

Realities of conducting digital health research: Challenges to consider

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Abstract

The health sector has been slow to adopt and integrate new technological advances into antiquated workflows and processes. The onset of smart health applications and devices has initiated a push for healthcare systems as well as physicians to incorporate and utilize such technology and the big data it collects. However, without considering the challenges experienced in large-scale trials, physicians and their clinics will run into similar barriers to implementation and uptake. Thoughtful implementation and preparation will make the use of such technological advances possible, palatable and effective in improving clinical care.

Keywords

Digital health, health technology, clinical research, wearable, personalized health

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Introduction

For decades, the prevalence of cardio-metabolic risk factors such as obesity, diabetes and hypertension in the United States has been on the rise. Since 2008, a reported 29 million Americans have been diagnosed with Type 2 diabetes, while obesity and hypertension irrespectively burden over 32% of the US population.^{1,2,3} Treatment of cardio-metabolic risk factors costs the US over 500 billion dollars per annum.^{1,4,5} Thus, prevention has become and remains a top priority in the healthcare community. Among the many risk factors for cardio-metabolic disease, inadequate physical activity is of a particularly important standing. While increasing physical activity has proven successful in decreasing the deleterious effects of chronic disease conditions, keeping participants enrolled and engaged in behavior and lifestyle modifications remains a challenge. Patients are primarily responsible for targeting deleterious behaviors and sustaining the lifestyle changes necessary to decrease their cardio-metabolic risk factors. Physicians, while helpful, are left with little time to discuss or review these changes during inevitably short annual visits. There remains a need not only to maintain physical activity in at-risk patients, but also to connect what the patients are

doing outside of the clinic with what the physician is hearing inside the consulting room. A more complete understanding, supplemented by data, to support a patient's ability to sustain lifestyle changes between clinic visits can reduce routine healthcare costs and time for both the patient as well the physician.

Today, wearable tracking devices and smartphone applications (apps) offer a window into patient activities outside of the clinic and have become increasingly popular.⁶ Often, however, these devices are not sufficiently interactive or personalized for the user. Health information may not be checked by their physician or they may not have access to the information in a timely manner. At Partners Connected Health, we recently conducted a study to evaluate the effect of a smartphone application paired with a smart watch on physical activity (measured in steps) in a group of participants recruited from the Greater Boston area. Unlike many applications currently on the market,

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the app being tested was designed to create a hyper-personalized experience for the users and to respond specifically to each individual's behavior patterns. For example, if the app noticed that a participant was more active when listening to a specific type of music, it may suggest listening to this music to the participant on a day when their step count is low. In another instance, if the app receives weather information that it is a sunny and warm day, the app may suggest going for a walk outside to gain more steps. A physician portal allows for doctors to check on their patient's progress in reaching their fitness goals as well as to send encouraging messages to keep the patient motivated. Despite the mobile app's hyper-personalization, we still faced challenges with participant engagement and data collection. These challenges inherent to conducting a large trial with digital health solutions may be mirrored in real-world clinical care settings, and as such are worthy of highlighting.

Tech advances versus study timeline

To be included in the study, participants had to be adults at risk of cardio-metabolic disease, not currently taking medication that would affect their weight, and physically independent. Due to the large number of participants needed, recruitment took place over 29 months. Finally, 275 participants were recruited, randomized and followed for six months. They were given an Android smartphone and smart watch which were procured before the study began. Over the duration of the study, two newer versions of the phone and newer versions of the smart watch were released. Furthermore, the app was affected by software updates as old platforms were retired and new operating software versions were released. Issues pairing the smart watch with the smartphone became more prevalent as the study progressed. This is something that patients can also experience in everyday settings when using older devices and phone versions. Connectivity issues can lead to the inability to properly sync the smart watch to the mobile device and thus an inaccuracy of parameters being tracked. These issues can cause users to become disengaged or demotivated by the inaccuracy of their activity tracker. Additionally, less accurate information could lead physicians to see this information as unreliable and unusable.

In order to mitigate tech advances and study timeline issues, it is important to start small and implement in phases. This strategy allows for troubleshooting and implementation adjustments to be made concurrently. Additionally, it avoids challenges such as incompatible platforms, outdated devices and software updates which occur with a long study or implementation timeline. Finally, analyzing and receiving feedback from

physicians and patients early on and making necessary changes reduces the potential for retention, adoption and engagement issues.⁷

Designing for a single platform

The application we were testing was designed for Android phones. As such, we asked all participants to switch from their current cellphone to the study-provided Android phone. This phone was to be used as the participant's primary phone throughout the study duration. As we began to recruit participants, study staff encountered issues surrounding brand loyalty. Though statistically there are more Android users across the world, we found that in our study population, many potential participants were iOS users.⁸ We found that some otherwise eligible recruits who were iOS users would hesitate to switch to an Android phone, hindering our recruitment rate. Additionally, for those participants willing to switch to an Android phone, there was a learning curve associated with using the new Android platform. In some cases, the frustrations related to learning how to use a new phone affected retention, engagement and accuracy of data collection. Thus, knowing your audience and choosing devices and platforms that are adaptable to both Android and iOS can reduce the potential for platform and brand loyalty issues. This allows for widespread implementation, utilization and ultimately better integration into workflows. Furthermore, making technology choices to best support the needs of both the physician and patient will reduce push-back and drop off in use.

Lost or stolen device

Any study using portable devices is susceptible to loss or theft of hardware. Often, there is a lag time between the device and/or devices being reported lost or stolen and the time it takes to equip the participant with a replacement device. Without the study device, participants can lose interest or momentum in their interaction with the intervention. Additionally, inability to retrieve or transfer data from the lost device leads to gaps in the dataset. The data can thus become unreliable and skewed. Lastly, study staff spend additional resources replacing and setting up new devices for participants. This can increase the costs associated with the study, particularly if participants lose a device more than once.

Keeping these considerations in mind while planning a study or trying to initiate a digital solution with a patient can help to increase engagement, retention, accurate data collection and monitoring and ultimately promote the desired behavior change.

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