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59 Using Digital Health Technology to Promote Cardiovascular Disease Risk Reduction in Secondary Prevention

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KEY POINTS

- A broad spectrum of hybrid and alternative secondary prevention delivery models that incorporate novel digital health technologies have been proposed for rectifying barriers to low rates of utilization of traditional cardiac rehabilitation (CR) programs, and for the provision of ongoing, evidence-based, secondary prevention interventions.
- The COVID-19 pandemic has created a digital health technology inflection point by accelerating the widespread acceptance and adoption of virtual/remotely delivered interventions, and this momentum is likely to continue in the era of COVID-19 and beyond.
- Despite the flaws and limitations of existing research, the preponderance of evidence to date is highly supportive of the great potential of digital health technologies to facilitate lifestyle modification and cardiovascular disease (CVD) risk reduction.
- Digital health interventions appear to be most effective when integrated with evidence-based behavioral change strategies and direct interaction between participants and healthcare providers.
- Additional research and healthcare policy change are needed to move the promise of new digital health technologies for CVD risk reduction toward reality.

59.1 INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of death globally and is projected to account for over 23.6 million annual deaths by 2030.[1] Although sound clinical reasons exist for emphasizing secondary prevention in day-to-day medical practice, studies indicate that physicians often fail to provide recommended CVD risk reduction interventions and, even when provided, patients often fail to comply with the prescribed lifestyle and pharmacologic interventions.[2] Moreover, the COVID-19 and CVD pandemics have interacted to create a so-called "perfect storm" in which each pandemic is contributing to the worsening of the other.[3] Clearly, to achieve the American Heart Association's (AHA) 2030 Impact Goal of equitably increasing healthy life expectancy from 66 to at least 68 years of age across the United States and from 64 to at least 67 years of age worldwide by 2030, and to reduce premature CVD mortality, increased emphasis is needed on CVD risk reduction through evidence-based management of health behaviors and risk factors.[1]

Traditional center-based outpatient CR reduces morbidity, hospital readmissions, and mortality versus usual care.[2,4–8] Every recent secondary prevention guideline from the AHA and American College of Cardiology (ACC) provides a Class I level recommendation (i.e., there is evidence for and/or general agreement that the intervention is beneficial, useful, and effective; the intervention should be performed) for CR referral.[2,4–8] However, despite the proven benefits, the use of CR remains dismally low.[2,4–8] Multiple strategies have been proposed for rectifying barriers to participation in, and completion of, traditional center-based CR programs. These include a broad spectrum of hybrid and home-based alternative secondary prevention delivery models that incorporate novel technologies to facilitate CVD risk reduction.[2,4–11]

Modern-day cardiovascular medicine is a "high-tech" industry.[12] According to a 2017 report of the ACC Task Force on Health Policy Statements and Systems of Care,[13] key recent technological innovations of paramount importance for the future transformation of CVD care include the following: (1) digital health, with smartphone, wearable, sensor-based, and other electronic technologies; (2) big data, comprising the aggregation of large quantities of structured and unstructured health information and sophisticated analyses with artificial intelligence (including machine learning and natural language processing techniques); and (3) precision health, using approaches aimed at the identification of individual-level risks and determinants of wellness and pathogenicity. The intra- and inter-connections among emerging innovations and developments in digital health, big data, and precision health, as summarized by the ACC, are shown in Figure 59.1. In this chapter, we focus primarily on the use of digital health to promote CVD risk reduction.

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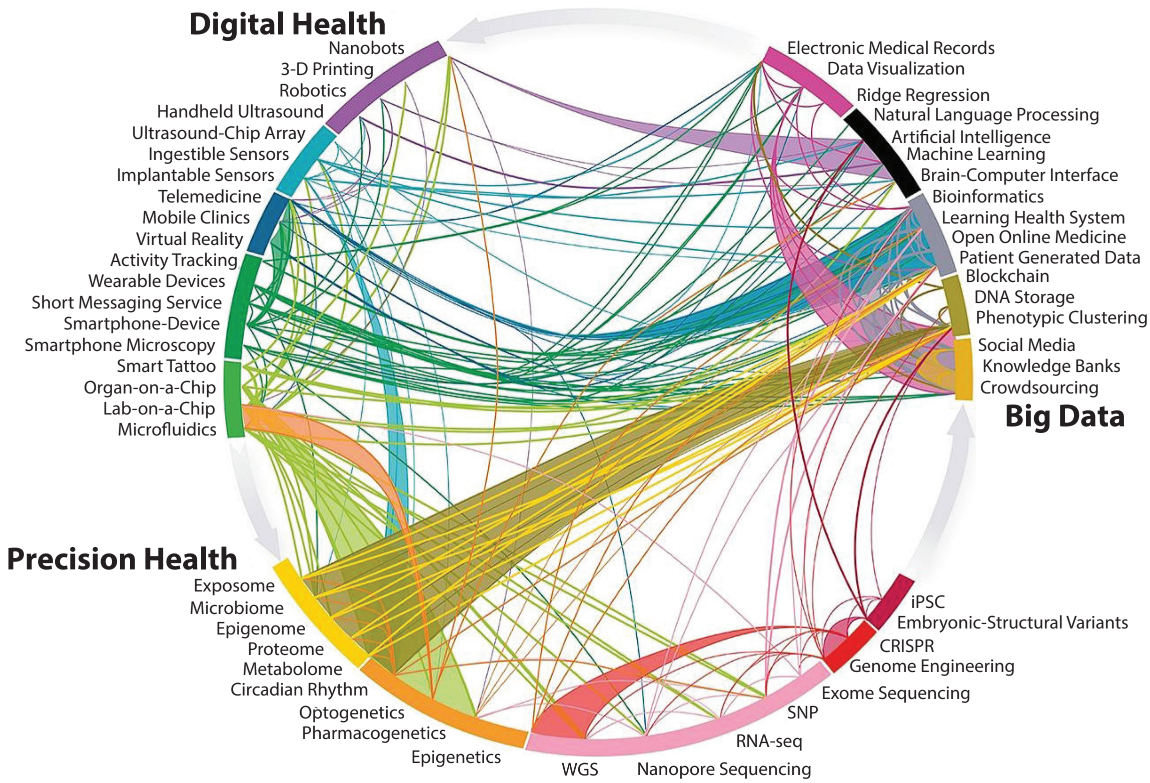

FIGURE 59.1 New innovations in cardiovascular healthcare: Infographic of emerging innovations and developments in digital health, big data, and precision health and their intra- and inter-connections. Abbreviations: 3d, 3-dimensional; CRISPR, clustered regularly interspaced short palindromic repeats; DNA, deoxyribonucleic acid; iPSC, induced pluripotent stem cells; RNA, ribonucleic acid; SNP, single nucleotide polymorphism; WGS, whole genome sequencing (from Bhavnani SP, Parakh K, Atreja A, et al., *J Am Coll Cardiol* 2017;70:2696-2718. With permission)

A 2015 scientific statement from the AHA on the consumer use of mobile health for CVD prevention defines eHealth (also referred to as digital health) as the use of emerging communication and information technologies, especially the Internet, to improve health and healthcare and mHealth as a subsegment of eHealth that involves the use of mobile computing and communication technologies for health services and information (see the glossary of commonly used terms in Table 59.1).[14] While digital technologies have revolutionized broad sectors of our society and economy, ranging from entertainment to dating, travel, news, and finance, the healthcare industry generally has been slower to respond.[12,13] However, given the ubiquity of mobile devices and Internet access, digital health interventions that incorporate various technologies (such as telemedicine, videoconferencing, text messaging, mobile phone apps, and data from electronic medical records, blood pressure monitors, digital scales, blood glucose monitors, heart rate monitors, activity trackers, and other wearable/monitoring devices) are now rapidly emerging as an integral component of traditional CR programs and, especially, hybrid and home-based alternative CR/secondary prevention delivery models. Moreover, COVID-19-related lockdowns and other disruptions have created a digital health technology inflection point by accelerating the widespread acceptance and adoption of virtual/remotely delivered interventions.[3] This momentum is likely to continue for the foreseeable future in the era of COVID-19 and beyond.

59.2 EFFECTIVENESS AND THE ROLE OF HOME-BASED ALTERNATIVE CR AND SECONDARY PREVENTION DELIVERY MODELS

A 2017 Cochrane systematic review of data from 23 randomized controlled trials involving 2890 participants compared the effect of home-based and supervised center-based CR in adult patients who were post-myocardial infarction or had angina, heart failure, or underwent coronary revascularization.[15] For the review, home-based CR was defined as a structured program (including exercise training) with clear objectives for the participants, including monitoring, follow-up visits, letters or telephone calls from staff, or at least self-monitoring diaries. The review found no evidence of a significant difference between home- and center-based CR, either in the short-term (3 to 12 months) or longer-term (up to 24 months), for total mortality, cardiac events, exercise capacity, multiple modifiable CVD risk factors, or health-related quality of life.

Similarly, a 2019 scientific statement from the American Association of Cardiovascular and Pulmonary

TABLE 59.1
Glossary of Commonly Used Digital Health Terms

Term	Explanation
eHealth	eHealth, or digital health, is the use of emerging communication and information technologies, especially the use of the Internet, to improve health and healthcare.
mHealth	A subsegment of eHealth, mHealth is the use of mobile computing and communication technologies (e.g., mobile phones, wearable sensors) for health services and information.
Smartphone	A handheld personal computer with a mobile operating system and an integrated mobile broadband cellular network connection for voice, SMS, and Internet data communication; most if not all smartphones also support Wi-Fi.
SMS	A text messaging service component of mobile devices. It uses standardized communications protocols to allow mobile phone devices to exchange short text messages. The terms text messaging and texting are used interchangeably to refer to both the medium and messages, and the term text message refers to the individual message sent.
MMS	The next evolutionary step from SMS. MMS allows mobile phone users to exchange pictures with sound clips on their handsets or digital cameras.
App	App is short for application, which is the same thing as a software program. Although an app may refer to a program for any hardware platform, it is most often used to describe programs for mobile devices such as smartphones and tablets.
Wireless	Being wireless means not using wires to send and receive electronic signals (i.e., sending and receiving electronic signals by using radio waves).
Wi-Fi	A wireless networking technology that allows computers and other devices to communicate over a wireless signal.
Bluetooth	This wireless technology enables communication between Bluetooth-compatible devices. It is used for short-range connections between desktop and laptop computers, a mouse, digital cameras, scanners, cellular phones, earphones, headsets, and printers.
Operating system	An operating system, or OS, is software that communicates with the hardware and allows other programs to run. Common mobile OSs include Android, iOS, and Windows Phone.
iOS	A mobile OS developed by Apple. It was originally called the iPhone OS but was renamed to iOS in June 2009. The iOS currently runs on the iPhone, iPod Touch, and iPad.
Android OS	A Linux-based open-source platform for mobile cellular handsets developed by Google and the Open Handset Alliance. Android 1.0 was released in September 2008.
Bandwidth	In computer networks, bandwidth is used as a synonym for data transfer rate, the amount of data that can be transmitted from one point to another in a given time period (usually a second). Network bandwidth is usually expressed in bits per second (bps); modern networks typically have speeds measured in the millions of bits per second (megabits per second or Mbps) or billions of bits per second (gigabits per second or Gbps).

MMS indicates multimedia messaging service; OS, operating system; and SMS, short messaging service. (From Burke LE et al., *Circulation* 2015;32:1157–213. Adapted with permission.)

Rehabilitation (AACVPR), AHA, and ACC reported on the findings of a systematic review of 23 published studies of home-based compared with center-based CR.[16] Interestingly, from a safety and wearable technology perspective, only three of the 23 studies utilized heart rate monitors and only two others used electrocardiographic telemetry monitoring for home-based CR. Consistent with the findings of the abovementioned Cochrane systematic review, the AHA scientific statement concluded that home- and center-based CR programs can achieve similar improvements in three- to 12-month clinical outcomes, and that home-based CR may be a reasonable option for selected clinically stable low- to moderate-risk patients who are eligible for CR but cannot attend a traditional center-based program. The scientific statement further recommended that prioritization be given to the testing and implementation of evidence-based hybrid approaches to CR that combine the positive and complementary aspects of both center- and home-based CR to personalize and optimize services for each patient, and to promote long-term adherence and favorable behavioral change. Regarding the latter (i.e., hybrid approaches), the Million Hearts Cardiac Rehabilitation Think Tank: Accelerating New Care Models has subsequently proposed a new model for describing CR delivery that: (1) includes a variety of modes of CR service delivery, namely, in-person (i.e., synchronous CR where patients and clinicians are in the same location at the same time and with in-person/direct patient observation during an exercise session), virtual (i.e., synchronous CR delivered with real-time audiovisual communication technology to facilitate patient and clinician interaction during an exercise session), and remote (i.e., CR delivered with asynchronous activities without real-time communication between patients and clinicians at the time of an exercise session); and (2) provides the option for an individual program to offer ≥1 mode of delivery and an individual patient to participate through ≥1 mode of delivery.[8]

Wongvibulsin et al. conducted a systematic literature review of 31 studies published from January 1990 to October 2018 that deployed digital health interventions for CR.[17] For this review, the authors defined digital as the technology employed to deliver virtual/remote care beyond the use of the telephone (e.g., the delivery of care using the Internet, wearable devices, and mobile apps). The reviewed interventions primarily targeted physical activity counseling (100% of studies), baseline assessment (97% of studies), and exercise training (87% of studies). Approximately one-third of the studies addressed the CR core components of nutrition counseling, psychological management, and weight management, and less than a third of the studies addressed other CR core components, such as smoking cessation and lipid, diabetes, and blood pressure management. The most commonly used modalities were smartphones or mobile devices (65% of studies), web-based portals (58% of studies), and email/text messaging (35% of studies). The authors concluded that digital CR was feasible and as effective as traditional CR in improving outcomes, whether as an adjunct or an alternative to traditional CR.

In 2022, Nkonde-Price et al. reported on a retrospective cohort study of 2556 demographically diverse patients, including those who were medically complex, from a large integrated healthcare system who participated in a center-based (n = 1315) or technology-enabled home-based (n = 1241) CR program.[18] After adjusting for demographic and clinical characteristics, patients who received home-based CR had a lower odds of all-cause hospitalization at 12 months of follow-up (OR, 0.79; 95% CI, 0.64–0.97) compared with patients who received center-based CR. The authors concluded that their study strengthens the evidence supporting home-based CR, including in previously understudied patient populations.

In a multi-center study involving 12,984 patients who completed a traditional center-based CR program, very few patients had all CVD risk factors at levels currently recommended for ideal cardiovascular health at program completion.[19] These data emphasize the need for ongoing surveillance and intensive intervention aimed at residual CVD risk reduction in most patients who complete traditional center-based CR programs. In addition to their use as an alternative to center-based programs, home-based programs that incorporate novel digital health technologies can be leveraged to provide ongoing secondary prevention intervention after completion of center-based CR.

59.3 EFFECTIVENESS OF DIGITAL HEALTH TECHNOLOGIES FOR LIFESTYLE INTERVENTION AND CVD SECONDARY PREVENTION

The global smartphone penetration rate is estimated to have reached over 78% in 2020 and, according to a Deloitte survey, in the United States, the smartphone market penetration rose from 82% in 2017 to 85% in 2018.[20] The survey further indicated that the growth in smartphone penetration was strongest among older age groups (particularly those aged 45–54 and $\geq$55 years). From the perspective of addressing existing disparities in the provision of CR and CVD secondary prevention services, it is especially important to note that according to 2021 statistics from the Pew Research Center, 76% of individuals with an annual household income below $30,000 owned a smartphone.[21] Moreover, smartphone ownership was similar among Whites (85%), Blacks (83%), and Hispanics (85%). Thus, unlike the initial digital divide that placed Internet access and computer use beyond the reach of many disadvantaged populations, smartphones have been widely adopted across demographic groups, including ethnic minorities and older, lower socioeconomic status, and/or other currently underserved populations who may be most in need of secondary prevention interventions.[14]

The 2015 AHA scientific statement on consumer use of mobile health reviewed the scientific literature on mHealth tools related to CVD prevention.[14] Key findings pertaining to the use of mHealth to improve weight management, physical activity participation, smoking cessation, self-management of diabetes, hypertension care, and management of dyslipidemia were evaluated together with gaps in knowledge, and suggestions were made for future research. Several common themes and concerns were noted, including: (1) study design concerns such as the use of pre-post designs without concurrent control groups or randomized comparison groups, reliance on self-reported data, failure to use intention-to-treat analyses, evaluation in motivated participants and selected settings, and short duration of the studies; (2) evaluation of a single digital health technology compared with usual care rather than head-to-head studies comparing various digital health technologies with each other; (3) unanswered questions about product safety; (4) inability to demonstrate which components in an intervention are pivotal to success or whether the impact of a specific digital health product varies depending on the mode of use or delivery; and (5) absence of meaningful data on how best to incorporate the digital health technologies into a broader collaborative model of healthcare. Even with the abovementioned flaws, limitations, and unanswered questions, the authors concluded that their review of the evidence clearly demonstrates the great potential that mobile technologies can have to aid in lifestyle modification and that the current absence of sufficient evidence should not be interpreted as evidence of an absence of effectiveness. The authors encouraged healthcare professionals to rise to the challenge of producing the needed evidence on the effectiveness of digital health technologies and how best to adopt them in daily clinical practice.[14]

In a 2016 publication, Afshin et al. systematically reviewed the scientific evidence on the effectiveness of novel information and communication technologies to reduce non-communicable disease risk.[22] The authors searched PubMed for studies evaluating the effect of the Internet, mobile phones, personal sensors, or stand-alone computer software on diet, physical activity, adiposity, tobacco, or alcohol use among generally healthy adults. From 8654 abstracts, 224 relevant reports were identified. The authors concluded that Internet and mobile interventions improve important lifestyle behaviors for up to one year and that their review supports the need for long-term interventions to evaluate sustainability. Interestingly, the authors also observed that: (1) using evidence-based behavioral change strategies could increase the effectiveness of Internet and mobile phone interventions (for example, in studies of diet/adiposity, interventions were more effective if adopting multiple modes of communication, using tailored messages, and integrating goal setting and self-monitoring; and in studies of physical activity, developing the Internet intervention content based on psychological theories of behavioral change increased both effectiveness and participant retention); and (2) interaction with healthcare providers could increase the success rate of the interventions.

In a 2017 publication, Khan et al. reviewed studies addressing digital health technologies to promote lifestyle change and medication adherence, including text messaging, smartphone apps, and wearable devices.[23] They concluded that: (1) the current literature indicates that digital health technologies will likely play a prominent role in future CVD management, risk reduction, and delivery of healthcare in both resource-rich and resource-limited settings; (2) additional clinical research and healthcare policy change are needed to move the promise of new digital health technologies toward reality; and (3) with many new digital health interventions bypassing clearance from the Food and Drug Administration, academic medical centers and professional medical organizations should provide broader guidance to consumers/patients. The authors also expressed concern that, because the development of digital health technologies is often driven by non-clinicians, unique challenges exist related to integration into daily clinical workflows. Moreover, because clinicians are increasingly burdened by the time-consuming use of electronic medical records and data overload, there may be limited capacity for them to take on additional responsibilities by processing and reacting to digital health-related data.

Through a comprehensive search of databases from 2002 to 2016, Park et al. conducted a quantitative systematic review of mobile phone interventions for the secondary prevention of CVD.[24] A large majority of studies (22 of 28, or 79%) demonstrated that text messaging, mobile apps, and telemonitoring via mobile phones were effective in improving outcomes. Key factors associated with successful interventions included personalized messages with tailored advice, greater engagement (e.g., two-way text messaging and higher frequency of messages), and the use of multiple digital health modalities. Overall, text messaging appeared more effective than smartphone-based interventions. Based on their observations and experiences, the authors speculated that future mHealth interventions will likely use a combination of different technologies (e.g., basic cellular phones, smartphones, computers, and tablets) and that with the widespread proliferation of smartphones, mHealth apps will likely expand on their connectivity with social media to maximize consumer engagement. However, in doing so, concerns of privacy and security issues will need to be adequately addressed.

A 2019 AHA scientific statement on harnessing mobile health technology for secondary CVD prevention in older adults, reported on the findings from a systematic review of 26 studies that used mHealth for secondary CVD prevention focusing on lifestyle behavior change and medication adherence in cohorts with a mean age ≥60 years.[25] Improvements in multiple health behaviors and medication adherence were observed, particularly when there was a text message component involved. In studies with app-only interventions, the majority of patients reported ease of use (>60%), patients found the app helpful, and self-reported use of the app was high. However, many of the apps tested were intended for very specific purposes. Although mobile technologies are becoming more mainstream and starting to blend more seamlessly with standard healthcare, the scientific statement concluded that there are still distinct barriers that limit implementation, including affordability, usability, privacy, and security issues. The scientific statement further emphasized that: (1) future studies on the type of mHealth that is the most effective are essential; and (2) as our population ages, identifying and implementing widely accepted, cost-effective, and time-efficient mHealth interventions to improve cardiovascular health should be a top priority.

59.4 HEALTHCARE TRANSFORMATION IN THE ERA OF DIGITAL HEALTH

Newly developed and rapidly evolving technological innovations have the potential to play a pivotal role in the shift from volume- to value-based healthcare. However, as emphasized in the 2017 report of the ACC Task Force on Health Policy Statements and Systems of Care[13] technological transformation often occurs too rapidly for existing healthcare practice to keep pace, thus creating a mismatch between the rate of development of novel technologies and preparedness of the healthcare system for effective integration and utilization of novel technologies. Thus, despite billions of dollars of investment in digital health technologies, there are numerous reasons why the digital transformation of healthcare still lags the rate of transformation that has occurred in other industries.[12,13]

Simultaneous with the publication of the 2017 ACC Task Force report, Walsh and Rumsfeld[12] proposed the following concerns among key reasons for healthcare lagging other industries in the adoption of potentially transformative new technologies: (1) healthcare is not entertainment; the healthcare system is extremely complex and simply not set up to rapidly absorb innovation; (2) the stakes in healthcare are very high, often involving life-or-death decisions and, thus, rightfully requiring convincing evidence for technology solutions before widespread clinical adoption; (3) many technology companies lack the necessary clinical insights; (4) while electronic medical records were a first step in the digital transformation of healthcare, dissatisfaction and criticism abound, with many physicians considering the introduction of electronic medical records a significant misstep; (5) digital health companies have often been fearful of entering the healthcare regulatory process, and many have chosen not to aim innovation at the clinician-patient interface, instead solely developing consumer products; and (6) for the most part, there are non-aligned incentives or payment models in place to support digital health transformation of care delivery.

When deploying digital health technologies as a component of alternative CVD secondary prevention models, the following key policy recommendations from the AHA should be considered: (1) CR and secondary prevention programs should be reengineered to include an array of service options that meet the needs of individual patients and provide more flexible programs within and beyond the traditional clinical center to enhance access, adherence, and effectiveness; (2) such alternative approaches should not replace traditional programs, but should be used to engage the many patients who currently do not participate, and to provide ongoing monitoring and treatment after completion of traditional center-based CR programs; (3) alternative approaches should meet reputable quality standards, and existing standards may need to be customized for each model accordingly; (4) any new approach should not be widely implemented until it has been shown to be effective as evidenced by results of clinical studies published in peer-reviewed journals; and (5) third-party payers should cover the costs of evidence-based alternative models of delivery, such as hybrid programs and technology-enabled home-based models, that have been shown to be effective in peer-reviewed published clinical trials.[4,16] Regarding the latter, as a result of the COVID-19 pandemic, the Centers for Medicare and Medicaid Services (CMS) in the United States provided waivers to expand CR reimbursement to include virtual, synchronous (but not remote, asynchronous) service delivery. While the future of reimbursement for virtual CR is unknown at this time (September 2022), there is great enthusiasm to make the CMS waivers permanent.[8] It should also be noted that, in certain instances, there is currently the ability to leverage other newly reimbursable options for the provision of virtual/remote CVD secondary prevention services (e.g., chronic care management, principal care management, and remote patient monitoring) in the United States.

59.5 CASE STUDY OF AN EVIDENCE-BASED, DIGITAL HEALTH TECHNOLOGY-ENABLED, CVD RISK REDUCTION PROGRAM

We have spent over 25 years developing, testing, and implementing an evidence-based lifestyle management and CVD risk reduction telehealth coaching intervention that utilizes a variety of digital health technologies and has been shown to be effective in individuals with or at heightened risk for CVD.[26] The primary objectives of the digital technology-enabled telehealth coaching program are to help participants: (1) make and adhere to meaningful, evidence-based lifestyle changes (especially, regular exercise/physical activity, healthy nutrition, weight management, stress management, and tobacco cessation); (2) learn about CVD, CVD risk factors, and comorbidities, and acquire appropriate self-management skills (including use of relevant wearables/monitoring devices for remote patient monitoring, understanding untoward symptoms/signs, knowing when to contact their physicians/providers, and avoiding re-hospitalization); (3) address gaps in preventive care (e.g., complying with recommended preventive screenings/tests/vaccinations); and (4) comply with prescribed medications and other aspects of their regular medical care. To accomplish these objectives and help ensure the attainment of clinically meaningful/reproducible outcomes, telehealth coaching is delivered using a formal, structured, systematic approach together with rigorous continuous quality improvement protocols. The core components of the program and the key steps involved in their delivery are summarized in Figure 59.2.

There is no one single innovation that makes the telehealth coaching intervention novel; rather, it is due to the synergistic manner in which multiple novel approaches and digital health technologies have been incorporated into a single program to facilitate the provision of comprehensive CVD risk reduction services and the achievement of reproducible outcomes. A few of the many innovative aspects of the telehealth coaching intervention include the use of:

(1) A home-based program that was originally based on the protocols/procedures deployed in the Stanford Coronary Risk Intervention Project,[27] subsequently enhanced over more than 25 years and addresses not only prescribed physical activity/exercise training but also the other important core components of comprehensive CR/secondary prevention as part of a single integrated intervention. These other core components include modification of multiple CVD risk factors via education and behaviorally oriented health coaching, stress/mental health interventions, symptom management, and compliance with prescribed evidence-based CVD risk reduction medications, recommended preventive tests/vaccinations, and other aspects of regular medical care. The program is in daily use throughout the United States and Canada in a variety of real-world settings, including in English, Spanish, and French.

(2) Multiple novel digital health technologies, including telemedicine, videoconferencing, text messaging, online smartphone apps, game-based learning, and integration of data from electronic medical records, laboratories, blood pressure monitors, digital scales, blood glucose monitors, heart rate monitors, activity trackers, and other wearable devices/sensors. While the telehealth

Step 1: Participant identification and enrollment
- Physicians can refer patients using a variety of methods, including via a smartphone app and leveraging electronic medical records
- Potential participants are also identified using multiple data sources, such as health risk assessments, laboratory data, medical/pharmacy claims data, and data from wearables/other remote patient monitoring devices

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Step 2: Intake assessment and risk stratification
Self-reported data (including medical history, risk factors, lifestyle habits, and readiness to change) can be entered directly by participants into the program's HIPAA-compliant, secure, mobile-friendly (iOS and Android phones, tablets, etc.), participant-facing, online portal/application
- Data are integrated into participants' records from multiple sources, including electronic medical records, laboratory data, medical/pharmacy claims data, and wearables/other monitoring devices
- Automated real-time risk stratification algorithms determine the most appropriate nature and intensity of the coaching intervention

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Step 3: Goal setting and care/action plan formulation
Based on the intake assessment and with the use of artificial intelligence:
- Computer-generated, individualized, short- and long-term goals are set for multiple CVD risk factors and health behaviors
- Computer-generated, individualized, care/action plans are formulated to help participants achieve their short/long-term goals
- In addition to behavior modification, care/action plans identify the need for specific preventive screenings, immunizations, other self-care activities, and physician referrals (e.g., for medication changes to optimize CVD risk reduction, including statins, antihypertensive agents, antidiabetic medications, and platelet inhibitors)

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Step 4: Review/revision of goals and care/action plans
- Based on their interaction with participants and/or input from the participants' physicians/healthcare providers, health coaches can revise the computer-generated goals/care/action plans
- Participants can access their goals/care/action plan reports via the online participant portal
-If the action plan includes referral to a physician/other healthcare provider, the health coach emphasizes the importance, facilitates the referral, and documents the outcome of the referral in the program's HIPAA-compliant, secure, mobile-friendly, online coaching portal

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Step 5: Care/action plan implementation
- With guidance from the online coaching portal, and using behavioral interventions derived from multiple well-established behavior change models (e.g., adult learning theory, social learning theory, cognitive behavioral therapy, motivational interviewing, single concept learning, and the stages of change model), coaches assist participants in implementing their individualized care/action plans
- Coaching occurs during proactive, formally structured, 1-on-1, brief (usually-15-30 minutes in duration) prescheduled telephone appointments supplemented by secure videoconferencing, online chat, and/or e-mail
- Participants can access numerous resources/features via the online participant portal, including: personalized reports; interactive (storage of participant responses to activities), behaviorally-oriented, educational modules with audios on over 100 comprehensive topics, including quizzes to check/document mastery of content; interactive self-monitoring diaries/logs (e.g., exercise, nutrition, stress, tobacco, symptoms/signs, medications); recipes; health-related challenges and accompanying rewards/incentives; ability to synchronize numerous wearable/other monitoring devices to the portal (for remote patient monitoring), including heart rate monitors, activity trackers, scales, blood pressure monitors and blood glucose monitors; and game-based learning activities that consider health literacy

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Step 6: Follow-up assessment, with provision of progress reports and revision of goals/care/action plans
- After ~ 12 weeks and 1 year of program participation, and at least annually thereafter, participants typically complete formal follow-up assessments and receive online reports documenting their progress and updating their goals/care/action plans
-If the revised care/action plan includes referral to a physician/other healthcare provider, the health coach emphasizes the importance, facilitates the referral, and documents the outcome of the referral in the online coaching portal

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Step 7: Maintenance
Compliance with scheduled coaching sessions and interventions is tracked using the online coaching portal's participant management and tracking features (participants typically enroll in the program for 1 year at a time and may re-enroll on an annual/ongoing basis)
- Ongoing mining/analysis of multiple data sources is performed to identify participants requiring special intervention (e.g., for untoward symptoms/signs, out-of-range values, and non-compliance with recommended interventions)

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Step 8: Outcomes assessment
- Detailed aggregate outcomes reports are generated on a regular basis for specific groups of program participants
- Benchmarking may be included using book-of-business analyses

FIGURE 59.2 Summary of core components and key steps involved in an evidence-based, technology-enabled, lifestyle management and cardiovascular disease risk reduction program. Abbreviations: CVD, cardiovascular disease; HIPAA, Health Insurance Portability and Accountability Act of 1996

coaching program incorporates multiple digital technologies, individuals who are unable to use such technologies are still able to participate and achieve meaningful clinical benefits, making the intervention suitable for use with a broad spectrum of underserved populations. In fact, the minimum needed for participation is telephone access. All core participant educational materials are available in hard copy format, interactive online format (including health coaches having access to online activities completed by participants), and audio formats (for verbal learners and individuals who, for example, are illiterate or visually impaired). No special resources (e.g., exercise equipment or fitness center membership) are required but participants can elect to use and synchronize a variety of wearable/monitoring devices to the program's online portal.

(3) A sophisticated online coaching portal that provides professional health coaches access to the resources, data, and automated guidance they need to provide evidence-based, behaviorally oriented, coaching aimed at helping participants acquire the skills, motivation, and support needed

TABLE 59.2

Case Study of an Evidence-Based, Digital Health Technology-Enabled, CVD Risk Reduction Program: Key Published Randomized Clinical Trials

Reference, Objectives; Study Design/Duration	Results, Conclusions, and Implications
Gordon et al.[35] This randomized clinical trial compared the clinical effectiveness of two, less-costly and potentially more accessible, approaches to CVD risk reduction with that of a contemporary phase 2 center-based CR program. Low- or moderate-risk coronary artery disease patients (n = 155) were randomly assigned to 12 weeks of participation in a contemporary phase 2 CR program (n = 52), a physician-supervised, nurse-case-managed CVD risk reduction program (n = 54), or a comprehensive health coaching program administered by exercise physiologists guided by a computerized participant management system based on reputable national clinical guidelines (n = 49); 142 patients (91.6%) completed testing at baseline and after 12 weeks of intervention.	For patients with abnormal baseline values, statistically significant ($p \leq 0.05$) improvements were observed with all three interventions for multiple CVD risk factors. With the exception of maximal oxygen uptake, no statistically significant risk factor differences were observed among the three programs. For patients with a baseline maximal oxygen uptake <7 METs, maximal oxygen uptake increased to a greater degree in patients in the contemporary phase 2 CR program and the health coaching program versus the physician-supervised, nurse-case-managed program. These data demonstrate that an evidence-based, technology-enabled health coaching program can be at least as effective as other more costly and potentially less accessible interventions (including traditional center-based CR) in low- and moderate-risk coronary artery disease patients. The data have important potential implications for cost-containment and for increasing accessibility to clinically effective comprehensive CVD risk reduction services.
Maron et al.[36] This randomized clinical trial evaluated how the intensity of intervention after the provision of a health risk assessment affects CVD risk; 133 employees with CVD risk factors were randomly assigned for one year to a health risk assessment plus comprehensive health coaching group (higher-intensity intervention; HC group) or a health risk assessment plus information about worksite health promotion programs group (lower-intensity intervention; HRA group). The HC group participated in a one-year technology-enabled, health coaching program, whereas the HRA group received one feedback session about their CVD risk factors and information about free worksite health promotion programs. The primary outcome measure was the change in Framingham ten-year coronary heart disease risk scores.	In the HC group, the mean Framingham ten-year coronary heart disease risk score decreased by 22.6% (relative risk reduction); in the HRA group, the mean score rose by 4.3% ($p = 0.017$ for the difference between groups). The data demonstrate that a health risk assessment followed by participation in an evidence-based, technology-enabled, health coaching program can be more effective than a health risk assessment followed by one feedback session and the provision of information about free worksite health promotion programs. The data also serve to highlight that not just any kind of lifestyle management program done in any way at all will produce high levels of clinical benefit. It is evident from this study that lifestyle management programs must be appropriately designed and executed effectively to significantly impact multiple clinical variables and facilitate CVD risk reduction.
Derdeyn et al.[30]; Turan et al.[31]; Turan et al.[32]; and Turan et al.[33] This study, conducted at 50 medical centers in the United States, randomly assigned 451 patients with recent transient ischemic attack or stroke related to 70–99% stenosis of a major intracranial artery to aggressive medical management (including anti-platelet therapy, intensive management of vascular risk factors, and participation in an evidence-based, technology-enabled, telehealth coaching program) or aggressive medical management plus intracranial stenting with the Wingspan stent. The primary endpoint was any of the following: stroke or death within 30 days after enrollment, ischemic stroke in the territory of the qualifying artery beyond 30 days of enrollment, or stroke or death within 30 days after a revascularization procedure of the qualifying lesion during follow-up. Patients were followed for a median of 32.4 months.	In the medical management-only group, 15% of patients had a primary endpoint event, while 23% of patients in the stenting group had a primary endpoint event. The primary endpoint rate in the medical management-only group (14.1% at two years) was much lower than was projected based on the results of the WASID trial (24.7% at two years), an observation that was attributed to differences in medical treatment in these trials, including use of telehealth coaching in SAMMPRIS but not WASID. Throughout the duration of the study, there were continued improvements in CVD risk factor control. Multivariate analyses demonstrated that of the various CVD risk factors, physical inactivity was by far the most important predictor of poor outcomes—greater physical activity decreased the likelihood of a recurrent stroke, myocardial infarction, or vascular death by 40% (odds ratio 0.6, confidence interval 0.4–0.8). The investigators attributed increases in physical activity to compliance with the telehealth coaching program, which also contributed to the high percentage of patients achieving other risk factor targets. The study highlights the potential benefits of physical activity for the prevention of recurrent stroke and the role that evidence-based, digital technology-enabled, telehealth coaching can play in helping patients achieve CVD risk factor goals. The study also helps allay concerns regarding the long-term sustainability of CVD risk factor control.

CR, cardiac rehabilitation; CVD, cardiovascular disease; SAMMPRIS, Stenting and Aggressive Medical Management for Prevention of Recurrent Stroke in Intracranial Stenosis; WASID, Warfarin Aspirin Symptomatic Intracranial Disease (adapted, in part, from Gordon NF et al., *Am J Lifestyle Med* 2017;11:153–166).

to implement and adhere to their individualized care/action plans.

(4) Multiple features to facilitate provider engagement and interaction with participants to improve adherence to evidence-based secondary prevention interventions. For example, using artificial intelligence, evidence-based, individualized goals and care/action plan reports and progress reports are automatically generated for program participants. Healthcare providers are able to access these reports, recommend changes, and, in certain instances, provide electronic input to their patients' health coaches. Where indicated on the basis of reputable clinical guidelines, including optimizing CVD risk reduction medication management, coaches facilitate the referral of participants to their healthcare providers.

(5) Big data mining to provide business intelligence to enhance participant engagement and optimize the nature and intensity of CVD risk reduction interventions. Data sources include health risk assessments, electronic medical records, laboratory data, medical/pharmacy claims data, and data from wearables/other monitoring devices.

The program's effectiveness has been evaluated as part of numerous formal research initiatives. The telehealth coaching program was successfully deployed as part of the aggressive medical management component of the National Institutes of Health (NIH)-funded Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) multi-center clinical trial,[28–33] and is currently being used as part of the aggressive medical management components of the multi-center NIH-funded Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Study (CREST-2)[34] and Comparison of Anti-coagulation and Anti-Platelet Therapies for Intracranial Vascular Atherostenosis (CAPTIVA) clinical trials. The telehealth coaching program is also being used by participants in the Canadian Diabetes Prevention Program (CDPP) clinical trial (funded, in part, by the Public Health Agency of Canada) and the Telehealth-Enhanced Assessment and Management after Stroke-Blood Pressure (TEAMS-BP) multi-center clinical trial (funded by the Patient Centered Outcomes Research Institute). Results of several of the key published randomized clinical trials are summarized in Table 59.2.[28–33,35,36]

CLINICAL IMPLICATIONS

1. Newly developed and rapidly evolving technological innovations, including digital health, have the potential to play a pivotal role in the shift from volume- to value-based healthcare.
2. Hybrid and home-based digital health technology-enabled lifestyle management and CVD risk reduction programs are a viable alternative to traditional center-based CR programs.
3. Such alternative approaches should not be used to replace center-based CR but rather to engage the many patients who currently do not participate and provide ongoing, evidence-based, CVD secondary prevention interventions post-CR.
4. Healthcare professionals should rise to the challenge of producing the needed evidence on the long-term effectiveness of digital technologies and determine how best to adopt them in daily practice to help optimize patient health.

DISCLOSURES

Neil Gordon, Richard Salmon, and Prabakar Ponnusamy are members and/or employees of a population health management company (INTERVENT International, LLC).

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