Effectiveness of Digital Tools

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Introduction to digital health tools

The concept of digital health tools has been rapidly evolving since its first introduction in the year 2000[1]. Digital health tools encompasses a wide range of technologies including mobile applications, health information technology, smart wearable devices, remote monitoring, health platforms, telehealth and telemedicine[1]. Recent data showed that the number of these tools are continuously increasing. The number of health applications available in the App Store currently exceed 318,000 applications and more than 200 new applications are added on a daily basis[2].

This booming trend resulted from the World Health Organization (WHO) resolution issued in 2005 which urged countries to prioritize the development of an action plan for implementing and expanding eHealth services to promote equitable, affordable, and universal access to healthcare services[3]. This resolution recognized the potential of health technologies to improve population health outcomes by advancing medical services and allowing the exchange and sharing of health information[3]. The United Nations 2030 Sustainable Development Goal (SDG) Agenda has also highlighted the potential of health technologies to accelerate progress towards achieving health-related SDGs[3]. With this recognition, there has been a growing global consensus in the health community that the use of digital health tools will contribute to ensuring that 1 billion more people will benefit from universal health coverage, will be better protected from health emergencies, and will have enhanced health and well-being[3].

Digital health tools have been used in a wide variety of healthcare services including promoting healthy behaviors (for example: smoking cessation, healthy eating, and physical activity), improving health outcomes in people with chronic conditions such as cardiovascular disease, diabetes, and mental health conditions, and providing remote access to treatments (for example: computerized cognitive behavioral therapy for mental health and somatic problems)[4, 5]. These technologies can aid in disease prevention, early diagnosis, and management of chronic conditions[6]. In addition to giving healthcare providers a more holistic view of patient health through access to relevant data, digital health tools also provide an opportunity for patients to have more control over their health enabling them to make better informed decisions[6]. The use of digital health technologies aims to enhance efficiency, improve access and quality of health services while reducing associated cost, and ensure healthcare services are more personalized for patients[6]. The recent COVID-19 pandemic has accentuated the necessity of digital health tools; where lockdowns and public health measures have prompted health care professionals to adopt different remote strategies and eHealth tools to provide healthcare services to their patients[7].

Digital health tools in cardiovascular health

Similar to other healthcare services, the use of digital health solutions is promising for improving cardiovascular health outcomes in patients[8]. Cardiovascular diseases (CVD), covering a wide range of health conditions, including ischemic heart disease, cerebrovascular disease, hypertensive heart disease, peripheral vascular disease, rheumatic heart disease, cardiomyopathies and arrhythmias, are the leading cause of death globally[9-11]. According to the Global Burden of Disease Report, the burden of CVD continues to increase globally. In 2019, it was estimated that there are over 523 million CVD cases and 18.6 million deaths recorded globally due to CVD[12].

Besides addressing the biological risk factors, proper CVD management and prevention is based on addressing modifiable behavioral risk factors by promoting healthy lifestyle[13, 14] and adhering to prescribed medications[12]. However, delivering comprehensive risk factor management to diverse populations have proven to be challenging due to practical, logistical, financial and geographical obstacles[9]. Applications of digital health tools in CVD health can help healthcare professionals reach a wider group of people in more efficient and effective ways[9]. These tools have many potential applications in CVD health. For example, digital health applications that target behavioral changes such as smoking cessation, increasing physical activity, promoting healthy diets, and enhancing adherence to medications are used to improve CVD health outcomes[8, 9]. Moreover, smartwatches can provide continuous rhythm monitoring and help in the diagnosis of arrhythmias. Inflatable blood pressure cuffs that are connected to phone applications are another example of monitoring applications in CVD health. Mobile applications can also improve the health literacy of CVD patients and can monitor and manage their health conditions through record keeping and automatic reminders. In addition, recent innovations in Artificial Intelligence and machine learning can allow the development of new medicines and more accurate prediction of CVD outcomes[9, 15, 16].

Effectiveness of digital Health tools in improving cardiovascular health outcomes

Despite the fast proliferation of digital health tools and the increased interest in health applications among patients, there has been limited evidence on their effectiveness in improving targeted health outcomes[17, 18]. Thus, careful and systematic monitoring and evaluation of these tools are essential. In general, evaluating the effectiveness of digital health tools has been hindered by the rapid change in digital product development, which mandates these tools to be constantly evolving to keep up with the changing trends[19]. As such, efficacy trials that extend for a prolonged period of time may become obsolete in supporting current decisions about these tools. In addition, reviews also found that many mobile health applications are developed with limited consideration to theoretical frameworks to guide behavioral changes[20]. The absence of data on the effectiveness of health applications in improving health outcome are also a result of lack of standards for collecting data across health applications and the absence of healthcare regulation for these applications[21]. In its 2020–2025 global strategy on digital health, the WHO highlighted the importance of developing metrics for the monitoring and evaluation of the effectiveness of digital health strategies and tools[3]. Recently, governments and donors have added more stringent guidelines on digital health innovations, calling for better evaluation of quality and effectiveness of these interventions[22].

Concerning digital health technologies targeting cardiovascular health outcomes, although there have been some studies evaluating their effectiveness[23-28], the evidence of effect is still at an early stage[29]. There is a lack of robust scientific evidence to date to support the use of these digital health tools in cardiovascular health. In fact, few of these tools have been

designed or evaluated in a clinical setting[29]. A recent review found that most studies in the literature have evaluated the effectiveness of three main types of modalities used in digital interventions aiming to improve cardiovascular health outcomes including text-messaging programs, smartphone applications and wearable devices[9]. Text-messaging programs are the most studied type of digital health interventions and the majority of published Randomized Controlled Trials (RCTs) have demonstrated the effectiveness of using these programs to enhance medication adherence in patients with cardiovascular diseases. However, the quality of evidence of these RCTs was low due to small sample size[9].

Compared to text-messaging programs, the use of mobile applications in improving health outcomes are more sophisticated, as they are computer-like programs with multiple functionalities[9]. Many of the health applications available to the public have not been designed with input from professionals and are often developed without guidance from evidence-based standards[9]. In fact, a recent review showed that only 15% of these applications are associated with medical organizations or societies[30]. Even those applications designed with support from health organizations, evidence on their effectiveness is still limited. CarePlans, a tool designed by the American Heart Association (AHA) to improve health outcomes among patients with atrial fibrillation, coronary artery disease, heart failure, stroke, high blood pressure, high cholesterol and diabetes, is one example of these applications[31]. The American Heart Association Center for Health Technology & Innovation has been developing digital care plans designed for mobile applications in the management of cardiovascular disease. These care plans have evolved into a digital coaching platform that emphasize the need for using best practices in health coaching, health literacy, motivational interviewing, creating a personalized approach, that address the mental health of the patient. [31]. Some patients may feel motivated enough to make behavioral changes simply due to the education offered or the fact that the application is based on AHA guidelines and scientific statements, while other patients may not feel the same way[31]. Thus, understanding these differences in motivations and priorities is important to design effective tools that instigate effective behavioral changes among targeted populations.

Overall, the literature supporting the use of mobile applications in improving CVD outcomes have been growing but remains limited, with conflicting evidence showing some studies favoring their use but others showing negative results. A review conducted in 2018 evaluating the effectiveness of health applications in cardiovascular disease management and control found that all the reviewed studies had low-quality of evidence, either due to the limited number of RCTs, the small sample sizes, or the short duration of the studies[32]. However, these reviews highlighted some potential benefits in using these applications for improving cardiovascular health[32]. More recent RCTs published after 2017 have demonstrated conflicting results and have not confirmed the benefits associated with the use of health applications in improving cardiovascular health. Similarly, another review by Choi et al. (2020) assessing the effectiveness of mobile applications in improving health outcomes in patients with cardiovascular problems and hypertension also found inconsistent effects[33].

Effectiveness of digital health tools among different population groups

This interest in digital health tools has been substantially increasing, particularly due to its potential to reduce healthcare disparities among racial and ethnic minority groups. However, to address these health disparities, information on the adoption and effectiveness of using these digital health tools among different population groups is needed. Various studies have identified numerous barriers in the adoption and utilization of these tools among vulnerable

population groups, such as racial and ethnic minorities and displaced populations. Some of those barriers include, lack of perceived benefits of digital health tools, complex educational or instructional materials and/or technology content, limited access to computers or other technologies, cognitive and physical disabilities, lack of cultural relevance, and poor computer knowledge and literacy[34].

In addition, the literature has demonstrated that the contextual and cultural factors that influence patients' health can impact the effectiveness of these tools[4]. Cultural differences in how people perceive and use these digital health tools is not well evidenced in the literature[35]. In fact, the existing body of literature provides a predominantly Western viewpoint of the application of these tools, revealing a major limitation[35]. The cultural context is particularly important in cardiovascular health, as most CVD outcomes have both biological and behavioral risk factors. The latter may be influenced by a wide range of social and cultural factors, such as perception of disease risks, interaction with and trust in the healthcare system, social support, etc[36, 37]. For instance, studies that assessed the effectiveness of digital health tools in cardiovascular health among different population groups found that blood pressure (BP) monitoring was more effective in improving BP outcomes in black patients than in white patients[38, 39]. Other studies found that the use of digital tools improved medicine adherence more among white people when compared to other racial groups[40].

Similar to other vulnerable populations, very few studies exist that evaluate the use of these tools in the humanitarian context, although they are increasingly being used among displaced populations and refugees[41]. This may be due to the complex and unpredictable nature of the humanitarian context that discourage their evaluation by researchers[41]. However, digital health tools could improve the health of refugees as they face many challenges in accessing traditional healthcare services due to language and cultural differences, transportation challenges, lack of medical records, fear of deportation, and prejudice[42]. These disparities in healthcare can be reduced with the adoption of digital tools that empower these populations by providing some control over their health[42].

The Health Belief Model (HBM) and Socio-ecological Model comes into play when analyzing the differences between different population groups. The HBM suggests that a person's perception of the level of threat of an illness or a disease, along with the patient's perception regarding the effectiveness of the recommended behavioral change will predict the likelihood of the patient adopting this behavior[43]. The HBM entails 6 perceived constructs including perceived susceptibility, severity, benefits, and barriers, cue to action, and self-efficacy, which impacts a patient's likelihood of adopting the recommended actions. Thus, ultimately a tool will achieve optimal behavioral change when it successfully targets the patient's perceived constructs – which are often driven by unique socio-cultural health beliefs and experiences [43, 44]. The socio-ecological model, which reflects the complex interplay between individual, organizational, community, and societal factors, also provides useful insights to enhance the tools' uptake and effectiveness among different groups of patients[45]. The interpersonal level (i.e, social environment) of the framework highlights the socio-cultural beliefs that create, enable, and reinforce health behaviors and the need for culturally-sensitive interventions that target different groups of patients[45]. A day may come where digital health tools will have to be certified for cultural, linguistics and human factors appropriateness for utilization among different population groups, including vulnerable ones[34]. As such, evaluating the effectiveness of digital health tools across different racial and social groups to inform the design of culturally appropriate tools, is important[38, 46-48]. Research suggested that the effectiveness of these tools should be based on

the degree to which it can lead to behavioral changes and to the extent to which it takes into consideration local needs of the targeted populations[49].

Methods used to evaluate the effectiveness of digital health tools

In order to evaluate the effectiveness of these tools, a wide range of study designs have been used worldwide. The majority of those studies adopted quantitative methods such as pilot studies and RCTs, with only a few studies using qualitative designs[35]. Although, RCTs are recognized as the gold standard for clinical evaluations, their application in evaluating digital health tools have been widely questioned[1, 50]. RCTs often have pre-established protocols and stringent criteria that may sometimes hinder the identification of wider implementation issues in "real-world" applications[35, 50]. The use of RCTs are also considered to be no longer practical due to the fast-paced changes in technology development and iterative upgrading[1]. RCTs often require the innovator to stop innovating, resulting in the reporting of a solution that is several cycles behind. Study designs that allow for innovation to continue will likely result in more relevant findings, but at the expense of a lack of control in the study.

In addition, the evaluation of digital health tools is still mainly driven by technical aspects, with limited focus on the needs and expectations of the end users[3, 51]. Therefore, there is a gap in the literature providing a clear understanding of the users' experiences and challenges in using digital health tools[35]. As discussed above, there are various patient-related barriers that can limit the widespread application of these tools, including the cultural contexts and characteristics of the targeted populations[50, 52]. Therefore, conducting qualitative methods to explore the experiences, needs and preferences of the end-users is important as it can help provide a clear picture of the widespread application of these digital tools and help inform better future tool designs that is both effective and accepted by a wide range of population groups[29].

Digital Tools and the American Heart Association

As the health technology industry becomes more mature there is a continuing need, and current gap in high quality evaluation and research. While the emphasis tends to be on the technology, the systems and solutions are limited by the quality of the content and the ability to demonstrate outcomes. While high quality research is always the goal, there is a need to strike a balance between the high cost and time commitment of randomized clinical trials (RCTs) and the need for innovation. The duration of an RCT creates the problem of reporting results that are several innovation cycles behind. There is a need for innovation in research design of technology solutions so that innovation can proceed even while the endpoints are tracked.

The American Heart Association Center for Health Technology & Innovation's research agenda includes a three-step approach. Step 1 is a focus on implementation and functionality evaluation. This is an initial study of the functionality and effectiveness of the system. Does it work, and it is effective. It will also assess the usability of the system. Do patients use the system, and if so, how long? This is a simple study design, using a convenience sample and comparison to baseline or to a benchmark. The study population includes users of the system, and the focus will be on their behaviors. In addition to the study variable(s), the baseline assessment will look at usability issues, such as terms of use, privacy, ownership, and ease of use. The duration of the study will be 8-12 weeks at a single site.

The second step is a focus on innovation and performance excellence. Innovation and Performance excellence will focus on the process used by the system, with a focus on achieving excellence and looking for opportunities for

improvement. The process domains evaluate the approach, deployment, cycle of learning, and integration. The results domain includes levels, trends, comparisons, and integration. Gaps in the performance excellence criteria will then take a performance improvement approach, using lean and six sigma. The lean six sigma process using a DMAIC approach (define, measure, analyze, improve, and control). The define and measure components are measured in the feasibility and effectiveness study, so this part will include the cycles of learning.

The final step is a focus on effectiveness. This step includes the endpoints found in an RCT but uses a mixed methods design to get deeper insights from patients and consumers as well as healthcare professionals. This design also runs in cycles of innovation, allowing the solution to continue to improve throughout the study.

Recommendations for future studies

The Intelligent Health Solution provides Care Plans focused on cardiovascular conditions such as heart failure, hypertension, atrial fibrillation, and cardiac rehabilitation. The application aims to increase engagement, facilitate shared decision making, and increase quality of life. To this end, current research study aims to evaluate the effectiveness of the Intelligent Health Solution among a diverse pool of users, from various ethnic and racial backgrounds, including displaced populations. The effectiveness of this approach is being tested in multiple use cases [53].

Our research intends to present qualitative evidence on the perspectives and experiences. Quantitative evidence includes improved biometrics, such as blood pressure, and improved psychometrics, such as depression and anxiety. To this end, current research study aims to evaluate the effectiveness of the Intelligent Health Solution users in order to provide recommendations and strategies to enable this tool in reaching a wide base of users, while maintaining a high level of effectiveness.

The recommendations will guide the development of sound evidence-based designs integrating a tailored and personalized approach to digital health tools. COVID-19 has resulted in an accelerated adoption of digital health tools and much has been learned regarding the use of technology. Telemedicine and remote patient monitoring have been a lifeboat for many patients who did not have access to medical care due to social distancing, program closure and reallocation of resources. Programs such as cardiac rehabilitation, that were already underutilized before the pandemic were significantly impacted, resulting in the increased use of home-based cardiac rehab. The lessons learned are that digital technology can improve access, and can be delivered safely and effectively[54]. Hybrid models, that include center-based and home-based components, supported by telemedicine and remote patient monitoring may become the standard of care in the post-pandemic world.

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