Patient Use of Cardiovascular Devices and Apps: Are We Getting Our Money's Worth?

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ABSTRACT: The evolution of technology makes it likely that a large number of people will invest in and use health-related mobile applications and wearable devices. Yet the question remains: Do these technology-based interventions modify health behavior and improve health…and are we getting our money's worth? The vast majority of studies concerning health-related apps and wearable devices have small sample sizes and short time spans of 6 months or less, so it is not clear if these durations were determined by lack of consistent use over time. Furthermore, many of the most popular applications have not been subjected to randomized trials. Overall, the small demonstrated improvements in outcomes are often associated with professional involvement from clinicians, coaches, or diabetes educators provided in conjunction with use of mobile health (mHealth) platforms. This paper explores the use of mHealth technologies that address cardiovascular disease/prevention (eg, diabetes, diet, physical activity, and associated weight loss) and discusses the lack of adequate evidence to support even minimal patient investment in mobile applications or wearable devices at this time.

INTRODUCTION

Advances in digital health technologies such as mobile phone apps and wireless devices have generated considerable public health and behavior research as a potential strategy to improve self-management of chronic disease. Numerous smartphone applications have been developed and sold to promote medicine adherence, record and display health factors and trends (such as blood pressure, blood glucose, insulin, and weight), and track diet and fitness. Wearable devices can monitor a dizzying number of parameters, such as heart rate, stress, physical activity, sleep, and levels of social interaction. Apps and wearable devices can provide instant personalized and goal-oriented reminders and recommendations, and many mobile health (mHealth) platforms are also able to monitor advanced cardiovascular data. Wearable platforms use a variety of strategies to engage consumers, such as competitive gamification and positive reinforcement through virtual "rewards." The evolution of these technologies makes it likely that most individuals in the United States will have access to mHealth platforms, but this begs the question: Do these technology-based interventions modify health behavior and improve health, and are they worth it? This paper discusses several health-related apps and studies the evidence base for mHealth technologies that address cardiovascular disease and prevention related to diabetes, diet, physical activity, and weight loss.

DIABETES SELF-MANAGEMENT

According to a recent systematic review, there are 3,369 Android and 1,799 iOS apps for supporting diabetes self-management.[1] A study of 719 clinicians found that more than 62% endorse incorporating mobile apps into disease management.[2] Clinicians recognized apps as an effective alternative to pen and paper to help patients with diet tracking (62%), recording physical activity (58%), losing weight (45%), monitoring blood glucose (43%), and making healthier food choices (34%).[2] Clinicians reported recommending apps such as MyFitnessPal, CalorieKing, and Fitbit wearables to patients.[2]

However, clinician recommendations and patient use have proceeded without a solid evidence base. Recognizing the lack of scientific evidence to help patients and clinicians identify quality evidence-based apps, Veazie and colleagues examined the evidence for several popular diabetes self-management mobile apps.[3] Out of 11 total studies, only one had a duration longer than 6 months. Only two (one each for type 1 and type 2 diabetes) demonstrated moderate quality and reported a statistical difference in HbA1c. Two other studies for type 1 and type 2 diabetes reported a significant difference in HbA1c but demonstrated low quality. Only two of the eight apps available for evaluation and testing had "acceptable" usability. Importantly, additional support from a health care provider (HCP) or research staff may have been partially responsible for even the minimal improvements. No study reported improvements in participant quality of life measures, weight, blood pressure, disease management, or treatment satisfaction.[3]

A systematic review of randomized controlled trials (RCTs) including 1,550 participants from 21 studies concurred with these findings.[4] Only four studies were longer than 6 months. Again, caregiver involvement was important: Studies without

HCP feedback reported a mean reduction in HbA1c of 0.24%, whereas HbA1c decreased by 1.12% in studies with high HCP feedback.[4]

A 2020 meta-analysis enrolling 2,129 patients with type 2 diabetes found that only two of nine studies were 12 months in duration, and both reported among the lowest weight change.[5] Overall, the meta-analysis detected that incorporating mobile applications yielded some evidence for weight loss (weight mean difference, -0.84 kg; 95% CI, -1.51 to -0.17 kg) and decreased waist circumference (-1.35 cm; 95% CI, -2.16 to -0.55 cm), with less indication of decreased body mass index (-0.08 kg/m^2; 95% CI, -0.41 to 0.25 kg/m^2).[5] Again, the reductions were more pronounced in studies combining mobile app interventions in conjunction with behavior components such as coaching.

Popular Apps for Diabetes Management

MySugr is a popular app for tracking blood glucose. For a $2.99 monthly fee, the app can track a variety of parameters and synchronize to Apple health, enabling fitness and sleep tracking. Beginning in 2017, a mySugr bundle was available for $49 a month, which includes an Accu-Chek® Guide Me blood sugar meter, testing strips, and access to personalized advice from a certified diabetes educator. Debong and colleagues evaluated five retrospective studies assessing the mySugr app between 2015 and 2016 and noted that none evaluated the app for longer than 6 months. Furthermore, all involved only "highly engaged patients" who used the app 5 days per week for the study duration. In one of the retrospective reports, the mean blood glucose decreased significantly at 2 to 4 weeks and did not change further at 6 months.[6] Although the studies implied that use of the mySugr app can positively impact glucose control and that this may be more pronounced in those with poorly controlled diabetes, the findings are limited by their retrospective observational design and are not generalizable.

In a study of another popular app called Glucose Buddy, use of the app combined with weekly text messages from a certified diabetes educator led to a significant decrease in HbA1c over a 9-month RCT compared to a control group receiving only usual care.[7] Importantly, the app did not replace diabetes counseling; it was evaluated as a supplemental support, not a stand-alone intervention.

DIET TRACKING

Other applications and wearables focus on lifestyle changes such as diet and exercise. Using apps to make healthier food choices is an often-stated objective, yet few studies have examined whether education and behavior change strategies (such as goal setting and self-monitoring) translate to healthier choices or long-term improved outcomes. One large meta-analysis included 41 studies (27 RCTs) of 30 apps, with 34 studies assessing at least a single nutrition-related health outcome. Researchers separated and analyzed behavioral outcomes by calorie consumption and fruit and vegetable intake, analyzing effect sizes, but unfortunately did not give values of those parameters. For example, the apps helped reduced obesity ($P < .001$) in studies lasting up to 6 months but showed no significant difference in studies lasting longer than 6 months. For blood pressure, blood lipids, and cholesterol, the differences were statistically different but less so, again with no significant effect in studies longer than 6 months. There was no significant effect on blood sugar.[8]

Prevalence and use of mHealth applications is growing exponentially, but the question of whether these applications are superior to traditional methods remains. A fundamental component of behavioral weight-loss programs is self-monitoring one's diet by systematically tracking daily food and beverage consumption.[9] Mobile diet trackers test well on usability, support behavior change principles, and demonstrate accurate calorie and carbohydrate coding.[10]

One potentially important finding was from a meta-analysis of 13 studies comparing weight loss between participants assigned to a standard web-based health intervention versus a web-based intervention with additional mobile features (eg, texts and mobile apps). Researchers found the additional mobile components generated a mean difference of 1.46 kg greater weight loss.[11]

Importantly, even with mobile features to make diet tracking more expedient and convenient (such as integrated bar code scanners, frequently used food quick entry and even photo-recording options), adherence to diet-tracking is problematic. A secondary analysis of two separate 6-month randomized trials found that more than half of the sample abandoned tracking by the tenth week.[12]

Popular Apps for Diet Tracking

One of the highest-rated free apps for calorie monitoring is MyFitnessPal, which has a database of 3 million food items. However, an RCT that evaluated the app for 6 months concluded that participants experienced almost no weight reduction.[13] Furthermore, the participant app logins sharply decreased to almost zero logins after only 1 month.[13]

Another popular app for physical fitness and weight loss, Lose-It!, was tested in a 6-month trial with four arms: app-based monitoring alone, intensive diet/behavior counseling alone, app-based monitoring combined with intensive counseling, and less frequent counseling with app-based monitoring.[14] The

intervention group that had intensive counseling with app-based monitoring had the highest adherence, tracking diet and physical activity 53% and 34% of the time, respectively.[14] Participants in both app-based self-monitoring arms (with any level of counseling) tended to lose more weight than other groups. The counseling was an important component; participants in the no counseling app-based self-monitoring group lost the least weight, although no group differences were clinically significant.[14]

Mobile apps make recording food details more convenient and use tools such as personalized messaging or push notifications to motivate consumers, but they continue to have gradual disengagement and poor adherence.[11,15,16] Studies consistently report that use of apps may be associated with some weight loss up to 6 months, but few studies lasted longer than 6 months. Among the limited longer studies, the data do not show a significant change in weight control.

ACTIVITY TRACKERS

Currently, consumers can access hundreds of smartphone and wearable fitness-tracking apps to capture physical activity metrics and trends. Step counts are common and straightforward measures since the goal of 10,000 steps/day is a widely applied benchmark. Although research has validated the ability of wearables to provide accurate step counts,[17] steps alone do not sufficiently meet the physical activity and intensity guidelines established by the US Department of Health and Human Services and promoted by the American College of Cardiology and the American Heart Association.[18,19] Not all steps are created equal: the recommended 150 min/week of moderate-intensity aerobic activity (or 75 min/week of vigorous exercise) requires brisk walking, at a minimum, with "extra credit" for more vigorous exercise (eg, running or cycling). Unfortunately, a scoping review of consumer physical activity apps only identified one out of 379 apps that incorporated the recommended 150 min/week aerobic physical activity guideline.[20] In this context, it is important to note that most of the available studies on physical activity wearables/apps use step count as a primary outcome. A recent meta-analysis of mobile apps and wearable devices including 18 RCTs found that using wearables and smartphone applications yielded a 34% increase in daily step count, from 4,050 to 5,463 ($P <$ .01).[21] Another meta-analysis in populations diagnosed with cardiometabolic chronic disease found statistically significant increases in objective measures of both steps per day (2,592) across 19 RCTs and increased moderate vigorous physical activity minutes per week (36.31 min/wk; 95% CI, 18.33-54.29) across 11 studies.[22] Importantly, most of the studies included in this analysis had durations between 1 to 4 months, therefore long-term adherence is still unstudied.[22] Many wearables do feature heart rate sensor technology, but devices come up short in assessing physical activity intensity with precision and consistency.[23,24]

Finally, a small body of evidence suggests that using wearable devices as part of a fitness plan (which may include coaching or health education components) may generate some positive changes in weight control. A meta-analysis of 19 RCTS detected a moderate and significant effect size on body weight across all studies and waist circumference across four studies, and it found a large and significant effect on body mass index across 12 studies. The researchers also discovered that using wearable devices for 12 weeks or longer was more effective than shorter durations.[25] However, loss to follow-up rates varied across studies, making it difficult to draw conclusions about effects among all participants because studies only report data from participants who were consistently engaged throughout the intervention.

Popular Apps for Activity Tracking

A research team evaluated seven of the most popular wrist-worn devices including Apple Watch, Basis Peak, Fitbit Surge, Microsoft Band, MIO Alpha 2, PulseOn, and Samsung Gear S2. Each of these devices offers consumers continuous measurement of heart rate (HR) and 24-hour battery life. Sixty healthy participants tested the devices through a standardized exercise protocol.[24] Most wrist-worn monitoring devices measure heart rate accurately (below a 5% threshold for the cycling activity among six devices and below the 10% margin for the walking task for all devices). The Apple Watch performed the best overall, and the Samsung Gear S2 had the least favorable error profile.[24] Current Apple Watch (Series 5) devices start at $399. While heart rate measurements are sufficiently accurate, energy expenditure is a more important and telling measure. No devices reported energy expenditures within an acceptable error range, far surpassing a 10% margin of error for both cycling and walking activities.[24]

SUSTAINABLE CHANGE ASSOCIATED WITH THE USE OF APPS

As shown here, very few studies collected data for longer than 6 months, and almost none had durations longer than 12 months. One study of 471 participants with a 24-month follow-up examined the benefit of incorporating a wristband into a typical weight loss intervention after 6 months.[26] Participants in the wristband group only wore the wristband a median of 31% of the time, with nearly one in five participants never wearing the wristband at all. Weight change at 24 months differed significantly, with a 3.5 kg loss in the wristband group and 5.9 kg in the control group ($P = .002$). The wristband group lost less weight.[26] The authors concluded, "Devices that monitor

and provide feedback on physical activity may not offer an advantage over standard behavioral weight loss approaches."

CONCLUSION

Currently, anyone can develop and sell a mobile health app or wearable device. The consumer market is flooded with this technology, yet evidence for even the most popular devices and apps is extremely limited. Even among RCTs, the gold standard for research design, sample sizes are very small. Most evidence on diabetes self-management, diet trackers, and activity wearables suggests very modest short-term improvements in health outcomes. Involvement from a health care provider, counselor, coach, or diabetes educator appears to be a critical contributor to any change; patients using stand-alone mobile apps or wearable devices without additional guidance achieved less change.

Significant aspects of existing scholarship on mHealth technology are key for context and perspective on this technology. Even in the studies that extended to 6 months, the small improvements were decreasing. One study of 24 months reported a statistically significant change, with less improvement using the wearable device. It is not clear if these consistently short durations were designed with the knowledge that most participants will not use an app longer than 6 months.

Although the use of mHealth technology to reduce cardiovascular disease risk is promising, it has been difficult to integrate into routine clinical care and population health management. The wide availability of diverse technologies and lack of a comprehensive framework are key barriers for standardizing data collection and integration.[27] Important questions remain about the accuracy of data; therefore, incorporating data trends into clinical practice is still not advisable. Undeniably, the contribution of mHealth technology will continue to evolve to provide important value for patients with cardiovascular disease. However, based on this review, the response to the posed research question of "Are we getting our money's worth?" is no. Given nearly imperceptible effectiveness, almost any cost would be too much.

While this review evaluates the current state of the literature, this field is still relatively new. We expect that larger-scale RCTs with follow-ups of 1 year or longer will provide a better understanding of strategies that can leverage these emerging technologies to support chronic disease self-management and improve health.

Conflict of Interest Disclosure:
The authors have completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

KEY POINTS

- Mobile patient applications and wearable devices are wildly popular tools that claim to support health objectives, but scientific evidence is lacking to ascertain if these technologies improve self-management of chronic disease.
- Most evidence on diabetes self-management, diet trackers, and activity wearables suggests very modest short-term improvements in health outcomes; most of the small gains are achieved when health care personnel (eg, coaches or nurses) are also involved.
- The vast majority of the studies are less than 6 months. It is not clear whether this is because patients declined to use applications for a longer term.
- While this review evaluates the current state of literature about mobile health technologies, this field is still relatively new. We expect that larger-scale randomized studies with follow-ups of 1 year or longer will provide a better understanding of strategies to leverage these emerging technologies to support chronic disease self-management and improve health.
- The research question posed was "Are we getting our money's worth?" and the answer is no, we are not. Given the nearly rock-bottom effectiveness, almost any cost would be too much.

Keywords:
mobile health, wearable devices, mobile applications, fitness trackers, cardiovascular disease, diabetes self-management

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