The Use of Smartphones for Health Research

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Abstract

Because of their growing popularity and functionality, smartphones are increasingly valuable potential tools for health and medical research. Using ResearchKit, Apple's open-source platform to build applications ("apps") for smartphone research, collaborators have developed apps for researching asthma, breast cancer, cardiovascular disease, type 2 diabetes, and Parkinson disease. These research apps enhance widespread participation by removing geographical barriers to participation, provide novel ways to motivate healthy behaviors, facilitate high-frequency assessments, and enable more objective data collection. Although the studies have great potential, they also have notable limitations. These include selection bias, identity uncertainty, design limitations, retention, and privacy. As smartphone technology becomes increasingly available, researchers must recognize these factors to ensure that medical research is conducted appropriately. Despite these limitations, the future of smartphones in health research is bright. Their convenience grants unprecedented geographic freedom to researchers and participants alike and transforms the way clinical research can be conducted.

Over half a billion individuals globally[1] have downloaded at least 1 of the more than 100,000 available mobile health applications ("apps").[2] With their growing adoption and increasing functionality, smartphones can enhance health[3] and medical research.[4] However, the use of smartphone apps as a tool to conduct research is still in its infancy.

The March 2015 release of ResearchKit, Apple's open-source platform to build smartphone apps for medical research, may catalyze faster adoption of smartphones for research. Several forces led to the development of ResearchKit, including rapid adoption of smartphones,[5] the increased functionality of the embedded sensors, growing interest in health applications,[6] the development of Apple's HealthKit to serve as a repository for health data,[7] the recognition that novel technologies can address barriers to conducting effective research,[8] and the growing realization that apps can help improve health.[3] Initially, research apps for five chronic conditions (asthma, breast cancer, cardiovascular disease, type 2 diabetes, and Parkinson disease) were developed by academic collaborators using ResearchKit from August 2014 to March 2015 and released in March 2015 (Table 1); many more are expected. Each app is part of a research study that was reviewed and approved by the institutional review boards at each of the organizations leading the development of an app (see Table 1). Western Institutional Review Board reviewed and approved the smartphone research studies at Sage Bionetworks. In this piece, we summarize important advantages and limitations of using smartphone apps to conduct health research.

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Appreciating the Advantages

First, the apps remove geographic barriers to research participation. While participants must have an iPhone, individuals from anywhere in the United States who meet entry criteria may download the apps free of charge, complete the informed consent process within the app, and participate in the studies. This is a boon for those who live in remote areas or who are otherwise limited by disease or travel burdens. Participants do not need to live near or visit a research site to participate and may contact a researcher with any questions. Seven months after the apps' launch, over 70,000 individuals from nearly all 50 states and the District of Columbia had enrolled in these studies.

Second, the capacity to gather data through a smartphone provides a powerful platform for studying ways to motivate healthy behaviors. Real-time daily interaction with participants on decisions about diet, medications, and physical activity may permit greater insight into their health and create greater incentives for individuals to improve their health behaviors. For example, the asthma app provides regular reminders to participants about the importance of their maintenance medications, the diabetes app provides diet recommendations that are tied to an individual's blood glucose levels, and the cardiovascular app gives personalized feedback on how participants are meeting the American Heart Association's "Life's Simple 7" factors to improve heart health.

Third, unlike traditional clinical research studies, the frequency of assessments is high. All five apps enable continuous assessments via passive monitoring, daily assessments via brief surveys, or prompted tasks (e.g., walk 20 steps). The passive monitoring, in particular, enables valuable collection of "real-world" data (e.g., activity level, environmental exposure) that is not accessible in a traditional clinic visit and does so with little, if any, burden on participants. The resulting sheer volume of research data gathered in these studies will likely dwarf all but the largest previous research initiatives for these conditions. For example, individual participants in the Parkinson disease research study now have contributed over 500,000 data points, which will require novel machine learning techniques to analyze.

Table 1

Smartphone Medical Research Apps Released by Apple on March 9, 2015

Condition	Name of the app (lead organization)	Eligible participants	No. of participants enrolled as of October 5, 2015	Research objectives	Functionality of the app
Asthma	Asthma Health (Icahn School of Medicine at Mount Sinai)	Individuals over 18 with asthma confirmed by a doctor, currently taking medicines for asthma, not pregnant, who reside in the United States and understand English	7,770	• To assess the association between app use and asthma control, quality of life, and health care utilization scores • To develop and validate the medical accuracy of an algorithm for personalized trigger avoidance	• Surveys • Structured tasks, including electronic diary of symptoms and triggers • Passive monitoring of activity and local air quality • Daily maintenance medication reminders • Educational information
Breast cancer	Share the Journey (Sage Bionetworks)	Women between 18 and 80 years with a history of breast cancer or without a history of any cancer, who reside in the United States and understand English	2,508	• To monitor common symptoms during recovery from breast cancer treatment • To understand the variation of these symptoms, their sources, and their potential modulators • To assess feasibility of using mobile technology to engage participants in research without study visits	• Surveys to assess cognitive changes, changes in mood, fatigue, sleep patterns, and exercise • Randomization to daily expressive diary and exercise motivation • Passive monitoring of movement, exercise, and typing patterns • Educational information
Cardiovascular disease	MyHeart Counts (Stanford University School of Medicine)	Individuals over 18 with and without cardiovascular disease who reside in the United States, United Kingdom, or Hong Kong, and understand English	44,841	• To compare measured physical activity, fitness, and cardiovascular health in a broad population • To follow factors most predictive of maintaining or improving cardiovascular health • To study motivational tools to improve physical activity and promote cardiovascular health	• Surveys • Passive monitoring of physical activity through phone or wearables • Structured tasks, including assessments of fitness and guideline-based cardiovascular risk scores
Diabetes	GlucoSuccess (Massachusetts General Hospital)	Individuals over 18 with prediabetes or type 2 diabetes who reside in the United States and understand English	5,595	• To understand how health behaviors (e.g., diet, exercise, medication adherence) influence glucose control at the individual and population level	• Surveys on sleep, diabetes care, quality of life • Blood glucose tracking (from device or manual entry) • Food logging • Passive monitoring of physical activity through phone or wearables • Insights relating users' blood glucose levels with health behaviors
Parkinson disease	mPower (Sage Bionetworks)	Individuals over 18 with and without Parkinson disease who reside in the United States and understand English	15,340	• To characterize the variation of symptoms over time • To identify potential modulators (e.g., exercise, medication) of those symptoms • To provide real-time feedback to participants	• Surveys • Structured tasks, including assessments of voice, motor speed, memory, gait, and posture • Passive monitoring of activity and mobility

Fourth, many assessments conducted are objective. Most studies include objective assessments of an individual's condition, symptoms, performance, or environment (e.g., gait, location). These objective assessments can help quantify the variability and progression of disease and eventually assist in determining the efficacy of novel interventions.[9] These assessments can be especially valuable for conditions, like Parkinson disease, that have external manifestations that are currently evaluated by subjective scales[10] and now can be assessed with smartphone sensors.[11] Similarly, the cardiovascular app includes a six-minute walk test, which is a powerful predictor of longevity. The asthma app uses the global positioning system to capture location-specific environmental exposures (e.g., weather and pollution information) and allows users to avoid potential triggers and researchers to correlate environmental factors with asthma symptoms.

Fifth, and perhaps most important, the studies engage participants in a new model of research. Unlike traditional research studies, participants receive real-time feedback on their individual results. Using these data, participants can track their results and evaluate the potential benefits of different behaviors or interventions (e.g., diet, medications) and readily communicate observations to researchers and clinicians. Thus, these studies could create a more informed participant populace, leading to more favorable health outcomes. Individuals also have flexibility to decide when and where to complete study activities. In addition, participants control who has access to their data and can decide which sets of researchers (e.g., the studies' investigators or the broader research community) can access their research data.

Considering the Limitations

Although the promise is great for studies conducted with these apps, they do have important limitations, including selection bias, identity uncertainty, design limitations, retention, and privacy. Initially, these research studies are limited to adult participants who have a recent iPhone, reside in the United States, and read and understand English. Whereas 64% of Americans have a smartphone,[5] only about half of smartphone owners have an iPhone, and those who do own iPhones are more likely to be highly educated and wealthier than other smartphone users, who as a group are themselves more highly educated and wealthier than the general population.[5] Although these limitations must be considered in generalizing future study results, traditional clinical studies frequently also suffer from selection bias.[12,13] The open-source framework will likely speed the availability of similarly featured apps on other smartphone platforms, and ongoing efforts are aimed at including participants from many other countries.

Because data gathering is phone based, the identity of the person actually completing the activities may be uncertain. To mitigate this risk, the apps require individuals to confirm participation by e-mail and to provide a passcode to access the application. However, friends or family members could theoretically use the apps, although the incentives to do so in a sustained manner are unclear.

The design of the current studies is also limited, as participants self-report many symptoms and are not blinded. Like other efforts seeking to accelerate medical research,[14] these studies rely heavily on participants for data. Although many of the scales have been designed and validated for self-report, some data (e.g., food logs) may differ from traditional measures. In addition, the assessments are not blinded, so evaluations of the effects of exercise, for example, may be open to bias. Importantly, initial efforts are under way to enable randomizing participants to different types of phone-based (e.g., behavioral) interventions. Just as other studies using Internet-based technologies have successfully used blinding and randomization,[15,16] smartphone research apps of the future will likely do the same.

The long-term use of these research apps by participants remains to be determined. Many smartphone apps have enjoyed robust initial interest that rapidly fades.[17] Similarly, interest in these initial studies, as measured by daily use, has waned substantially over time (see Figure 1). Although there was a decline, retention rates in these studies are better than those observed in other apps.[18] Feedback to participants may improve app engagement, but greater functionality and value will be required in the future to maintain engagement. Some of that functionality will come from new tools (e.g., wearables) for monitoring physiological parameters and connections to broader data sources, including detailed environmental data, which can be used to identify asthma triggers, for example.

Finally, the privacy of participants' health data is a major consideration. The apps handle participant and data privacy according to established principles of human research and the Health Insurance Portability and Accountability Act. As indicated in the ResearchKit announcement,[19] Apple does not collect data from these apps. Personal health information is separated from study data at enrollment, so anonymized data can reside in secure research databases hosted at Sage Bionetworks. Although

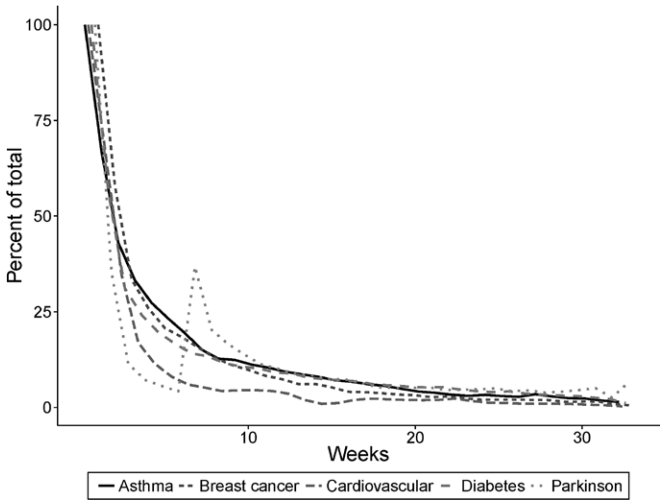

Figure 1 Proportion of daily users in the first five smartphone research apps developed using ResearchKit, March 9 to October 5, 2015.

the research databases are anonymized, this process, as the consents indicate, cannot be 100% immune from dedicated efforts by individuals trying to recreate an individual's identity. The ability to protect an individual's data will be critical to the success of these and similar efforts.

Looking to the Future

Despite the limitations, the future of smartphone apps in health research is bright. These apps could empower individuals affected by, or at risk for, these conditions and provide unprecedented geographic freedom to participate in research. Studies using smartphone apps also offer the potential to characterize the natural history of chronic conditions in novel and insightful ways. ResearchKit also provides a reusable framework for consent, enrollment, and data collection that can reach large audiences in other disease communities, as demonstrated by the 10 additional study apps that have been launched with a focus ranging from lesbian, gay, bisexual, and transgender health to mole tracking to autism. Finally, these initial apps provide a platform for future efforts with enhanced functionality and additional sensors (e.g., biometrics) that could yield new public health and biomedical knowledge, deliver individuals real-time insights related to their health, and, eventually, facilitate improved care and health. Health improvements will likely come from changes in behavior, improved data on which to base clinical decisions, and, eventually, greater access to care—likely through the same device that individuals are using to advance research.

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