data privacy and confidentiality, the location of data storage, and user access to data collected by the trial device. As research participants become more involved in capturing their own data to inform trial endpoints, their user-preferences of mobile technology, such as those described here, should be considered in the design and conduct of mobile clinical trials.

1. Introduction

Clinicians have shown increasing interest in integrating mobile technologies into the delivery of health care services [1–4] and the management of health conditions [5–7]. The use of mobile technologies offers a number of advantages in clinical care, including the ability of patients to monitor their health, the ability to collect data beyond time and geographical constraints, and the potential to reduce the need for clinic visits that can be a substantial burden for many patients with limited mobility [4,5]. Clinical researchers have also begun using mobile technologies to objectively capture and measure clinical biomarkers and performance outcomes as primary and secondary study endpoints [8]. In addition to capturing established measures (eg, via an electronic patient-reported outcome survey), mobile technologies can capture new types of data that would not be possible without remote (ie, outside of the clinic setting) and continuous (or frequent) participant monitoring [8]. To maximize the clinical and scientific benefits offered by mobile technologies, it is critical to understand and incorporate the perspectives of potential research participants in planning clinical trials that use mobile technologies to capture trial outcomes—i.e., mobile clinical trials.

Earlier studies exploring the use and acceptability of mobile technologies in health care have suggested that user age was often an important factor, with older populations requiring greater technical support and reporting lower acceptability of using mobile technologies [9–11]. However, more recent nationwide surveys have suggested that, though adults older than 65 years use mobile technologies less frequently than adults younger than 65 years, smartphone use among older adults has increased from 18% in 2013 to 42% in 2017 [12]. Other sociodemographic factors, including limited prior use of technology, lack of prior internet use, lower annual household income, and lower educational attainment have had a mixed association with...
the acceptability of mobile technology [9–11].

Despite accelerating interest in the potential of mobile technologies, knowledge of patients’ preferences with respect to using them in clinical research is limited. With the growing movement for patient-centered design of clinical trials [13–19], understanding the mobile clinical trial preferences of patients can provide evidence for best practices in the design and conduct of clinical research using mobile technologies.

The Clinical Trials Transformation Initiative (CTTI) conducted a survey to document and describe patient preferences on the use of mobile technologies in clinical research as part of a larger program focused on mobile clinical trials [20]. CTTI is a public–private partnership between the US Food and Drug Administration and Duke University that seeks to identify and drive adoption of practices that increase the quality and efficiency of clinical trials. In this manuscript, we describe findings from a survey of potential research participants on their perceptions of, and willingness to participate in, clinical trials that use mobile technologies, their preferred procedures in trials that use mobile technologies, and the attributes of mobile technologies used in clinical trials that they find preferable or undesirable.

2. Methods

2.1. Sampling, recruitment, and eligibility criteria

We used ResearchMatch [21]—a national web-based platform that links research volunteers with researchers—to recruit a nonprobability sample of patients who are potentially eligible to participate in future mobile clinical trials. We posted a recruitment announcement on ResearchMatch describing the study, and interested individuals were sent a link to an online Qualtrics survey [22] if they met the eligibility criteria. Individuals were eligible to participate if they were 18 years or older, had access to a computer and a reliable internet connection, were able to read English, and self-reported having Parkinson's disease, heart disease, diabetes, or arthritis.

2.2. Data collection

We first asked questions about demographic characteristics and familiarity and experience with mobile technologies. Survey respondents then viewed embedded videos that described hypothetical traditional and mobile clinical trial scenarios tailored to the patients’ self-reported health condition. Patients were then asked closed- and open-ended questions on their willingness to join either type of trial. The mobile-specific scenarios described specific technologies and trial designs based on a systematic review of available literature on clinical research studies for those conditions using mobile technology to assess study outcomes [8]. Respondents were randomized 1:1 to hear about either the traditional or the mobile clinical trial scenario first.

For the remainder of the survey, respondents answered questions on (1) the acceptability of bring-your-own-device approaches in clinical research; (2) mobile clinical trial procedural preferences; (3) concerns about security and data privacy; (4) willingness to use disease-specific mobile technologies (ie, mobile applications, wearable health monitors, wearable patches, bodily-fluid diagnostic devices, ingestible technologies) in clinical research; and (5) mobile technology design preferences in the context of a clinical trial. Illustrations and descriptions of all devices referenced in the questions were provided (Fig. 1).

Before finalizing the survey, we conducted 12 cognitive interviews with patients with the specific health conditions of interest to ensure respondent understanding and acceptability of the survey questions and responses. The survey was administered between July 14 and August 8, 2017, and took approximately 30 min for respondents to complete.

2.3. Analysis

Respondents who completed the first 3 sections of the survey (ie, demographic characteristics, familiarity and experiences with mobile technologies, and willingness to join a mobile vs traditional clinical trial) were included in this analysis. We used descriptive statistics to summarize and present the data. We also used Pearson chi-square tests or Fisher exact tests on nominal categorical variables and Mantel-Haenszel chi-square tests and Kruskal-Wallis tests on ordinal categorical variables to assess the relationships between pre-identified variables. For measures related to willingness to participate in a trial and familiarity and experience with mobile technologies, respondents were asked to report their responses on a 5-point Likert scale. Ordinal values from 1 to 5 were attributed to these scales for statistical analysis. Our intentions were to describe the study population and to explore potential associations with acceptability outcomes, and not to conduct specific hypothesis testing. We analyzed responses from the open text fields using a rapid qualitative analysis approach [23]. To efficiently categorize respondent statements and identify themes, responses were first transferred to and organized into matrices in Microsoft Excel. Analysts then reviewed statements provided by each respondent, by domain, and identified emergent themes based on the frequency of responses [24].

2.4. Ethics

The institutional review board (IRB) of the Duke University Health System determined that the research was exempt from IRB review and, therefore, informed consent was not required. The introductory first page of the survey summarized the purpose of the study and included information on the potential risks and benefits of participation, survey data confidentiality, and voluntariness of participation. Survey respondents were informed that by continuing with the survey they were agreeing that their data could be used for study purposes. All responses were anonymous.

3. Results

3.1. Study population

A total of 220 people responded to the survey, and 193 were included in the analysis. Respondents’ ages ranged from 23 to 83 years (median, 61 years; interquartile range, 55–68 years). A total of 171 respondents (89%) were non-Hispanic white, 120 (62%) were women, and 184 (95%) had some college credit or higher. The distribution of self-reported disease conditions were: 99 respondents (51%) with arthritis; 63 (33%) with diabetes; 18 (9%) with Parkinson’s disease; and 13 (7%) with heart disease (Table 1). Respondents diagnosed with more than one of these health conditions were asked to select one for the hypothetical trial scenarios.

Nearly three-quarters of respondents (n = 141, 73%) were diagnosed with their health condition 5 or more years ago, and 143 (74%) see their medical provider 2 or more times a year. Seventy-eight respondents (40%) said their health condition impacts how they feel day to day “somewhat” and another 64 (33%) respondents said it impacts how they feel “a lot.” The majority (n = 121, 63%) reported receiving their overall health as “good” or “very good.”

3.2. Use of and familiarity with mobile technology

Most respondents, 168 (87%), reported daily use of a smartphone, and 97 (50%) reported daily use of a tablet. Two-thirds of respondents, 125 (65%), used a mobile app to monitor their health, and 166 (88%) felt “comfortable” or “very comfortable” using mobile apps (Table 2). A majority reported no experience with using a wearable fitness monitor (56.5%) or a heart monitor (86.8%) in the last year. Among those with experience using these devices, 78 (84%) felt “comfortable” or “very comfortable” using the device. Nearly three-quarters of all respondents, 139 (72%), reported no prior clinical trial participation.
3.3. Willingness to participate in mobile and traditional clinical trials

Of the 193 respondents, 99 were randomly assigned to the mobile clinical trial scenario first and 94 respondents were randomly assigned to the traditional clinical trial scenario first. Overall, 155 (81%) respondents reported they were willing to participate in the mobile trial, compared to 98 (51%) who were willing to participate in the traditional trial (Table 3). We observed an order effect such that respondents who viewed the traditional trial second (ie, after the mobile trial scenario) were significantly less willing to join the traditional trial than if they viewed the traditional trial first ($P < 0.0001$). There was no order effect on respondents’ willingness to join the mobile trial.

We found that some respondent characteristics were associated with greater willingness to participate in the traditional or mobile trial scenario. Men were more likely to report willingness to participate in a traditional clinical trial than women (55% vs 49%; $P = 0.05$). In addition, respondents reporting that their day-to-day lives were impacted “a lot” by their health condition were more likely to report willingness to take part in a traditional clinical trial ($P = 0.05$). There was no association between gender or disease burden and respondents’ willingness to join the mobile clinical trial.

We also found that more frequent use of a smartphone was
associated with a greater willingness to participate in the mobile clinical trial \( (P = 0.03) \): 139 (83%) respondents who reported daily use of smartphones were willing to participate in the mobile trial compared to 8 (62%) respondents who used a smartphone less frequently and 8 (67%) who had never used a smartphone. Similarly, more frequent use of mobile health applications on a phone or tablet was associated with a greater willingness to participate in the mobile clinical trial \( (P < 0.01) \): 51 (88%) respondents who reported daily use of mobile health apps and 56 (85%) respondents with less than daily use of mobile health apps, were willing to participate in the mobile trial compared to 48 (71%) of those who never use mobile health apps. Additionally, respondents who used wearable fitness monitors in the previous year were more willing to participate in the mobile clinical trial \( (P = 0.04) \): 25 (83%) respondents who used a wearable fitness monitor year round and 47 (90%) who had some use of wearable fitness monitors in the last year were willing to join the mobile trial compared to 81 (75%) who had no prior use of a wearable fitness monitor. However, opinions varied when respondents were asked directly if the inclusion of mobile technology in the clinical trial influenced their willingness to join the mobile trial: 95 (49%) said they were “more likely” to participate because of the use of mobile technology while 42 (42%) said it had no direct impact on their willingness to participate.

When asked to choose which trial option they preferred, 146 (76%) respondents reported preferring the mobile trial scenario over the traditional scenario. Only 14 (7%) said they would prefer the traditional trial, 23 (12%) had no preference, and 8 (4%) were uninterested in both trials. Reasons for preferring the mobile trial primarily focused on reduced participant burden, including fewer visits to the trial clinic and perceived easier daily compliance with trial-related procedures. A respondent described her rationale for preferring a mobile clinical trial:

Keeping journals or diaries is a pain. Monthly 1–3 hour doctor’s visits eat up precious time. Using an app and a fitbit type of device is a time saver and I don’t have to worry about forgetting to journal what is going on daily. (woman, age 53 years)

Other reasons respondents gave for preferring the mobile trial included (1) a perception that more accurate data would be collected because of the use of a more objective data collection tool; (2) the perceived ability to see their data and track their own health (though the ability of respondents to do so was not explicitly stated in the description of the mobile trial scenario); (3) use of an interesting technology; and (4) perception of more responsive safety monitoring. A respondent explained:

Using mobile apps and monitors makes this a no brainer. I do not have to focus solely on what’s going on with my diabetes and the medicine I’m taking. I can continue my normal routine which would give you more accurate results to how I live my life. What I am doing right or wrong. How I sleep, etc. (woman, age 58 years)

Reasons respondents gave for preferring the traditional trial scenario primarily focused on the perception that use of mobile technology might be more burdensome. For example, respondents expressed concerns about daily device maintenance and record keeping, as well as a preference not to wear a device 24 h a day, 7 days a week. In addition, some respondents said they preferred the traditional scenario because it allowed for more frequent direct interaction with the trial doctor:
Table 3
Willingness to Participate in Mobile vs Traditional Trials.

| Willing to join traditional trial, n (%) | Overall, n = 193 | Arthritis, n = 99 | Diabetes, n = 63 | Parkinson’s Disease, n = 18 | Heart Disease, n = 13 |
|-----------------------------------------|------------------|------------------|-----------------|---------------------------|------------------|
| Definitely no or Probably no            | 47 (24.5)        | 26 (26.5)        | 16 (25.4)       | 1 (5.6)                   | 4 (30.8)         |
| Not sure                                | 47 (24.5)        | 27 (27.6)        | 13 (20.6)       | 5 (27.8)                  | 2 (15.4)         |
| Definitely yes or Probably yes          | 98 (51.0)        | 45 (45.9)        | 34 (54.0)       | 12 (66.7)                 | 7 (53.8)         |
| Missing                                 | 1 (0.5)          | 1 (1.0)          | 0 (0)           | 0 (0)                     | 0 (0)            |
| **Willing to join mobile trial, n(%)**  |                  |                  |                 |                           |                  |
| Definitely no or Probably no            | 16 (8.3)         | 8 (8.2)          | 7 (11.1)        | 0 (0)                     | 1 (7.7)          |
| Not sure                                | 21 (10.9)        | 16 (16.3)        | 4 (6.3)         | 0 (0)                     | 1 (7.7)          |
| Definitely yes or Probably yes          | 155 (80.7)       | 74 (75.5)        | 52 (82.5)       | 18 (100.0)                | 11 (84.6)        |
| Missing                                 | 1 (0.5)          | 1 (1.0)          | 0 (0)           | 0 (0)                     | 0 (0)            |
| **Preferred trial (regardless of order of randomization), n(%)** |                  |                  |                 |                           |                  |
| Mobile                                  | 146 (76.4)       | 72 (74.2)        | 47 (74.6)       | 16 (88.9)                 | 11 (84.6)        |
| Traditional                             | 14 (7.3)         | 6 (6.2)          | 7 (11.1)        | 0 (0)                     | 1 (7.7)          |
| Either                                   | 23 (12.0)        | 15 (15.5)*       | 6 (9.5)         | 2 (11.1)                  | 0 (0)            |
| Neither                                  | 8 (4.2)          | 4 (4.1)          | 3 (4.8)         | 0 (0)                     | 1 (7.7)          |
| **Effect of mobile technology use on willingness to join mobile trial, n(%)** |                  |                  |                 |                           |                  |
| More likely to take part                 | 95 (49.2)        | 47 (47.5)        | 33 (52.4)       | 9 (50.0)                  | 6 (46.2)         |
| Equally likely to take part             | 81 (42)          | 44 (44.4)        | 22 (34.9)       | 9 (50.0)                  | 6 (46.2)         |
| Less likely to take part                | 15 (7.8)         | 7 (7.1)          | 7 (11.1)        | 0 (0)                     | 1 (7.7)          |
| I prefer not to respond                 | 2 (1.0)          | 1 (1.0)          | 1 (1.6)         | 0 (0)                     | 1 (0)            |

* Two patients only viewed one of the scenarios so their responses are excluded.

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3.3.1. Willingness to use other mobile technologies in clinical trials

With respect to the 5 mobile technologies described in the survey (Fig. 1), 180 (95%) respondents were willing to use wearable health monitors, 177 (93%) were willing to use a smartphone or tablet app, and 171 (90%) were willing to use patches in a mobile clinical trial. Many respondents (n = 163, 86%) were also willing to use bodily-fluid diagnostic devices. Ingestible sensors were the least preferred, though 139 (73%) respondents said they would be willing to use such devices. Of those respondents who were willing to use wearable devices, 150 (83%) were willing to use the device daily for a year or more, or for as long as the trial lasted. Among respondents who were willing to use the apps, patches and other devices, between 64% and 68% (depending on the technology) were willing to use the technology daily for at least a year or for as long as the trial lasted (Table 4).

3.4. Mobile trial preferences

3.4.1. Acceptability of bring-your-own-device approaches

For the questions on bring-your-own-device approaches, we asked respondents to assume that they owned a comparable health monitor to the one used in a mobile clinical trial. Over half (n = 100, 55%) stated they preferred using the technology provided by the trial rather than their own device. Another 57 (32%) had no preference for using a trial-provided technology or their own. In addition, if required to use the trial-provided technology, 144 (75%) respondents said that they would only use that device, while another 41 (21%) said they would use both the provided device and their own device during the trial. Most respondents (n = 155, 86%) felt it was at least “somewhat important” that they not incur any personal charges for data minutes when using their own technology in the study.

3.4.2. Device training preferences

Over half of respondents indicated that in-person training by trial staff (n = 111, 58%) and written step-by-step instructions (n = 103, 53%) would be best for learning how to use a new mobile technology. A short instructional video was also reported as helpful by almost half of the respondents (n = 98, 48%), and a few (n = 15, 8%) suggested

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Table 4
Acceptable daily use of mobile technology during a trial (N = 190).

| Willingness to use, n (%) | Mobile apps | Wearable monitor | Patch | Bodily-fluid diagnostic device | Ingestible |
|--------------------------|-------------|------------------|-------|--------------------------------|------------|
| Yes                      | 177 (93.2)  | 180 (94.7)       | 171 (90.0)     | 163 (85.8)                  | 139 (73.2) |
| No                       | 13 (6.8)    | 9 (4.7)          | 19 (10.0)      | 25 (13.2)                   | 44 (22.2)  |
| I prefer not to respond | 0 (0)       | 1 (0.5)          | 0 (0)          | 2 (1.1)                     | 7 (3.7)    |
| **Acceptable duration of daily-use during a trial, n (%)** |                  |                  |                 |                           |            |
| For one day only         | 2 (1.1)     | 0 (0)            | 0 (0)          | 3 (1.9)                     | 3 (2.2)    |
| One week                 | 9 (5.1)     | 1 (0.6)          | 4 (2.4)        | 10 (6.2)                    | 12 (8.7)   |
| One month                | 22 (12.4)   | 5 (2.8)          | 20 (11.8)      | 16 (9.9)                    | 16 (11.6)  |
| 2–5 months               | 13 (7.3)    | 8 (4.5)          | 28 (16.6)      | 15 (9.3)                    | 7 (5.1)    |
| 6–11 months              | 9 (5.1)     | 13 (7.3)         | 6 (3.6)        | 9 (5.6)                     | 4 (2.9)    |
| One year                 | 30 (16.9)   | 28 (15.8)        | 17 (10.1)      | 15 (9.3)                    | 16 (11.6)  |
| More than a year         | 3 (1.7)     | 4 (2.3)          | 2 (1.2)        | 3 (1.9)                     | 2 (1.4)    |
| As long as the trial lasts| 85 (48.9)   | 118 (66.7)       | 91 (53.8)      | 88 (54.7)                   | 76 (55.1)  |
| I prefer not to respond | 4 (2.3)     | 0 (0)            | 1 (0.6)        | 2 (1.2)                     | 2 (1.4)    |

* Among those who said they were “willing to use” the technology.
Table 5
Mobile trial procedural preferences.

| Training preferences, n = 193 (select all that apply) | n (%) |
|------------------------------------------------------|-------|
| In person training by trial staff                     | 111 (57.5) |
| Written step-by-step instructions                      | 103 (53.4) |
| A short video                                         | 93 (48.2) |
| Hearing instructions over the phone                   | 15 (7.8) |
| Another way                                           | 6 (3.1) |
| I prefer not to respond                               | 1 (0.5) |

Clinic visits and communication preferences

| Frequency of clinic visits, n = 187                  | n (%) |
|-----------------------------------------------------|-------|
| I would prefer to see the trial doctor at the beginning and end of the trial | 88 (47.1) |
| It doesn’t matter to me how often I see the trial doctor | 57 (30.5) |
| I would prefer to see the trial doctor numerous times during the trial | 30 (16.0) |
| I would prefer to never to have to see the trial doctor | 10 (5.3) |
| I prefer not to respond                              | 2 (1.1) |

| Means of communicating with trial doctor, n = 177*   | n (%) |
|------------------------------------------------------|-------|
| I would be willing and able to use another form of communication | 148 (89.7) |
| I would need to meet in person                        | 16 (9.7) |
| I prefer not to respond                               | 1 (0.6) |
| Missing                                               | 12 |

Alternate forms of communication, n = 148 (select all that apply)

| Email                                      | 125 (84.5) |
|--------------------------------------------|------------|
| Telephone                                  | 119 (80.4) |
| Online live chat                           | 106 (71.6) |
| Online video conferencing                   | 100 (67.6) |
| Text message                               | 92 (62.2)  |

Trouble-shooting, n = 190

| Trial staff                                 | 150 (78.9) |
|---------------------------------------------|------------|
| The company who made the mobile technology  | 30 (15.8)  |
| Someone else                               | 9 (4.7)    |
| No one. I would stop using it if it stopped working | 1 (0.5) |

Data privacy and confidentiality, n = 187

| Worry about other people, not among research staff, seeing the data | n (%) |
|-------------------------------------------------------------------|-------|
| Extremely worried                                                | 9 (4.8) |
| Worried                                                           | 12 (6.4) |
| A little worried                                                  | 57 (30.5) |
| Not worried                                                       | 103 (55.1) |
| Not sure                                                         | 6 (3.2) |

Comfort with Geolocation Tracking

| Very uncomfortable   | 13 (7.0) |
| Comfortable          | 42 (22.5) |
| Very comfortable     | 93 (49.7) |
| Not sure             | 23 (12.3) |

Willingness to take part if confidentiality of data is uncertain

| Definitely no         | 38 (20.3) |
| Probably no           | 53 (28.3) |
| I am not sure         | 43 (23.0) |
| Probably yes          | 39 (20.9) |
| Definitely yes        | 14 (7.5) |

Participants' access to data

| Importance of participants' access to information collected by mobile tech, n = 190 | n (%) |
|-------------------------------------------------------------------------------------|-------|
| Very important                                                                      | 91 (47.9) |
| Important                                                                           | 60 (31.6) |
| Somewhat important                                                                  | 35 (18.4) |
| Not important                                                                       | 4 (2.1) |

Preferred method of data access, n = 186 (select all that apply)

| Through a website page designed just for you that summarizes your information     | 122 (65.6) |
| Displayed on the technology itself                                                | 96 (51.6) |
| In a one-on-one meeting with trial staff                                          | 55 (29.6) |
| Printouts of your information that are sent to you                                | 45 (24.2) |
| Another way                                                                        | 8 (4.3) |

Preferred frequency of data access, n = 185

| Instantly                        | 30 (16.2) |
|----------------------------------|-----------|
| Every day                        | 46 (24.9) |
| Every week                       | 48 (25.9) |
| 2 to 3 times per month           | 13 (7.0)  |
| Once per month or less           | 28 (15.1) |

Table 5 (continued)

| After the trial is over           | n (%) |
|-----------------------------------|-------|
| 20 (10.8)                         |       |

* Asked of participants reporting interest in seeing a trial doctor.

3.4.4. Clinic visits and communication preferences

Nearly half of respondents (n = 88, 47%) preferred to see the trial doctor only at the beginning and end of the mobile trial; 57 (31%) had no preference. Among those who wanted to interact with a trial doctor during the mobile trial (n = 175, 95%), only 10% indicated that visits must be in person. Among those willing to use other forms of communication with the trial doctor (n = 148, 90%), multiple methods were widely acceptable, including email, telephone, live online chat, video conferencing, and text message. There was no association between demographic variables and preferred means of communication.

3.4.5. Data privacy and confidentiality

More than half of respondents (n = 103, 55%) were not worried that others beyond the research team would be able to see their data collected by the mobile technology; only 21 (11%) were “worried” or “extremely worried.” However, nearly half (n = 91, 48%) would “probably not” or “definitely not” participate in a trial if it were uncertain whether the information collected by the mobile technology would remain confidential, and 43 (23%) others were uncertain about whether they would participate. Over half of respondents (n = 116, 62%) reported that they were “comfortable” or “very comfortable” with using mobile technology that tracked their geographic location.

3.4.6. Participants’ access to data

Most respondents reported that it was “very important” or “important” (n = 151, 80%) to have access to the information collected about them by the mobile technology. Only 4 (2%) reported that access was “not important.” In addition, the majority preferred weekly or more frequent access to information (n = 124, 67%); of these, 30 (24%) preferred “instant” access, and 46 (37%) preferred access to information “every day.”

With respect to how to receive the information collected about them by the mobile technologies, 122 (66%) respondents preferred a webpage designed specifically for them, 96 (52%) preferred receiving information directly on the mobile technology, 55 (30%) preferred one-on-one meetings with trial staff, and 45 (24%) wanted printouts of their information sent to them.

3.4.7. Data storage

A few respondents said they were “uncomfortable” or “very uncomfortable” with having data locally stored on the mobile technology and with having their data transferred and remotely stored on trial servers (Table 6). However, more respondents (between 14% and 18% depending on type of mobile technology) were uncomfortable with data being stored on the manufacturers’ server rather than on the mobile technology itself (2% regardless of mobile technology) or on the trial's server (2% and 5% depending on mobile technology).

3.4.8. Device preferences

All respondents reported that wearable monitors used in mobile...
trials should be designed to be “easy to learn” and “convenient to use,” and 176 (99%) reported that wearable monitors should be “physically comfortable” and that technical support should be available when problems arise (Table 7). Similar preference patterns were reported for the other mobile technologies (Fig. 1). When compared to other attributes, fewer respondents indicated that it was important that the technology be attractive, “not easily noticed or seen,” or “fun to use.” In addition, across all 4 mobile technologies explored in the survey, more than half of respondents felt that it was “important” or “somewhat important” for technology to display the information collected either on a smartphone, tablet, or computer (Table 7).

4. Discussion

Most survey respondents reported that they would rather take part in a mobile clinical trial than a traditional trial, expressing preferences related to the greater convenience of mobile trials, eliminating travel to in-person visits, and perceived greater data collection accuracy offered by the mobile technology. Respondents were also very willing to wear any one of the different mobile technologies presented—mobile apps, wearables devices and patches, bodily-fluid diagnostic devices, and ingestible sensors—for as long as 24 h a day, 7 days a week, for over a year, or as long as the trial continues. Provided devices were preferred over personal devices, and several key attributes were consistently viewed across the mobile technologies as important for patient acceptance: devices must be comfortable, convenient, and easy to use. Responses to our survey questions also suggest the importance of trial-provided training on how to use the mobile technology and readily available tech-support by trial staff in case of malfunction.

The survey findings also suggest that patient concerns about privacy and confidentiality may not be a major concern when participating in trials that use mobile technologies. While there were few concerns related to data storage, responses showed a small preference for data to be stored locally on the device or on trial-specific data servers and not by the technology manufacturer. In addition, respondents who were concerned about the security of their health data were less likely to join a mobile clinical trial. We did not explain or assess comprehension of the human subject protection regulations on privacy and confidentiality of study data when we asked these questions.

Almost all respondents wanted access to their data collected by the mobile technology in a clinical trial. Given the frequent access to data from consumer wearable technologies and health tracking devices, this expectation is not surprising. Most respondents preferred viewing their information via a display on the technology itself or through a personalized website. We did not ask specifically about the types of information patients expect to receive.

Many respondents also would prefer having a limited number of visits with trial doctors, which suggests alignment between patient preferences and the potential for mobile technologies to facilitate more efficient, less costly trials. However, the greater focus on in-person visits was one of the important reasons some respondents stated that they preferred the traditional trial scenario over the mobile trial scenario in this survey.

4.1. Limitations

The intent of the survey was to gather descriptive data on participant preferences. We did not aim to gather data to generalize the findings to a larger patient population. Although we targeted patients who might be eligible for future mobile clinical trials given their diagnosed illness, the survey population lacks diversity and may not be similar to future participants in mobile clinical trials. Our survey respondents may also have been more motivated to participate in research than the general population. We recruited exclusively through the ResearchMatch website, which is designed to match motivated patients to potential opportunities to participate in research. Therefore, this study population may have had more time and interest in participating in our survey to share their preferences relating to hypothetical clinical research scenarios than other patient populations. In addition, our respondents may have been more tech-savvy compared to other patient populations, as they must have had computer access and a reliable internet connection, though few had recent experience using a wearable device. Finally, although the survey used scenarios that were as realistic as possible, including elements from disease-relevant mobile clinical trials and technologies, the scenarios were hypothetical.

5. Conclusion

There has been little research on the user-acceptability of mobile technologies in clinical research. Mobile clinical trials depend upon patient acceptance and study-defined use of mobile technologies to gather necessary data to inform outcomes. In mobile clinical trials, patients often serve not only as trial participants but also as primary data collectors. As mobile technology-generated endpoints continue to be incorporated into clinical trials [8], more focus should be placed on gathering patient feedback on the shifting forms of trial burden (eg, burden of coming into the clinic regularly compared to maintaining a liable internet connection, though few had recent experience using a wearable device). Our findings give insight into patients’ willingness to join mobile clinical trials and to use a variety of mobile technologies in a hypothetical mobile clinical trial.

Both additional research and sharing of practical experience are needed to ensure efficient and effective use of mobile technologies in clinical trials. Findings from this study may be used to inform future research designed to test hypotheses for factors associated with patient’s acceptability of mobile clinical trials. Other important issues must also be addressed in future research, such as better understanding of how underserved, diverse patient populations with limited access to technology might perceive participation in clinical research utilizing mobile

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Table 6
Comfort with data storage and access.

|                          | Wearable monitor, n = 180 | Patch, n = 171 | Bodily-fluid diagnostic device, n = 163 | Ingestible, n = 139 |
|--------------------------|---------------------------|----------------|----------------------------------------|--------------------|
| **Local storage on the device, smartphone or tablet**, n (%) | Very uncomfortable or Uncomfortable: 5 (2.9) | 6 (3.6) | 8 (5.1) | 2 (1.5) |
|                          | Very comfortable or Comfortable: 167 (97.1) | 161 (96.4) | 149 (94.9) | 134 (98.5) |
|                          | Missing: 8                  | 4              | 6                                        | 3                  |
| **Electronic transfer and remote storage on trial server**, n (%) | Very uncomfortable or Uncomfortable: 4 (2.3) | 3 (1.8) | 3 (1.9) | 2 (1.5) |
|                          | Very comfortable or Comfortable: 170 (97.7) | 166 (98.2) | 156 (98.1) | 133 (98.5) |
|                          | Missing: 6                  | 2              | 4                                        | 4                  |
| **Remote storage on manufacturer’s server**, n (%) | Very uncomfortable or Uncomfortable: 27 (15.9) | 30 (18.3) | 26 (16.9) | 18 (13.5) |
|                          | Very comfortable or Comfortable: 143 (84.1) | 134 (81.7) | 128 (83.1) | 115 (86.5) |
|                          | Missing: 10                 | 7              | 9                                        | 6                  |

* Data would be encrypted to limit access by others who were not part of the trial.
** Data would be de-identified (ie, name would be replaced with unique ID).
Table 7
Relative importance of mobile technology attributes in a mobile clinical trial.

| Wearable monitor, n = 177 | Patch, n = 168 | Bodily-fluid diagnostic device, n = 160 | Ingestible, n = 138 |
|---------------------------|---------------|---------------------------------|-----------------|
|                           | Very important| Important/ Somewhat important   | Not important   | Very important| Important/ Somewhat important | Not important | Very important| Important/ Somewhat important | Not important   | Very important| Important/ Somewhat important | Not important   | Very important| Important/ Somewhat important | Not important   | Very important| Important/ Somewhat important | Not important   | Very important| Important/ Somewhat important |
| Be physically comfortable | 79%           | 20%                            | 1%              | 76%           | 23%                        | 0%            | 65%           | 33%                        | 3%              | 72%           | 28%                        | 0%              |
| Be convenient to use      | 68%           | 32%                            | 0%              | –             | –                          | –             | 61%           | 39%                        | 1%              | 70%           | 28%                        | 1%              |
| Not interfere with your normal daily activities | 63%           | 32%                            | 3%              | 63%           | 35%                        | 2%            | 65%           | 29%                        | 5%              | 71%           | 26%                        | 3%              |
| Collect data on its own (so you don’t have to enter it yourself) | 61%           | 34%                            | 2%              | –             | –                          | –             | –             | –                          | –               | –             | –                          | –               |
| Has tech support available if there is a problem | 61%           | 36%                            | 1%              | 54%           | 45%                        | 0%            | 64%           | 36%                        | 1%              | –             | –                          | –               |
| Be simple to use          | 56%           | 43%                            | 1%              | 61%           | 39%                        | 0%            | 59%           | 40%                        | 1%              | –             | –                          | –               |
| Be easy to learn how to use | 59%           | 41%                            | 0%              | 51%           | 47%                        | 2%            | 63%           | 36%                        | 2%              | –             | –                          | –               |
| Not take a lot of your time to use | 51%           | 45%                            | 4%              | 45%           | 49%                        | 5%            | 49%           | 44%                        | 6%              | 57%           | 38%                        | 4%              |
| Is waterproof             | 38%           | 55%                            | 7%              | 54%           | 43%                        | 4%            | –             | –                          | –               | –             | –                          | –               |
| Has a long battery life   | 41%           | 55%                            | 3%              | –             | –                          | –             | –             | –                          | –               | –             | –                          | –               |
| Be lightweight            | 38%           | 57%                            | 5%              | –             | –                          | –             | 34%           | 58%                        | 9%              | –             | –                          | –               |
| Be small in size          | 23%           | 68%                            | 9%              | 26%           | 63%                        | 12%           | 27%           | 55%                        | 18%             | 64%           | 31%                        | 4%              |
| Displays your data on your smartphone, tablet or computer | 38%           | 55%                            | 7%              | 30%           | 61%                        | 9%            | 29%           | 63%                        | 8%              | 30%           | 59%                        | 11%             |
| Has a password that you enter before you view your data | 33%           | 43%                            | 21%             | –             | –                          | –             | 32%           | 47%                        | 21%             | –             | –                          | –               |
| Not be easily noticed or seen | 10%           | 58%                            | 32%             | 19%           | 57%                        | 25%           | 23%           | 51%                        | 26%             | –             | –                          | –               |
| Be fun to use             | 10%           | 53%                            | 36%             | –             | –                          | –             | 12%           | 31%                        | 57%             | –             | –                          | –               |
| Be attractive             | 7%            | 57%                            | 36%             | 7%             | 38%                        | 55%           | 6%            | 33%                        | 61%             | –             | –                          | –               |
technologies.

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