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Patient preferences for using mobile technologies in clinical trials

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ABSTRACT

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 than a 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 text messaging, lack of prior internet use, lower annual household income, and lower educational attainment have had a mixed association with

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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 disease-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 perceiving 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 health 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.

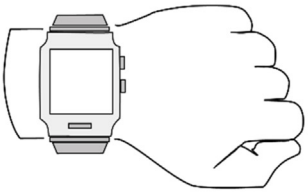
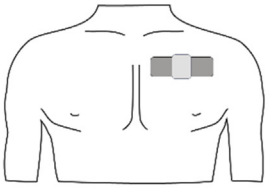
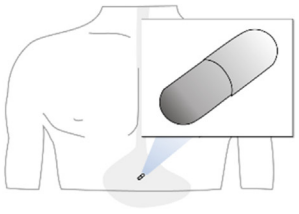
Below is a list of mobile technologies that have been used in clinical trials to collect information from participants. If you were asked to join a trial, would you be willing to use:	
	…a **smartphone or tablet app** where you enter information about yourself? For example, the time you went to bed.
	…a **wearable health monitor** that you could wear around your wrist, ankle or waist? These devices typically collect information about fitness and mobility. Some monitors send the information wirelessly to an app on your smartphone or tablet. The app then sends the information to trial staff. Other monitors store the information until the monitor is returned to trial staff. Staff then download the information to their computers.
	…a **patch** that adheres to your skin? These patches stick to your skin, like a Band-Aid. They are usually placed somewhere on your torso. They can collect vital signs such as heart rate, blood pressure, breathing rate and body temperature. In the future, some patches may collect information about cholesterol or bodily nutrients. The patch sends the information wirelessly to an app on your smartphone or tablet. The app then sends the information to trial staff. The battery on the patch will last up to four days and can be disposed of in the trash after use. The patch will need to be replaced every three days. You can do all your normal daily activities, such as showering, while wearing the patch.
	…a **bodily-fluid diagnostic device** that measures chemicals and nutrients in the body? These devices measure body chemistry that is found in bodily fluids, such as blood, saliva, sweat or urine. Body chemistry are blood glucose, cholesterol, bodily nutrients, or toxins, drugs or alcohol. Some devices can detect pregnancy. The device requires users to place the bodily fluid on a test strip, which is then put in a device attached to a smartphone or tablet. The sample of the test strip is analyzed by the device. The results are automatically sent to trial staff when you have a wireless signal by an app on the smartphone or tablet.
	…a **device that is swallowed** (ingested)? Ingestible technologies are sensors that are often put on a pill that is swallowed by a patient. The sensor remains in the stomach and/or digestive track for about a day. It can measure the presence of medication and vital signs, such as heart rate and breathing. Some sensors can also take pictures. The information gathered from the sensor is sent wirelessly to a patch the patient wears on the skin. Then the information is sent directly to trial staff. Sometimes it is sent to an app on the patient's smartphone and then sent to trial staff. The sensor will be disposed of in the toilet after use.

Fig. 1. Illustrations and descriptions of all devices referenced in the survey.

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

Table 1
Characteristics of the study population.

Age	n (%)
60 and over	108 (56.3)
59 and under	84 (43.8)
Race/ethnicity	
White, Not Hispanic or Latino	170 (88.5)
Black or African American, Not Hispanic or Latino	10 (5.2)
White, Hispanic or Latino	5 (2.6)
Other	7 (3.6)
Missing	1
Gender	
Female	120 (62.2)
Male	73 (37.8)
Marriage	
Married or domestic partnership	120 (62.8)
Widowed, divorced, or separated	49 (25.7)
Single, never married	22 (11.5)
Missing	2
Education	
Some college credit or higher	184 (95.3)
High school diploma or less	9 (4.7)
Employment	
Retired	74 (38.3)
Employed full-time	62 (32.1)
Unable to work	27 (14.0)
Employed part-time	18 (9.3)
A homemaker	4 (2.1)
A student	4 (2.1)
Out of work and looking for work	3 (1.6)
Out of work but not currently looking for work	1 (0.5)

Table 2
Mobile technology familiarity.

Use of a smartphone, n = 193	n (%)
Never	12 (6.2)
Once a month or less, 2 to 3 times a month, or Every week	13 (6.7)
Every day	168 (87.0)
Use a tablet, such as an iPad, n = 193	
Never	38 (19.7)
Once a month or less, 2 to 3 times a month, or Every week	58 (30.1)
Every day	97 (50.3)
Use of a mobile app to monitor health, n = 193	
Never	68 (35.2)
Once a month or less, 2 to 3 times a month, or Every week	67 (34.7)
Every day	58 (30.1)
Use of fitness monitor in last year, n = 191*	
Never	108 (56.5)
Some of the year or Most of the year**	53 (27.7)
All year long**	30 (15.7)
Missing	2
Use of wearable health monitor in last year, n = 189***	
Never	164 (86.8)
Some of the year or Most of the year	14 (7.4)
All year long	11 (5.8)
Missing	4
Comfort using apps unassisted	
Comfortable or Very comfortable	166 (87.8)
Uncomfortable or Very uncomfortable	23 (12.2)
Missing	1
Comfort using a wearable health monitor	
Comfortable or Very comfortable	78 (83.9)
Uncomfortable or Very uncomfortable	15 (16.1)
Missing	1
Prior clinical trial participation	
Yes******	49 (25.4)
No	139 (72.0)
I do not recall	4 (2.1)
I prefer not to respond	1

* A wearable fitness monitor was defined as a device that can automatically track the user's movement-related activity, such as distance walked or run, heart rate and in some cases sleep quality (eg, Fitbit, Jawbone, Misfit, Garmin or Apple watch).
** Among those that used a fitness monitor: 91.4% (n = 74) used it to monitor physical activity, 48.1% (n = 39) used it to monitor sleep, 42% (n = 34) used it to monitor heart rate, and 11.1% (n = 9) used it for other purposes.
*** A wearable health monitor was defined as a device that can automatically track the user's health or wellbeing, often without the user putting in information into the device themselves (eg, continuous glucose monitor, ambulatory blood pressure monitor, or electrocardiograph).
**** Among those that had prior clinical trial experience, 95.9% (n = 47) reported not using a wearable health monitor as part of the trial.

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 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.

	Overall, n = 193	Arthritis, n = 99	Diabetes, n = 63	Parkinson's Disease, n = 18	Heart Disease, n = 13
Willing to join traditional trial, n (%)					
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.

> I believe seeing medical personnel with greater frequency during the trial better monitors the patient's safety and wellbeing. (man, age 65 years)

> I would rather the researcher (doctor) do the information gathering. I would feel safer taking an experimental drug with potential harmful side effects with a doctor monitoring me. I would like to wear the monitor that would record my information, but I would not like to be bothered with the additional responsibility of charging the device, connecting to Wi-Fi. I would rather take the device into the appointment - have you download the info and recharge my device while the doctor monitors my health. (man, age 58 years)

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

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

	Mobile apps	Wearable monitor	Patch	Bodily-fluid diagnostic device	Ingestible
Willingness to use, n (%)					
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 (23.2)
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 (48.0)	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)
Missing	0	3	2	2	1

* Among those who said they were “willing to use” the technology.

Table 5
Mobile trial procedural preferences.

	n (%)
Training preferences, n = 193 *(select all that apply)*	
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	
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 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*	
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	
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)
Uncomfortable	42 (22.5)
Comfortable	93 (49.7)
Very comfortable	23 (12.3)
Not sure	16 (8.6)
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	
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)
After the trial is over	20 (10.8)

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

hearing instructions over the phone (Table 5). Respondents 60 years and older (n = 70, 64%) had a greater preference for in-person training than respondents 59 years and younger (n = 40, 37%; $P = 0.02$).

3.4.3. 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.

3.4.4. Troubleshooting device issues

Most respondents (n = 150, 79%) preferred contacting trial staff if they had an issue with their mobile technology rather than directly contacting the mobile technology manufacturer.

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 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

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).

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 provided mobile technology). 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

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
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 light weight	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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References

[1] J.H. Bergmann, V. Chandaria, A. McGregor, Wearable and implantable sensors: the patient's perspective, Sensors 12 (2012) 16695–16709, https://doi.org/10.3390/s121216695.
[2] J.H. Bergmann, A.H. McGregor, Body-worn sensor design: what do patients and clinicians want? Ann. Biomed. Eng. 39 (2011) 2299–2312, https://doi.org/10.1007/s10439-011-0339-9.
[3] A.H. Mohammad, H. Tawfik, D. Al-Jumeily, et al., MoHTAM: a technology acceptance model for mobile health applications, Developments in E-Systems Engineering (DeSE). Dubai, United Arab Emirates, IEEE, 2011, pp. 13–18.
[4] Y. Seko, S. Kidd, D. Wiljer, et al., Youth mental health interventions via mobile phones: a scoping review, Cyberpsychol., Behav. Soc. Netw. 17 (2014) 591–602, https://doi.org/10.1089/cyber.2014.0078.
[5] K. Anderson, O. Burford, L. Emmerton, Mobile health apps to facilitate self-care: a qualitative study of user experiences, PLoS One 11 (2016) e0156164, , https://doi.org/10.1371/journal.pone.0156164.
[6] N. Cook, S.L. Winkler, Acceptance, usability and health applications of virtual worlds by older adults: a feasibility study, JMIR Res Protoc 5 (2016) e81, https://doi.org/10.2196/resprot.5423.
[7] K. Mercer, L. Giangregorio, E. Schneider, et al., Acceptance of commercially available wearable activity trackers among adults aged over 50 and with chronic illness: a mixed-methods evaluation, JMIR Mhealth Uhealth 4 (2016) e7, https://doi.org/10.2196/mhealth.4225.
[8] B. Perry, W. Herrington, J.C. Goldsack, et al., Use of mobile devices to measure outcomes in clinical research, 2010–2016: a systematic literature review, Digital Biomarkers 2 (2018) 11–30, https://doi.org/10.1159/000486347.
[9] D.P. Miller Jr., K.E. Weaver, L.D. Case, et al., Usability of a novel mobile health iPad app by vulnerable populations, JMIR Mhealth Uhealth 5 (2017) e43, https://doi.org/10.2196/mhealth.7268.
[10] A. Rai, L. Chen, J. Pye, et al., Understanding determinants of consumer mobile health usage intentions, assimilation, and channel preferences, J. Med. Internet Res. 15 (2013) e149, https://doi.org/10.2196/jmir.2635.
[11] S. Zarghom, D. Di Fonzo, F.H. Leung, Does socioeconomic status affect patients' ease of use of a touch-screen (iPad) patient survey? Interact J Med Res 2 (2013) e1, https://doi.org/10.2196/ijmr.2314.
[12] M. Anderson, A. Perrin, Tech Adoption Climbs Among Older Adults, Pew Research Center, Washington, DC, 2017.
[13] D. Bloom, J. Beetsch, M. Harker, et al., The rules of engagement: CTTI recommendations for successful collaborations between sponsors and patient groups around clinical trials, Ther Innov Regul Sci 52 (2018) 206–213, https://doi.org/10.1177/2168479017720247 2018/05/02.
[14] L.P. Forsythe, L.E. Ellis, L. Edmundson, et al., Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned, J. Gen. Intern. Med. 31 (2016) 13–21, https://doi.org/10.1007/s11606-015-3450-z.
[15] L.P. Forsythe, V. Szydlowski, M.H. Murad, et al., A systematic review of approaches for engaging patients for research on rare diseases, J. Gen. Intern. Med. 29 (Suppl 3) (2014) S788–S800, https://doi.org/10.1007/s11606-014-2895-9.
[16] B. Levitan, K. Getz, E.L. Eisenstein, et al., Assessing the financial value of patient engagement: a quantitative approach from CTTI's patient groups and clinical trials project, Therapeutic Innovation & Regulatory Science 52 (2017) 220–229.
[17] S.K. Smith, W. Selig, M. Harker, et al., Patient engagement practices in clinical research among patient groups, industry, and academia in the United States: a survey, PLoS One 10 (2015) e0140232, , https://doi.org/10.1371/journal.pone.0140232.
[18] US Food & Drug Administration. *Plan For Issuance Of Patient-Focused Drug Development Guidance: under 21st Century Cures Act Title III* Section 3002. 2017. Silver Spring, Maryland: US FDA.
[19] US Food & Drug Administration, Center for Devices and Radiological Health's 2018-2020 Strategic Priorities, US FDA, Silver Spring, Maryland, 2018.
[20] Clinical Trials Transformation Initiative. Mobile Clinical Trials (MCT), https://www.ctti-clinicaltrials.org/projects/mobile-devices , Accessed date: 17 July 2017.
[21] Vanderbilt University, ResearchMatch, (2018) www.researchmatch.org.
[22] Qualtrics, Qualtrics: Research Core, (07/2017), p. USA2018 Provo, Utah.
[23] D.Z. Meyer, L.M. Avery, Excel as a qualitative data analysis tool, Field Methods 21 (2009) 91–112.
[24] J.B. Averill, Matrix analysis as a complementary analytic strategy in qualitative inquiry, Qual. Health Res. 12 (2002) 855–866, https://doi.org/10.1177/104973230201200611.