

## Current Science on Consumer Use of Mobile Health for Cardiovascular Disease Prevention

### A Scientific Statement From the American Heart Association

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Although mortality for cardiovascular disease (CVD) has declined for several decades, heart disease and stroke continue to be the leading causes of death, disability, and high healthcare costs. Unhealthy behaviors related to CVD risk (eg, smoking, sedentary lifestyle, and unhealthy eating habits) remain highly prevalent. The high rates of overweight, obesity, and type 2 diabetes mellitus (T2DM); the persistent presence of uncontrolled hypertension; lipid levels not at target; and the  $\approx 18\%$  of adults who continue to smoke cigarettes pose formidable challenges for achieving improved cardiovascular health.<sup>1,2</sup> It is apparent that the performance of healthful behaviors related to the management of CVD risk factors has become an increasingly important facet of the prevention and management of CVD.<sup>3</sup>

In 2010, the American Heart Association (AHA) made a transformative shift in its strategic plan and added the concept of cardiovascular health.<sup>2</sup> To operationalize this concept, the AHA targeted 4 health behaviors in the 2020 Strategic Impact Goals: reduction in smoking and weight, healthful eating, and promotion of regular physical activity. Three health indicators also were included: glucose, blood pressure (BP), and cholesterol. On the basis of the AHA Life's Simple 7 metrics for

improved cardiovascular health,  $<1\%$  of adults in the United States follow a healthful eating plan, only 32% have a normal body mass index, and  $>30\%$  have not reached the target levels for lipids or BP. National Health and Nutrition Examination Survey (NHANES) data revealed that people who met  $\geq 6$  of the cardiovascular health metrics had a significantly better risk profile (hazard ratio for all-cause mortality, 0.49) compared with individuals who had achieved only 1 metric or none.<sup>2</sup> The studies reviewed in this statement targeted these behaviors (ie, smoking, physical activity, healthful eating, and maintaining a healthful weight) and cardiovascular health indicators (ie, blood glucose, lipids, BP, body mass index) as the primary outcomes in the clinical trials testing mobile health (mHealth) interventions.

eHealth, or digital health, is the use of emerging communication and information technologies, especially the Internet, to improve health and health care<sup>4</sup> (Table 1). mHealth, a subsegment of eHealth, is the use of mobile computing and communication technologies (eg, mobile phones, wearable sensors) for health services and information.<sup>4,5</sup> mHealth technology uses techniques and advanced concepts from an array of disciplines, for example, computer science, electrical and

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This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on April 21, 2015, and the American Heart Association Executive Committee on May 22, 2015. A copy of the document is available at <http://my.americanheart.org/statements> by selecting either the "By Topic" link or the "By Publication Date" link. To purchase additional reprints, call 843-216-2533 or e-mail [kelle.ramsay@wolterskluwer.com](mailto:kelle.ramsay@wolterskluwer.com).

The American Heart Association requests that this document be cited as follows: Burke LE, Ma J, Azar KMJ, Bennett GG, Peterson ED, Zheng Y, Riley W, Stephens J, Shah SH, Suffoletto B, Turan TN, Spring B, Steinberger J, Quinn CC; on behalf of the American Heart Association Publications Committee of the Council on Epidemiology and Prevention, Behavior Change Committee of the Council on Cardiometabolic Health, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, Council on Quality of Care and Outcomes Research, and Stroke Council. Current science on consumer use of mobile health for cardiovascular disease prevention: a scientific statement from the American Heart Association. *Circulation*. 2015;132:XXX-XXX.

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(*Circulation*. 2015;132:00-00. DOI: 10.1161/CIR.000000000000232.)

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*Circulation* is available at <http://circ.ahajournals.org>

DOI: 10.1161/CIR.000000000000232

biomedical engineering, and medicine and health-related sciences.<sup>16</sup> Mobile devices that permit collection of data in real time are increasingly ubiquitous, enabling researchers to assess multiple behaviors in various contexts and thus inform the development of interventions to prompt behavior change. Technology-supported behavioral health interventions are designed to engage individuals in health behaviors that prevent or manage illness, and they have led to fundamental changes in health practices.<sup>17</sup> In addition to permitting more frequent and convenient community-based assessment of health parameters, these technology-mediated tools support the exchange of health information among consumers and between consumers and health providers, enable health decision making, and encourage positive health behaviors, including self-management and health promotion.<sup>18,19</sup> Consequently, mHealth technologies are becoming more prevalent, and their use will continue to grow,<sup>20</sup> consistent with the Institute of Medicine's call to increase the design and testing of health technologies.<sup>21</sup>

The ubiquity of mobile devices presents the opportunity to improve health outcomes through the delivery of state-of-the-art medical and health services with information and communication technologies.<sup>22</sup> Because of their diverse capabilities and advanced computing features, smartphones are often considered pocket computers.<sup>16</sup> In addition to these devices that can inform and communicate, there are wearable sensors that can be worn for short or extended periods and monitor activity or physiological changes (eg, exercise, heart rate, sleep). These sensors can provide data in real time or save the data to a device for later uploading and review.

The US Food and Drug Administration has a public health responsibility to oversee the safety and effectiveness of medical devices. However, this applies only to applications (apps) that are accessory to regulated medical devices (eg, apps that diagnose a condition). Many mobile apps are not medical devices, meaning that they do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act, and the US Food and Drug Administration does not regulate them. Some mobile apps may meet the definition of a medical device, but because they pose a lower risk to the public, the US Food and Drug Administration intends to exercise enforcement discretion over these devices. Most of the mHealth apps on the market at this time fit into these 2 categories.<sup>23,24</sup>

Numerous innovations in health information technology are empowering individuals to assume a more active role in monitoring and managing their chronic conditions and therapeutic regimens, as well as their health and wellness.<sup>25</sup> These advances are increasingly accepted by the public.<sup>26</sup> Unlike the initial digital divide that placed computer use and Internet access beyond the reach of many older, disabled, and low-income individuals, mobile devices have been widely adopted across demographic and ethnic groups, especially those most in need of health behavior interventions.<sup>27,28</sup> This trend is confirmed in the 2014 statistics from the Pew Research Center's Internet and American Life Project, which showed that 81% of households with an income above \$75000/y owned a smartphone, and nearly half (47%) of those with an annual household income below \$30000 owned a smartphone.<sup>29</sup>

**Table 1. Glossary of Commonly Used mHealth Terms**

|                  |   |
|------------------|---|
| eHealth          | eHealth, or digital health, is the use of emerging communication and information technologies, especially the use of the Internet, to improve health and health care. <sup>4</sup>  |
| mHealth          | A subsegment of eHealth, mHealth is the use of mobile computing and communication technologies (eg, mobile phones, wearable sensors) for health services and information. <sup>4,5</sup>  |
| SMS              | SMS is 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. <sup>6</sup>   |
| MMS              | MMS is the next evolutionary step from SMS. MMS allows mobile phone users to exchange pictures with sound clips on their handsets or digital cameras. <sup>7</sup>  |
| 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. <sup>8</sup>  |
| Wireless         | Being wireless means not using wires to send and receive electronic signals (ie, sending and receiving electronic signals by using radio waves). <sup>9</sup>   |
| Wi-Fi            | Wi-Fi is a wireless networking technology that allows computers and other devices to communicate over a wireless signal. <sup>10</sup>  |
| 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, and printers. <sup>11</sup>  |
| 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. <sup>12</sup>  |
| iOS              | iOS is a mobile OS developed by Apple. It was originally called the iPhone OS, but was renamed to the iOS in June 2009. The iOS currently runs on the iPhone, iPod Touch, and iPad. <sup>13</sup>   |
| Android OS       | Android OS is 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. <sup>14</sup>  |
| 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). <sup>15</sup> |

MMS indicates multimedia messaging service; OS, operating system; and SMS, short messaging service.

The highest smartphone ownership was among Hispanic and blacks, at 61% and 59%, respectively. Of those with phones who use the Internet, 34% mostly use their phones, rather than a desktop or laptop, to access online programs.<sup>30</sup>

Mobile devices offer great promise for improving the health of the populace. Most smartphones include basic functionalities, for example, video streaming, e-mail, Internet access, and high-quality imaging. These developments in wireless technology and the shift to mobile devices are demanding a re-examination of technology as it currently exists within the healthcare infrastructure.<sup>16</sup> However, the pace of science in evaluating these apps is incongruent with the business and industry sectors and the consumer demands. There are concerns that the health-promoting smartphone apps being developed fail to incorporate evidence-based content and that rigorous testing to provide efficacy data is trailing behind their adoption.<sup>31–34</sup> However, a systematic review of the literature suggests a positive impact of consumer health informatics tools on select health conditions. For example, there were intermediate outcomes such as knowledge, adherence, self-management, and change in behaviors related to healthful eating, exercise, and physical activity but not obesity.<sup>35</sup> Another review suggests that smartphone apps are useful tools at the point of care and in mobile clinical communication, as well as in remote patient monitoring and self-management of disease.<sup>36</sup>

Recent articles have reviewed the latest technological advances in digital social networks related to health<sup>37</sup> and wireless devices for cardiac monitoring.<sup>38</sup> What is missing in the scientific literature is a report on the health-related mobile technologies focused specifically on CVD prevention. In particular, it is important to investigate the degree to which these CVD-focused technologies include best content and have been evaluated for their effectiveness. In the absence of such data, clinicians may be hesitant to recommend or endorse any program to their patients and thereby potentially miss an opportunity to improve their engagement in healthful behaviors.

The aims of this scientific statement are to review the literature on mHealth tools available to the consumer in the prevention of CVD (eg, dietary self-monitoring apps, physical activity monitors, and BP monitors); to provide the current evidence on the use of the vast array of mobile devices such as use of mobile phones for communication and feedback, smartphone apps, wearable sensors, or physiological monitors that are readily available and promoted to the public for monitoring their health; and to provide recommendations for future research directions. The goal is to provide the clinician and researcher a review of the current evidence on using mHealth tools and devices when targeting behavior change, cardiovascular risk reduction, and improved cardiovascular health. This statement is divided into sections by the behaviors or health indicators included in the AHA's Life's Simple 7 program: achieving a healthful weight, improving physical activity, quitting smoking, achieving blood glucose control, and managing BP and lipids to achieve target levels. Within each section, the recent evidence for studies using mHealth approaches is reviewed, gaps are identified, and directions for future research are provided.

Although the majority of studies reported the use of mobile devices, for example, basic mobile phones that support the use

of text messaging (short message service [SMS]) or smartphones that provide Internet access, several reported interventions delivered via the Internet such as studies reporting on increased physical activity or BP management. The writing group made the decision to include these studies because there is an increasingly greater proportion of people accessing the Internet via mobile devices. As noted in a Pew report in February 2014, 68% of adults access the Internet with mobile devices.<sup>39</sup> This figure has likely increased in the past year. Moreover, in some of the designated areas of cardiovascular risk, there were few studies reporting on the use of mHealth supported interventions.

## Review of the Scientific Literature on mHealth Tools Related to CVD Prevention

### Search Strategy

We conducted a literature search that included the following terms: *mHealth*; *mobile health*; *mobile phone*; *mobile device*; *mobile technology*; *mobile communication*; *mobile computer*; *mobile PC*; *cell phone*; *cellular phone*; *cellular telephone*; *handheld computer*; *handheld device*; *handheld technology*; *handheld PC*; *hand held computer*; *hand held device*; *hand held technology*; *hand held PC*; *tablet device*; *tablet computer*; *tablet technology*; *tablet PC*; *smartphone*; *smart phone*; *iPad*; *Kindle*; *Galaxy*; *iPhone*; *Blackberry*; *iPod*; *Bluetooth*; *short message service*; *SMS*; *pocket PC*; *pocketPC*; *PDA*; *personal digital assistant*; *Palm Pilot*; *PalmPilot*; *smartbook*; *mobile telephone*; *messaging service*; *MP3 player*; *portmedia player*; *podcast*; *email*; *e-mail*; *electronic mail*; and *electronic message*. Search terms used within the technology or clinical topic (eg, diabetes mellitus) groups were divided with “or,” and the search terms between the technology and clinical topic were connected with “and.” Within each subsection, the key terms used in the search for a given clinical topic are identified. The search was limited to the past 10 years (2004–2014) and to studies reported in the English language. We limited our review to studies enrolling adults except for smoking cessation, for which we included adolescents. We included studies conducted in the United States and in developed countries. We also briefly discuss key systematic reviews or meta-analyses in each topic area, except in management of dyslipidemia.

### Use of mHealth to Improve Weight Management

Obesity causes or contributes to myriad physical and mental health conditions such as CVD, T2DM, and depression, which, either individually or collectively, represent the leading causes of morbidity and mortality in the United States.<sup>40–42</sup> More than 35% of US adults >20 years are obese,<sup>43</sup> and >1 in 4 Americans have multimorbidity,<sup>45</sup> which is associated with high healthcare use and costs, functional impairment, poor quality of life, psychological distress, and premature death.<sup>46–50</sup> Sustained weight loss of 3% to 5% can delay or possibly prevent T2DM<sup>51,52</sup> and significantly improve CVD risk factors (eg, abnormal glucose, elevated BP).<sup>53–56</sup> However, effective treatments for obesity that are accessible to consumers, affordable for diverse socioeconomic groups, and scalable at a population level are lacking.

The 2013 obesity treatment guideline by the AHA, the American College of Cardiology (ACC), and The Obesity Society recommended that clinicians advise overweight and obese individuals who would benefit from weight loss to participate for  $\geq 6$  months in a comprehensive lifestyle program characterized by a combination of a reduced calorie intake, increased physical activity, and behavioral strategies.<sup>57</sup> The guideline panelists found evidence of moderate strength supporting the efficacy of electronically delivered, comprehensive lifestyle programs that include personalized feedback from a trained interventionist, defined as programs delivered to participants by the Internet, e-mail, mobile texting, or similar electronic means. Therefore, it was recommended that electronically delivered interventions are an acceptable alternative to in-person interventions, although it was recognized that the former may result in smaller weight loss than the latter.

#### **Use of mHealth in Weight Management Interventions**

This review is limited to technology-supported lifestyle behavioral interventions for weight loss. Readers are referred to numerous systematic reviews of more traditional Internet-, e-mail-, and telephone-based lifestyle interventions for weight loss.<sup>58–63</sup> Overall, weight management interventions have used a range of mobile technologies,<sup>60,64–68</sup> including texting (SMS), smartphone applications, handheld personal digital assistants (PDAs), and interactive voice response (IVR) systems.<sup>66,69,70</sup> Numerous network-connected devices have also been used,<sup>60,64</sup> including e-scales and wireless physical activity monitoring devices.<sup>71</sup> The use of mobile devices and their functionality (eg, SMS and multimedia messaging service, mobile Internet, and software apps) in weight loss interventions have improved exponentially in recent years. In this section, we focus on the latest evidence on mobile technology interventions for weight loss.

With few exceptions,<sup>72</sup> most interventions have used a single, predetermined technology and did not give participants the option of choosing between a single or multiple forms of technology simultaneously (which has become commonplace for commercial applications). Most technologies have been created in research settings, although at least 1 published study used a commercially available app.<sup>71</sup> The majority of these trials were focused primarily on efficacy testing, and it was unclear whether these interventions used strategies designed to promote user engagement (eg, using established design principles, conducting usability testing, or undergoing iterative development and testing). Additionally, a key translational challenge is that many commercial apps have not been tested empirically, and many apps with empirical data are not commercially available.

#### **Review of Evidence for the Efficacy of mHealth-Based Weight Loss Interventions**

We conducted an electronic literature search using Medline (PubMed), CINAHL, and PsychInfo in June 2014 and extended to 2004. Search terms for this topic included the following: *overweight, obese, obesity, body mass, adiposity, adipose, weight loss, and weight gain*. Only original studies with human subjects with a primary outcome of weight loss and published in English were included. Of 184 references identified, 169 were excluded on the basis of a review of the

title (n=19), abstract (n=121), and full text (n=29). Fourteen references were eligible for this review, including 10 studies conducted among US adults and 2 among adults outside the United States.

Table 2 includes the studies reviewed and provides details on study design, intervention, sample characteristics, and primary outcomes. Five of the 8 US randomized, controlled trials (RCTs)<sup>74–76,83,84</sup> reported significantly more weight loss in the intervention group than in the control or comparison group. The testing and use of mobile technologies varied a great deal, and combinations of mHealth components and tools were often very specific to a particular study. Five investigators used text messaging, also referred to as SMS,<sup>73,74,79,82,83</sup> in studies that ranged from 8 weeks to 1 year in duration. Patrick et al<sup>74</sup> permitted the participant to set the frequency of the SMS (2–5 times a day) and found a significant difference in weight loss between the 2 groups at 4 months, whereas Napolitano et al<sup>83</sup> observed better weight loss in the Facebook plus SMS than the Facebook alone group at 8 weeks. Only 1 study,<sup>79</sup> which used SMS and multimedia messaging service 4 times a day in addition to a monthly e-newsletter in a 12-month study, did not observe a significant difference in weight loss compared with a monthly e-newsletter control group. Two of the SMS studies were conducted outside the United States. Carter et al<sup>82</sup> observed greater weight loss at 6 months in the group receiving SMS compared with the Web site plus Internet forum or paper diary plus Internet forum groups, whereas Haapala et al<sup>73</sup> demonstrated similar results in a study that compared SMS with a wait-list control group at 12 months. Although none of the US studies using SMS reported positive findings beyond 9 months, the Finnish study<sup>73</sup> showed that an SMS intervention could result in significantly greater weight loss than no intervention for up to 12 months.

Shuger et al<sup>76</sup> reported a study that tested the Bodymedia armband for monitoring daily physical activity with a wrist-watch display with or without a behavioral intervention and compared it with 2 groups not using the armband. Only the armband plus intervention group achieved significantly greater weight loss than the self-directed control group at 9 months. Two investigators<sup>77,84</sup> used PDAs for self-monitoring. Burke et al<sup>77</sup> compared 3 standard behavioral weight loss interventions that differed in the method of self-monitoring by using a paper diary or a PDA with or without daily tailored feedback messages via the PDA and found no difference in weight loss at 2 years. Spring et al<sup>84</sup> compared a biweekly group weight loss intervention with the same intervention plus PDA-based self-monitoring and personalized coach feedback by phone. They observed significantly different weight loss at 6 months, but the effect was not sustained at 12 months.

Turner-McGrievy et al<sup>75</sup> reported that a theory-based podcast delivered via MP3 players or computers led to significantly greater weight loss than a non-theory-based weight loss podcast at 12 weeks. Building on this study, the investigators<sup>80,81</sup> conducted a follow-up study to compare the incremental effect of adding mobile apps for self-monitoring and communication with a health coach and group members to the theory-based podcast. However, the addition did not result in significantly greater weight loss than the podcast alone at 6 months.<sup>80,81</sup>

**Table 2. Description of Studies Using mHealth for Weight Loss or Weight Maintenance**

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components   | Technology Used                                      | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)  |
|--|--|---|--|--|--|
| Haapala et al, <sup>73</sup> 2009<br>Design: 2-group RCT<br>Outcome: wtΔ and waist circumference Δ<br>Setting: Community<br>Country: Finland | N=125<br>Int1: n=62<br>Int2: n=63<br>Women: 77.4%<br>Mean age (SD):<br>Int1: 38.1 (4.7) y<br>Int2: 38.0 (4.7) y<br>BMI:<br>Int1: 30.6 (2.7) kg/m <sup>2</sup><br>Int2: 30.4 (2.8) kg/m <sup>2</sup><br>Retention:<br>Int1: 73%<br>Int2: 65%  | Int1: SMS (for personalized feedback) and study Web site (for tracking and information)<br>Diet: Cut down on unnecessary food intake and alcohol<br>PA: Increase daily physical activity<br>Behavior: Self-monitoring and reporting of wt via SMS or study Web site<br>Int2: Wait list control<br>No Intervention   | Mobile phone, SMS, study Web site                    | Duration: 1 y<br>Contacts:<br>Int1: Real time when participants reported wt via text messaging<br>Int2: No intervention contact<br>Intervention adherence:<br>Mean No. (SD) of Ps reporting wt via SMS or study Web site per week:<br>3 mo:<br>Int1: 8.2 (4.0)<br>6 mo:<br>Int1: 5.7 (4.6)<br>9 mo:<br>Int1: 3.7 (3.5)<br>12 mo:<br>Int1: 3.1 (3.5)<br>Interventionist:<br>Int1: Automated<br>Int2: NA | ITT (LOCF)<br>12 mo:<br>wtΔ, kg, M (SD):<br>Int1: -3.1 (4.9)<br>Int2: -0.7 (4.7)<br>P=0.008<br>Waist circumference Δ, cm, M (SD):<br>Int1: -4.5 (5.3)<br>Int2: -1.6 (4.5)<br>P=0.002 |
| Patrick et al, <sup>74</sup> 2009<br>Design: 2-group RCT<br>Outcome: wtΔ<br>Setting: Community<br>Country: United States                     | N=78<br>Int1: n=39<br>Int2: n=39<br>Mean age (SD):<br>44.9 (7.7) y<br>Women: 80%<br>White: 75%<br>Black: 17%<br>BMI:<br>Int1: 32.8 (4.3) kg/m <sup>2</sup><br>Int2: 33.5 (4.5) kg/m <sup>2</sup><br>Retention:<br>Int1: 67%<br>Int2: 67%   | Int1: Mobile phone wt loss program<br>Diet goal: 500-kcal/d reduction<br>PA: Increase from baseline<br>Behavior: Self-monitoring weekly wt using mobile phone; time/frequency of tailored SMS set by Ps (2–5 times/d), monthly phone calls by coach<br>Int2: Mail<br>Diet: No intervention<br>PA: No intervention<br>Behavior: Monthly mailings (healthful eating, PA, and wt loss) | Mobile phone SMS and MMS                             | Duration: 4 mo<br>Contacts:<br>Int1: Daily SMS and MMS, frequency set by Ps<br>Int2: 4 monthly mailings<br>Intervention adherence:<br>Int1: 100% adherence to responding to all messages requesting a reply; by week 16, ≈66%.<br>Int2: NR<br>Interventionist:<br>Int1: Health coach+automated<br>Int2: NA   | LOCF imputation<br>4 mo:<br>wtΔ, kg, M (SE):<br>Int1: -2.10 (0.51)<br>Int2: -0.40 (0.51)<br>P=0.03<br>Completers only:<br>Int1: -2.46 (0.64)<br>Int2: -0.47 (0.64)<br>P=0.04         |
| Turner-McGrievy et al, <sup>75</sup> 2009<br>Design: 2-group RCT<br>Outcome: wtΔ<br>Setting: Community<br>Country: United States             | N=78<br>Int1: n=41<br>Int2: n=37<br>Mean age (SD):<br>Int1: 37.7 (11.8) y<br>Int2: 39.6 (12.2) y<br>Women:<br>Int1: 68%<br>Int2: 81%<br>White:<br>Int1: 85%<br>Int2: 78%<br>BMI:<br>Int1: 31.8 (3.2) kg/m <sup>2</sup><br>Int2: 31.4 (4.1) kg/m <sup>2</sup><br>Retention:<br>Int1: 90%<br>Int2: 92% | Int1: Social cognitive theory-based wt loss podcast<br>Diet: Increase fruit and vegetable intake, decrease fat intake<br>PA: Increase from baseline<br>Behavior: Encourage tracking wt, calories, and exercise<br>Int2: Non-theory-based wt loss podcast<br>Diet: Avoid overeating<br>PA: NR<br>Behavior: NR  | Podcast via MP3 player or computer for Int1 and Int2 | Duration: 12 wk<br>Contacts:<br>Int1: 2 podcasts/wk (mean length, 15 min)<br>Int2: Same as Int1 (mean length, 18 min)<br>Intervention adherence:<br>Mean (SD) No. of podcasts listened to (n =24):<br>Int1: 17.5 (8.1)<br>Int2: 16.6 (7.5)<br>P<0.67<br>Interventionist:<br>Int1: Automated<br>Int2: Automated   | ITT (BOCF)<br>12 wk:<br>wtΔ, kg, M (SD):<br>Int1: -2.9 (3.5)<br>Int2: -0.3 (2.1)<br>P<0.001<br>BMI Δ, kg/m <sup>2</sup> , M (SD):<br>Int1: -1.0 (1.2)<br>Int2: -0.1 (0.7)<br>P<0.001 |

(Continued)

Table 2. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components  | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)  |
|---|--|--|---|--|--|
| Shuger et al, <sup>76</sup> 2011<br>Design: 3-group RCT<br>Outcome: wt<br>Setting: Community<br>Country: United States  | N=197<br>Int1: n=49<br>Int2: n=49<br>Int3: n=49<br>Int4: n=50<br><br>Mean age (SD):<br>46.9 (10.8) y<br><br>Women: 81.7%<br><br>White: 66.8%<br>Black: 32.1%<br><br>BMI:<br>Int1: 33.0 (5.0) kg/m <sup>2</sup><br>Int2: 33.2 (5.4) kg/m <sup>2</sup><br>Int3: 33.1 (4.8) kg/m <sup>2</sup><br>Int4: 33.7 (5.5) kg/m <sup>2</sup><br><br>Retention:<br>At 4 mo: 70%<br>At 9 mo: 62% | Int1: Group-based behavioral wt loss program+armband<br>Diet: adopt healthful eating pattern<br>PA: Increase PA+armband<br>Behavior: Self-monitoring of daily meal, lifestyle activity, and emotion/mood+weekly weigh-in and coach-directed sessions for wt loss support and maintenance<br><br>Int2: Armband alone<br>Diet: adopt healthful eating pattern<br>PA: Increase PA+armband<br>Behavior: self-monitoring of daily meal, lifestyle activity, and emotion/mood+real-time feedback on energy expenditure, minutes spent in moderate and vigorous PA, and steps/d<br><br>Int3: Group-based behavioral wt loss program alone<br>Diet: Same as Int1+emphasis on wt loss<br>PA: Same as Int1<br>Behavior: Same as Int1+weekly weigh-in and coach-directed sessions for wt loss support and maintenance<br><br>Int4: Self-directed wt loss program following an evidence-based manual<br>Diet: Adopt healthful eating pattern<br>PA: Increase PA<br>Behavior: Self-monitoring of daily meal, lifestyle activity, and emotion/mood | Bodymedia armband with a real-time wrist watch display and a personalized wt management solutions<br>Web account      | Duration: 9 mo<br><br>Contacts:<br>Int1: Same as Int2 and Int3<br>Int2: Real time when participants uploaded armband and recorded daily energy intake and body wt to the Web site<br>Int3: 14 weekly group sessions during the first 4 mo; 6 1-on-1 phone counseling sessions during the final 5 mo<br>Int4: 1 Self-directed wt loss manual<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Health coach+automated<br>Int2: Automated<br>Int3: Health coach<br>Int4: NA | ITT (how handled missing data NR)<br>Baseline:<br>Wt, kg, M (SE):<br>Int1: 100.32 (2.97)<br>Int2: 101.15 (2.95)<br>Int3: 101.84 (2.95)<br>Int4: 102.22 (2.97)<br>NSD among 4 groups<br><br>4 mo:<br>Wt, kg, M (SE):<br>Int1: 96.83 (2.99)<br>Int2: 98.48 (2.97)<br>Int3: 100.74 (2.99)<br>Int4: 101.23 (3.03)<br>P=NR<br><br>9 mo:<br>Wt, kg, M (SE):<br>Int1: 93.73 (2.99)<br>Int2: 97.60 (2.99)<br>Int3: 99.98 (3.00)<br>Int4: 101.32 (3.05)<br>Int1 vs Int4: P=0.04<br>Int2 or Int3 vs Int4: P=NR |
| Burke et al, <sup>77</sup> 2012;<br>Burke et al, <sup>78</sup> 2011<br>Design: 3-group RCT<br>Outcome: % wtΔ at 6 and 24 mo<br>Setting: Community/academic center<br>Country: United States | N=210<br>Int1: n=68<br>Int2: n=70<br>Int3: n=72<br><br>Mean age (SD):<br>46.8 (9.0) y<br><br>Women: 84.8%<br><br>White: 78.1%<br><br>Median BMI (IQR):<br>33.09 (6.89) kg/m <sup>2</sup>   | Int1: PDA only<br>Diet: 1200–1800/d calorie goal based on wt and sex; ≤25% of total calories from fat<br>PA: Increase by 30 min semiannually to 180 min by 6 mo<br>Behavior: Self-monitoring with PDA  | PDA with dietary and PA self-monitoring program, daily remotely delivered feedback message in real time to Int2 group | Duration: 24 mo<br><br>Contacts:<br>Int1: Weekly group sessions for months 1–4, biweekly for months 5–12, and monthly for months 13–18, 1 session during the last 6 mo<br>Int2: Same as Int1<br>Int3: Same as Int1   | ITT (0.3 kg/mo was added to previous observation)<br>6 mo:<br>% wtΔ, %, M (SD):<br>Int1: –4.88% (6.20)<br>Int2: –6.58% (6.77)<br>Int3: –4.59% (5.66)<br>NSD<br><br>24 mo:<br>% wtΔ, %, M (SD):<br>Int1: –1.18% (8.78)<br>Int2: –2.17% (7.04)<br>Int3: –1.77% (7.23)<br>NSD   |

(Continued)

Table 2. Continued

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components  | Technology Used          | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)  |
|--|--|--|--------------------------|---|--|
|  | Retention:<br>Int1: 86.8%<br>Int2: 84.3%<br>Int3: 86.1%  | Int2: PDA with daily tailored feedback message<br>Diet: Same as Int1<br>PA: Same as Int1<br>Behavior: Self-monitoring with PDA and receiving automated daily feedback on calories or fat intake.<br><br>Int3: Paper diary<br>Diet: Same as Int1<br>PA: Same as Int1<br>Behavior: Self-monitoring with paper diary and a nutritional reference book   |                          | Intervention adherence:<br>≥30% adherent to dietary self-monitoring at 18 mo<br>Int1: 19%–20%<br>Int2: 19%–20%<br>Int3: 8%<br><br>Interventionist:<br>Int1: Dietitians and exercise physiologists<br>Int2: Dietitians and exercise physiologists+automated<br>Int3: Dietitians and exercise physiologists   |  |
| Shapiro et al, <sup>79</sup> 2012<br>Design: 2-group RCT<br>Outcome: % wtΔ<br>Setting: Community<br>Country: United States   | N=170<br>Int1: n=81<br>Int2: n=89<br><br>Mean age (SD):<br>41.9 (11.8) y<br><br>Women: 65%<br><br>White: 64%<br><br>BMI:<br>Int1: 32.4 (4.2) kg/m <sup>2</sup><br>Int2: 32.0 (4.0) kg/m <sup>2</sup><br><br>Retention:<br>Int1: 79%<br>Int2: 89%   | Int1: e-newsletter+SMS and MMS+Web site<br>Diet: 500 kcal/d reduction goal<br>PA goal: 12 000 steps/d with a gradual increase of 750 steps/wk, then encourage increase PA time or walk at a faster pace<br>Behavior: Self-monitoring daily step count and weekly wt, automated personalized feedback on progress via mobile phone, accessing health tips, recipes, food and PA logs, wt chart on a Web site<br><br>Int2: e-newsletter control<br>Diet: Same as Int1 from e-newsletters only<br>PA: Same as Int1 from e-newsletters only<br>Behavior: No intervention | Mobile phone SMS and MMS | Duration: 12 mo<br><br>Contacts:<br>Int1: SMS and MMS 4 times/d, monthly e-newsletters<br>Int2: Monthly e-newsletters<br><br>Intervention adherence:<br>Responses to SMS:<br>Int1: knowledge testing questions: 60%, the first pedometer steps questions: 51%, and the first wt questions: 55%<br>Int2: NA<br><br>Interventionist:<br>Int1: Automated<br>Int2: NA | Imputation via MICE<br>At 6 mo (primary):<br>wtΔ, lb, M (SE):<br>Int1: -3.72 lb (9.37)<br>Int2: -1.53 lb (7.66)<br>P=0.110<br><br>12 mo (secondary):<br>wtΔ, lb, M (SE):<br>Int1: -3.64 lb (12.01)<br>Int2: -2.27 lb (9.39)<br>P=0.246 |
| Turner-McGrievy and Tate, <sup>80</sup> 2011, Turner-McGrievy et al, <sup>81</sup> 2013<br>Design: 2-group RCT<br>Outcome: wtΔ<br>Setting: Community<br>Country: United States | N=96<br>Int1: n=47<br>Int2: n=49<br><br>Mean age (SD):<br>Int1: 42.6 (10.7) y<br>Int2: 43.2 (11.7) y<br><br>Women:<br>Int1: 77%<br>Int2: 73%<br><br>White:<br>Int1: 75%<br>Int2: 78%<br><br>BMI:<br>Int1: 32.9 (4.8) kg/m <sup>2</sup><br>Int2: 32.2 (4.5) kg/m <sup>2</sup><br><br>Retention:<br>Int1: 89%<br>Int2: 90% | Int1: Podcast+mobile group<br>Diet: Reduction of ≥500 kcal/d, decrease dietary fat to <30% of total energy, limit added sugar, increase fruit and vegetable consumption<br>PA: Goal minimum of 30 min/d of moderate to vigorous PA by week 4<br>Behavior: Same as Int2+self-monitoring diet, PA using mobile app, social support group members via Tweets app  | App on mobile phone      | Duration: 6 mo<br><br>Contacts:<br>Int1: Same as Int2+daily contacts with coaches and group members via mobile app<br>Int2: 2 15-min podcasts/wk for 3 mo, 2 mini-podcasts/wk for 3 mo<br><br>Intervention adherence:<br>Podcasts (n=24) downloaded, %:<br>0–3 mo:<br>Int1: 68%<br>Int2: 60.4%<br>4–6 mo:<br>Int1: 37.5%<br>Int2: 34.1%                           | ITT (BOCF)<br>3 mo:<br>% wtΔ, %, M (SD):<br>Int1: -2.6% (3.5)<br>Int2: -2.6 % (3.8)<br>NSD<br><br>6 mo (primary):<br>% wtΔ, %, M (SD):<br>Int1: -2.7% (5.6)<br>Int2: -2.7% (5.1)<br>NSD  |

(Continued)

Table 2. Continued

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BMI, Study Retention   | Study Groups and Components  | Technology Used                 | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)   |
|--|---|--|---------------------------------|---|---|
|  |   | Int2: Podcast group<br>Diet: Same as Int1<br>PA: Same as Int1<br>Behavior: overcoming barriers and problem solving, self-monitoring diet using book with calorie and fat gram content  |                                 | % Adherence to self-monitoring diet:<br>0–3 and 4–6 mo:<br>Int1: 41.4% and 24.3%<br>Int2: 34.3% and 18.6%<br>Percent adherence to recording PA:<br>0–3 and 4–6 mo:<br>Int1: 34.3% and 21.4%<br>Int2: 37.1% and 22.8%<br><br>Interventionist type:<br>Int1: Study coordinator<br>Int2: NA  |   |
| Carter et al, <sup>82</sup> 2013<br>Design: 3-group RCT<br>Secondary outcome: wtΔ, BMIΔ, %body fatΔ<br>Setting: Community<br>Country: United Kingdom | N=128<br>Int1: n=43<br>Int2: n=42<br>Int3: n=43<br><br>Mean age (SD):<br>Int1: 41.2 (8.5) y<br>Int2: 41.9 (10.6) y<br>Int3: 42.5 (8.3) y<br><br>Women: 77.3%<br><br>White:<br>Int1: 100%<br>Int2: 92.9%<br>Int3: 83.3%<br><br>BMI:<br>Int1: 33.7 (4.2) kg/m <sup>2</sup><br>Int2: 34.5 (5.6) kg/m <sup>2</sup><br>Int3: 34.5 (5.7) kg/m <sup>2</sup><br><br>Retention:<br>Int1: 93%<br>Int2: 55%<br>Int3: 53% | Int1: Apps on mobile phone+SMS+Internet forum (for social support)<br>Diet: NR<br>PA: NR<br>Behavior: Wt loss goal setting, self-monitoring daily calorie intake, PA, and wt, instant or weekly feedback via SMSs to enhance self-efficacy and reinforce positive behaviors<br><br>Int2: Web site+Internet forum (for social support)<br>Diet: NR<br>PA: NR<br>Behavior: Goal setting and self-monitoring<br><br>Int3: Paper diary+Internet forum (for social support)<br>Diet: NR<br>PA: NR<br>Behavior: Goal setting and self-monitoring | App on mobile phone, SMS        | Duration: 6 mo<br><br>Contacts:<br>Int1: Instant and weekly<br>Int2: No intervention contact<br>Int3: No intervention contact<br><br>Intervention adherence:<br>Mean days of dietary self-monitoring:<br>Int1: 92 (67)<br>Int2: 35 (44)<br>Int3: 29 (39)<br>P<0.001<br><br>Interventionist type:<br>Int1: Automated<br>Int2: NA<br>Int3: NA | ITT (BOCF)<br>6 mo (not powered to detect significance):<br>wtΔ, kg, M (95% CI):<br>Int1: -4.6 (-6.2 to -3.0)<br>Int2: -1.3 (-2.7 to 0.1)<br>Int3: -2.9 (-4.7 to -1.1)<br>Int1 vs Int2: P<0.05; Int1 vs Int3: P=0.12<br><br>BMI Δ, kg/m <sup>2</sup> , M (95% CI):<br>Int1: -1.6 (-2.2 to -1.1)<br>Int2: -0.5 (-0.9 to 0.0)<br>Int3: -1.0 (-1.6 to -0.4)<br>P=NR<br><br>% Body fat Δ, %, M (95% CI):<br>Int1: -1.3 (-1.7 to -0.8)<br>Int2: -0.5 (0.9 to 0.0)<br>Int3: -0.9 (-1.5 to -0.4)<br>P=NR |
| Napolitano et al, <sup>83</sup> 2013<br>Design: 3-group RCT<br>Outcome: wtΔ<br>Setting: Academic setting<br>Country: United States                   | N=52<br>Int1: n=17<br>Int2: n=18<br>Int3: n=17<br><br>Mean age (SD):<br>20.5 (2.2) y<br><br>Women: 86.5%<br><br>White: 57.7%<br>Black: 30.8%<br>Hispanic: 5.8%<br>Asian: 1.9%<br><br>BMI: 31.36 (5.3) kg/m <sup>2</sup>   | Int1: Facebook<br>Diet: Calorie target based on wt<br>PA: Target ≥ 250 min of mod intensity exercise per week<br>Behavior: Self-monitoring, planning, stress management, social support, special occasion tips, relapse prevention   | Mobile phone, SMS, social media | Duration: 8 wk<br><br>Contacts:<br>Int1: 8 weekly Facebook sessions<br>Int2: Same as Int1, daily SMSs<br><br>Intervention adherence:<br>Responses to SMS<br>Int1: NA<br>Int2: Self-monitoring SMS 68.5%, general monitoring SMS 79.8%<br>Int3: NA   | ITT (ways to deal with missing data NR)<br>4 wk:<br>wtΔ, kg, M (SD):<br>Int1: -0.46 kg (1.4)<br>Int2: -1.7 kg (1.6)<br>Int3: 0.28 kg (1.7)<br>P≤0.01<br>Post hoc contrasts showed Int2 was significantly different from Int1 (P<0.05) and Int3 (P≤0.001)  |

(Continued)



Table 2. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components  | Technology Used | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)   |
|---|--|--|-----------------|--|---|
|   | Retention:<br>Int1: 100%<br>Int2: 89%<br>Int3: 100%  | Int2: Facebook+SMS and personalized feedback<br>Diet: Same as Int1<br>PA: Same as Int1<br>Behavior: Same as Int1, sent self-monitoring data via SMS, received daily SMS on self-monitoring of calorie, PA, and wt goals, received weekly summary reports via Facebook link, and selected a buddy for support<br><br>Int3: Wait list control<br>No intervention   |                 | Interventionist type:<br>Int1: NA<br>Int2: Automated<br>Int3: NA   | 8 wk (primary):<br>wtΔ, kg, M (SD):<br>Int1: -0.63 kg (2.4)<br>Int2: -2.4 kg (2.5)<br>Int3: -0.24 kg (2.6)<br><i>P</i> <0.05<br>Post hoc contrasts showed Int2 was significantly different from Int1 ( <i>P</i> <0.05) and Int3 ( <i>P</i> <0.05)   |
| Spring et al, <sup>84</sup> 2013<br>Design: 2-group RCT<br>Outcome: wtΔ<br>Setting: Veterans Affairs medical center<br>Country: United States | N=70<br>Int1: n=35<br>Int2: n=35<br><br>Mean age (SD):<br>57.7 (11.9) y<br><br>Women: 14.5%<br><br>White: 69.6%<br>Minorities: 30.4%<br><br>BMI:<br>Int1: 36.9 (5.4) kg/m <sup>2</sup><br>Int2: 35.8 (3.8) kg/m <sup>2</sup><br><br>Retention:<br>Int1: 83%<br>Int2: 80% | Int1:<br>Standard+connective mobile technology system<br>Diet: Same as Int2, calorie reduction was wt loss based.<br>PA: Same as Int2, goal=60 min/d of mod-intensity PA with 25% increase if previous goal met<br>Behavior: Wt loss phase (1–6 mo): Same as Int2, self-monitoring and regulating food intake and PA using PDA daily first 2 wk, then weekly until 6 mo, personalized feedback from coach every 2 wk via 10–15 min phone call; Maintenance phase (7–12 mo): Same as Int2, recorded and transmitted data biweekly during 7–9 mo and 1 wk/mo during 10–12 mo<br><br>Int2: Standard of care<br>Diet: 18 MOVE! group sessions<br>PA: 18 MOVE! sessions<br>Behavior: Wt loss phase (1–6 mo): 12 bi-weekly MOVE! sessions, self-monitoring encouraged; Maintenance phase (7–12 mo): 6 monthly MOVE! support group sessions | PDA             | Duration: 12 mo<br><br>Contacts:<br>Int1: Biweekly group sessions in months 1–6, monthly sessions in months 7–12<br>Int2: Same as Int1<br><br>Intervention adherence:<br>Mean number of MOVE! sessions attended<br>Int1: 6.2 (34%) of 18 sessions<br>Int2: 5.9<br><i>P</i> =0.54<br>Mean (SD) number of treatment calls received by Int1:<br>8.9 (2.8)<br><br>Interventionist type:<br>Int1: Dietitians, psychologists, or physicians<br>Int2: Dietitians, psychologists, or physicians+paraprofessional coach | ITT, ways to deal with missing data NR<br>3 mo:<br>wtΔ, kg, M (95% CI):<br>Int1: -4.4 kg (-2.7 to -6.1)<br>Int2: -0.86 kg (-0.04 to -1.8)<br><i>P</i> <0.05<br>6 mo:<br>wtΔ, kg, M (95% CI):<br>Int1: -4.5 kg (-2.1 to -6.8)<br>Int2: -1.0 kg (0.7 to -2.5)<br><i>P</i> <.05<br>9 mo:<br>wtΔ, kg, M (95% CI):<br>Int1: -3.9 kg (-0.8 to -6.9)<br>Int2: -0.9 kg (1.1 to -2.9)<br><i>P</i> <.05<br>12 mo:<br>wtΔ, kg, M (95% CI):<br>Int1: -2.9 kg (-0.5 to -6.2)<br>Int2: -0.02 kg (2.1 to -2.1)<br>NS |

(Continued)

Table 2. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention | Study Groups and Components  | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist | Primary Outcome: Mean Weight Loss (kg, kg/m <sup>2</sup> , or % Change)   |
|---|---|--|-------------------|--|---|
| Systematic review and meta-analysis   |   |  |                   |  |   |
| Siopis et al, <sup>66</sup> 2014<br>Design: Meta-analysis of 6 RCTs<br>Outcome: Mean wtΔ<br>Setting: NR | N ranged from 51–927<br>Retention: 47%–96%                        | Int1: SMS<br>Int2: Group session diet/exercise intervention or no intervention | Mobile phone, SMS | Duration: 8 wk–12 mo<br>Intervention adherence: NR   | Pooled wtΔ, kg, M (95%CI)<br>Int1: –2.56 (–3.46 to –1.65)<br>Int2: –0.37 (–1.22 to –0.48)<br><br>Meta-regression results:<br>Int mean wt Δ 2.17 kg higher than Int2 group (95% CI, –3.41 to –0.93; P=0.001) |

Automated indicates without a clinician who generates, tailors, or modifies the output; BMI, body mass index; BOCF, baseline observation carried forward; CI, confidence interval; Δ, change or difference; Int, intervention group; IQR, interquartile range; ITT, intention to treat; LOCF, last observation carried forward; M, mean; MICE, multivariate imputation by chained equations; MMS, multimedia messaging service; n, subgroups; N, total sample; NA, not applicable; NR, not reported; NS, not significant; NSD, not significantly different; P, participant; PA, physical activity; PDA, personal digital assistant; RCT, randomized control trial; SMS, short message service; and wt, weight.

Two adult RCTs were conducted outside the United States (Table 2). The 6-month UK study<sup>82</sup> compared a self-directed smartphone app for goal setting and self-monitoring plus automated tailored feedback via text messaging with a Web site control and a paper diary control. Compared with the 2 other groups, the smartphone group achieved significantly greater mean weight loss at 6 months. The 1-year Finnish study<sup>73</sup> was the only mobile technology intervention reviewed in the 2013 AHA/ACC/TOS obesity treatment guideline. It tested a weight loss intervention via text messaging for instructions, self-monitoring, and automated personalized feedback versus a no-intervention control group among overweight or obese adults. Although none of the US adult studies reported positive findings beyond 9 months, the Finnish study showed that a text messaging intervention could result in significantly greater weight loss than no intervention up to 12 months (ie, intermediate term).

Also included in Table 2 is the only meta-analysis<sup>66</sup> to date that has focused on text messaging interventions for weight loss that showed that the pooled mean weight change was significantly better in intervention participants than in the control conditions. However, both the intervention and control subgroups were heterogeneous, and the funnel plot suggested a possible publication bias.

Khaylis and colleagues<sup>69</sup> identified 5 key components to efficacious technology-based weight loss interventions: use of a structured program, self-monitoring, feedback and communication, social support, and individual tailoring. These components found in the mobile technology interventions were shown to produce greater weight loss than in a randomized control group, although the extent and nature of the implementation of each component varied across studies. Additionally, all of the effective mobile interventions focused on calorie-reduced healthy eating, increased physical activity, and behavior change, which is consistent with the 2013 AHA/ACC/TOS guideline recommendation for comprehensive behavioral weight loss interventions.<sup>57</sup> Evidence from the reviewed RCTs suggests that these technologies may be effective when used

alone or in conjunction with traditional weight loss intervention delivery modalities (eg, telephonic coach feedback, in-person group sessions, Web sites) to achieve modest weight loss of clinical significance in the short term.

#### Recommendations for Consumers and Healthcare Practitioners

During the past decade, the mHealth field has made great strides developing efficacious mobile weight loss approaches. Indeed, mobile interventions can produce weight loss in motivated populations, albeit at a lower magnitude relative to traditional treatment approaches. The characteristics of successful mobile interventions are quite comparable to those of their offline counterparts: The largest weight losses are produced by comprehensive, multicomponent interventions that are personally tailored, promote regular self-monitoring, and involve a qualified interventionist.<sup>69</sup> The accumulated evidence, although limited, supports intervention delivery through a range of technology channels (including the Web, SMS, e-mail, telephone, and IVR), with limited variability in the magnitude of weight loss outcomes.

Standard behavioral weight loss treatment is delivered by a trained healthcare professional to promote calorie-controlled healthy eating, increased physical activity, and behavior change in in-person group or individual sessions of a prescribed frequency and duration. It is encouraging that sufficient evidence derived mainly from studies of Internet-, e-mail-, and telephone-based interventions has accrued to buttress the 2013 AHA/ACC/TOS obesity treatment guideline recommending electronically delivered comprehensive weight loss programs encompassing personalized coach feedback as an acceptable, albeit possibly less effective, alternative to standard in-person treatment.

Our review finds that self-monitoring and automated personalized feedback are common features in the contemporary mobile weight loss interventions. On the basis of consistent findings from multiple RCTs of fair and good quality, the evidence is strong for short-term weight loss benefits in adults

from text messaging interventions for self-monitoring and feedback when supported by other methods (coach telephone calls, Web sites, or private peer groups via social media)<sup>74,83</sup> or incorporated into an existing comprehensive lifestyle program,<sup>84</sup> with some evidence suggesting sustained intervention effectiveness through 12 months.<sup>57</sup> Importantly, there is no evidence to suggest that SMSs as a stand-alone intervention are effective. One RCT in the United Kingdom showed the effectiveness of a self-directed smartphone app as a stand-alone intervention in overweight and obese adults,<sup>82</sup> although the translatability of the results to US adults is unclear as a result of a lack of research.

Until more evidence emerges, health practitioners looking to implement or recommend mHealth interventions to their overweight and obese patients should ensure that the programs and tools they recommend include established evidence-based content and components of a comprehensive lifestyle intervention (ie, calorie-controlled healthy eating and increased physical activity with specified goals and behavioral strategies) and facilitate adoption of evidence-based weight loss behaviors (eg, self-monitoring, personalized feedback, and social support from coaches or peers). In the context of these programs, mobile technologies, particularly SMS/multimedia messaging service messaging and smartphone apps, may be the primary intervention modality when supported by other methods (Web sites or telephone calls). At present, no recommendations can be made for US consumers on the effectiveness of text messaging as a stand-alone intervention for weight loss or the effectiveness of any particular smartphone app.

### **Gaps and Recommendations for Future Research**

There is great need for studies that explore mobile interventions in diverse contexts, particularly general consumer samples, and in clinical practice settings. Although great strides have been made, we do not have an answer to the question that consumers are most likely to ask: Are commercial mobile weight loss apps efficacious? We know little about the efficacy of the >1000 apps that purport to help consumers lose weight. Moreover, few, if any, research-tested apps have been widely disseminated or commercialized. Academic-industry partnerships are needed from the intervention development stage to formative evaluation to confirmatory research and then to dissemination and implementation.

The research literature investigating mobile weight loss interventions remains in its infancy, with many important questions yet to be answered. Indeed, we know little about how to best integrate mobile interventions into the primary care setting, where they might serve as adjuncts to weight loss counseling delivered by primary care or other providers such as dietitians or nurses. There are potentially significant opportunities to explore the integration of mobile technologies, given health system changes associated with the Affordable Care Act and the 2011 Center for Medicare and Medicaid Services decision to reimburse qualified providers for delivering intensive behavioral treatment for obesity. We need to also expand the range of populations that have been studied. Thus far, we know the least about those populations with the highest obesity rates and those who bear the greatest burden of obesity-associated disease: racial/ethnic minorities and the

socioeconomically disadvantaged.<sup>85</sup> This fails to deliver on the promise of digital health approaches, which have potential for extending the reach of intervention approaches. Despite their higher levels of mobile phone ownership and use,<sup>28,86</sup> early evidence suggests that high-risk populations experience suboptimal weight losses,<sup>85</sup> as is often observed with traditional treatment approaches.

More work is necessary to assess and improve the magnitude of weight loss outcomes produced by mobile interventions and long-term maintenance of weight loss. A particular priority is identifying strategies to promote sustained user engagement. Indeed, across a large number of studies, weight loss outcomes have been shown to be dependent largely on the level of participant engagement.<sup>63,72</sup> Unfortunately, declining engagement and attrition (often as high as 40%–50%) are characteristic of digital health interventions.<sup>87</sup> Mobile interventions developed in research settings might benefit from leveraging the iterative design and testing conventions that are commonly used in the commercial market to promote user engagement. Furthermore, the most successful trials have combined interventionist support with a mobile intervention. We know much less about the efficacy of stand-alone mobile interventions, those that have the greatest potential for broad dissemination.

At present, there is considerable variability in the technologies, intervention components, design, and delivery schedules of mobile interventions. We know little about which technologies or intervention components, or combinations thereof, are best equipped to produce clinically meaningful weight loss. There does not appear to be substantial variability in the magnitude of weight loss outcomes in the mHealth approaches we reviewed. We have identified the following gaps and directions for future research:

- The applications of mobile technology for weight loss have been limited in conceptualization and narrow in implementation. Future mobile technology weight loss interventions should build on the best evidence of the efficacious core components of comprehensive lifestyle programs.
- Text messaging has been the primary delivery format researched to date; however, it is only one of a growing number of mobile delivery formats (eg, smartphone apps, wearable sensors that synchronize data with smartphones). We need to address the many pitfalls in the current mHealth approaches, for example, the absence of a theoretical basis, limited application of the best practices in technology design, low use of empirically supported behavioral strategies, and limited scientific rigor, by engaging in transdisciplinary collaboration and inclusion of the end users, the clinicians and patients, in all phases from the intervention development to implementation.
- Mixed methods research should be used to elucidate the frequency, timing and duration of various mobile delivery formats that can enhance the usability and acceptability of technology.
- Future work needs to focus on comparative effectiveness research using alternative designs, for example, equivalence and noninferiority trials. In addition, we need to use more flexible study designs that are able to provide

answers within a shorter time frame than the conventional 5-year clinical trial when testing a delivery mode that will become obsolete before the end of the trial.<sup>88</sup>

- Finally, we need to capitalize on the currently available technologies that permit collection and transmission of data in real time to better learn about the behaviors and moods of individuals in their natural setting, referred to as ecological momentary assessment, which can inform the development of interventions that can be delivered in real time and thus provide support when individuals are in need of it.<sup>89,90</sup>

### Use of mHealth Interventions to Increase Physical Activity

Regular physical activity is important in improving cardiovascular health. The Centers for Disease Control and Prevention, the American College of Sports Medicine, and the AHA recommend that adults participate in  $\geq 30$  minutes of moderate-intensity physical activity on most days of the week.<sup>91</sup> According to the 2008 Physical Activity Guidelines for Americans,<sup>92</sup> adults should avoid inactivity or extended periods of sedentary activity, do at least 150 minutes of moderate-intensity activity weekly, and do muscle-strengthening activities on at least 2 d/wk.<sup>93</sup> Sustained physical activity has many health benefits such as decreasing the risk for premature death, T2DM, stroke, some forms of cancer, osteoporosis, and depression.<sup>94</sup> There is sufficient evidence that physical activity can help reduce CVD risk factors such as high BP.<sup>94</sup>

Physical activity in the United States has significantly declined over the past 2 decades. Since the late 1980s, the proportion of adult women who report no leisure-time activity has increased from 19.1% to 51.7%, and the proportion of adult men reporting no leisure-time activity rose from 11.4% to 43.5%.<sup>95</sup> The participation in leisure-time activity is lowest in blacks, with  $>55\%$  not meeting the guidelines, followed by those identifying as Hispanic or Latino, with  $>54\%$  not meeting guidelines.<sup>96</sup> More than 66% of those who have not completed high school do not meet the 2008 Physical Activity Guidelines for Americans.<sup>96</sup>

#### Review of Evidence for the Efficacy of Mobile Technology–Based Interventions to Promote Physical Activity

We searched PubMed using the terms *physical activity*, *physically active*, *walk*, *aerobic*, *sport*, *lifestyle*, and *sedentary*. The literature search yielded 1490 studies. Of these, 1415 were excluded after review of title ( $n=797$ ), abstract ( $n=528$ ), or full text ( $n=122$ ). Of the 122 that did not qualify on the basis of full text review, articles were excluded for the following reasons: 44 were focused on diabetes mellitus, 39 were focused on weight loss, and 41 did not meet RCT criteria. Therefore, 41 articles were eligible for the present review: 12 were literature reviews of physical activity for CVD prevention, 15 were studies validating technology, and 14 were RCTs that are detailed in Table 3. The literature search yielded studies reporting numerous types of technology that can be used for increasing physical activity: texting or SMS messaging on mobile phone ( $n=3$ ), pedometer ( $n=1$ ), e-mail ( $n=1$ ), and Internet ( $n=9$ ). Several studies included a combination of technologies.

Nine of the 14 studies reported significant increases in physical activity in the intervention group compared with the control

condition.<sup>98, 97,100–103,106,107,109</sup> Overall, the technology that was used most often to increase physical activity was the Internet through Web sites, online tutorials, or networking opportunities. Many of the programs that used the Internet also used other forms of technology, including pedometers and feedback messages via e-mail. Of the 9 studies that used the Internet as the main intervention component, 5 reported significant differences between groups in increasing physical activity.<sup>98,100,102,106,107</sup> The outcomes differed in each study and included increases in step counts, increases in moderately vigorous physical activity, increases in moderate physical activity, and increases in minutes per week of physical activity. Two of the 14 studies examined the use of SMS,<sup>103,109</sup> and both reported significant differences between the intervention and control or comparative conditions.<sup>103,109</sup> Two additional studies reported testing the use of messages, either through a PDA or e-mail, and found significantly greater increases in physical activity in the intervention group compared with the control or nonintervention group.<sup>97,101</sup>

A systematic review of 26 studies published in 2014 by Bort-Roig et al<sup>111</sup> examined the use of smartphones to influence physical activity. Only 5 studies in the review assessed interventions for physical activity, and 4 reported an increase in steps per day. However, the studies were limited by small samples, with only 1 study having a sample size  $>50$ . A systematic review of 11 studies by Buchholz et al<sup>112</sup> in 2013 reported that  $<10$  RCTs using SMS to target physical activity had been conducted across 7 countries and found that a small number of studies had examined the use of SMS for promotion of physical activity. The median effect size for differences in change scores between intervention and control groups for the studies was 0.50 but ranged from 0.20 to  $>1.00$ . The review noted that there was no evidence to suggest why there were such vast differences in the effect size.<sup>112</sup>

One area that is growing in acceptance among consumers is active video gaming or exergaming. The studies using this technology had some methodological limitations and thus were not included in this review. However, a systematic review by Peng et al<sup>113</sup> reported that laboratory studies have demonstrated that this technology is capable of providing light to moderate physical activity. However, only 3 studies in that review supported gaming as an effective tool to significantly increase physical activity or exercise attendance.

Most mobile technology interventions that have been reported in the published literature allow users to self-monitor physical activity by manually entering exercise bouts or total accumulated activity. However, more technologically sophisticated approaches for physical activity monitoring are rapidly becoming widely available. Physical activity tracking devices, also referred to as wearables, have become highly prevalent among consumers for self-monitoring daily activity. Most of these devices include accelerometers that capture users' duration and intensity of physical activity.<sup>114</sup> Some devices also include global positioning service (GPS) functionality that can capture the location of exercise sessions. Originally designed to be worn on the hip, wearables can now be placed comfortably in a range of locations (wrist, ankle, arm, shoe). The majority of current smartphones also include accelerometers and gyroscopes, allowing them to provide functionality similar to wearable devices. A host of third-party software

**Table 3. Description of Studies Using mHealth for Enhancing Physical Activity**

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention   | Study Groups and Components  | Technology Used                                      | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome   |
|---|---|--|--|--|---|
| Plotnikoff et al, <sup>97</sup> 2005<br>Design: 2-group<br>Outcome: Mets/min<br>Setting: Workplace<br>Country: Canada   | N=2121<br>Int1: n=1566<br>Int2: n=555<br>Mean age (SD):<br>Int1: 44.9 (6.2) y<br>Int2: 45.0 (6.4) y<br>Women: 73.5%<br>White: NR<br>Mean BMI (SD):<br>Int1: 27.2 (5.7) kg/m <sup>2</sup><br>Int2: 27.0 (5.7) kg/m <sup>2</sup><br>Retention: NR | Int1: Received 1 PA and 1 parallel nutrition message per week for 12 wk<br>Int2: Received no weekly messages   | E-mail   | Duration: 12 wk<br>Contacts: Int group received a total of 24 messages over the 12 wk<br>Intervention adherence: NR<br>Interventionist:<br>Int1: NR<br>Int2: NR  | Completer's analysis (n=2074)<br>12 wk:<br>PA, mean MET/min:<br>Int1: 683.68<br>Int2: 592.66<br>P<0.01  |
| Hurling et al, <sup>98</sup> 2007<br>Design: Randomized, stratified, controlled trial<br>Outcome: Δ in MPA (METs/wk)<br>Setting: Community<br>Country: United Kingdom | N=77<br>Int1: n=47<br>Int2: n=30<br>Mean age (SD):<br>Int1: 40.5 (7.1) y<br>Int2: 40.1 (7.7) y<br>Women: 66%<br>Mean BMI (SD):<br>Int1: 26.2 (2.8) kg/m <sup>2</sup><br>Int2: 26.5 (4.1)kg/m <sup>2</sup><br>Retention: 100%                    | Int1: 9 wk of tailored solutions for barriers, mobile phone and e-mail reminders to exercise, message board, real-time feedback via Internet<br>Int2: Verbal advice on recommended PA levels | Internet, mobile device, e-mail                      | Int lasted 9 wk<br>Study duration: 12 wk<br>Contacts:<br>Int1: Not specified<br>Intervention adherence: 85% of Int1 Ps logged onto Web site in first 4 wk, 75% logged in during the past 5 wk. Only 33% of participants accessed all components of the system<br>Interventionist:<br>Int1: Automated<br>Int2: NR | ITT, ways to deal with missing data NR<br>12 wk:<br>Accelerometer data, MPA, METs/wk, M (SE):<br>Int1: 5.39 (0.01)<br>Int2: 5.34 (0.01)<br>P=0.02                                 |
| Spittaels et al, <sup>99</sup> 2007<br>Design: 3-group RCT<br>Outcome: Total PA<br>Setting: Workplace<br>Country: Belgium   | N=526<br>Int1: n=174<br>Int2: n=175<br>Int3: n=177<br>Mean age (SD):<br>39.5 (8.5) y<br>Women: 31%<br>White: NR<br>Mean BMI (SD):<br>24.4 (3.3) kg/m <sup>2</sup><br>Retention: 72%   | Int1: Online tailored PA advice+stage-based reinforcement e-mails<br>Int2: Online-tailored PA advice only<br>Int3: Online nontailored standard PA advice                                     | Internet, e-mail                                     | Duration: 6 mo<br>Contacts:<br>Online-tailored PA advice+e-mail group received 5 e-mails over 8 wk<br>Intervention adherence: Int1 group, 77% of Ps read the e-mails they received<br>Interventionist:<br>Int1: NR<br>Int2: NR<br>Int3: NR   | Completer's analysis (n=379)<br>6 mo:<br>Total PA, min/wk, M (SD):<br>Int1: 776 (540)<br>Int2: 682 (452)<br>Int3: 708 (514)<br>NSD  |
| Dunton and Robertson, <sup>100</sup> 2008<br>Design: 2-group RCT<br>Outcome: Δ in walking time and MVPA<br>Setting: Community<br>Country: United States               | N=156<br>Int1: n=85<br>Int2: n=71<br>Mean age (SD):<br>Int1: 42.8 (12.8) y<br>Int2: 42.8 (10.5) y<br>Women: 100%<br>White: 65%<br>Retention: 85%  | Int1: Individually tailored PA plans via Internet, strategies to overcome barriers via Internet, 10 weekly follow-up e-mails<br>Int2: Wait list  | E-mail, Internet (Web site, Women's Fitness Planner) | Duration: 3 mo<br>Contacts: 3 mo access to Web site, 10 weekly follow-up e-mail newsletters<br>Intervention adherence: Int1: 6% reported not receiving weekly e-mails, 23% opened all e-mails, 8% opened none; 8% visited the Web site >10 times   | ITT (MRCM, HGLM)<br>3 mo:<br>Δ in walking time, mean min/wk:<br>Int1: 69<br>Int2: 32<br>P=0.035 (1 tailed)<br>MVPA Δ, mean min/wk<br>Int1: +23<br>Int2: -25<br>P=0.045 (1 tailed) |

(Continued)

Table 3. Continued

| Study Cited, Design, Primary Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BMI, Study Retention   | Study Groups and Components   | Technology Used     | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome  |
|--|---|---|---------------------|---|--|
| King et al, <sup>101</sup> 2008<br>Design: 2-group RCT<br>Outcome: min/wk of PA<br>Setting: Community<br>Country: United States                      | N=37<br>Int1: n=19<br>Int2: n=18<br>Mean age (SD):<br>Int1: 60.7 (6.8) y<br>Int2: 59.6 (7.6) y<br>Women: 43%<br>White: 78.5%<br>Retention: 100%       | Int1: PDA programmed to monitor PA levels twice per day for 8 wk. Daily and weekly individualized feedback, goal setting, and support<br>Int2: Written PA educational materials   | PDA                 | Int2: 11% reported not receiving the weekly newsletters<br>Interventionist:<br>Int1: NR<br>Int2: NR<br>Duration: 8 wk<br>Contacts:<br>Int1: Daily contacts for 8 wk<br>Intervention adherence:<br>Int1 Ps completed an average of 68% of the PDA entries over the 8 wk<br>Interventionist:<br>Int1: NR<br>Int2: NR  | 8 wk<br>PA, min/wk, M (SD):<br>Int1: 310.6 (267.4)<br>Int2: 125.5 (267.8)<br>P=0.048   |
| Ferney et al, <sup>102</sup> 2009<br>Design: 2-group RCT<br>Outcome: min/wk of PA<br>Setting: Community<br>Country: Australia                        | N=106<br>Int1: n=52<br>Int2: n=54<br>Mean age (SD):<br>Int1: 51.7 (4.1) y<br>Int2: 52.2 (5.0) y<br>Women: 72%<br>White: NR<br>Retention: 88%          | Int1: Ps received access to a neighborhood environment-focused Web site, received tailored information for increasing PA through e-mails<br>Int2: Access to a motivational-information Web site, received nontailored e-mails       | E-mail and Internet | Duration: 26 wk<br>Contacts:<br>Both groups: received 11 e-mails over the 26 wk<br>Weeks 1-4: weekly e-mails<br>Weeks 5-12: biweekly e-mails<br>Weeks 13-26: monthly e-mails<br>Intervention adherence:<br>13% of Ps used the self-monitoring tool and 25% sent e-mail to the activity counselor in Int group<br>Interventionist:<br>Int1: NR<br>Int2: NR | ITT (BOCF)<br>26 wk:<br>Total PA $\Delta$ , mean min/wk:<br>Int1: +57.8<br>Int2: +13<br>Interaction effect:<br>P<0.05  |
| Fjeldsoe et al, <sup>103</sup> 2010<br>Design: 2-group RCT<br>Outcome: $\Delta$ in MVPA and walking time<br>Setting: Community<br>Country: Australia | N=88<br>Int1: n=45<br>Int2: n=43<br>Mean age (SD):<br>Int1: 28 (6) y<br>Int2: 31 (6) y<br>Women: 100%<br>Education level <10 y: 17%<br>Retention: 69% | Int1: A face-to-face PA goal-setting consultation, phone consultation, a goal-setting magnet, 3-5 personally tailored SMSs/wk, and a nominated support person who received SMSs each week<br>Int2: Face-to-face information session | SMS                 | Duration: 13 wk<br>Contacts:<br>Int1:<br>0 and 6 wk: face-to-face PA goal-setting consultation<br>42 tailored SMSs on behavioral and cognitive strategies:<br>Weeks 0-2: 5/wk<br>Weeks 3-4: 4/wk<br>Weeks 5-12: 3/wk<br>11 weekly goal check SMSs<br>Int2: No contact apart from reminder telephone calls to confirm 6- and 13-wk assessments             | ITT<br>13 wk:<br>$\Delta$ in MVPA duration, M (SE) min/wk:<br>Int1: 18.26 (24.94)<br>Int2: 16.36 (25.53)<br>P=0.26<br>$\Delta$ in walking duration, M (SE) min/wk:<br>Int1: 16.67 (13.33)<br>Int2: 0.34 (13.64)<br>P=0.005 |

(Continued)

Table 3. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components   | Technology Used       | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome  |
|---|--|---|-----------------------|--|--|
| Richardson et al, <sup>104</sup> 2010<br>Design: 2-group RCT<br>Outcome: Step count<br>Setting: Community<br>Country: United States | N=324<br>Int1: n=254<br>Int2: n=70<br>Mean age (SD): 52.0 (11.4) y<br>Women: 66%<br>White: 86%<br>Mean BMI (SD): 33.2 (6.2) kg/m <sup>2</sup><br>Retention: 76%  | All Ps wore pedometers and had access to individually tailored messages, weekly goals<br>Int1: Had access to post and read messages from other Ps<br>Int2: Had no access to message board | Internet, pedometers  | Intervention adherence:<br>13 wk: 84% of Int1 group meeting MVPA goal<br>10 wk: 24% response to SMS<br>6 wk: 64% of Int2 Ps remaining in the trial (n=36) reported reading the SMSs and then storing them, 33% reported reading the SMSs and then deleting them, and 1 P (3%) reported deleting the SMS without reading them<br><br>Interventionist:<br>Int1: Trained behavioral counselor+automated<br>Int2: Trained behavioral counselor | ITT (BOCF)<br>16 wk:<br>Step counts, steps/d,<br>M (SD):<br>Int1: 6575 (3127)<br>Int2: 5438 (2667)<br>P=0.20   |
| Aittasalo et al, <sup>105</sup> 2012<br>Design: 2-group RCT<br>Outcome: Δ in walking time<br>Setting: Community<br>Country: Finland | N=241<br>Int: n=123<br>Control: n=118<br>Mean age (SD):<br>Int1: 44.1 (9.4) y<br>Int2: 45.3 (9.1) y<br><br>Women:<br>Int1: 71%<br>Int2: 66%<br><br>BMI :<br>Int1: >25 kg/m <sup>2</sup> : 63%<br>Int2: >25 kg/m <sup>2</sup> : 76%<br>Retention: 77% | Int1: 1 group meeting, log-monitored pedometer use, 6 e-mail messages<br>Int2: No intervention  | Pedometers and e-mail | Duration: 12 mo<br>Contacts: 6-mo treatment duration, 1 e-mail/mo, pedometer use daily<br>Intervention adherence: 60% of Int Ps used pedometer regularly; 37% reported using pedometer irregularly for 6 mo<br>E-mails reached 99% of Ps, 80% reported reading the messages<br><br>Interventionist:<br>Int1: NR<br>Int2: NR  | Completer's analysis (n=164)<br>12 mo:<br>Total walking, min/wk,<br>M (SD):<br>Int: 521 (468)<br>Control: 395 (319)<br>P=NS<br><br>% of Ps walking stairs:<br>Int1: 88%<br>Int2: 86%<br>OR, 2.24 (95% CI, 0.94–5.31)<br><br>% of Ps walking for leisure:<br>Int1: 87%<br>Int2: 76%<br>OR, 2.07 (95% CI, 0.99–4.34) |

(Continued)



Table 3. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BMI, Study Retention  | Study Groups and Components  | Technology Used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome   |
|---|--|--|--|--|---|
| Reid et al, <sup>106</sup> 2012<br>Design: 2-group RCT<br>Outcome: steps/d; $\Delta$ in MVPA<br>Setting: Community<br>Country: Canada                 | N=223<br>Int1: n=115<br>Int2: n=108<br>Mean age (SD): 56.4 (9.0) y<br>Women: 16.7%<br>Mean BMI (SD): 29.3 (4.8) kg/m <sup>2</sup><br>Retention: 69%  | Int1: Personally tailored PA plan on discharge from the hospital, provided access to a secure Web site for activity planning and tracking, 5 online tutorials, and e-mail access with an exercise specialist<br>Int2: PA guidance from an attending cardiologist   | Internet   | Duration: 12 mo<br>Contacts: 5 online tutorials over a 6-mo period and e-mail contact with an exercise specialist for Int1 group<br>Intervention adherence: Mean No. of online tutorials completed by Int1 Ps: 2.7 of maximum of 5, 61.7% of Ps completed $\geq 3$ of 5 tutorials<br>37 Int1 Ps e-mailed exercise specialist $\geq 1$ time.<br>Interventionist:<br>Int1: Exercise specialist<br>Int2: Cardiologist | ITT (multiple imputation of missing values)<br>12 mo:<br>Step counts, steps/d, M (SD):<br>Int1: 7392 (3365)<br>Int2: 6750 (3366)<br>P=0.023<br>$\Delta$ in MVPA, min/wk, M (SD):<br>Int1: 201.4 (179.8)<br>Int2: 163.4 (151.3)<br>P=0.047 |
| Bickmore et al, <sup>107</sup> 2013<br>Design: 2-group RCT<br>Outcome: Steps/d<br>Setting: Community<br>Country: United States                        | N=263<br>Int1: n=132<br>Int2: n=131<br>Mean age (SD): 71.3 (5.4) y<br>Women: 61%<br>White: 37%<br>High school diploma or less: 51%<br>Retention: 86% | Int1: Mobile tablet computers with touch screens for 2 mo, directed to connect pedometers to tablet, interact with a computer-animated virtual exercise coach daily. Next 10 mo, given opportunity to interact with coach in a kiosk in clinic waiting room.<br>Int2: Pedometer that only tracked step counts for an equivalent period of time   | Internet via tablet with virtual exercise coach, pedometer | Duration: 12 mo<br>Contacts: Ps interact with coach in a clinic kiosk between months 2 and 10<br>Intervention adherence: Int1 group interacted with coach 35.8 (19.7) times during the 60-d intervention phase and accessed the kiosk an average of 1.0 (2.9) times during the 10-mo follow-up.<br>Interventionist:<br>Int1: NR<br>Int2: NR  | Completer's analysis (n=200)<br>2 mo:<br>Steps/d, M:<br>Int1: 4041<br>Int2: 3499<br>P=0.01<br>Completer's analysis (n=128)<br>12 mo:<br>Steps/d, M:<br>Int1: 3861<br>Int2: 3383<br>P=0.09   |
| Gotsis et al, <sup>108</sup> 2013<br>Design: Randomized, crossover design<br>Outcome: Days/week of PA<br>Setting: Community<br>Country: United States | N=142<br>Int1: n=64<br>Int2: n=43<br>Mean age (SD): 35.6 (9.5) y<br>Women: 67.6%<br>Asian: 18%<br>Hispanic: 28%<br>Retention: 61%                    | Int1: Diary+game group: additional features: (1) rewards, (2) virtual character, (3) choosing virtual locations for wellness activities, (4) collecting virtual items, (5) wellness animations by spending points, (6) virtual character wellness activities as updates<br>Int2: Diary group: (1) posting updates of PA, (2) private messages, (3) history posted, (4) viewing display of PA | Internet, social networking                                | Duration: 13 wk<br>Contacts: Follow-up visits at 5–8 and 10–13 wk<br>Intervention adherence: Ps accessed the Web site every other day, with the number of total logins ranging from 1–102 (mean, 38.00; SD, 22.31)<br>Interventionist:<br>Int1: NR<br>Int2: NR   | Completer's analysis (n=87)<br>13 wk:<br>$\Delta$ in PA, d/wk, M:<br>Int1: 3.43<br>Int2: 0.88<br>P=0.08   |
| Kim et al, <sup>109</sup> 2013<br>Design: 2-group RCT   | N=45<br>Int1: n=30<br>Int2: n=15   | Int1: Pedometer and manual to record steps plus motivational SMSs<br>3 times/d, 3 d/wk for 6 wk  | SMS  | Duration: 6 wk<br>Contacts: 3 times/d for 3 d/wk for 6 wk  | Completer's analysis (n=36)   |

(Continued)



Table 3. Continued

| Study Cited, Design, Primary Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BMI, Study Retention   | Study Groups and Components  | Technology Used                                  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome  |
|--|---|--|--|--|--|
| Outcome: Steps/day<br>Setting: Community<br>Country: United States   | Mean age (SD):<br>Int1: 69.3 (7.3) y<br>Int2: 70.6 (7.5) y<br><br>Women: 80%<br><br>Black: 100%<br><br>Mean BMI (SD):<br>Int1: 30.2 (7.0) kg/m <sup>2</sup><br>Int2: 31.4 (7.4) kg/m <sup>2</sup><br><br>Retention: 80% | Int2: Pedometer and manual to record steps but not SMSs  |  | Intervention adherence: NR<br><br>Interventionist:<br>Int1: Automated<br>Int2: NR  | 6 wk: Δ in step count, M:<br>Int1: +679<br>Int2: +398<br>P<0.05  |
| King et al, <sup>110</sup> 2014<br>Design: 2-group RCT<br>Outcome: Δ in MVPA<br>Setting: Community<br>Country: United States | N=148<br>Int1: n=73<br>Int2: n=75<br><br>Mean age (SD):<br>60 (5.5) y<br><br>Women: NR<br><br>White: NR<br><br>Mean BMI (SD):<br>29.5 (5.4) kg/m <sup>2</sup><br><br>Retention: 78%                                     | Int1: 12-mo home-based MVPA, primarily walking, program delivered via a trained telephone counselor (human advice arm)<br><br>Int2: Similar program delivered via an automated, computer interactive telephone system (automated advice arm) | Automated, computer interactive telephone system | Duration: 12 mo; study, 18 mo<br><br>Contacts:<br>Ps in both groups received one 30-min in-person, one-on-one instructional session followed by a similar number of advisor-initiated telephone contacts across the 12-mo period<br><br>Intervention adherence: NR<br>Interventionist:<br>Int1: Trained phone counselor<br>Int2: Automated | ITT (BOCF)<br>18 mo:<br>Int1: 167.0±135.6<br>Int2: 145.2±134.5<br>P=0.41   |
| Systematic review and meta-analysis  |   |  |  |  |  |
| Bort-Roig et al, <sup>111</sup> 2014<br>Design: Systematic review of 26 RCTs   | NR<br>Among the 26 reviewed articles, 17 implemented and evaluated a smartphone-based intervention, 5 used single group pre-post designs and 2 used pre-post designs relative to a control or comparison group          | Interventions that used smartphones to influence PA  | Smartphone                                       | NR   | 4 studies (3 pre-post and 1 comparative) reported PA increases (12–42 participants, 800–1104 steps/d, 2 wk–6 mo), and 1 case-control study reported PA maintenance (n=200 participants; >10 000 steps/d) over 3 mo |

Automated indicates without a clinician who generates, tailors, or modifies the output; baseline, 0; BMI, body mass index; BOCF, baseline observation carried forward; CI, confidence interval; Δ, change or difference; HGLM, hierarchical generalized linear model; Int, intervention group; ITT, intention to treat; M, mean; MET, metabolic equivalent; MPA, moderate physical activity; MRCM, multilevel random coefficient modeling; MVPA, moderate- to vigorous-intensity physical activity; n, subgroups; N, total sample; NR, not reported; NS, not significant; NSD, not significantly different; OR, odds ratio; P, participant; PA, physical activity; PDA, personal digital assistant; RCT, randomized control trial; and SMS, short message service.

applications have emerged to leverage this technology, and some mobile operating systems include physical activity tracking as a default functionality. There is emerging evidence that combining physical activity tracking devices with group behavioral treatments will produce larger weight loss outcomes than either the device or group treatment alone.<sup>76</sup>

**Gaps and Recommendations for Future Research**

A large number of smartphone applications and wearable devices (FitBit, JawBone) exist that are designed to monitor, track, and promote physical activity, but none of these apps have been compared with the established methods of objectively measuring physical activity such as accelerometers and thus have no empirical basis. More than 20% of US adults are

tracking their health with some form of technology, and 1 in 5 adults with a smartphone has at least 1 health application. The most popular health applications (38% of downloads) are those related to exercise, pedometer use, and heart rate monitoring.<sup>115</sup> However, with the exception of the Bodymedia armband, which was used as part of a weight loss intervention study reported by Shuger et al,<sup>76</sup> none of the studies identified in this review tested these wearable monitors for efficacy. Therefore, it is recommended that future studies include the use of these commercially available devices in RCTs to determine their efficacy in improving physical activity. The data on established accuracy for these consumer wearable physical activity trackers are limited. One study examining the accuracy and precision of these devices (eg, Bodymedia FIT, Fitbit Zip, Jawbone Up) reported



that most wearable devices yielded reasonably accurate reporting of energy expenditure, within about 10% to 15% error, compared with a portable metabolic analyzer.<sup>116</sup> Equivalence testing revealed that the estimates from the Bodymedia FIT and Fitbit Zip were within the 10% equivalence zone around the indirect calorimetry estimate.<sup>116</sup> Thus, rigorous RCTs with diverse populations are needed to establish an empirical basis for the use of the apps and mobile tracking devices for improving physical activity or reducing sedentary activity.

The realm where there seems to have been a prolific explosion of wearable devices and trackers is physical activity; however, compared with some of the other health-related areas, the research conducted to date is limited. The following list outlines the gaps and recommendations for future research in the area of mHealth interventions for promoting physical activity:

- Little is known about the use of wearable consumer devices, although many adults are using this technology. Therefore, large-scale, randomized trials of diverse populations need to be conducted to test the efficacy of this technology in increasing physical activity or reducing sedentary behavior.
- Health-related apps are among the most popular downloads, yet they are not being rigorously tested. Therefore, commercially available apps that are downloaded by the public need to be validated and examined for efficacy and acceptability and for sustainability of engagement. Only then can we provide the consumer with evidence for their use.
- Similarly, additional testing is recommended for the use of exergaming to increase physical activity levels in both children and adults.
- The Internet was the platform tested most often for the delivery of technology targeting increased physical activity. Thus, other platforms need to be tested for promoting physical activity, for example, SMS or more recently developed approaches that can be delivered on a smartphone or tablet.

### Use of mHealth for Smoking Cessation

Tobacco use remains the most significant preventable risk factor for CVD. The AHA Task Force on Risk Reduction noted that approximately a third of CVD deaths are attributable to smoking and that a substantial and rapid decrease in risk results from smoking cessation.<sup>117</sup> Although there are a number of effective pharmacological and behavioral interventions for smoking cessation, the delivery of these interventions has been inconsistent. Practice guidelines for smoking cessation incorporate the 5 As: ask, advise, assess, assist, and arrange.<sup>118</sup> Although most healthcare providers report asking about smoking and advising their patients to quit, they are much less likely to assess willingness to quit, assist with cessation, or arrange follow-up.<sup>119</sup> Given the limitations of smoking cessation delivered by health professionals, technologies have been leveraged to facilitate the delivery of smoking cessation interventions. Early approaches used the Internet to deliver these interventions,<sup>120</sup> and current and reputable Internet interventions such as smokefree.gov are available.<sup>121</sup> The advent

of mobile technologies provides potential delivery advantages over Internet interventions via desktop or laptop computers.

Smoking urges occur frequently throughout the day in response to various triggers, and indoor smoking bans have moved smoking behavior outside, away from computers used at work and home. Mobile devices are therefore more likely to be available when smokers experience the urge to smoke and can deliver interventions at these times. These mobile devices also offer the promise of “just-in-time adaptive interventions” that adapt interventions on the basis of context and potentially preempt smoking behavior by anticipating when urges are likely to occur.<sup>122</sup>

Current commercially available mobile apps for smoking cessation have generally failed to deliver empirically supported interventions or to make optimal use of the capabilities of mobile phones. A series of studies by Abrams and colleagues<sup>123,124</sup> have shown that most commercially available smoking cessation apps do not adhere to practice guidelines for smoking cessation. Some of these practice guidelines, developed for delivery by healthcare professionals, may not be appropriate criteria for mobile interventions. For instance, should a smoking cessation mobile app ask about smoking, or is it reasonable to assume that, if a user has downloaded an app for quitting smoking, he or she is a smoker? Additionally, some empirically supported approaches that are amenable to a computerized intervention such as scheduled gradual reduction of smoking<sup>125</sup> may not have been included in the practice guidelines because of the difficulty of delivery by healthcare professionals. Even with these caveats, commercially available mobile apps for smoking cessation are generally incomplete and lack empirical basis. Abrams and colleagues<sup>123,124</sup> have documented that, although some smoking cessation apps are downloaded more than a million times per month, smartphone apps adhere, on average, to only about a third of the practice guidelines for smoking cessation interventions.

Although most commercially available smoking cessation apps are incomplete or lack empirical support, there has been considerable research on the efficacy of mobile interventions for smoking cessation that we review below. Until quite recently, these empirically tested interventions developed by smoking cessation researchers were not commercially available. Much of the initial research on SMS for smoking cessation occurred outside of the United States, and the programs, if available at all, are available only in those countries. Additionally, researchers developing these mobile smoking cessation programs often did not partner with commercial entities capable of marketing the program once evaluated; however, there are recent examples of commercially available programs developed by researchers.<sup>126,127</sup>

### Review of Evidence for the Efficacy of Mobile Technology–Based Interventions to Promote Smoking Cessation

We searched PubMed for the years 2004 to 2014 using the terms *quit smoke*; *stop smoke*; *stopped smoke*; *ceased smoke*; *smoking cessation*; *cigarette smoke*; *smokeless tobacco*; *smoker*; *tobacco cessation*; *tobacco use*; *nicotine replacement*; *nicotine gum*; *nicotine lozenge*; *nicotine nasal*; *nicotine patch*; and *nicotine inhalant*. These terms were cross-referenced with the mobile technology terms described previously. This search resulted in 286 identified articles. Of these, most (211) were not relevant to mobile technologies for smoking cessation. These were

predominately Internet-based interventions or studies that used mobile technologies for recruitment or measurement purposes but not for intervention. Of the remaining 85 publications, 14 were RCTs of mobile technologies for smoking cessation, and these trials are described in Table 4. The remaining reports of mobile technologies for smoking cessation were a range of studies including descriptions of design and development; reports of feasibility, acceptability, and usability data; uncontrolled trials; and various systematic reviews. For completeness, 2 Cochrane meta-analyses of this area<sup>140,141</sup> are included in the table.

### **SMS for Smoking Cessation**

Most of the research on mobile smoking cessation interventions has focused on text messaging as the delivery medium. Why was SMS the focus when there are so many other delivery mediums on today's smartphones? First, many of the early studies using mobile phones for smoking cessation<sup>128,142</sup> predate the advent of the smartphone; hence, SMS was one of the few functions available on feature phones for the delivery of interventions. Second, SMS is a relatively inexpensive development environment that will run on any cell phone, whereas a smartphone app needs to be developed for each operating system (eg, Android, iOS) and updated with each operating system update. Third, although smartphone use is increasing dramatically and is now at >50% in the United States,<sup>29</sup> smartphone use was reported as lowest by adults in lower socioeconomic groups.<sup>143</sup> Smoking rates are disproportionately higher in lower socioeconomic groups<sup>144</sup> that remain predominately feature phone users. Recent Pew statistics show, however, that Hispanics and blacks have higher rates of smartphone use than whites, indicating the demographic shift in mobile phone use that could make smartphone apps a viable medium for cessation interventions targeting minorities.<sup>30</sup>

### **Cochrane Meta-Analysis**

Controlled studies of mobile phone programs for smoking cessation have been summarized in a Cochrane meta-analysis<sup>140</sup> and update.<sup>141</sup> The details of studies reviewed in these 2 meta-analyses are listed in Table 4. For both reviews, the primary outcome was smoking abstinence of  $\geq 6$  months and included both sustained and point prevalence abstinence and both self-reported and biochemically validated smoking status. However, the number of studies reviewed was 4 and 5, respectively, in the 2 meta-analyses, and there was considerable heterogeneity of effect across studies.

The initial Cochrane review<sup>140</sup> identified 9 articles relevant to smoking cessation via mobile phones in which the mobile intervention was a core component, not just an adjunct to an Internet or in-person program. Of these, 4 were small, non-randomized feasibility trials, and 2 had insufficient follow-up for inclusion. Of the 4 studies included in the meta-analysis, 2 assessed the same text messaging program delivered in 2 different countries,<sup>128,131</sup> and the remaining 2 trials<sup>129,130</sup> evaluated a combined Internet and mobile phone intervention. The 4 studies lacked long-term follow-up or biochemical validation in more than a small subsample of participants, but all 4 studies showed significantly greater abstinence at 6 months compared with control subjects (Table 4 provides details).

In the 2012 update of the Cochrane review,<sup>141</sup> 5 trials were included: a video messaging mobile phone intervention,<sup>133</sup> a Web-based quit coach and text messaging intervention,<sup>136</sup>

and 3 evaluations of an SMS or text messaging intervention.<sup>128,131,132</sup> Pooled across these 5 studies, the relative risk for long-term quit rates was 1.71. Among the studies reviewed in the Cochrane update, the large, well-controlled UK study by Free and colleagues<sup>132</sup> accounted for more than half (50.45%) of the subjects in the meta-analysis. In this single-blind trial, 5800 smokers willing to quit were randomly assigned either to a mobile phone text program (txt2stop) that included behavior change support and motivational messages or to a control group that received SMSs unrelated to quitting smoking. On the basis of biochemically verified continuous abstinence at 6 months, quit rates were significantly greater in the txt2stop (10.7%) than in the control group (4.9%), and the abstinence rates were similar when those lost to follow-up were treated as smokers. Since the Cochrane update in 2012, there have been a number of RCTs of smoking cessation programs delivered via mobile phone technologies, and they are listed in Table 4.

### **Special Populations**

There are limited intervention options for pregnant smokers. In a preliminary trial comparing smoking cessation programs in pregnant smokers,<sup>134</sup> there were no significant differences in self-reported smoking abstinence between groups who received educational materials and those who received tailored SMSs. Further research is needed to identify minimal risk interventions that are effective for pregnant smokers.

Likewise, young adults with low education are a particularly vulnerable population for smoking that warrants additional research on both prevention and cessation interventions. Two recent studies<sup>138,139</sup> compared the effectiveness of technology-based smoking cessation interventions with educational pamphlets in adolescent vocational students. Neither study reported significant differences in self-reported abstinence after intervention between the groups receiving text messaging interventions and those receiving paper-based educational materials; however, the sample sizes in these 2 studies may have been inadequate to detect differences.

### **Recent Studies**

Ybarra and colleagues<sup>135</sup> first studied an SMS program delivered in Turkey and more recently studied the effects of their SMS intervention in a study of young adult smokers in the United States.<sup>126</sup> Although the intervention produced significantly higher abstinence rates at 4 weeks, these differences were not sustained at 3 months.

Abroms and colleagues<sup>127</sup> recently published a controlled trial of Text2Quit, an automated, tailored, interactive text messaging program for smoking cessation. In contrast to many previous programs that primarily push out texts, the Text2Quit program is interactive and prompts users to track smoking and report cravings. Using keyword texts, users have the ability to reset quit dates, request help with a craving, obtain program and data summaries, and indicate if they have slipped and smoked. Mailed saliva cotinine-verified point prevalence abstinence at 6 months showed an 11% abstinence rate for intervention compared with 5% for control subjects. In contrast to the studies and programs in the earlier Cochrane reviews, this study was conducted in the United States and evaluated a program that is commercially available to smokers in the United States.

**Table 4. Description of Studies Using mHealth for Smoking Cessation**

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Study Retention   | Study Groups and Components  | Technology Used                              | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome   |
|---|---|--|--|--|---|
| Rodgers et al, <sup>128</sup> 2005<br>2-group RCT<br>Primary Outcome: 6 wk abstinence<br>Secondary outcomes: 12 wk and 26 wk abstinence<br>Setting: Community<br>Country: New Zealand | N=1705<br>Int1: n=853<br>Int2: n=852<br>Women: 58.5%<br>Median age (IQR): 22 (19–30) y<br>European ethnicity: 63.0%<br>Maori: 20.8%<br>Pacific Islander: 3.5%<br>Other: 12.7%<br>Baseline Fagerstrom Score, median (IQR): 5 (3–6)<br>Mean (SD) of number of CPDs: 15 (3)<br>Average previous quit attempts: 2/person<br>Lost to follow-up:<br>6 wk:<br>Int1: 46<br>Int2: 35<br>Retention: 95.2%<br>26 wk:<br>Int1: 261<br>Int2: 179<br>Retention: 74.2% | Int1: Quit day established within 30 d, received personalized texts. Ps received free SMSs for 1 mo after quit date.<br>Int2: Texts related to appreciation for participating, Ps received 1 mo of free SMSs on completion (not dependent on quit status).<br>Neither group was advised to cease using other resources for quitting smoking.<br>SMS was an add-on to standard treatment. | SMS  | Duration: 26 wk (6 mo)<br>Contacts:<br>Int1: 5 SMSs/d for the first 5 wk then 3 SMSs/wk until end of 6 mo<br>Int2: 1 SMS every 2 wk<br>Follow-up via phone at 6, 12, and 24 wk for both groups<br>Interventionist:<br>Int1: Automated, tailored SMS<br>Int2: Automated, nontailored SMS  | ITT (assuming missing=smoking)<br>Abstinence:<br>6 wk:<br>Int1: 239 (28%)<br>Int2: 109 (13%)<br>RR, 2.2 (95% CI, 1.79–2.70)<br><i>P</i> <0.001<br>12 wk:<br>Int1: 247 (20%)<br>Int2: 160 (29%)<br>RR, 1.55 (95% CI, 1.30–1.84)<br><i>P</i> <0.001<br>26 wk:<br>Int1: 216 (25%)<br>Int2: 202 (24%)<br>RR, 1.07 (95% CI 0.91–1.26)<br><i>P</i> =NS<br>Of 83 Int1 and 42 Int2 self-reported abstainers at 6 wk asked to provide saliva for cotinine assay, bioverification confirmed abstinence in:<br>Int1: 17 (20.5%)<br>Int2: 6 (14.3%)<br>RR, 2.84 (95% CI, 1.12–7.16), <i>P</i> =0.02 |
| Brendryen et al, <sup>129</sup> 2008<br>Design: 2-group RCT<br>Outcome: 1-, 3-, 6-, 12-mo 7-d no-puff self-report abstinence<br>Setting: Community<br>Country: Norway                 | N=290<br>Int1: n=144<br>Int2: n=146<br>Mean age (SD):<br>Int1: 39.5 (11.0) y<br>Int2: 39.7 (10.8) y<br>Women: 50%<br>Mean (SD) cigarettes smoked per day:<br>Int1: 16.6 (7.2)<br>Int2: 17.6 (7.0)<br>College degree:<br>Int1: 49%<br>Int2: 52%<br>Mean (SD) nicotine dependence:<br>Int1: 4.5 (2.3)<br>Int2: 4.6 (2.2)<br>Retention: 77.9%<br>Int1: 81.9%<br>Int2: 74.0%  | Int1: Happy Endings group: Received Happy Endings (Internet and mobile phone smoking cessation program)<br>Int2: Received 44-page self-help book   | E-mail, Web pages, IVR, SMS, craving hotline | Duration: 12 mo<br>Contacts: 1-, 3-, 6-, and 12-mo abstinence reports<br>Intervention adherence: Number of Web and phone responses<br>1 mo:<br>Int1: n=139<br>Int2: n=127<br>3 mo:<br>Int1: n=135<br>Int2: n=131<br>6 mo:<br>Int1: n=124<br>Int2: n=120<br>12 mo:<br>Int1: n=131<br>Int2: n=123<br>Discontinued treatment:<br>Int1: n=57 (47%)<br>Interventionist:<br>Int1: Automated<br>Int2: booklet | ITT, missing assumed=smoking;<br>7-d no-puff point abstinence:<br>1 mo:<br>Int1: 42%<br>Int2: 17%<br><i>P</i> =0.001<br>3 mo:<br>Int1: 35%<br>Int2: 16%<br><i>P</i> =0.001<br>6 mo:<br>Int1: 29%<br>Int2: 14%<br><i>P</i> =0.002<br>12 mo:<br>Int1: 33%<br>Int2: 23%<br><i>P</i> =0.07<br>Complete case analysis<br>Repeated point abstinence:<br>1+3 mo:<br>Int1: 30%<br>Int2: 12%<br><i>P</i> =0.001  |

(Continued)

Table 4. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Study Retention  | Study Groups and Components   | Technology Used             | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome  |
|---|--|---|-----------------------------|---|--|
|   |  |   |                             |   | 1+3+6 mo:<br>Int1: 24%<br>Int2: 7%<br>P=0.001  |
|   |  |   |                             |   | 1+3+6+12 mo:<br>Int1: 20%<br>Int2: 7%<br>P=0.002   |
| Brendryen and Kraft, <sup>130</sup> 2008<br>Design: 2-group RCT<br>Outcome: 1-, 3-, 6-, 12-mo 7-d no-puff self-report abstinence<br>Setting: Community<br>Country: Norway | N=396<br>Int1: n=197<br>Int2: n=199<br>Mean age (SD):<br>Int1 35.9 (10.0) y<br>Int2: 36.4 (10.5) y<br>Women:<br>Int1: 50.8%<br>Int2: 19.8%<br>College degree:<br>Int1: 42.1%<br>Int2: 39.7%<br>CPD:<br>Int1: 18.3±5.9<br>Int2: 18.1±5.8<br>Precessation self-efficacy:<br>Int1: 4.9±1.3<br>Int2: 5.1±1.3<br>Retention:<br>Int1: 88%<br>Int2: 84% | Int1: Happy Endings Internet and cell phone-based smoking cessation program, 400+ contacts by e-mail, Web pages, IVR, and SMS<br>Int2: 44-page self-help booklet<br>Both groups offered NRT | E-mail, Web pages, IVR, SMS | Duration: 54 wk<br>Contacts: 1-, 3-, 6-, and 12-mo abstinence reports<br>NRT adherence:<br>Int1: 93%<br>Int2: 87%<br>P=NS<br>Discontinued treatment:<br>Int1: n=45 (23%)<br>Interventionist:<br>Int1: Automated<br>Int2: NA   | ITT, missing assumed=smoking; 7-d no-puff point prevalence abstinences:<br>1 mo:<br>Int1: 50.3%<br>Int2: 29.6%<br>P=0.001<br>3 mo:<br>Int1: 44.7%<br>Int2: 28.6%<br>P=0.001<br>6 mo:<br>Int1: 37.1%<br>Int2: 21.6%<br>P=0.001<br>12 mo:<br>Int1: 37.6%<br>Int2: 24.1%<br>P=0.005 |
| Free et al, <sup>131</sup> 2009<br>Design: 2-group RCT<br>Outcome: 4-wk and 6-mo self-reported abstinence<br>Setting: Community<br>Country: United Kingdom                | N=200<br>Mean age (SD): 36 (9) y<br>Women: 38%<br>Median No. of cigarettes smoked: 20/d<br>Manual occupations: 33%<br>Retention: 92%   | Int1: Received SMS smoking cessation program (txt2stop) made up of motivational messages and behavioral-change support.<br>Int2: Received SMS messages unrelated to quitting smoking        | Mobile phone SMS            | Duration: 6 mo<br>Contacts: Int1 group received daily SMSs starting at randomization with a countdown to quit day and then 5 messages/d for 4 wk after the quit day. Intervention continued with a maintenance package of 3 SMSs/wk for 26 wk.<br>Int2 group received simple, short, generic SMS every 2 wk.<br>Intervention adherence:<br>Response rate:<br>At 4 wk: 96%<br>At 6 wk: 92%<br>Interventionist:<br>Int1: Automated<br>Int2: Automated | Completer sample, self-report point prevalence abstinence<br>4 wk:<br>Int1: 26%<br>Int2: 13%<br>P=0.02<br>RR, 2.08 (95% CI, 1.11–3.89)<br>6 mo:<br>Int1: 8.5%<br>Int2: 6.7%<br>P=0.6   |



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(Continued)

Table 4. Continued

| Study Cited, Design, Primary Outcome, Setting, Country   | Sample Characteristics, Group Size, Study Retention   | Study Groups and Components  | Technology Used                                    | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome   |
|--|---|--|--|---|---|
| Free et al, <sup>132</sup> 2011<br>Design: Single-blind 2-group RCT<br>Outcome: 6 mo biochemically verified smoking abstinence<br>Setting: Community<br>Country: United Kingdom  | N=5800<br>Int1: n=2911<br>Int2: n=2881<br>Women: 45%<br>Mean age (SD):<br>Int1: 36.8 (11.0) y<br>Int2: 36.9 (11.1) y<br>White:<br>Int1: 89%<br>Int2: 88%<br>Previous quit attempts (1–5 times):<br>Int1: 74%<br>Int2: 76%<br>Fagerstrom score ≤5:<br>Int1: 60%<br>Int2: 60%<br>Retention: 95% | Int1: SMS txt2stop mobile phone smoking cessation program. Set quit date within 2 wk, received 5 SMSs/d first 5 wk, then 3/wk for next 26 wk<br>Participants can text back “crave” or “lapse” and receive supportive instant message<br>Int2: Received SMS unrelated to quitting, every 2 wk, short, SMSs related to the importance of participation | Mobile phone SMS                                   | Duration: 6 mo<br>Contact: 4 wk and 6 mo<br>Intervention adherence:<br>Received entire intervention<br>Int1: n=2509<br>Int2: n=2734<br>Interventionist:<br>Int1: Automated<br>Int2: Automated   | ITT, missing data multiple imputations 6 mo:<br>Self-reported continuous abstinence biologically verified by postal salivary cotinine or in-person exhaled carbon monoxide:<br>Int1: 10.7%<br>Int2: 4.9%<br>P<0.0001  |
| Whittaker et al, <sup>133</sup> 2011<br>Design: 2-group RCT<br>Outcome: 6-mo self-reported continuous abstinence<br>Setting: Community<br>Country: New Zealand   | N=226<br>Predominantly Maori<br>Int1: n=110<br>Int2: n=116<br>Mean age (SD):<br>Int1: 27.5 (9.5) y<br>Int2: 16.6 (7.8) y<br>Women:<br>Int1: 53%<br>Int2: 42%<br>Retention:<br>Int1: 63%<br>Int2: 78%  | Int1: Quit date prompt and 2 SMSs/d, video messages on cessation<br>Int2: Quit date prompt and 2 SMSs/d, video   | SMS and video messaging to mobile phones; Internet | Duration: 12 wk<br>Contacts: 1–3 messages/d, reduced to alternating days during maintenance<br>Intervention adherence: 29% used the text “crave” function; 16% used the text “relapse” function requesting assistance<br>Interventionist:<br>Int1: Automated<br>Int2: Automated   | ITT, missing assumed=smoking 6 mo:<br>Continuous abstinence:<br>Int1: 26.4%<br>Int2: 27.6%<br>P=NS  |
| Naughton et al, <sup>134</sup> 2012<br>2-group RCT<br>Outcomes:<br>12-wk self-reported and cotinine-validated 7-d point prevalence abstinence and cognitive determinants of quitting<br>Feasibility and acceptability of a tailored self-help SC intervention for pregnant smokers (MiQuit)<br>Setting: Community<br>Country: United Kingdom | N=207 pregnant<br>Int1: n=102<br>Int2: n=105<br>White: 100%<br><21-wk gestation<br>Mean age (SD):<br>Int1: 27.2 (6.4) y<br>Int2: 26.5 (6.2) y<br>12-wk retention:<br>Int1: n=86 (84%)<br>Int2: n=89 (85%)   | Int1: MiQuit sent a 4-d, colored, tailored, self-help leaflet via mail and received tailored SMS<br>Int2: Received a nontailored leaflet via mail; received no tailored SMS but did receive assessment SMS at 3 and 7 wk   | SMS  | Duration: 11 wk<br>Total contacts: A 4-page leaflet for both intervention groups; 2 assessment SMSs, 1 at 3 wk and 1 at 7 wk; 3-mo follow-up for acceptability, cognitive determinants of quitting, and smoking outcomes. Int1 also received ≈80 tailored SMSs over 11 wk; 0, 1, or 2 SMSs were sent daily at various times over 11 wk<br>Feasibility: 94% (81/86; 95% CI, 89–99) of MiQuit participants and 80% (71/89; 95% CI, 71–88) of control subjects received both SMS and the leaflet | ITT, missing assumed=smoking 12 wk:<br>Self-reported abstinence:<br>Int1: 22.9%<br>Int2: 19.6%<br>OR, 1.22 (95% CI, 0.62–2.41); P=NS<br>Cotinine-validated abstinence:<br>Int1: 12.5%<br>Int2: 7.8%;<br>OR, 1.68 (95% CI, 0.66–4.31); P=NS<br>Process outcomes:<br>Int1 more likely to set a quit date (P=0.049) and have higher levels of self-efficacy (P=0.024), harm beliefs (P=0.052), and determination to quit (P=0.019) |

(Continued)

Table 4. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Study Retention   | Study Groups and Components  | Technology Used                                       | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome  |
|---|---|--|---|---|--|
| Ybarra et al, <sup>135</sup> 2012<br>2-group RCT<br>Primary Outcome: Bioverified sustained abstinence at 3 mo<br>Setting: Community<br>Country: Ankara, Turkey  | N=151<br>Int1: n=76<br>Int2: n=75<br><br>Mean age (SD):<br>Int1: 36.1 (9.5) y<br>Int2: 35.6 (10.3) y<br><br>Women:<br>Int1: 46.1%<br>Int2: 32.0%<br><br>Mean CPD (SD):<br>Int1: 18.7 (7.2)<br>Int2: 20.4 (9.2)<br><br>Fagerstrom score mean (SD):<br>Int1: 4.8 (2.3)<br>Int2: 4.9 (2.5)<br><br>Retention:<br>Int1: n=46 (61%)<br>Int2: n=51 (68%) | Int1: 6-wk daily messages aimed at quitting skills. Messages automated except for 2 and 7 d after quit day, when RAs manually assigned Ps to content paths based on whether they had relapsed or had maintained quitting.<br><br>Int2: 7-page brochure   | SMS   | Acceptability: 9% (95% CI, 4–15) of MiQuit participants opted to discontinue SMS<br><br>Interventionist:<br>Int1: Automated tailored SMS<br>Int2: Automated assessment SMS<br><br>Duration: 3 mo<br>Int duration: 6 wk<br><br>Contacts:<br>Int1: Varied by P (dependent on stage of change and whether relapse occurred; range, 91–146)<br>Int2: No SMS<br>Each group had in-person visits at baseline, 4 wk after quit day, and at 3-mo follow-up<br><br>Intervention adherence:<br>NR<br><br>Interventionist:<br>Int1: Automated+RA manually assigned to content path<br>Int2: NA | ITT, missing assumed=smoking<br><br>3-mo cessation bioverified by carbon monoxide:<br>Int1: 11%<br>Int2: 5%<br>P=NS<br><br>Secondary outcome: Smoking <20<br>Int1: 17%<br>Int2: 0%<br>P=0.02 |
| Borland et al, <sup>136</sup> 2013<br>Design: 5-group RCT<br>Outcome: self-reported continuous abstinence at 6 mo<br>Setting: Community<br>Country: Australia   | N=3530<br>Int1: n=809<br>Int2: n=756<br>Int3: n=785<br>Int4: n=758<br>Int5: n=422<br><br>Mean age (range):<br>42.1 (18–80) y<br><br>Women: 60%<br><br>Currently smoking:<br>87.4%<br><br>Average No. of cigarettes smoked: 16.9/d<br><br>Retention: 86.5%   | 5 conditions:<br>Int1: QuitCoach personalized tailored Internet-delivered advice program<br>Int2: onQ, an interactive automated SMS program<br>Int3: An integration of both QuitCoach and onQ<br>Int4: A choice of either Internet or SMS alone or the combined program<br>Int5: Minimal Int and was offered a simple informational Web site | Internet and SMS                                      | Duration: 7 mo<br><br>Contacts:<br>Int. lasted 7 mo, follow-up surveys at 1 and 7 mo<br><br>Intervention adherence:<br>Used intervention: 42.5%<br>Tried it: 14.6%<br>Did not use it: 43%<br><br>Interventionist:<br>Int1: Automated<br>Int2: Automated<br>Int3: Automated<br>Int4: Automated<br>Int5: NA   | ITT, assuming missing=smoking, LOCF, and completers' analysis<br><br>6-mo sustained abstinence:<br>Int1: 9.0%<br>Int2: 8.7%<br>Int3: 8.7%<br>Int4: 9.1%<br>Int5: 6.2%<br>P=NS                |
| Ali et al, <sup>137</sup> 2013<br>Design: Randomized pre-post 2-group design<br>Outcome: 7-d point prevalence self-reported abstinence at 6 wk, 30-d point prevalence abstinence at 12 wk<br>Setting: Community<br>Country: United States | N=102<br><br>Mean age (SD):<br>Int1: 25.5 (NR) y<br>Int2: 24.3 (NR) y<br><br>Women:<br>Int1: 45%<br>Int2: 57%<br><br>White:<br>Int1: 70%<br>Int2: 76%   | Int1: Smokers received smartphone application (REQ-Mobile) with interactive tools<br><br>Int2: Assigned to the onQ group who received a SMS system   | Smartphone application (REQ-Mobile), SMS system (onQ) | Duration: 12 wk<br><br>Contacts: Pretest, 6-wk posttest, and 12-wk posttest smoker-reported smoking status<br><br>Intervention adherence:<br>60% used allocated service<br><br>Interventionist:<br>Int1: Interactive online<br>Int2: Automated SMS  | ITT, assuming missing=smoking and completers' analyses<br>6 wk (completers' analysis, n=66):<br>7-d point prevalence abstinence:<br>Int1: 30%<br>Int2: 58%<br>P=0.03                         |

(Continued)

**Table 4. Continued**

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Study Retention   | Study Groups and Components   | Technology Used      | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome   |
|---|---|---|----------------------|--|---|
|   | Cigarettes smoked per day: Int1: 16.8<br>Int2: 17.1<br>Attempted to quit in the past year:<br>Int1: 66%<br>Int2: 71%<br>Retention: 67%  |   |                      |  | 12 wk:<br>ITT 30-d point prevalence abstinence:<br>Int1: 18%<br>Int2: 31%<br>P=NS<br>Completers' 30-d point prevalence abstinence:<br>Int1: 27%<br>Int2: 46%<br>P=NS                                |
| Haug et al. <sup>138</sup> 2013<br>Design: 2-group cluster randomized design<br>Outcome: 7-d self-reported abstinence at 6 mo<br>Setting: Vocational schools<br>Country: Switzerland  | N=755 in 178 classes<br>Int1: n=383 in 88 classes<br>Int2: n=372 in 90 classes<br>Mean age (SD):<br>Int1: 18.2 (2.4) y<br>Int2: 18.3 (2.2) y<br>Women: 49%<br>Smoking status:<br>Occasional: 29%<br>Daily: 71%<br>Retention at 6 mo:<br>Int1: 79.3%<br>Int2: 71.0%          | Int1: Online assessment, weekly SMS assessment, 2 weekly tailored messages, integrated quit day and relapse prevention<br>Int2: No intervention   | SMS to mobile phones | Duration: 3 mo<br>Contacts: 3 SMS per week<br>Intervention adherence: 2.4% unsubscribed<br>Mean number of replies to weekly assessment: 6.5 of a 11 possible replies<br>Interventionist:<br>Int1: Automated<br>Int2: Assessment  | ITT with 30 imputed data sets<br>6 mo:<br>7-d self-reported abstinence:<br>Int1: 12.5%<br>Int2: 9.6%<br>OR, 1.03 (95% CI, 0.59-1.79; P=NS)  |
| Shi et al. <sup>139</sup> 2013<br>Design: 2-group cluster randomized design<br>Outcome: 7-d self-reported abstinence at 12 wk<br>Setting: Vocational schools<br>Country: China        | N=179 in 6 schools<br>Int1: n=92 in 3 schools<br>Int2: n=87 in 3 schools<br>Mean age (SD):<br>Int1: 17.6 (NA) y<br>Int2: 16.9 (NA) y<br>Women:<br>Int1: 7%<br>Int2: 2%<br>Smoking status:<br>Occasional: 29%<br>Daily: 71%<br>Retention at 12 wk:<br>Int1: 83%<br>Int2: 53% | Int1: Tailored daily SMS based on transtheoretical model<br>Int2: Smoking cessation pamphlet  | SMS to mobile phones | Duration: 12 wk<br>Contacts: Daily SMS<br>Intervention adherence: 87 participants completed the intervention, receiving a median of 129 messages and sending a median of 32 messages<br>Interventionist:<br>Int1: Automated daily SMS<br>Int2: NA                            | ITT, assuming missing=smoking<br>12 wk:<br>7 day self-reported abstinence:<br>Int1: 14%<br>Int2: 8%<br>OR, 1.8 (95% CI, 0.7-4.2)  |
| Ybarra et al. <sup>126</sup> 2013<br>Design: 2-group RCT<br>Primary outcome: 3-mo continuous abstinence verified by significant other<br>Setting: Community<br>Country: United States | N=164<br>Int1: n=101<br>Int2: n=63<br>Mean age (SD):<br>Int1: 21.6 (2.1) y<br>Int2: 21.6 (2.1) y<br>Women<br>Int1: 44%<br>Int2: 28%<br>White:<br>Int1: 65%<br>Int2: 41%<br>Retention at 3 mo:<br>Int1: 81/101 (80%)<br>Int2: 51/63 (81%)                                    | Int1: 6-wk SMS (Stop My Smoking) intervention provided tailored SMS based on relapse status and quit day date. Included buddy support and craving support.<br>Int2: Attention-matched control group with similar number of SMS as intervention but aimed at improving sleep and PA. Not tailored to quit day status. Buddy support and craving support not available. | SMS                  | Duration: 3 mo<br>Intervention: 6 wk<br>Contacts: 2 follow-up appointments: 1 at 6 wk and 1 at 3 mo<br>Varying No. of SMS sent per day to each group, which was dependent on time point in the study<br>Interventionist:<br>Int1: Automated SMS+buddy<br>Int2: Automated SMS | ITT, with missing assumed=smoking<br>4 wk:<br>Quit rate:<br>Int1: 39%<br>Int2: 21%<br>OR, 3.33 (95% CI, 1.48-7.45)<br>3 mo:<br>Quit rate:<br>Int1: 40%<br>Int2: 30%<br>OR, 1.59 (95% CI, 0.78-3.21) |

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Table 4. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Study Retention   | Study Groups and Components   | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome  |
|---|---|---|---|--|--|
| Abroms et al, <sup>127</sup> 2014<br>Design: 2-group RCT<br>Outcome: 6-mo biochemically validated point prevalence abstinence<br>Setting: Community<br>Country: United States   | N=503<br>Int1: n=262<br>Int2: n=241<br><br>Mean age (SD): 35.7 (10.7) y<br>Women: 66%<br>Average No. of cigarettes/d: 17.3<br>Retention: 76% at 6 mo  | Int1: Interactive SMS timed and tailored around the user's quit date<br><br>Int2: Receive smokefree.gov site until site included SMS, then changed to Clearing the Air Web site                             | SMS; Internet   | Duration: 3-mo push SMS followed by 3 mo of SMS on request<br><br>Contacts: 2 SMS/d on average but up to 5/d around quit date<br><br>Intervention adherence: 85% received at least 1 SMS<br>Mean of 28 SMS received of those who received at least 1<br><br>Interventionist:<br>Int1: Interactive SMS<br>Int2: Automated | ITT, missing assumed=smoking<br>Point prevalence abstinence at 6 mo bioverified by saliva cotinine:<br>Int1: 11.1%<br>Int2: 5.0%<br>RR, 2.22 (95% CI, 1.16–4.26);<br>P<0.05  |
| Systematic reviews and meta-analyses  |   |   |   |  |  |
| Whittaker et al, <sup>140</sup> 2009<br>Meta-analysis of MEDLINE, EMBASE, Cinahl, PsycINFO, The Cochrane Library, the National Research Register, and ClinicalTrials Register<br>Outcome: self-reported point prevalence abstinence | 4 trials split into 2 analyses<br>N1=1905<br>Int1: n1=954<br>Con1: n1=951<br>N2=696<br>Int2: n2=348<br>Con2: n2=348<br><br>Included smokers of any age who wanted to quit and used any type of mobile phone-based intervention.<br><br>Retention range for all 4 studies:<br>Int: 69%–92%<br>Control: 79%–92% | 4 studies included (in 5 articles)<br><br>Used the Mantel-Haenszel risk ratio fixed-effect method in which there was no evidence of substantial statistical heterogeneity as assessed by the I(2) statistic | Analysis 1: SMS<br>Analysis 2: SMS+Internet   | Analysis 1: Studies were 6-mo duration<br>Analysis 2: Studies were 12-mo duration<br><br>Intervention contacts varied by study<br>Intervention adherence: NR   | Analysis 1: When the studies were pooled, significant increase in short-term self-reported abstinence (RR, 2.18; 95% CI, 1.8–2.65)<br><br>Analysis 2: When the data from the Internet and mobile phone programs were pooled, there were significant increases in short- and long-term self-reported quitting (RR, 2.03; 95% CI, 1.40–2.94) |
| Whittaker et al, <sup>141</sup> 2012<br>Meta-analysis of the Cochrane Tobacco Addiction Group Specialized Register<br>Outcome: 6 mo smoking abstinence, allowing 3 lapses or 5 cigarettes   | 5 randomized or quasi-randomized trials<br>N=9100<br>Int1: n=4730<br>Int2: n=4370<br><br>Retention at 6 mo varied across studies:<br>Int1: 68%–94%<br>Int2: 78%–97%   | Used the Mantel-Haenszel risk ratio fixed-effect method.<br><br>There was substantial statistical heterogeneity as indicated by I(2) statistic: I(2)=79%  | 3 studies used SMS, which was adapted over the course of the studies for different populations and contexts;<br>1 multiarm study used SMS intervention and an Internet QuitCoach separately and in combination; 1 study used video messaging delivered via mobile phone | Study duration: ≥6 mo<br>Adherence rates: NR   | Mobile phone interventions increase long-term quit rates vs control programs at 6 mo (RR, 1.71; 95% CI, 1.47–1.99; >9000 participants)   |

Automated indicates without a clinician who generates, tailors, or modifies the output; CI, confidence interval; CPD, cigarettes per day; Δ, change or difference; Int, intervention group; IQR, interquartile range; ITT, intention to treat; IVR, interactive voice response; LOCF, last observation carried forward; M, mean; n, subgroups; N, total sample; NA, not applicable; NR, not reported; NRT, nicotine replacement therapy; OR, odds ratio; P, participant; PA, physical activity; RA, research assistant; RCT, randomized, controlled trial; RR, relative risk; SC, smoking cessation; and SMS, short message service.

Gaps and Recommendations for Future Research

- There is substantial evidence that mobile phone apps for smoking cessation, particularly SMS programs, are effective for smoking cessation. The effects found for mobile phone smoking cessation interventions are comparable to the effects found for other smoking cessation interventions, including nicotine replacement therapies.<sup>145</sup>
- The considerable heterogeneity of this evidence, however, suggests that not all text messaging programs are

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created equal and that there is considerable individual variability in response to these programs. Therefore, although these text messaging programs have sufficient empirical support to be recommended to patients interested in quitting smoking, the selection of text messaging intervention may matter.

- Unfortunately, many of these empirically supported text messaging programs were developed and evaluated outside the United States and are not available, commercially or otherwise, to US smokers. This lack of access in the United States to proven text messaging programs is beginning to change. Abrams and colleagues<sup>127</sup> recently published evidence for their Text2Quit program, which is commercially available.
- Although hundreds of smartphone applications for smoking cessation are commercially available, there is considerable evidence that these applications have a limited empirical basis,<sup>123,124</sup> and we could find no published study testing the efficacy of any of these commercially available smartphone apps. In the 1 study that compared smartphone apps with text messaging,<sup>137</sup> text messaging produced better quit rates. Although it is clearly premature to recommend any smartphone application for smoking cessation at this time, smartphone applications hold potential future promise as smoking cessation interventions. Smartphones provide a range of potential features and functions not available via text messaging modalities that have not been adequately leveraged to date for smoking cessation. For example, movement and location sensors in smartphones could be used to learn the contexts in which users smoke and deliver interventions preemptively before the urge to smoke occurs.<sup>122</sup> Sensors connected to smartphones such as carbon monoxide monitors<sup>146</sup> provide objective measures of smoking status.
- Another promising approach that builds on the use of smartphones is ecological momentary interventions, an approach to the delivery of interventions to people during their everyday lives (ie, in real time) and in natural settings (ie, the real world).<sup>147</sup> This approach is gaining increasing attention as a potential approach across multiple behavioral domains and was tested in an earlier study for smoking cessation with significantly higher quit rates in the intervention group than in the control group at 6 and 12 weeks, but this rate was not sustained at 26 weeks.<sup>128,147</sup> Ongoing studies are testing this approach with the currently available smartphone technology.
- One critical but inadequately researched area is how to engage smokers to initiate the use of these mobile phone SMS programs. The well-controlled, population-based, multiarm trial of Borland and colleagues<sup>136</sup> had fewer than half of the intervention participants engage with the intervention on even a minimal basis. In the follow-up study by Riley and colleagues,<sup>148</sup> participants were assisted with program initialization as a result of the findings of an earlier trial in which 37% of the participants completed baseline measures but failed to initialize the SMS program on their own.<sup>142</sup> Bock and colleagues<sup>148a</sup> conducted focus groups on preferences for a SMS-based smoking cessation program for potential users. Participants recommended including social

networking components, greater control of program output via online profile, and more interactive text messaging features. In parallel with research on the efficacy of these mobile phone programs for those who engage with them, research on how to engage smokers and keep them engaged in these programs is also needed.

### **Summary and Recommendations**

Smoking cessation via mobile phone intervention is a relatively young area of research with only 10 years of published literature. Within this short period, however, a number of large, well-controlled studies have shown that SMS programs produce approximately double the abstinence rates of minimal intervention control conditions. Despite this success, the failure rate from these programs is still unacceptably high ( $\approx 90\%$  fail to quit at 6 months), and the heterogeneity of effect across studies suggests that certain varieties of SMS interventions may work better than others and in certain populations differentially from others. Until more is known on optimal intervention components of SMS for smoking cessation and on which smokers are more likely to benefit from these approaches, the current literature is able to support only that SMS interventions should be considered along with other efficacious smoking cessation interventions for smokers trying to quit.

### **Use of mHealth for Self-Management of Diabetes Mellitus**

Diabetes mellitus occurs in 9.3% of the US population (29.1 million individuals). Of increasing concern is the number of US adults with undiagnosed diabetes mellitus (8.1 million) or prediabetes (86 million).<sup>149</sup> CVD and stroke are serious complications of diabetes mellitus. The majority of US adults  $\geq 18$  years of age with diabetes mellitus have CVD risk factors, including high BP (71%), high cholesterol (65%),<sup>159</sup> and obesity (70%).<sup>150</sup> Although death rates for heart attack and stroke have decreased, adults with diabetes mellitus are twice as likely to be hospitalized for and to die of these diseases as people who do not have diabetes mellitus. Because people with diabetes mellitus are living longer, the prevalence of obesity is not abating, and the rate of diagnosed new cases is increasing (7.8–12.0 per 1000 in 2012, depending on age), scientists expect that the number of people with diabetes mellitus and CVD will continue to rise. However, because the rates of survival after heart attack and stroke continue to improve, more people with diabetes mellitus will continue to live into older age with comorbidities of CVD and diabetes mellitus. According to the joint statement of the AHA and American Diabetes Association, glycemic control in diabetes mellitus management for both type 1 diabetes mellitus and T2DM is important in risk reduction for CVD events. Hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) is the clinical measure of glycemic control, and the self-monitoring of blood glucose is done by the consumer (patient). A general population target of HbA<sub>1c</sub>  $< 7\%$  is recommended for clinician consideration and health plan targets, but an individualized approach to glycemic control at the patient level is suggested. It is important to note that the consumer (patient) role in glycemic control requires problem solving and daily decision making about multiple behaviors (eating, activity, monitoring, and medication taking), and the

healthcare provider role is collaborating with the patient to prescribe the appropriate diabetes mellitus medication(s) and monitoring the impact.<sup>151</sup>

### **Consumer/Patient Perspective**

There are thousands of mobile applications for supporting diabetes mellitus self-management, serving primarily as tracking and reference apps. Few have been evaluated, and even fewer have demonstrated outcomes.<sup>137</sup> In fact, <1% of mobile applications have been evaluated through research. It can be hoped that increased federal and private foundation investments in mHealth and behavioral, clinical, and health system interventions combined with new regulatory requirements will provide consumers and providers with evidence of effectiveness or what works.

A number of pharmacological and lifestyle interventions for diabetes mellitus management have been confirmed by multiple RCTs; however, only 48.7% of patients meet the HbA<sub>1c</sub>, BP, and lipid goals for diabetes mellitus care, and only 14.3% meet these 3 measures and the goals for tobacco use.<sup>137</sup> The National Standards for Diabetes Self-Management Education/Support, jointly published by the American Diabetes Association and the American Association of Diabetes Educators, incorporate the American Association of Diabetes Educators 7 self-care behaviors (physical activity, healthy eating, taking medication, monitoring, self-management problem solving, reducing risks, and healthy coping) as essential behaviors for improving diabetes mellitus self-management.<sup>152,153</sup>

Mobile technologies for diabetes mellitus self-management can be categorized in the following way: SMS apps via mobile phone, diabetes mellitus medical devices (eg, blood glucose meters, insulin pumps) with connectivity to smartphone apps, and bidirectional data sharing between patients and providers through smartphones. This classification did not exist when most of the reviewed articles were published. Interventions delivered via mobile technologies and directed at consumers may be supported by behavior change theories or principles, for example, the self-efficacy theory. However, most studies have limited theoretical foundations or lack an empirical basis. Moreover, healthcare providers lack knowledge about what apps are available or how to evaluate them and thus are hesitant to recommend them.<sup>23</sup>

Although large, primary care RCTs of mobile diabetes mellitus management are limited, smaller studies addressing the feasibility, usability, and acceptability have generally identified the following components as essential to successful diabetes mellitus management: personalized engagement, provision of actionable feedback for consumers, and connection with providers or healthcare systems. Additional contributors to usability include mobile technologies to support community health workers and peer-supported self-care behaviors.<sup>155</sup>

### **Review of Evidence for the Efficacy of Mobile Technology-Based Interventions to Promote Self-Management of Diabetes Mellitus**

We searched PubMed for the years 2004 to 2014 using the terms *type 2 diabetes*; *NIDDM*; *maturity onset diabetes*; *adult onset diabetes*; *non-insulin dependent*; *noninsulin dependent*; *slow onset diabetes*; *stable diabetes*; *hyperinsulinemia*;

*hyperinsulinism*; *insulin resistance*; *hyperglycemia*; *glucose intolerance*; *metabolic syndrome*; *metabolic X syndrome*; *dysmetabolic syndrome*; and *metabolic cardiovascular syndrome*. These terms were cross-referenced with the mobile technology terms described previously. This search resulted in 242 identified articles. Of these, 83 were not relevant to the use of mobile technology with diabetes mellitus, and 159 were reviewed further. Of these 159 references identified, 142 were excluded after review of the title, abstract, and full text. Similar to other sections of this review, mobile technologies may target multiple behaviors singly or in combination to improve numerous clinical and behavioral outcomes. Therefore, for this review, we focused on studies with change in the clinical metric of HbA<sub>1c</sub> as the primary outcome, considered the gold standard in diabetes mellitus improvement. Seventeen articles were eligible for this review, and 10 of these 17 were international studies.

The types of mobile technologies used for diabetes mellitus self-management research interventions include mobile platforms with diabetes mellitus-specific software apps or SMS. Table 5 provides details of the RCTs using these mobile tools that we reviewed.

When evaluating interventions, we considered an HbA<sub>1c</sub> reduction of at least 0.3% as a clinically meaningful treatment effect<sup>175</sup> and a 1% decrease in HbA<sub>1c</sub> as a clinically meaningful indicator of reduced risk of diabetes mellitus complications on the basis of the Diabetes Control and Complications Trial (DCCT) and UK Prospective Diabetes Study (UKPDS) clinical trials.<sup>176,177</sup> One US study<sup>170</sup> reported a significantly greater HbA<sub>1c</sub> decrease in the intervention group than in the control group. Quinn et al<sup>170</sup> evaluated a mobile phone software application with a patient and provider Web portal. The average HbA<sub>1c</sub> decline over the 1-year intervention was 1.9% for the intervention group versus 0.7% for the control group, a difference of 1.2% ( $P < 0.001$ ). Among 4 studies<sup>156,158,159,165</sup> using SMS alone and SMS with Web tracking, 3 studies reported significant changes in HbA<sub>1c</sub>.<sup>156,159,165</sup> Six studies used a mixture of technologies for the intervention, including mobile phones, Internet, Web portals, SMS, and glucose meters that provided messaging.<sup>164,166,168,171,178</sup>

We also include in Table 5 a systematic review by Liang et al<sup>173</sup> and a Cochrane review.<sup>174</sup> The systematic review included 22 trials. The meta-analysis of 1657 participants showed that mobile phone interventions for diabetes mellitus self-management reduced HbA<sub>1c</sub> values by a mean of 0.5% over a median of 6 months of follow-up. A subgroup analysis of 11 studies of patients with T2DM reported a significantly greater reduction in HbA<sub>1c</sub> compared with studies of those with type 1 diabetes mellitus (0.8% [9 mmol/mol] versus 0.3% [3 mmol/mol];  $P = 0.02$ ). The authors reported that the effect of the mobile phone intervention did not differ significantly by other participant characteristics or intervention strategies. The Cochrane review reported computer-based diabetes mellitus self-management interventions for adults with T2DM in 4 studies. The interventions addressed in this review included those using computer-based software applications that were based on user input (touch screen or other clinic support), desktop computer-based and mobile phone-based interventions. The Cochrane review also included other outcomes besides HbA<sub>1c</sub>, for example, health-related quality of life, death resulting from any cause, depression, adverse

**Table 5. Description of Studies Using mHealth for Blood Glucose Control**

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention   | Study Groups and Components   | Technology Used                                 | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: HbA <sub>1c</sub> (% or % Change)   |
|---|--|---|---|--|--|
| Kim <sup>156</sup> and Kim and Jeong, <sup>157</sup> 2007<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea                | N=60<br>Int1: n=30<br>Int2: n=30<br><br>Mean age (SD):<br>Int1: 46.8 (8.8) y<br>Int2: 47.5 (9.1) y<br><br>Women: 56.9%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 8.1 (1.7)<br>Int2: 7.6 (1.1)<br><br>Retention: 85%           | Int1: Ps tracked their blood glucose levels and medications on a Web portal and received weekly feedback from a diabetes nurse<br><br>Int2: Usual care  | SMS with Web-based tracking of glucose levels   | Duration: 6 mo<br><br>Contacts:<br>Int1: Weekly feedback via SMS<br>Int2: 1–2 times during the 6 mo<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Diabetes nurse<br>Int2: Clinician   | Completer's analysis (n=51)<br>3 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 6.9 (1.0)<br>Int2: 7.7 (0.9)<br>P<0.05<br><br>6 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.0 (1.4)<br>Int2: 7.7 (0.9)<br>Group×time: P=0.008             |
| Faridi et al, <sup>158</sup> 2008<br>Design: 2-group RCT<br>Outcome: Δ in HbA <sub>1c</sub><br>Setting: Community<br>Country: United States                                     | N=30<br>nt1: n=15<br>Int2: n=15<br><br>Mean age (SD): 56 (9.7) y<br><br>Women: 63%<br>White: NR<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 6.4 (0.6)<br>Int2: 6.5 (0.7)<br><br>Retention: 13%                                  | Int1: 1-day training and 3-mo intervention using the NICHE system (transmits glucometer and pedometer data to online server which then transmits tailored feedback to Ps via text messaging).<br><br>Int2: Continued standard diabetes mellitus self-management and tracked step count with pedometer | Internet and SMS                                | Duration: 3 mo<br><br>Contacts: 1-y training workshop on NICHE device; Ps required to upload once-daily glucose and pedometer data daily and receive tailored SMS messages<br><br>Intervention adherence: 13.3% completely adherent; 26.7% adherent for 1–2 mo; 26.7% adherent for 1 wk; 33.3% did not transmit any information<br><br>Interventionist:<br>Int1: Nurse practitioners<br>Int2: NR | ITT<br>3 mo:<br>HbA <sub>1c</sub> Δ, %, M (SD):<br>Int1: -0.1 (0.3)<br>Int2: 0.3 (1.0)<br>P=NS   |
| Kim and Song <sup>159</sup> and Kim and Kim, <sup>160</sup> 2008<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Outpatient clinic<br>Country: South Korea | N=40<br>Int1: n=20<br>Int2: n=20<br><br>Mean age (SD):<br>Int1: 45.5(9.1) y<br>Int2: 48.5(8.0) y<br><br>Women: 52.9%<br>White: NR<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 8.1(1.9)<br>Int2: 7.6 (0.7)<br><br>Retention: 85% | Int1: Ps recorded daily glucose values in Web portal; received weekly SMS feedback from diabetes educator<br><br>Int2: Usual care   | SMS feedback based on Web-based tracking portal | Duration: 12 mo<br><br>Contacts:<br>Int1: Weekly feedback via SMS<br>Int2: Contact at 3 and 6 mo<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Diabetes physician+diabetes educator<br>Int2: Diabetes physician+diabetes educator   | Completer's analysis (n=34)<br>6 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.1 (1.5)<br>Int2: 7.7 (0.5)<br>Group×time: P=0.04<br><br>12 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 6.7 (0.8)<br>Int2: 8.2 (0.5)<br>Group×time: P=0.02 |
| Yoon and Kim, <sup>161</sup> 2008<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea  | N=60<br>Int1: n=30<br>Int2: n=30<br><br>Mean age (SD):<br>Int1: 46.8 (8.8) y<br>Int2: 47.5 (9.1) y<br><br>Women: 56.9 %<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 8.1 (1.7)<br>Int2: 7.6 (1.1)<br><br>Retention: 85.0%        | Int1: Completed self-monitoring blood glucose levels, entered values and medication data on a Webpage; this information was used to tailor recommendations to Ps. Tailored messages sent via SMS and Internet, weekly medication adjustments communicated to the Ps' physician.                       | SMS and Web                                     | Duration: 12 mo<br><br>Contacts: Baseline and posttest assessments; blood draws at baseline, 3, 6, 9, and 12 mo<br>Int1: Had 52 messages over 1 y<br>Int2: Same assessment time points as Int1, but in-person contact at outpatient clinic was variable per Ps   | Completer's analysis (n=51)<br>12 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 6.8 (0.8)<br>Int2: 8.4 (1.0)<br>P=0.001   |

(Continued)

Table 5. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention  | Study Groups and Components   | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: HbA <sub>1c</sub> (% or % Change)   |
|---|---|---|---|---|--|
|   |   | Int2: Met with endocrinologist in person at an outpatient clinic and was given basic information  |   | Intervention adherence: Assessment attendance (completed posttest):<br>Int1: 83.3%<br>Int2: 86.7%<br><br>Interventionist:<br>Int1: Physicians and nurses<br>Int2: Endocrinologist   |  |
| Istepanian et al, <sup>162</sup> 2009<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: United Kingdom | N=137<br>Int1: n=72<br>Int2: n=65<br><br>Mean age (SD):<br>Int1: 60 (12) y<br>Int2: 57 (13) y<br><br>Women: NR<br><br>White: 34%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.9 (1.5)<br>Int2: 8.1 (1.6)<br><br>Retention: 64%                                | Int1: SMBG via Bluetooth upload; data were reviewed by research team; analysis was sent via mail to Ps and PCP. Ps had hotline access to research team for questions<br><br>Int2: Standard care   | Glucometer adapted to send data via Bluetooth to mobile phone | Duration: 9 mo<br><br>Contacts: Int1 P's blood glucose measurements transmitted wirelessly; research clinicians sent letters to Ps and their providers with treatment recommendations<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Clinicians<br>Int2: Clinicians   | ITT<br><br>Mean 9 mo HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.9 (NR)<br>Int2: 8.2 (NR)<br><br>Completer's analysis (n=87)<br>HbA <sub>1c</sub> (%), M (SD):<br>Int2: 7.8 (NR)<br>Int2: 8.4 (NR)<br><br>P=0.17<br><br>P=0.06 |
| Rodríguez-Idígoras et al, <sup>163</sup> 2009<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub><br>Setting: Community<br>Country: Spain      | N=328<br>Int1: n=161<br>Int2: n=167<br><br>Mean age (95% CI):<br>Int1: 63.3 (61.6–5.0)<br>Int2: 64.5 (63.0–66.1)<br><br>Women: 48%<br><br>White: NR<br><br>HbA <sub>1c</sub> (%), M (95% CI):<br>Int1: 7.6 (7.4–7.9)<br>Int2: 7.4 (7.2–7.6)<br><br>Retention: 91% | Int1: Ps provided mobile phone and tele-assistance system (DIABECOM) using real-time transmission of blood glucose results, with immediate reply when necessary, and telephone consultations<br><br>Int2: Standard clinical care  | Mobile phone, tele-assistance system                          | Duration: 12 mo<br><br>Contacts: Ps made average of 3 calls/mo; average, 2.6 reminder or follow-up calls from call center<br><br>Intervention adherence: Use of tele-assistance system (%):<br>Int1: 62%<br>Int 2: NA<br><br>Interventionist:<br>Int1: Physician and a nurse specializing in diabetes and diabetes education<br>Int2: NR  | ITT (n=321)<br>12 mo:<br>HbA <sub>1c</sub> (%), M (95% CI):<br>Int1: 7.4 (7.2–7.6)<br>Int2: 7.4 (7.1–7.6)<br><br>P=0.34  |
| Yoo et al, <sup>164</sup> 2009<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea           | N=123<br>Int1: n=62<br>Int2: n=61<br><br>Mean age (SD):<br>Int1: 57.0 (9.1) y<br>Int2: 59.4 (8.4) y<br><br>Women: 47.2%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.6 (0.9)<br>Int2: 7.4 (0.9)<br><br>Retention: 90.2%                                       | Int1: UCDC system using mobile phones and Web-based interaction. UCDC included device attached to mobile phone that transmitted blood glucose data. Ps received SMS reminder to check blood glucose, also tips via SMS 3 times/d. Physicians could track the Ps' data and send individualized messages as needed.<br><br>Int2: Usual Care. Ps visited according to usual schedule and received usual care in the outpatient setting | SMS and Internet  | Duration: 3 mo<br><br>Contacts:<br>Int1: 2 alarms daily to remind Ps to measure blood glucose values and blood pressure and 1 alarm daily for weight. Additionally, each P received at least 3 SMSs daily<br>Int2: Dependent on usual care routine. Each P was seen at baseline and at 3 mo to collect anthropometric and laboratory data | Completer's analysis (n=111)<br>3 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.1 (0.8)<br>Int2: 7.6 (1.0)<br><br>Group×time: P=0.001   |

(Continued)

Table 5. Continued

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention   | Study Groups and Components   | Technology Used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: HbA <sub>1c</sub> (% or % Change)   |
|--|--|---|--|--|--|
| Kim et al, <sup>165</sup> 2010<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea      | N=100<br>Int1: n=50<br>Int2: n=50<br>Mean age (SD):<br>Int1: 47.8 (9.6) y<br>Int2: 49.0 (10.7) y<br>Women: 50%<br>White: NR<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 9.8 (1.3)<br>Int2: 9.8 (1.2)<br>Retention: 92%    | Int1: Received daily insulin dose adjustments via SMS based on logged data sent via mobile phone to Web site<br>Int2: Self-adjusted basal insulin according to daily self-monitored capillary FBG measurements using glucometers        | SMS with Web tracking                                  | Intervention adherence:<br>Int1: Sent in glucose readings 1.84±0.31 times/d with a compliance rate of 92.2±15.4%<br>Blood pressure readings sent in 1.72±0.32 times/d with a compliance rate of 86.0±16.2%<br>Weight measurements were sent in 0.87±0.20 times/d with a compliance rate of 87.4±20.1%<br>Interventionist:<br>Int1: Automated<br>Int2: Physician<br>Duration: 12 wk<br>Contacts:<br>Ps' dose adjustments were reviewed by the investigator at 4- and 8-wk clinical visits.<br>Intervention adherence:<br>No. of checks of blood glucose monitoring:<br>Int1: 51.8 (16.1) checks<br>Int2: 42.2 (13.2) checks<br>P=0.002<br>Interventionist:<br>Int1: Automated<br>Int2: NR | Completer's analysis (n=92)<br>12 wk:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.4 (0.7)<br>Int2: 7.8 (0.8)<br>P=0.02<br>Δ in weight (kg), M (SD):<br>Int1: 2.4 (3.0)<br>Int2: 2.2 (2.8)<br>P=0.65 |
| Noh et al, <sup>166</sup> 2010<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea      | N=44<br>Int1: n=24<br>Int2: n=20<br>Mean age (SD):<br>Int1: 42.5 (10.6) y<br>Int2: 42.3 (7.6) y<br>Women: 22.5%<br>White: NR<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 9.0 (2.3)<br>Int2: 8.6 (1.2)<br>Retention: 90.9% | Int1: eMOD, a Web-based ubiquitous information system, for mobile phone users along with a Web site for Internet users to provide diabetes education<br>Int2: educational books with contents similar to that in eMOD Web site          | eMOD mobile and Web application for diabetes education | Duration: 6 mo<br>Contacts:<br>All Ps visited their physicians every 2 mo<br>Intervention adherence:<br>Int1: eMOD system was accessed via computer 160 times during the study period<br>Interventionist:<br>Int1: Physicians<br>Int2: Physicians  | Completer's analysis (n=40)<br>6 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.5 (1.4)<br>Int2: 8.1 (0.3)<br>P=0.23   |
| Carter et al, <sup>167</sup> 2011<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: United States | N=74<br>Mean age (SD):<br>Int1: 52 (NR)<br>Int2: 49 (NR)<br>Women: 64%<br>Black: 100%<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 9.0 (NR)<br>Int2: 8.8 (NR)  | Int1: Ps were provided laptop with peripherals (scale, BP cuff, glucometer) with automatic transmission to Internet; biweekly video conferencing with nurse; access to Internet-based self-management module with tailored action plan, | Internet, wireless scales, BP cuffs, and glucometers   | Duration: 9 mo<br>Contacts:<br>Ps weigh daily, check BP weekly, SMBG 3 times daily; biweekly 30-minute video conferences with telehealth nurse to develop tailored action plan<br>Intervention adherence:<br>NR  | Completer's analysis (n=47)<br>9 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 6.8 (NR)<br>Int2: 7.9 (NR)<br>P<0.05<br>Δ in weight (lb), M:<br>Int1: -73.0<br>Int2: -58.1<br>P<0.05                 |

(Continued)

Table 5. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention   | Study Groups and Components   | Technology Used                                  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: HbA <sub>1c</sub> (% or % Change)   |
|---|--|---|--|---|--|
|   | Retention: 64%<br>Int1: n=26<br>Int2: n=21   | health education module, and social networking module<br><br>Int2: standard clinical care   |  | Interventionist:<br>Int1: Nurse<br>Int2: NR   | Δ in systolic BP, M:<br>Int1: -7<br>Int2: -8<br>P>0.05<br><br>Δ in diastolic BP, M:<br>Int1: -15<br>Int2: -14<br>P>0.05  |
| Lim et al, <sup>168</sup> 2011<br>Design: 3-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea                       | N=154<br>Int1: n=51<br>Int2: n=51<br>Int3: n=52<br><br>Mean age (SD):<br>Int1: 67.2 (4.1) y<br>Int2: 67.2 (4.4) y<br>Int3: 68.1 (5.5) y<br><br>Women: 55.8%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.8 (1.0)<br>Int2: 7.9 (0.9)<br>Int3: 7.9 (0.8)<br><br>Retention: 93.5% | All Ps were standardized with diabetes mellitus education<br><br>Int1: Usual healthcare: SMBG+SMS feedback<br><br>Int2: SMBG<br><br>Int3: usual care  | SMS, Gluco Dr Supersensor, AGM-2200, Allmedicus  | Duration: 6 mo<br><br>Contacts:<br>All Ps visited the outpatient clinic every 3 mo for an interview conducted by their physician and provided a blood sample<br><br>Intervention adherence:<br>Frequency of SMBG, n/wk:<br>Int1: 10.5 (5.1)<br>Int2: 8.2 (4.2)<br>Int3 2.4 (3.3)<br><br>Interventionist:<br>Int1:<br>Automated+specialized diabetes management team consisting of well-trained professionals, including diabetologists, nurses, dietitians, and exercise trainers; organized and directed patient education<br>Int2: Specialized diabetes management team consisting of well-trained professionals, including diabetologists, nurses, dietitians, and exercise trainers; organized and directed patient education<br>Int3: NR | Completer's analysis (n=144)<br>6 mo:<br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.4 (1.0)<br>Int2: 7.7 (1.0)<br>Int3: 7.8 (1.0)<br>P<0.05 (Int1 vs Int2 and Int1 vs Int3)                           |
| Quinn et al, <sup>169</sup> 2008<br>Design: RCT<br>Outcome: Δ in HbA <sub>1c</sub> (%)<br>Setting: Primary care practices<br>Country: United States         | N=30<br>Int1: n=NR<br>Int2: n=NR<br><br>Mean age (SD): 51.04 (11.03) y<br><br>Women: 65%<br><br>Black: 62%   | Int1: Mobile phone-based diabetes management software system used with Web-based data analytics and therapy optimization tools<br><br>Int2: Usual care by PCP   | Mobile phone                                     | Duration: 3 mo<br><br>Total contacts: Baseline, 3-mo follow-up<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Healthcare providers<br>Int2: PCP   | Complete analysis (n=26)<br>Δ in HbA <sub>1c</sub> (%), M (95% CI):<br>Int1: 2.03%<br>Int2: 0.68%<br>(P<0.02, 1 tailed)  |
| Quinn et al, <sup>170</sup> 2011<br>Design: Cluster RCT<br>Outcome: Δ in HbA <sub>1c</sub> (%)<br>Setting: Primary care practices<br>Country: United States | N=213<br>Int1: n=62<br>Int2: n=38<br>Int3: n=33<br>Int4: n=80  | Int1: CO. Ps received educational and motivational messages after putting data into the phone. Ps also received supplemental electronic messages within the application, generated by "virtual educators" based on longitudinal data trends | App designed for diabetes management, Web portal | Duration: 12 mo<br><br>Total contacts: Baseline, 12-mo follow-up. Charts reviewed for HbA <sub>1c</sub> at 3, 6, and 9 mo<br><br>Intervention adherence: NR   | Completer's analysis (n=163)<br>12 mo:<br>Δ in HbA <sub>1c</sub> (%), M (95%CI):<br>Int1: -0.7 (-1.1 to -0.3)<br>Int2: -1.6 (-2.3 to -1.0)<br>Int3: -1.2 (-1.8 to -0.5)<br>Int4: -1.9 (-2.3 to -1.5) |

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Table 5. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention  | Study Groups and Components   | Technology Used                  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: HbA <sub>1c</sub> (% or % Change)   |
|---|---|---|----------------------------------|---|--|
|   | Mean age (SD):<br>Int1: 53.2(8.4) y<br>Int2: 52.8(8.0) y<br>Int3: 53.7(8.2) y<br>Int4: 52(8.0) y<br><br>Women: 44.2%<br>White: 52.8%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 9.2 (1.7)<br>Int2: 9.3 (1.8)<br>Int3: 9.0 (1.8)<br>Int4: 9.9 (2.1)<br><br>Retention:<br>76.5% | Int2: Coach PCP portal. Same as CO except PCP was able to view raw data and discuss with the Ps<br><br>Int3: Coach PCP portal with decision support. Same as CO except PCPs received Ps' analyzed data that summarized glycemic and metabolic control, adherence to medication, self-management skills; related to evidence-based guidelines and standards of care.<br><br>Int4: Usual care |                                  | Interventionist:<br>Int1: Coach<br>Int2: Coach diabetes educators+PCP<br>Int3: Coach diabetes educators+PCP<br>Int4: Usual care clinicians  | $P=0.001$ (Int4 vs Int1),<br>$P=0.02$ (Int2 vs Int1),<br>$P=0.40$ (Int3 vs Int1)<br><br>$\Delta$ in systolic BP (mm Hg), M (95% CI):<br>Int1: 2 (-3 to 7)<br>Int2: 4 (-4 to 11)<br>Int3: 2 (-6 to 10)<br>Int4: -2 (-6 to 3)<br>$P>0.05$<br><br>$\Delta$ in diastolic BP (mm Hg), M (95% CI):<br>Int1: 1 (-2 to 4)<br>Int2: 2 (-2 to 7)<br>Int3: -2 (-6 to 3)<br>Int4: -1 (-4 to 2)<br>$P>0.05$   |
| Orsama et al, <sup>171</sup> 2013<br>Design: 2-group RCT<br>Outcome: $\Delta$ in HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: Finland    | N=55<br>Int1: n=29<br>Int2: n=26<br><br>Mean age (SD):<br>Int1: 61.5 (9.1) y<br>Int2: 62.3 (6.5) y<br><br>Women: 45.8%<br><br>HbA <sub>1c</sub> (%), M (SD):<br>Int1: 7.1 (1.5)<br>Int2: 6.9 (1.6)<br><br>Retention: 87.3%  | Int1: Ps participated in remote patient reporting of health status parameters and linked health behavior change feedback (called Monica)<br><br>Int2: Received standard of care, including diabetes education and healthcare provider counseling  | Internet, mobile phone           | Duration: 10 mo<br><br>Contacts:<br>Int1: Ps received real time feedback<br><br>Intervention adherence:<br>NR<br><br>Interventionist:<br>Int1: Automated+healthcare provider<br>Int2: Healthcare provider                             | Completer's analysis (n=48)<br>10 mo:<br>$\Delta$ in HbA <sub>1c</sub> (%), M (95% CI):<br>Int1: -0.40 (-0.67 to -0.14)<br>Int2: 0.04 (-0.23 to 0.30)<br>$P=0.02$<br><br>$\Delta$ in weight (kg), M (95% CI):<br>Int1: -2.1 (-3.6 to -0.6)<br>Int2: 0.4 (-1.1 to 1.9)<br>$P=0.02$<br><br>$\Delta$ in systolic BP (mm Hg), M (95% CI):<br>Int1: -13.5 (-21.3 to -5.8)<br>Int2: -17.1 (-24.3 to -9.9)<br>$P=0.51$<br><br>$\Delta$ in diastolic BP (mm Hg), M (95% CI):<br>Int1: -7.3 (-10.9 to -3.8)<br>Int2: -9.5 (-12.9 to -6.2)<br>$P=0.38$ |
| Forjuoh et al, <sup>172</sup> 2014<br>Design: 4-group RCT<br>Outcome: $\Delta$ in HbA <sub>1c</sub><br>Setting: Community<br>Country: United States | N=376<br>Int1: n=101<br>Int2: n=81<br>Int3: n=99<br>Int4: n=95<br><br>Mean age (SD):<br>57.6 (10.9) y<br><br>Women: 55%<br>White: 64%   | Int1: Chronic Disease Self-Management Program<br><br>Int2: PDA<br><br>Int3: Chronic Disease Self-Management Program+PDA<br><br>Int4: Usual care   | PDA with diabetes pilot software | Duration: 12 mo<br><br>Contacts:<br>Int1: 6 wk, 2.5 h/wk classroom-based program for diabetes self-management<br>Int2: Diabetes pilot software on a PDA (with training; software tracks glucose, BP, medications, PA, dietary intake) | Completer's analysis (n=263)<br>12 mo:<br>HbA <sub>1c</sub> $\Delta$ , % (SD)<br>Int1: -0.7 (NR)<br>Int2: -1.1 (NR)<br>Int3: -0.7 (NR)<br>Int4: -1.1 (NR)<br>$P=0.77$  |

(Continued)



Table 5. Continued

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline HbA <sub>1c</sub> , Study Retention   | Study Groups and Components  | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: HbA <sub>1c</sub> (% or % Change)  |
|--|--|--|---|--|---|
|  | HbA <sub>1c</sub> (%), M (SD):<br>Int1: 9.4 (1.7)<br>Int2: 9.3 (1.6)<br>Int3: 9.2 (1.4)<br>Int4: 9.2 (1.6)<br><br>Retention: 70% |  |   | Intervention adherence:<br>Attendance (4/6 sessions):<br>Int1: 75.6%<br>Int3: 72.7%<br>No. of entries/y:<br>Int2: 342<br>Int3: 359<br><br>Interventionist:<br>Int1: NR<br>Int2: NR<br>Int3: NR<br>Int4: NR |   |
| Systematic reviews and meta-analyses   |  |  |   |  |   |
| Liang et al, <sup>173</sup> 2011<br>Design: Meta-analysis of 22 clinical trials<br>Outcome: Δ in HbA <sub>1c</sub> (%) | N=1657<br><br>Mean age (SD): 44 (18) y<br><br>Women: 45%<br>White: NR  | Studies on impact of mobile phone intervention on diabetes self-management   | SMS to deliver blood glucose test results and self-management information | Duration: median, 6 mo (range, 3–12 mo)  | Median 6 mo pooled Δ in HbA <sub>1c</sub> (%), M (95% CI): -0.5 (-0.3 to -0.7), indicating that the reduction of HbA <sub>1c</sub> value was 0.5% lower in mobile Int groups compared with other Int groups<br><br>Subgroup analysis showed greater Δ in HbA <sub>1c</sub> in type 2 than type 1 diabetes mellitus (-0.8% vs -0.3%)<br>P=0.02 |
| Pal et al, <sup>174</sup> 2013<br>Design: meta-analysis of data from 11 Trials<br>Outcome: HbA <sub>1c</sub> (%)       | N=3578<br><br>Mean age: 46–67 y<br><br>Time since diagnosis: 6–13 y  | Assess the effects on health status and health-related quality of life of computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus | Computer-based interventions  | Duration: range, 1–12 mo   | Based on 2637 Ps; 11 trials:<br>Pooled effect on HbA <sub>1c</sub> : 0.2% (95% CI, -0.4 to -0.1)<br>P=0.009<br><br>Based on 280 Ps; 3 trials. The effect size on HbA <sub>1c</sub> was larger in the mobile subgroup: mean difference in HbA <sub>1c</sub> : -0.5% (95% CI, -0.7 to -0.3)<br>P<0.00001  |



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Automated indicates without a clinician who generates, tailors, or modifies the output; Baseline, 0; BP, blood pressure; CI, confidence interval; CO, coach only; Δ, change or difference; eMOD, electronic Management of Diabetes; HbA<sub>1c</sub>; hemoglobin A1c; Int, intervention group; ITT, intention to treat; M, mean; n, subgroups; N, total sample; NA, not applicable; NICHE, Novel Interactive Mobile-Phone Technology for Health Enhancement; NR, not reported; P, participant; PA, physical activity; PCP, primary care physician; PDA, personal digital assistant; RCT, randomized, controlled trial; SMBG, self-monitoring blood glucose; SMS, short message service; and UCDC, Ubiquitous Chronic Disease Care.

effects, and economic data.<sup>174</sup> A review of 11 studies by Pal et al<sup>174</sup> provided data for a meta-analysis from which the authors reported pooled results indicating a small, statistically significant difference in outcomes between the intervention and comparison groups (mean difference, -0.21; 95% confidence interval, -0.4 to -0.1). However, for 8 of the reviewed studies, they reported that the significant mean difference in the HbA<sub>1c</sub> change for mHealth interventions compared with control condition ranged from 0.01 to -0.8 (95% confidence interval, -1.45 to 0.15).

An early review of evidence on barriers and drivers of the use of interactive consumer health information technology by the elderly, people with chronic conditions or disabilities, and the underserved concluded that questions remain as to the optimal frequency of use of systems by patients and providers and whether the success of interventions depends on repeated modification of the patient's treatment regimen or ongoing assistance with applying a static treatment plan.<sup>179</sup> A recent review focused on the effect of mobile phone interventions for

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glucose control in diabetes mellitus.<sup>173</sup> This meta-analysis of 22 studies with 1657 participants showed that mobile phone interventions significantly reduced HbA<sub>1c</sub> by a mean of 6 mmol/mol or 0.5% over a median follow-up of 6 months. Among the studies that we reviewed (Table 5), duration of interventions in the studies varied from 3 to 18 months. However, it should be noted that most clinical trials we reviewed examined change in HbA<sub>1c</sub> during a 3-month intervention, and very little was reported about the engagement and persistence of use with the technology. Participants randomized to the intervention arms of the trials received enhanced clinical attention and may have received diabetes mellitus management supplies. Therefore, it may be inaccurate to assume that a significant change in HbA<sub>1c</sub> in an intervention group at 3 months is attributable to technology instead of other nonspecific benefits of participation, especially considering a report from a 2011 survey that showed that 26% of downloaded health apps are used only once and 74% are abandoned by the 10th use.<sup>180</sup>

The use of heterogeneous interventions (mobile phones, SMS, or Internet based) makes it more difficult to determine the effect of any single technology component on HbA<sub>1c</sub>. As suggested in other reviews<sup>174,181</sup> of studies with different technology-based approaches (eg, automatic SMS messages versus personalized feedback), a single component of technology may affect different behaviors in ways not clearly distinguishable when intervention components are combined. Authors of 2 systematic reviews concluded that interventions were more likely to be successful if they selected and combined theory-based behavior change strategies,<sup>174,182</sup> including interactive components that involve tracking, personalized feedback, and peer support.

#### **Gaps and Recommendations for Future Directions**

Few studies focus on high-risk, underserved, or minority populations. Most studies do not report changes in antihyperglycemic medications during the intervention, which may affect the change in HbA<sub>1c</sub>. Without that information, it is difficult to determine whether changes in lifestyle behavior or changes in medications contributed to the effectiveness of the mobile intervention. It is possible that reports of the follow-up secondary analyses of such studies have not been published or that our search missed them. The reviewed studies did not report intervention dose or receipt, that is, the number of SMS messages or push notifications sent and opened by participants. Only 1 study<sup>170</sup> reported differences in HbA<sub>1c</sub> change as a function of different baseline HbA<sub>1c</sub> levels, which may be important for understanding who will most benefit when specific populations, including older adults, are targeted. Similar to other sections in this statement, we recommend here that future studies address the need to identify specific behaviors that may impact glucose management singly or in combination.

We recommend the following:

- Technology development or intervention development should be considered to meet the needs of specific population groups: older adults with age-related changes such as vision or touch, minorities needing culturally sensitive intervention content or materials and approaches, and low-income adults who may have inconsistent access to mobile technologies and supplies to support diabetes mellitus management.

- Studies should evaluate technology-supported glucose management for periods >3 months to determine the sustainability of engagement and the long-term effects of mHealth interventions in maintaining behavior changes.
- Studies are needed that include clinical, technical, and behavioral factors that may influence the initial engagement and ongoing use of mHealth and its associated impact on outcomes.
- Future studies should examine other outcomes related to improved diabetes mellitus management such as quality of life and acceptability of mHealth devices.
- Finally, we recommend that future studies examine the relationships among use of mHealth interventions, HbA<sub>1c</sub> change, and healthcare use and costs, including consumer and provider costs. As more public and private insurers reimburse for the cost of mHealth interventions, evaluation of claims data from these populations may add to our understanding of cost-effectiveness.

#### **Using mHealth to Improve Hypertension Care**

Hypertension is a highly prevalent chronic medical condition that is a major risk factor in CVD. The risk for CVD events such as stroke or myocardial infarction doubles for every 20-mmHg increase in systolic BP (SBP) and 10-mmHg increase in diastolic BP.<sup>183</sup> Best practices for treatment of hypertension include a combination of pharmacotherapy and preventive lifestyle counseling for exercise, healthful eating, and smoke-free living.<sup>183</sup> Despite widespread initiatives to treat hypertension and the availability of antihypertensive medications, <50% of people in the United States have controlled BP.<sup>150</sup> This is thought to be due largely to suboptimal adherence to self-care.<sup>184</sup>

Strategies to improve self-care and adherence have been explored. Face-to-face counseling has been shown to be associated with reductions of 3 to 8 mmHg in SBP among patients with hypertension.<sup>184</sup> Team-based hypertension care, with partnership between a primary care physician and other professionals such as nurses, pharmacists, or community health workers, has been shown to increase the percentage of patients with controlled BP by 12%.<sup>185</sup> Still, costs of such care models prevent dissemination and sustainability.

The rapid growth of the Internet and mobile telecommunication offers unprecedented opportunity to improve patient access to and engagement with hypertension care.<sup>186,187</sup> In general, they follow the premise that patients might spend only a few hours a year with a physician or nurse, but they spend 5000 waking hours each year engaged in choices that affect their health.<sup>188</sup> These eHealth programs can be delivered by the Internet, e-mail, SMS, or similar electronic means to engage patients in remote BP, medication, and behavior monitoring and to provide patients relevant education, counseling and motivational support.

One example of an mHealth intervention that has become accepted as beneficial to the management of hypertension is self-measured BP (SMBP) monitoring. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends SMBP monitoring as an adjunct method in the management of hypertension.<sup>183</sup> The AHA recommends SMBP for the evaluation of most patients with known or suspected

hypertension to assess response to treatment and possibly to improve adherence.<sup>189</sup> Still, much remains unknown about what other mHealth interventions are effective in improving hypertension care.

### **Review of Evidence for the Efficacy of Mobile Technology–Based Interventions to Promote BP Control**

Our review focuses on mHealth intervention effects on SBP specifically, given its association with cardiovascular outcomes. We searched PubMed for the years 2004 to 2014 using the following terms: *hypertension; hypertensive; antihypertensive; anti-hypertensive; pre-hypertensive; high blood pressure; elevated blood pressure; increased blood pressure; systolic blood pressure; and diastolic blood pressure*. These terms were cross-referenced with the mobile technology terms described previously. This search resulted in 316 identified articles; 191 were excluded because they were not relevant to mobile technologies. The remaining 125 were articles reporting descriptions of technology, pilot data, and surveys on physician or patient opinions; were editorials; or did not focus on BP. Of the 39 remaining, only 13 RCTs were of sufficient quality to be included in this review. These studies were published between 2008 and 2014 and permitted patients some form of electronic platform to assist with self-monitoring or support for hypertension (Table 6). We focused on interventions that offered some additional feature beyond simply SMBP monitoring, and we included Internet-based studies because an increasing number of people access the Internet on mobile devices.<sup>26</sup> We divided the review to describe first individual studies organized by the primary form of mHealth used to deliver the intervention and then existing systematic reviews. Here, we provide details on the salient studies and what was learned from the review.

Three RCTs used text messaging as the primary intervention modality.<sup>192–194</sup> The details of these studies are provided in Table 6. The 3 studies had methodological limitations including poor retention. Two of the studies<sup>193,194</sup> reported significant differences in BP reduction between the treatment conditions; however, all studies reported results using the completers' analysis approach rather than intention to treat.

E-mail was the primary intervention modality for 3 RCTs.<sup>191,195,202</sup> These studies ranged from 4 to 6 months, and all had high retention. The frequency of the e-mail contact was not specified in the Nolan et al<sup>195</sup> study and was frequent in the other studies. Madsen et al<sup>191</sup> augmented the e-mail information exchange with messages sent via a PDA. Cicolini et al<sup>202</sup> and Nolan et al,<sup>195</sup> using a completers' analysis, reported a significant difference between groups in BP changes, whereas Madsen et al,<sup>191</sup> using intention-to-treat analysis, did not find a difference in BP between groups but observed that a significantly higher proportion of the intervention group achieved the target BP.

A single study was found that used IVR as the primary intervention modality and was conducted in Honduras and Mexico.<sup>196</sup> Participants received weekly information on medication adherence and salt intake tailored to their BP through the IVR. There was only a trend for a significant difference in BP reduction from the control group, which may be attributable to only 67% completion of the IVR calls.

Two RCTs used a Web site as the primary intervention modality.<sup>197,201</sup> Thiboutot et al<sup>201</sup> enrolled 500 adults from

primary care practice offices in central Pennsylvania. The Web-based intervention provided feedback on reported BP and advice; however, only 35% of intervention participants used the Web site at least once monthly.<sup>201</sup> Watson et al enrolled 404 adults with high BP from 6 worksites for a 6-month study that included a Web site that displayed SMBP readings and provided education and custom messages based on BP reports.<sup>197</sup> Adherence to SMBP was low overall, with only 17% of intervention participants reporting SMBP in month 1 and 7% at month 6. Neither of these studies demonstrated significant reductions in BP, and no differences were seen between intervention and control conditions. It was not stated but it is possible that the adherence was so low because participants might not have had the capability to access the Web site via a mobile device.

Three RCTs used a mixture of mHealth modalities to deliver the intervention. Green et al<sup>190</sup> used Web access, including secure e-mail, medical records, a health library, and links to resources, versus a Web plus pharmacist or a control (usual care) condition. Only the Web plus pharmacist group reduced their SBPs significantly better than the other conditions at 12 months. That modality also resulted in increases in secure messaging between patient and provider/pharmacist and more antihypertensive medication classes being added. McKinstry et al<sup>199</sup> compared 6 months of SMBP with access to a Web site with graphical displays of SMBP data and optional automated SMS or e-mails with feedback on their BP control against a control condition. Adherence to uploading BP data was high, but the number of participants opting for SMS or e-mails was not reported. The mean reduction in SBP in the intervention group was significantly higher than in the control group. In addition, there were more outpatient care visits and antihypertensive medications prescribed in the intervention group. Magid et al<sup>198</sup> recruited patients from primary care clinics and randomized them to a control condition or an intervention using the Heart360 Web site (<https://www.heart360.org/>) to upload their SMBP, IVR reminders if patients did not enter BP data, and phone calls and e-mails from a pharmacist recommending antihypertensive pharmacotherapy changes. Although Magid et al used some components of mHealth in this intervention, it does not appear that the phone component was based on mobile devices. Adherence to uploading BP data was high, and there were higher rates of e-mails and phone calls with pharmacists in the intervention group. Results revealed a significant mean reduction in SBP in the intervention group at the end of the 6-month study. All 3 of these studies provided some combination of patient educational resources, timely delivery of BP data to providers, and personalized messages to patients. The positive results of the 3 trials may suggest that a combination of such strategies or modes of intervention delivery may be needed to engage patients. Whether these multimodal technology-based approaches can provide the same or better results than team-based in-person care for a lower cost remains unclear; the data at this time suggest that further investigations are warranted. What is clear from this review of studies targeting improved BP control and other sections that addressed interventions targeting behavior is that mHealth or digital health has no defined taxonomy or classification of interventions delivered by the existing technology. Thus, it is

**Table 6. Description of Studies Using mHealth for BP Control**

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention  | Study Groups and Components  | Technology Used                                | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean SBP (mm Hg or % Change)  |
|---|---|--|--|--|--|
| Green et al, <sup>190</sup> 2008<br>Design: 3-group RCT<br>Outcome: percent of Ps with BP <140/90 mm Hg<br>Setting: 10 medical centers<br>Country: United States          | N=778<br>Int1: n=258<br>Int2: n=259<br>Int3: n=261<br><br>Mean age (SD):<br>Int1: 59.5 (8.3) y<br>Int2: 59.3 (8.6) y<br>Int3: 58.6 y (8.5) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 152.2 (10.0)<br>Int2: 152.2 (10.4)<br>Int3: 151.3 (10.6)<br><br>Women:<br>Int1: 45.9%<br>Int2: 55.9%<br>Int3: 54.7%<br><br>White:<br>Int1: 86.1%<br>Int2: 79.3%<br>Int3: 82.9%<br><br>Retention:<br>Int1: 95.0%<br>Int2: 90.8%<br>Int3: 95.8% | Int1: Home BP monitoring, secure e-mail, refilling medications, viewing medical record, health library, links to resources<br><br>Int2: Int1+2-wk pharmacist interaction via Web (action plan) and secure messaging<br><br>Int3: Hypertension pamphlet | Home BPM equipment, Web site, secure messaging | Duration: 12 mo<br><br>Contacts:<br>Int1 and Int2: Office BP measurement at baseline and 12 mo<br>Int3: Office BP measurement at baseline and 12 mo<br><br>Intervention adherence:<br>PCP visits:<br>Int1: 2: 3.2<br>Int2: 1: 3.0<br>Int3: 3.2<br>Int1: 2..4 (4.6)<br>Int2: Pharmacist messages: 22.3 (10.2)<br>Int3: 3.3 (7.4)<br>Int1: 3.8 (5.0)<br>Int2: Pharmacist phone calls: 7.5 (9.3)<br>Int3: 4.0 (4.8)<br><br>Interventionist:<br>Int1: Pharmacist<br>Int2: Pharmacist<br>Int3: NA | Completer's analysis (n=730)<br>12 mo:<br>Achieved <140/90-mm Hg target:<br>Int1: 36%<br>Int2: 56%<br>Int3: 31%<br>P<0.001<br><br>Mean SBP Δ, mm Hg:<br>Int1: -8.2<br>Int2: -14.2<br>Int3: -5.3<br>P<0.001 |
| Madsen et al, <sup>191</sup> 2008<br>Design: 2-group RCT<br>Primary outcome: Office-based SBP<br>Setting: Primary care setting<br>Country: Denmark                        | N=236<br>Int1: n=113<br>Int2: n=123<br><br>Mean age (SD):<br>Int1: 55.0 (11.7) y<br>Int2: 56.7 (11.6) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 153.1 (13.2)<br>Int2: 152.2 (13.7)<br><br>Women:<br>Int1: 51.3%<br>Int2: 48.0%<br><br>White: NR<br><br>Retention:<br>Int1: 93%<br>Int2: 96%  | Int1: Ps self-monitored BP 3 times/wk for 3 mo, then 1 time/wk for 3 mo; transmission via secure Web site with Internet recommendations and PDA messages to P<br><br>Int2: Informed about study but no active intervention                             | Home BP monitoring equipment, PDA, e-mails     | Duration: 6 mo<br><br>Contacts:<br>Int1: Office BP measurement at baseline and 6 mo; continuous education and medication adjustment<br>Int2: Office BP measurement at baseline and 6 mo<br><br>Intervention adherence:<br>No data on adherence to home BP monitoring<br><br>Interventionist:<br>Int1: General practitioner<br>Int2: NA   | Completer's analysis (n=223)<br>6 mo:<br>Mean SBP Δ, mm Hg:<br>Int1: -11.9<br>Int2: -9.6<br>P=NS<br><br>Achieved BP target:<br>Int1: 60%<br>Int2: 38%<br>P<0.001   |
| Cottrell et al, <sup>192</sup> 2012<br>Design: Quasi-experimental (nonrandomized)<br>Outcome: SBP Δ<br>Setting: 10 general practitioner groups<br>Country: United Kingdom | N=488<br>Int1: n=124<br>Int2: n=364<br><br>Mean age (range):<br>Int1: 59 (25-86) y<br>Int2: 60 (36-87) y  | Int1: Ps self-monitoring BP. SMS results to a secure server. Reminders to check BP and recommendations to contact general practitioner were sent to Ps as SMS as needed. Results reviewed by general practitioner or nurse at least weekly             | Secure server, SMS                             | Duration: Minimum, 3 mo or until BP controlled; maximum, 6 mo<br><br>Contacts:<br>Int1: Daily measurement of home BP with daily reminders if no BP value received<br>Int2: BP abstracted from clinic chart   | Completer's analysis<br>Int1: n=89<br>Int2: n=NR<br>0-3 mo:<br>Mean SBP Δ, mm Hg:<br>Int1: -8<br>Int2: +1  |

(Continued)

Table 6. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention  | Study Groups and Components   | Technology Used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean SBP (mm Hg or % Change)   |
|---|---|---|--|---|---|
|   | Mean SBP (range) mm Hg:<br>Int1: 146 (82–194)<br>Int2: 136 (87–197)<br><br>Women:<br>Int1: 40%<br>Int2: 40%<br><br>White: NR<br><br>Retention: 41%  | Int2: Informed about study but no active intervention   |  | Intervention adherence: Continued 3–6 mo: 37 (30%)<br><br>Completed 3 mo and stopped: 51 (41%)<br><br>Interventionist:<br>Int1: General practitioner or nurse<br>Int2: NA   | 0–3 mo (Ps meeting criteria #2):<br>Mean SBP Δ, mm Hg:<br>Int1: –15.88<br>Int2: –11.42<br>P=NR  |
| Kiselev et al, <sup>193</sup> 2012<br>Design: 2-group RCT (unblinded)<br>Outcome: % P BP<br>Setting: Single-center cardiology practice<br>Country: Russia | N=199<br>Int1: n=97<br>Int2: n=102<br><br>Mean age (SD):<br>Int1: 49 (11) y<br>Int2: 51 (11) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 153.4 (9.6)<br>Int2: 158.2 (9.9) (P<0.05)<br><br>Women:<br>Int1: 45%<br>Int2: 50%<br><br>White: NR<br><br>Retention:<br>Int1: 64%<br>Int2: NR | Int1: Ps self-monitoring BP and other values requested from server by SMS and Ps' responses submitted by SMS. If weekly average BP not at target, Ps invited via SMS or phone for office visit or telephone consultation.<br><br>Int2: Standard-of-care drug therapy and lifestyle recommendations; Ps encouraged to check BP at home | Secure Internet-based Web site, SMS                        | Duration: 12 mo<br><br>Contacts:<br>Int1: SMS requests and reminders sent to Ps on a variable frequency (daily to semiannually) on factors related to BP control and medication adjustments. No minimum frequency of office visits.<br>Int2: No reminders sent; frequency of office visits determined by physician; but must be at least every 6 mo<br><br>Intervention adherence:<br>Ps withdrawn if did not respond to SMS for 1 mo.<br>Int1: 18 (51%) withdrew as a result of loss of interest, 12 (34%) as a result of technical difficulties, 5 (15%) for unknown reasons.<br>Int2: NR<br><br>Interventionist:<br>Int1: Physician<br>Int2: Physician | Completer's analysis (n=164)<br>12 mo:<br>% Ps achieving BP goal:<br>Int1: 77%<br>Int2: 12%<br>P<0.001<br><br>Mean SBP Δ, mm Hg:<br>Int1: –23.7<br>Int2: –6.9<br>P=NR                       |
| Logan et al, <sup>194</sup> 2012<br>Design: 2-group pilot RCT<br>Outcome: 7-d ambulatory SBP<br>Setting: 5 general practitioner groups<br>Country: Canada | N=110,<br>Int1: n=55<br>Int2: n=55<br><br>Mean age (SD):<br>Int1: 63.1 (9.0) y<br>Int2: 62.7 (7.8) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 142.6 (10.2)<br>Int2: 142.7 (10.9)<br><br>Women:<br>Int1: 38%<br>Int2: 51%<br><br>White:<br>Int1: 71%<br>Int2: 60%                      | Int1+self-care: Messages tailored to BP reading. Alerts to provider on abnormal SBP; automated voice messages when nonadherent to BP readings; printouts of summary BP to doctors. Interventionist: Physician<br><br>Int2: Home BP monitor, measure 2 times/wk in morning and 2 times/wk in evening                                   | Bluetooth, Blackberry smartphone software, home BP monitor | Duration: 1 y<br><br>Contacts:<br>Int1: Average alerts to Ps, 1.82 (3.69); alerts to doctors, 0.09 (0.35)<br>Int2: Only at assessments, Office BP measurement at baseline and 1 y<br><br>Intervention adherence:<br>Readings per week: 10.8 (6.7)<br>Decline in percent adherent per week: –1.8   | Completer's analysis (n=105)<br>12 mo:<br>SBP Δ, mm Hg, Mean (SD):<br>Int1: –9.1 (15.6)<br>Int2: –1.5 (12.2)<br>P<0.005<br><br>Achieved <130/80 target:<br>Int1: 51%<br>Int2: 31%<br>P<0.05 |

(Continued)



Table 6. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention  | Study Groups and Components  | Technology Used                                       | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean SBP (mm Hg or % Change)   |
|---|---|--|---|---|---|
|   | Retention:<br>Int1: 96.4%<br>Int2: 92.8%  |  |   | Interventionist:<br>Int1: Primary care physician<br>Int2: Primary care physician  |   |
| Nolan et al, <sup>195</sup> 2012<br>Design: RCT<br>Outcome: SBP $\Delta$<br>Setting: 3 sites<br>Country: Canada                     | N=387<br>Randomized:<br>Int: n=194<br>Control: n=193<br>Actual exposure (analyzed sample):<br>Int1: n=97<br>Int2: n=63<br>Int3: n=227<br>Mean age (95% CI):<br>Int1: 55.7 (54.3–57.0) y<br>Int2: 57.0 (55.2–58.8) y<br>Int3: 56.7 (55.7–57.7) y<br>Mean SBP mm Hg:<br>Int1: 143.3<br>Int2: 134.6<br>Int3: 139.6<br>Women:<br>Int1: 72.2%<br>Int2: 61.9%<br>Int3: 52.9%<br>White: NR<br>Retention:<br>Int1: 76.8%<br>Int2: 81.9% | Int1: E-counseling on recommendations for diet, exercise, smoke-free living based on stage of change ( $\geq 8$ e-mails over 4 mo)<br>Int2: Received Heartline e-newsletters from the Heart and Stroke Foundation that contained general information and advice for heart-healthy living | E-mail  | Duration: 4 mo<br>Contacts:<br>Int1:<br>Month 1: Weekly e-mails<br>Month 2: Bi-weekly e-mails<br>Months 3 and 4: Monthly e-mails<br>Intervention adherence:<br>BP readings:<br>Month 1: 17%<br>Month 6: 7%<br>Interventionist:<br>Int1: NR<br>Int2: NR  | ITT analysis: no significant difference between groups on $\Delta$ in primary outcomes.<br>Per-protocol analysis was conducted with 3 groups according to whether Ps received $\geq 8$ , 1–7, or 0 e-mails (control) 4 mo:<br>Mean SBP $\Delta$ , mm Hg:<br>Int1: $-8.9$ ( $-11.5$ to $-6.4$ )<br>Int2: $-5.8$ ( $-9.1$ to $-2.6$ )<br>Int3: $-5.0$ ( $-6.7$ to $-3.3$ )<br>$P=0.03$ (Int1 vs Int3) |
| Piette et al, <sup>196</sup> 2012<br>Design: 2-group RCT<br>Outcome: SBP<br>Setting: 8 clinics<br>Country: Honduras and Mexico      | N=200:<br>Int1: n=99<br>Int2: n=101<br>Mean age (SD):<br>Int1: 58.0 (1.3) y<br>Int2: 57.1 (1.1) y<br>Mean initial SBP (SD) mm Hg:<br>Int1: 153.2 (2.1)<br>Int2: 150.0 (2.0)<br>Women:<br>Int1: 66.3%<br>Int2: 68.4%<br>White: NR<br>Retention:<br>Int1: 90%<br>Int2: 91.1%  | Int1: BP readings; automated feedback through IVR (medication adherence, salt intake, BP checks), e-mail alerts for health workers, elect to enroll family/friend to get summaries of P status and support messages<br>Int2: Usual primary care  | Electronic home BP monitor, IVR, e-mails to providers | Duration: 6 wk<br>Intervention contacts with clinicians: unmeasured<br>Office BP measurement at baseline and 6 wk:<br>Int1 adherence: 67% completed phone calls, 20% received call from clinician as a result of automatic e-mails<br>Interventionist:<br>Int1: Automated phone calls<br>Int2: NR | Completer's analysis (n=181)<br>6 wk:<br>SBP $\Delta$ mm Hg, Mean (SD):<br>Int1: $-10.7$ (2.3)<br>Int2: $-6.4$ (2.4)<br>$P<0.09$<br>Achieved BP target:<br>Int1: 57%<br>Int2: 38%<br>$P<0.001$  |
| Watson et al, <sup>197</sup> 2012<br>Design: Cluster RCT<br>Outcome: SBP $\Delta$<br>Setting: 6 worksites<br>Country: United States | N=404<br>Int1: n=197<br>Int2: n=207<br>Sites:<br>Int1: 3<br>Int2: 3   | Int1: Ps self-monitoring BP, automatically transmitted data to a central server.<br>Data were displayed on a self-management Web site. Ps logged onto the Web site $\geq 1$ times/wk.  | Home BPM, modem, Web site                             | Duration: 6 mo<br>Contacts: NR<br>Intervention adherence:<br>BP readings:<br>Month 1: 17%<br>Month 6: 7%  | ITT (how to handle missing data NR) 6 mo:<br>Achieved SBP target:<br>Int1: 21.3%<br>Int2: 16.4%<br>$P=0.04$   |

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# Circulation

Table 6. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention   | Study Groups and Components  | Technology Used   | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean SBP (mm Hg or % Change)   |
|---|--|--|---|---|---|
|   | Mean age (SD):<br>Int1: 49.5 (8.0) y<br>Int2: 48.4 (8.0) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 134 (14)<br>Int2: 132 (14)<br><br>Women:<br>Int1: 21.3%<br>Int2: 25.1%<br><br>White:<br>Int1: 86%<br>Int2: 87%<br><br>Retention:<br>Int1: 95.4%<br>Int2: 98.5% | The Web site allowed Ps to track BP, access educational material, and receive automated, tailored messages.<br><br>Int2: Ps received training of BP self-monitoring but did not receive any feedback.  |   | Interventionist:<br>Int1: Automated messages<br>Int2: NA  | Mean SBP Δ, mm Hg:<br>0.49<br>P=0.8   |
| Magid et al, <sup>198</sup> 2013<br>Design: 2-group RCT<br>Outcome: proportion Ps achieved goal BP<br>Setting: 10 Kaiser Permanente clinics<br>Country: United States | N=348<br>Int1: n=175<br>Int2: n=173<br><br>Mean age (SD):<br>Int1: 60 (11.3) y<br>Int2: 59.1 (10.9) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 148.8 (16.2)<br>Int2: 145.5 (14.5)<br><br>Women: 40%<br>White: 83%<br><br>Retention:<br>Int1: 93%<br>Int2: 95%      | Int1: Provided home BP cuff, enrolled in Heart360 Web program, met with clinical pharmacy specialist for medication adjustment, provided lifestyle counseling.<br><br>Both groups received written educational materials on managing BP, diet, PA; instructed to follow up with PCP. | Web-enabled software for home BP monitoring (Heart360)  | Duration: 6 mo<br>Contacts:<br>Int1: Ps self-measure BP 3 times/wk, uploaded values into Heart360 Web site. Pharmacist made medication adjustments via telephone or secure e-mail to S and to PCP via EMR. Reminders for BP upload automated phone call.<br><br>Intervention adherence:<br>Median time to follow-up: 182 d in both groups.<br>Int1 group: 70% Ps adherent (uploading values at least once a week >80% of study duration)<br>Clinic visits, n (%):<br>Int1: 3.3 (2.5)<br>Int2: 3.1 (2.3)<br>Telephone contacts:<br>Int1: 5.3 (4.5)<br>Int2: 3.5 (3.8)<br>E-mail contacts:<br>Int1: 6.0 (5.5)<br>Int2: 2.4 (3.2)<br><br>Interventionist:<br>Int1: Clinical pharmacy specialist<br>Int2: PCP | Completer's analysis (n=326)<br>6 mo:<br>Achieved SBP goal:<br>Int1: 54.1%<br>Int2: 35.4%<br>Adjusted risk ratio 1.5 (95% CI, 1.2–1.9)<br>Mean SBP Δ, mm Hg:<br>Int1: –20.7<br>Int2: –8.2<br>P=NR |
| McKinstry et al, <sup>199</sup> 2013<br>Design: 2-group RCT<br>Outcome: SBP Δ<br>Setting: 20 primary care practices<br>Country: Scotland                              | N=401<br>Int1: n=200<br>Int2: n=201<br><br>Mean age (SD):<br>Int1: 60 (11.3) y<br>Int2: 59.1 (10.9) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 148.8 (16.2)<br>Int2: 145.5 (14.5)  | Int1: Self-monitor BP initially twice in morning, once in evening for first week and then weekly; used Bluetooth-enabled BP cuff with automated responses based on BP control and healthcare team review and recommendations<br><br>Int2: Standard-of-care BP management             | Electronic home BP monitor sent BP reading via Bluetooth to cellular, then transmitted via SMS to secure Web site | Duration: 6 mo<br>Contacts:<br>Int1: Automated response to patient based on BP control every 10 readings or weekly; healthcare team review at least weekly  | Completer's analysis (n=359)<br>6 mo:<br>Mean SBP Δ, mm Hg:<br>Int1: –6.0<br>Int2: –2.2<br>P=0.0002   |

(Continued)

**Table 6. Continued**

| Study Cited, Design, Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline BP, Study Retention   | Study Groups and Components  | Technology Used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean SBP (mm Hg or % Change)   |
|--|--|--|--|--|---|
|  | Women:<br>Int1: 38.3%<br>Int2: 41%<br>White: NR<br>Retention:<br>Int1: 97.5%<br>Int2: 98.5%  |  |  | Mean PCP visits (SD):<br>Int1: 3.66 (2.67)<br>Int2: 2.6 (2.52)<br>( <i>P</i> for $\Delta$ between groups=0.0002)<br><br>Intervention adherence:<br>Compliance with BP checks in Int:<br>Median of 76 BP readings; 89% of Ps completed >90% of expected minimum No. of readings.<br><br>Interventionist:<br>Automated messages, medication changes by physician<br>Int2: Doctor or practice nurse |   |
| Rifkin et al, <sup>200</sup> 2013<br>Design: 2-group RCT (2:1 ratio)<br>Outcome: SBP $\Delta$<br>Setting: VA, CKD, and hypertension clinic<br>Country: United States | N=43<br>Int1: n=28<br>Int2: n=15<br><br>Mean age (SD):<br>Int1: 68.5 (7.5) y<br>Int2: 67.9 (8.4) y<br><br>Mean daytime ambulatory SBP (SD) mm Hg:<br>Int1: 149 (16.2)<br>Int2: 147 (8.6)<br><br>Women:<br>Int1: 7%<br>Int2: 0%<br><br>White:<br>Int1: 75%<br>Int2: 73%<br><br>Retention:<br>Int1: 93.3%<br>Int2: 88.2% | Int1: Self-monitor BP using Bluetooth-enabled BP monitor, weekly phone calls for out-of-range BP readings (pharmacist counseling)<br><br>Int2: Home BP monitoring, standard-of-care BP management              | Electronic home BP monitor; home health hub (Bluetooth, Internet), secure Web site to view BPs | Duration: 6 mo<br>Contacts:<br>Int1: 2.7 over 6 mo; 1.9 medication changes per patient<br>Intervention adherence:<br>29 readings/mo; 78% of Ps used cuff 4 times/mo for 6 mo<br>Int2: 20% brought BP records to medication visit<br><br>Interventionist:<br>Int1: Physicians and pharmacist<br>Int2: Physicians  | Completer's analysis (n=43)<br>6 mo:<br>Mean SBP $\Delta$ , mm Hg:<br>Int1: -13<br>Int2: -8.5<br><i>P</i> =0.32   |
| Thiboutot et al, <sup>201</sup> 2013<br>Design: Cluster RCT<br>Outcome: SBP $\Delta$<br>Setting: 54 physician practices<br>Country: United States                    | N=500<br>Int1: n=282<br>Int2: n =218<br><br>Sites:<br>Int1: 27<br>Int2: 27<br><br>Mean age (SD):<br>Int1: 59.6 (12.1) y<br>Int2: 61.6 (11.4) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 132.7 (14.9)<br>Int2: 132.4 (15.2)   | Int1: Automated Web site with tailored messages based on self-report BP; suggestions for questions to ask PCP<br><br>Int2: Web site with general prevention service information unrelated to hypertension care | Internet Web site  | Duration: 12 mo<br>Contacts:<br>Int1 and Int2: Office visits at baseline, 12 mo<br>Intervention adherence:<br>34.8% used Web site $\geq$ 1 time each of 12 mo; 82.2% used Web site at least once.<br><br>Interventionist:<br>Int1: Automated messages<br>Int2: NA  | ITT (LMM)<br>12 mo:<br>Achieved target:<br>Int1: 71.3%<br>Int2: 65.6%<br><i>P</i> =0.31<br><br>Mean SBP $\Delta$ , mm Hg:<br>Int1: -4.4<br>Int2: -3.5<br><i>P</i> =0.88 |

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Table 6. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention  | Study Groups and Components   | Technology Used                                      | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Primary Outcome: Mean SBP (mm Hg or % Change)   |
|---|---|---|--|---|---|
| Cicolini et al, <sup>202</sup> 2014<br>Design: 2-group RCT (unblinded)<br>Outcome: SBP Δ<br>Setting: Single-center hypertension primary care Center<br>Country: Italy     | Women:<br>Int1: 58.5%<br>Int2: 56.4%<br><br>White:<br>Int1: 75.5%<br>Int2: 74.3%<br><br>Retention:<br>Int1: 84%<br>Int2: 83%<br><br>N=203<br>Int1: n=102<br>Int2: n=101<br><br>Mean age (SD):<br>Int1: 59.8 (15) y<br>Int2: 58.3 (13.9) y<br><br>Mean SBP (SD) mm Hg:<br>Int1: 150 (11)<br>Int2: 153 (12)<br>( <i>P</i> =0.12)<br><br>Women:<br>Int1: 50%<br>Int2: 48%<br><br>White: NR<br><br>Retention:<br>Int1: 98%<br>Int2: 97% | Int1: 1-h education program on risk factors and healthy lifestyle plus weekly e-mail alerts and phone calls from a nurse care manager<br><br>Int2: 1-h education program on risk factors and healthy lifestyle  | E-mail reminders                                     | Duration: 6 mo<br><br>Contacts:<br>Int1: Weekly e-mail reminders<br>Both groups: follow-up visits at 1, 3, and 6 mo<br>Daily self-assessment form of adherence to treatment.<br><br>Intervention adherence:<br>Mean PCP visits (SD):<br>Int1: 3.66 (2.67)<br>Int2: 2.6 (2.52)<br>( <i>P</i> =0.0002 for Δ between groups)<br>Compliance with therapy dose (%):<br>Int1: 100<br>Int2: 96.9<br>Compliance with therapy hours:<br>Int1: 91%<br>Int2: 96.9%<br><br>Interventionist:<br>Int1: Nurse care manager<br>Int2: Nurse care manager | Completer's analysis (n=198)<br>6 mo:<br>Mean SBP Δ, mm Hg:<br>Int1: -14.9 (8.1)<br>Int2: -10 (11.6)<br><i>P</i> <0.001 |
| Systematic reviews and meta-analysis  |   |   |  |   |   |
| Uhlig et al, <sup>203</sup> 2013<br>Design: Systematic review and meta-analysis<br>Outcome: SBPΔ<br>Setting: no setting restrictions<br>Country: no language restrictions | Prospective comparison studies with at least 8 wk follow-up.<br><br>Analysis 1:<br>SMBP+support vs usual care; 25 studies<br><br>Analysis 2:<br>SMBP+support vs SMBP; 13 studies  | Support included educational materials, letters to Ps and providers on treatment recommendations, Web resources, phone monitoring with electronic transmission of BP data, telecounseling, behavioral management, medication management with decision support, nurse or pharmacist visits, calendar pill packs, and adherence contracts | Only 1 study used<br>Web-based pharmacist counseling | Analysis 1: 5 quality A studies<br><br>Analysis 2: too heterogeneous<br><br>Intervention adherence: NR<br><br>Study duration: 8 wk  | Analysis 1:<br>12 mo:<br>Mean SBP Δ:<br>-2.1 to 8.3 mm Hg<br><br>Analysis 2: NR   |

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Table 6. Continued

| Study Cited, Design, Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline BP, Study Retention  | Study Groups and Components   | Technology Used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist   | Primary Outcome: Mean SBP (mm Hg or % Change)  |
|---|---|---|--|--|--|
| Liu et al, <sup>204</sup> 2013<br>Design: Systematic review and meta-analysis<br>Outcome: SBP $\Delta$<br>Setting: no setting restrictions<br>Country: no language restrictions<br>(56% in United States) | Prospective comparison studies testing preventive e-counseling or advice using Web sites or e-mails to modify exercise or diet as a means of improving blood pressure control of at least 8-wk duration.<br>13 studies:<br>N=2221<br>Mean age:<br>55 (range, 18–89) y<br>Mean SBP (SD) mm Hg:<br>136 (6.4)<br>Women: 44%<br>White: NR<br>Retention: 53%–94% | E-counseling or advice using Web sites or e-mails to modify exercise or diet as a means of improving BP control | Internet, e-mail<br>The Internet-based interventions were primarily self-guided, access was through desktop and mobile devices | Mean intervention duration (SD): 5.6 (3.6) mo<br>8 of the 13 studies were short term (<6 mo), 5 were long term (6–12 mo)<br>Intervention adherence: NR | Pooled: Mean SBP $\Delta$ , mm Hg:<br>Int: $-3.8$ (95% CI, $-5.63$ to $-2.06$ )<br><br>Pooled effect size: $-0.27$ (95% CI, $-0.4$ to $-0.1$ )<br><br>Longer interventions vs shorter interventions, effect size on SBP: $-0.44$ (95% CI, $-0.58$ to $-0.31$ ) vs $-0.23$ (95% CI, $-0.36$ to $-0.10$ )<br><br>$\geq 5$ vs $< 5$ behavioral change techniques effect size on SBP: $-0.46$ (95% CI, $-0.60$ to $-0.33$ ) vs $-0.19$ (95% CI, $-0.33$ to $-0.06$ ) |

Automated indicates without a clinician who generates, tailors, or modifies the output; baseline, 0; BP, blood pressure; BPM, blood pressure monitoring; CI, confidence interval; CKD, chronic kidney disease;  $\Delta$ , change or difference; EMR, electronic medical record; Int, intervention group; ITT, intention to treat; IVR, interactive voice response; LMM, linear mixed model; M, mean; n, subgroups; N, total sample; NA, not applicable; NR, not reported; NS, not significant; P, participant; PCP, primary care physician; PDA, personal digital assistant; RCT, randomized, controlled trial; SBP, systolic blood pressure; SD, standard deviation; SMS, short message service; and VA, Veterans Affairs.

difficult to summarize the study outcomes by such a classification of interventions. The current state of science suggests that all options all have an important place in targeting improved cardiovascular health.

In summary, 8 of the 12 studies detailed in Table 6 were conducted outside the United States, and 2 of those were conducted in Canada, so results may not be generalizable to all healthcare systems. Most but not all studies used self-monitoring of BP and used those data for reporting and receiving feedback. Eight of the studies reported a significant difference between the treatment conditions, but only 3 of the 12 studies used an intention-to-treat approach in analyzing the results. Instead, most studies reported results only in experimental subjects who were compliant with the mHealth technology used. This approach not only inflates the results and compromises randomization but also raises questions about the generalizability to a broad hypertensive population, particularly elderly or disabled patients such as those with stroke who may have difficulty using the technology.

We identified 2 systematic reviews and meta-analyses examining studies testing mHealth interventions for BP control.<sup>203,204</sup> Using the same quality assessment tool for systematic reviews and meta-analyses as in the AHA/ACC guideline, both systematic review studies were rated good quality (indicating a study with the least level of bias and results deemed valid). Both reviews focused on a slightly different topic but shared common features. Uhlig et al<sup>203</sup> focused on SMBP monitoring with or without additional support, and Liu et al<sup>204</sup> focused on Internet-based interventions for BP control. Both reviews suffered from heterogeneity across studies in SMBP equipment

used, intervention modality and components, participants, and BP end points, precluding direct comparisons across studies. Neither of the systematic reviews exclusively included RCTs. Both reviews focused on intervention comparison with usual care or no intervention, whereas only Uhlig et al examined comparison with an active control (SMBP self-monitoring), and only Liu et al attempted to determine which of the intervention characteristics were associated with better outcomes.

Uhlig et al<sup>203</sup> reviewed 25 studies that compared SMBP plus support with usual care. Among the 5 quality A studies that compared SMBP plus support with usual care, there was a net reduction in SBP of  $-2.1$  to  $-8.3$  mmHg. The type of support offered varied greatly across studies, and only 1 study used an mHealth support intervention.<sup>190</sup> Uhlig et al also examined 13 trials comparing SMBP with SMBP plus support and found no evidence to support the benefit of SMBP plus support over SMBP alone. Liu et al<sup>204</sup> examined 13 studies that compared Internet-based counseling interventions on BP control in prehypertensive and hypertensive patients, 11 of which were RCTs. They found that e-counseling interventions significantly reduced daytime SBP by 3.8 mmHg (95% confidence interval,  $-5.63$  to  $-2.06$ ). They also found that longer interventions (6–12 months) were associated with greater effects on SBP. Additionally, Liu et al also found trends of greater effects when interventions used multiple behavioral techniques and were proactive with patients (as opposed to reactive or passive). Nolan et al<sup>195</sup> conducted the 1 study to specifically explicate a theoretical framework.

A significant limitation of the current evidence for the use of mHealth for BP control is that the majority of studies (8 of



12) were conducted for  $\leq 6$  months, with no studies extending beyond 12 months. Given that hypertension is a chronic condition that requires long-term medical care, a sustained benefit of mHealth interventions beyond a few months should be demonstrated before this technology becomes widely accepted. Although adherence to some mHealth technologies over the short term may have been demonstrated, the ability to maintain the consumers' interest and active use of these tools over the long term requires further study.

### Gaps and Limitations

The results of the studies described above indicate that mHealth interventions in general show promise in reducing SBP in patients with hypertension but with large variability in behavioral targets, intervention components, delivery modalities, and patient engagement. Although behavioral targets for BP control include routine monitoring of BP, healthful dietary intake, physical activity, medication adherence, smoking cessation, and stress management, among others, existing mHealth interventions have not identified how best to address these behaviors. Questions remain about which behaviors need to be addressed to change BP and in whom, as well as whether to address behaviors at the same time or sequentially, scheduled or not scheduled.

Essential components of mHealth interventions to promote BP control also largely remain unknown but likely include behavioral techniques similar to those shown in in-person counseling interventions to be effective, including self-monitoring, goal setting, and problem solving. Evidence<sup>205</sup> suggests that education alone is not effective in changing behavior, and results from Liu et al<sup>204</sup> suggest that multiple techniques are likely to be more effective than fewer techniques. Other unknowns include whether mHealth intervention components should be proactive or reactive, expert driven (protocol driven, prescriptive messaging) or user driven (collaborative protocol with supportive messaging), and whether some specific behavioral theories are more useful than others to guide intervention components.

The modalities used to deliver mHealth interventions for BP control included Web-based, e-mail, SMS, and IVR interventions. The best modality may never be known, given the rapid pace of change in information and communication technologies. In addition, the best delivery modality may vary between individuals and within individuals, given their locations and settings. Individual consumer factors such as age, access to the Internet, and learning preferences may determine the successful use of specific tools in a specific individual. Therefore, consumer preference may ultimately determine the most effective method of delivery in an individual patient.

Patient engagement with mHealth for BP control remains limited by the fact that the majority of studies (8 of 12) were conducted for  $\leq 6$  months, with no studies extending beyond 12 months. Given that hypertension is a chronic condition that requires long-term medical care, a sustained benefit of mHealth interventions beyond a few months will likely be needed to show meaningful health benefits. In addition, estimates of patient engagement with mHealth interventions over these short periods were not possible because of the heterogeneity of studies reviewed and because the components useful to maintain engagement specifically were not studied.

Aside from these current scientific limitations and unknowns of how best to use mHealth interventions to improve BP control, the commercial availability of evidence-based mHealth interventions for patients and providers is scarce. For example, the only commercially available intervention of which we are aware is the Heart360 Web site (<https://www.heart360.org/>). However, the current use rates of such programs remain unknown, and consumer adherence outside monitored RCTs may be difficult to predict. Adoption of mHealth interventions for BP control in health systems may additionally be hindered by security and patient privacy policies concerning the transmission of identifiable patient data, nonexistent current reimbursement for eHealth interventions, and information technology interface difficulties.

### Suggestions for Future Research

- Identify behavioral targets that are tailored to an individual that will have the greatest effect on BP control and, if multiple behaviors, how best to attempt to change those behaviors.
- Leverage existing knowledge of effective intervention components for BP control from in-person counseling-based studies and adapt them to mHealth platforms while using the unique aspects of mHealth platforms to innovate components.
- Use delivery modalities that are currently used by individuals, meet the needs of their various lifestyles and preferences, and work across mHealth platforms. This includes trials testing mHealth interventions from a broader consumer base (elderly, disabled, etc).
- Study techniques to optimize retaining patient engagement beyond 6 months, including strategies such as gamification and contingency management (incentivization).
- Conduct trials comparing mHealth strategies with effective yet possibly more costly in-person counseling interventions.

### Use of mHealth in Management of Dyslipidemia

Dyslipidemia affects nearly 1 in 5 to 10 Americans.<sup>206</sup> Despite ready access of healthcare providers to evidence-based cholesterol management goals and potent, well-tolerated medical therapy, management of hyperlipidemia remains suboptimal.<sup>207</sup> A large body of evidence accumulated over the last 2 decades supports the link between dyslipidemia and atherosclerosis<sup>208–210</sup> and the clinical benefits of statin therapy in the treatment of lipoprotein abnormalities. This evidence provides the basis for a number of consensus-based guidelines<sup>19,211–217</sup> for optimizing lipid levels in adult and pediatric populations. However, despite the wide dissemination of these guidelines, hyperlipidemia remains prevalent and suboptimally treated in the United States.<sup>218</sup>

There are several reported potential barriers to the implementation of these evidence-based treatment guidelines in clinical practice, including provider and patient knowledge, attitudes, and behaviors; provider-patient communication issues; and system-based issues such as costs and the lack of organized systems of care around the recognition and treatment of hyperlipidemia.<sup>219,220</sup> Thus, a multimodal approach affecting providers, patients, provider-patient communication, and care delivery systems is likely needed to translate these guidelines into clinical practice and to maximize the use of mHealth technology.

Other barriers may include the unknown cost of delivering mHealth interventions to achieve optimal lipid control.

In 2012, the US Department of Health and Human Services<sup>124</sup> proposed a challenge seeking new mobile technology applications to help consumers assess their heart health risk, identify places to measure their BP and cholesterol, and use the results to partner with their healthcare professional to develop a treatment plan to improve their heart health. The new app would be part of a broader education effort in support of the Million Hearts initiative,<sup>221</sup> a public-private effort of the US Department of Health and Human Services that targets the prevention of a million heart attacks and strokes through clinical and community prevention programs.<sup>222</sup> In response to this challenge, the Marshfield Clinic developed the HeartHealth Mobile app, which allows users to obtain a health risk assessment based on several individual health factors such as blood cholesterol and BP values.

Currently, the majority of tools available for information delivery, education, motivation, and self-monitoring in dyslipidemia are contained within more comprehensive materials targeting overall CVD risk reduction.<sup>202,222–231</sup> Some of these materials provide the basis for the development of CVD risk scores and Web-based score calculators that are available for patients and providers. For example, the Framingham Risk Score was developed from predictive equations based on >5000 men and women who were 30 to 74 years old at baseline and were followed up for cardiovascular events for 12 years.<sup>232</sup> This score is sex specific and incorporates information on age, BP, total cholesterol, low-density lipoprotein cholesterol, diabetes mellitus, and smoking as predictors of CHD.<sup>233</sup>

Recently a task force of the ACC and the AHA published a set of guidelines aimed at reducing CVD risk.<sup>234</sup> The purpose of the guidelines was to define provider practices that meet the needs of patients; however, these guidelines were not meant as a replacement for clinical judgment. Although the guidelines had a relatively limited scope and focused on selected critical questions, they were based on the highest-quality evidence available. The guidelines were derived from evidence accumulated from RCTs, meta-analyses, and observational studies that were evaluated for quality and were derived from pooled cohort equations. CVD was defined as coronary death or nonfatal myocardial infarction or fatal or nonfatal stroke. A CVD 10-year and lifetime risk calculator was devised that is sex specific and incorporates information on age, race, total cholesterol, high-density lipoprotein cholesterol, SBP, treatment for high BP, diabetes mellitus, and smoking. The risk estimates are based on data from multiple community-based populations and are applicable to black and non-Hispanic white men and women 40 to 79 years of age. In addition, estimates of lifetime risk for CVD are provided for adults 20 to 59 years of age and are expressed as the lifetime risk for CVD for a 50-year-old individual without CVD who has the risk factor values entered into the spreadsheet. A downloadable spreadsheet and Web-based risk calculator are available on the AHA Web site ([http://www.heart.org/HEARTORG/Conditions/HeartAttack/HeartAttackToolsResources/Heart-Attack-Risk-Assessment\\_UCM\\_303944\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/HeartAttack/HeartAttackToolsResources/Heart-Attack-Risk-Assessment_UCM_303944_Article.jsp)).<sup>235</sup> Because the primary use of these lifetime risk estimates is to facilitate the discussion of risk reduction through lifestyle changes, it is felt that the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results. The guidelines were

derived from evidence accumulated from RCTs, meta-analyses, and observational studies that were evaluated for quality.<sup>235</sup>

### **Review of Evidence for the Efficacy of Mobile Technology-Based Interventions to Promote Management of Dyslipidemia**

We searched PubMed for the years 2004 to 2014 using the terms *anticholesteremic; cholesterol inhibitor; cholesterol level; cholesterol lowering; dyslipidemia; elevated cholesterol; HDL cholesterol; high density lipoprotein; hypercholesterolemia; hypercholesterolemia; hyper-triglyceride; LDL cholesterol; lipoprotein cholesterol; low density lipoprotein; total cholesterol; triglyceride; and high cholesterol*. We reviewed 24 articles in detail reporting on the use of mobile technology to manage dyslipidemia as one of the goals. The majority of studies evaluated usability, feasibility, efficacy, and adherence to cholesterol improvement programs using technology-based tools or strategies such as e-mail, text messaging, and Web sites. Of note, several studies aimed at reducing diabetes mellitus or hypertension complications also included lipids as a secondary outcome.<sup>164,202,228,236–239</sup> Of these, only 3 studies were of sufficient quality to include here. Because of the limited number of studies using mHealth as part of the intervention to target improved lipids, we included studies reporting lipid as a secondary outcome in Table 7. The study by Yoo et al<sup>164</sup> is also reported in the sections on diabetes mellitus.

Some of the existing publications were focused on design, rationale, and testing accuracy of tools with no lipid outcomes available at this time.<sup>223,240–242</sup> Others were focused on small studies with inconclusive results<sup>226,236,243</sup> or were pilot feasibility studies that did not provide adequate results.<sup>228,230</sup> Only 1 peer-reviewed publication<sup>244</sup> addressed the topic of consumer use of technology as stand-alone tools specifically for lipid disorders (Table 7). The vast majority of publications did not meet the criteria for inclusion in the tables because of the absence of a control group or because they did not include lipids as a primary outcome. However, there were a number of promising studies in this group of articles. In a quasi-experimental study, Park and Kim<sup>231</sup> showed that the use of a Web site and SMS improved total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides. Onescu et al<sup>242</sup> described a device that works with a smartphone camera to measure cholesterol. This device, if accurate and easy to use, might hold promise as a technology to allow self-monitoring of serum cholesterol; this should be evaluated in future research. Studies reported in design articles by Chow et al<sup>240</sup> and Redfern et al<sup>245</sup> show promise in the future management of dyslipidemia. RCTs testing interventions that specifically target lipid reduction are needed because there are no existing studies in this area. One study that used electronically monitored medication blisters and a reminder system reported that total cholesterol improved, but the study ended early.<sup>237</sup> Supplying patients with smartphones with Bluetooth-enabled BP monitors, glucometers, and a Web site for tracking resulted in decreases in total cholesterol; however, these studies did not include a control group.<sup>228,230</sup>

Research has shown that education of consumers and self-management interventions can be beneficial for patients. Advances in information technology and consumer health-related mHealth are emerging as promising tools for

**Table 7. Description of Studies Using mHealth for Management of Lipids**

| Study Cited, Design, Primary Outcome, Setting, Country   | Sample Characteristics, Group Size, Baseline Lipids, Study Retention   | Study Groups and Components  | Technology used          | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Secondary Outcome   |
|--|--|--|--------------------------|---|---|
| Kang et al, <sup>238</sup> 2010<br>Design: 3-group RCT<br>Outcome: reduction of diabetes mellitus risk factors<br>Setting: Community<br>Country: South Korea   | N=125<br>Int1: n=25<br>Int2: n=25<br>Int3: n=75<br><br>Mean age (SD):<br>Int1: 47.47 (5.79) y<br>Int2: 45.61 (6.06) y<br>Int3: 45.84 (5.17) y<br><br>Mean total cholesterol (SD) mg/dL:<br>Int1: 195.48 (31.12)<br>Int2: 222.32 (31.59)<br>Int3: 204.04 (32.10)<br><br>Mean LDL (SD) mg/dL:<br>Int1: 121.70 (34.62)<br>Int2: 135.20 (31.91)<br>Int3: 135.72 (31.39)<br><br>Mean HDL (SD) mg/dL:<br>Int1: (13.37)<br>Int2: 44.64 (13.66)<br>Int3: 49.87 (13.80)<br><br>Retention: 98.4% | Int1: 1-y face-to-face counseling (5 times over 12 wk), 10 e-mails over 30 wk, repeat assessment at 2 y<br><br>Int2: 2-y face-to-face counseling (5 times over 12 wk, 10 e-mails over 30 wk in year 1, repeated in year 2; repeat assessment at 2 y<br><br>Int3: Provided general health information at baseline, repeat assessment at 2 y | E-mail messaging         | Duration: 2 y<br><br>Contacts:<br>Int1: 15 intervention contacts<br>Int2: 30 intervention contacts<br><br>Intervention adherence: NR<br><br>Interventionist:<br>Int1: Trained staff<br>Int2: Trained staff<br>Int3: NA  | Completer's analysis (n=123)<br>24 mo:<br>Total cholesterol Δ, M (SD), mg/dL:<br>Int1: -0.09 (27.42)<br>Int2: -11.12 (19.56)<br>Int3: 5.75 (25.61)<br>Int1 vs Int2 P>0.05<br>Int1 vs Int3 P>0.05<br>Int2 vs Int3 P<0.05<br><br>LDL Δ, mg/dL, M (SD):<br>Int1: -6.65 (21.99)<br>Int2: -5.32 (26.64)<br>Int3: -11.41 (26.90)<br>Int1 vs Int2 P>0.05<br>Int1 vs Int3 P>0.05<br>Int2 vs Int3 P>0.05<br><br>HDL Δ, mg/dL, M (SD):<br>Int1: -2.78 (5.79)<br>Int2: -3.28 (10.08)<br>Int3: 0.67 (8.25)<br>Int1 vs Int2 P>0.05<br>Int1 vs Int3 P>0.05<br>Int2 vs Int3 P<0.05 |
| Dekkers et al, <sup>225</sup> 2011<br>Design: 3-group RCT<br>Outcome: reduction in CV risk factors (waist, skin fold, blood pressure, total cholesterol, aerobic fitness level, body weight, BMI)<br>Setting: Workplace intervention<br>Country: Netherlands | N=276<br>Int1: n=91<br>Int2: n=93<br>Int3: n=92<br><br>Mean age (SD):<br>44.0 (9.2) y<br><br>Women:<br>30.80%<br><br>Mean BMI (SD):<br>29.7 (3.1) kg/m <sup>2</sup><br><br>Total cholesterol:<br>4.9 (0.8) mmol/L<br><br>Retention:<br>Int1: 54%,<br>Int2: 54%,<br>Int3: 65%   | Int1: Internet ALIFE@ Work, a distance-counseling lifestyle intervention program by phone<br><br>Int2: Internet ALIFE@ Work, a distance-counseling lifestyle intervention program by Internet<br><br>Int3: Usual care (self-help materials on overweight, PA, and healthful diet brochures)  | Internet or mobile phone | Duration: 6 mo intervention, 2-y follow-up<br><br>Contacts:<br>Int1: Phone calls every 2 wk<br>Int2: Self-paced<br>Maximum, 10 counseling contacts during 6 mo<br><br>Intervention adherence:<br>Used modules:<br>Int1: 93.2%<br>Int2: 87.5%<br>Counseled on all modules:<br>Int1: 64%<br>Int2: 17%<br><br>Interventionist:<br>Int1: Counselors (dietitians, PA specialists)<br>Int2: Counselors (dietitians, PA specialists)<br>Int3: NA | Completer's analysis (n=141)<br>24 mo:<br>Total cholesterol Δ, mg/dL, M difference (95% CI):<br>Int1 vs Int3: 0.0 (-0.3 to 0.3)<br>Int2 vs Int3: -0.1 (-0.4 to 0.2)   |



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(Continued)

Table 7. Continued

| Study Cited, Design, Primary Outcome, Setting, Country  | Sample Characteristics, Group Size, Baseline Lipids, Study Retention   | Study Groups and Components  | Technology used  | Intervention Duration, No. of Intervention Contacts, Intervention Adherence, Interventionist  | Secondary Outcome  |
|---|--|--|------------------|---|--|
| Yoo et al, <sup>164</sup> 2009<br>Design: 2-group RCT<br>Outcome: HbA <sub>1c</sub> (%)<br>Setting: Community<br>Country: South Korea | N=123<br>Int1: n=62<br>Int2: n=61<br>Mean age (SD):<br>Int1: 57.0 (9.1) y<br>Int2: 59.4 (8.4) y<br><br>Women:<br>47.2%<br><br>Mean BMI (SD):<br>25.6 kg/m <sup>2</sup><br><br>Mean total cholesterol (SD):<br>4.6 mmol/L<br><br>Retention:<br>Int1: 91%<br>Int2: 89% | Int1: UCDC system using mobile phones and Web-based interaction. UCDC included device attached to mobile phone that transmitted blood glucose data. Ps received SMS reminder to check blood glucose and tips via SMS 3 times/d. Physicians could follow the Ps' data and send individualized messages as needed<br><br>Int2: Usual care. Ps visited according to usual schedule and received usual care in the outpatient setting. | SMS and Internet | Duration: 3 mo<br>Contacts:<br>Int1: 2 alarms daily to remind Ps to measure blood glucose values and blood pressure and 1 alarm daily for weight. Additionally, each P received at least 3 SMSs daily<br>Int2: Dependent on usual-care routine. Each P was seen at baseline and at 3 mo to collect anthropometric and laboratory data.<br><br>Intervention adherence:<br>Int1: Sent in glucose readings 1.84±0.31 times/d with a compliance rate of 92.2±15.4%<br>Sent in blood pressure readings 1.72±0.32 times/d with a compliance rate of 86.0±16.2%<br>Sent in weight measurements 0.87±0.20 times/d with a compliance rate of 87.4±20.1%<br><br>Interventionist:<br>Int1: Automated<br>Int2: NR | Completer's analysis (n=111)<br>Total cholesterol Δ, mmol/L, M:<br>Int1: -0.5, P<0.001<br>Int2: 0.0, P=0.882<br>P=0.011<br><br>LDL cholesterol Δ, mmol/L, M:<br>Int1: -0.4 P<0.001<br>Int2: -0.1, P=0.628<br>P=0.025 |

Automated indicates without a clinician who generates, tailors, or modifies the output; baseline, 0; BMI, body mass index; CI, confidence interval; Δ, change or difference; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; HDL, high-density cholesterol; Int, intervention group; LDL, low-density cholesterol; n, subgroups; N, total sample; NA, not applicable; NR, not reported; P, participant; PA, physical activity; RCT, randomized, controlled trial; SMS, short message service; and UCDC, Ubiquitous Chronic Disease Care.

facilitating the management of dyslipidemia, for example, home lipid testing with a smartphone, educational smartphone apps, and Web portals for patients and providers. Although there is evidence suggesting some benefit to their use, the amount of evidence-based literature in this area remains surprisingly low.

#### Gaps and Recommendations for Future Directions

The paucity of well-controlled trials for the use of mHealth interventions specifically for lipid disorders is remarkable, considering the prevalence of dyslipidemia in the general population.

- High-quality adequately powered trials are required to evaluate the role of mHealth-based interventions in dyslipidemia. As a result of a lack of adequately tested tools, guidelines for use cannot be provided.
- A critical but inadequately researched area is how to engage patients and providers to initiate the use of mHealth devices in education, evaluation, self-monitoring, and self-management of dyslipidemia. This first step

may lay the groundwork for the creation of treatment tools using mobile technology.

- Additional research is needed in how providers wish to approach the consumer about managing dyslipidemia. It is possible that other health-related apps such as mHealth apps focused on lifestyle behaviors and, as indicated in a previous section, tools for the self-management of diabetes mellitus could be used in this population.

#### Summary of Representation of the Studies Reviewed

Our review included a total of 69 studies that investigated the use of mobile technologies to reduce CVD risk behaviors, which included 10 RCTs targeting weight loss, 14 on increasing physical activity, 14 aiming to improve smoking cessation, 15 on blood glucose management, 13 on hypertension management, and only 3 targeting lipid management. The majority were RCTs. For completeness, we also included systematic reviews and meta-analyses in each topic

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**Table 8. Number of Apps Found in the iTunes and Google Play Stores**

|                             | Apple Store | Android |
|-----------------------------|-------------|---------|
| Weight loss                 | 3881        | 250     |
| Physical activity/exercise  | 72/6312     | 120/120 |
| Smoking                     | 732         | 250     |
| Diabetes mellitus           | 1175        | 180     |
| Hypertension/blood pressure | 214/588     | 250/250 |
| Cholesterol                 | 265         | 120     |
| Medication adherence        | 38          | 250     |

The search on these terms was conducted in April 2015.

area except dyslipidemia, for which none existed. Overall, the studies had samples that were mixed in ethnicity, with a large portion being comprised of whites, although 1 study on increasing physical activity and 1 study on diabetes mellitus had 100% black samples. Female subjects made up the majority of many samples; however, 1 study conducted in a Veterans Affairs setting had 93% male representation. The smoking cessation studies enrolled younger individuals, usually 18 to 45 years of age, compared with most other studies, which included participants up to 70 to 75 years of age. The geographic distribution was quite variable; weight loss studies were conducted in the United States, whereas studies focused on dyslipidemia were conducted outside the United States. Several studies focused on smoking cessation were conducted in Europe. Seven of the 15 RCTs in diabetes mellitus were done in South Korea, and 2 were conducted in Europe. Thus, our evidence base also has limitations related to general representation, resulting in limited knowledge on the effectiveness of augmenting traditional patient care with the use of mHealth-supported strategies in male, minority, or underserved populations and for specific risk behaviors (smoking) or conditions (diabetes mellitus) among US populations. Other limitations identified across the studies are the continued reliance on Internet-based or SMS interventions and the somewhat limited use of advances in mHealth strategies; however, this may be attributable to delays in publication. From a methodological perspective, several studies did not use intention to treat in their primary analysis and thus biased the results of their studies. Use of completer's analyses was most evident in the studies focused on physical activity, BP, and dyslipidemia. Finally, several studies in the areas outside weight loss used relatively brief interventions.

We conducted a search of the Google (Android) and iTunes (Apple) App Stores for the terms used in this article: *weight loss*, *physical activity/exercise*, *smoking*, *diabetes*, *hypertension/BP*, and *cholesterol* (Table 8). Because medication may be a component of the treatment, we also searched for medication adherence. There was a wide range in the number of apps available. Weight loss led the groups with nearly 4000 apps for the iOS and 250 for the Android operating systems. A search for physical activity yielded 72 apps, whereas exercise yielded 6312 apps for the iOS operating system and only 120 for both terms for the Android operating system. Cholesterol yielded the lowest numbers of apps for both operating systems. This wide array of apps included information delivery, education,

motivation, self-monitoring, lifestyle, drug therapies, reminders or alerts, and alternative therapies. However, although the number of apps continues to grow at an exponential rate, none have been critically evaluated, and their development was not evidence based, often not building on the theoretical frameworks that address behavior change.<sup>31,32,124,246–248</sup> Besides lacking efficacy data, there is almost an absence of data on sustainability of engagement by the individual and thus sustainability of the treatment effect, an issue that is extremely important in managing chronic conditions such as hypertension. The absence of an empirical base for these apps is a major deficit in this potential area of prevention of CVD. Two recent articles addressed these issues and called for more informed use of the health-related apps and more rigorous approaches to developing and evaluating those that affect medical management (eg, diabetes mellitus, hypertension).<sup>249,250</sup>

These limitations beg for some innovative changes in intervention studies using mHealth. First, a more rigorous approach to the analytic methods used is needed. Second, more diverse samples from an ethnic, socioeconomic, and sex perspective should be included. Third, longer-term studies are needed that inform about the sustainability of effects of using mHealth approaches and the numerous apps to augment intervention and to assess the long-term engagement by the user. Finally, we need to use more adaptive and diverse methods in the testing of the rapidly changing mHealth devices and strategies and use approaches that can optimize the intervention designs and provision of efficacy data in a period shorter than the conventional 5-year RCT.<sup>251–253</sup> Identifying the most effective features in a shorter time frame also will reduce costs and ensure the incorporation of the most effective components early in the development phase.

### How mHealth Tools Can Improve Healthcare Delivery When Partnered With Healthcare Providers

It is well established that a significant proportion of the CVD burden is preventable. Compared with pharmacological treatments for acute events and with secondary prevention, reductions in the prevalence of CVD risk factors have resulted in greater reductions in CVD-related mortality.<sup>254</sup> However, the amount of information that must be conveyed and the support that is necessary to counsel and motivate individuals to engage in behaviors to prevent CVD are far beyond what can be accomplished in the context of face-to-face clinical consultations or through traditional channels such as patient education leaflets.<sup>255</sup> mHealth or mobile technologies have the potential to overcome these limitations and to transform the delivery of health-related messages and ongoing interventions targeting behavior change. Moreover, the use of monitoring devices (eg, Bluetooth-enabled BP monitors and blood glucose monitors) permits the sharing of important patient self-management parameters with healthcare providers in real time and the delivery of feedback and guidance to patients when they need it. Furthermore, using mHealth tools for monitoring provides the clinician data that far exceed what can be measured in the brief clinical encounter and reflect the status of physiological or behavioral measures in the person's natural setting.

## Recommendations for Future Research

The development of drug and device therapies typically follows a standard path: Molecules that show promise in pre-clinical laboratory and animal testing are then evaluated in phase 1 human studies that provide an initial assessment of the safety of the agent. Those that survive phase 1 evaluation go on to larger phase 2 and 3 clinical trials in which the impact of the therapy is evaluated in progressively larger populations. Only those that are found to be clearly efficacious and safe in these rigorous evaluations are then eligible for regulatory approval and release to the general population. Even once on market, drugs and devices often undergo further monitoring to ensure that the findings seen in controlled trials are consistent with those seen in broader, more diverse patient populations and community settings.

In contrast, mHealth applications are often developed in the course of weeks to months as opposed to years for drugs. Once developed, mHealth applications have traditionally not been regulated by governmental agencies. Thus, these health apps may be offered to the public with limited to no information on the accuracy of their content; on whether they are based on proven learning theory or behavioral interventional strategies; or on whether they have undergone formal effectiveness and safety evaluation. While one may suggest that mHealth technologies do not require such careful scrutiny, there are arguments for such investigation. First, just like drugs or medical devices, these mobile technologies and applications have the potential to improve health, to be ineffective, or even to cause unanticipated harm. Second, without rigorous evidence to support them, it becomes difficult or impossible for care guidelines to recommend them or for clinicians to promote them. Third, the market is rapidly being flooded with these applications. Without evidence supporting the comparative usefulness of these apps, it is nearly impossible for the consumer (or clinician) to decide which to use. Finally, if a consumer who is motivated to modify his or her lifestyle selects an unhelpful product because of a lack of information, there is a true lost opportunity and a missed chance to improve health.

Specific sections above reviewed current mobile applications and technologies for treating obesity; encouraging regular physical activity, smoking cessation, control of hypertension, and dyslipidemia; and treating diabetes mellitus. Our literature searches uncovered a wide variety of products that have been developed. However, the reviews also identified the paucity of published empirical evaluation of their effectiveness. To date, many devices have no published evaluation, and those that have undergone evaluation are often limited to measuring customer satisfaction and user sustained engagement. Although such intermediate measures are important, they fall far short of actually determining whether the users of these products had clinically meaningful changes in biological parameters.

Several common themes were noted among each reviewed area. There were consistent concerns voiced about the designs of evaluative studies of mobile technologies. Studies often used a pre-post design without concurrent control groups or, better yet, randomized comparison groups. Without such controls, product effectiveness is likely to be overestimated.

Similarly, many studies relied on self-report, which again leads to overestimation of effectiveness in unblinded evaluations. Additionally, many trials elected not to use an intention-to-treat perspective, which again may inflate the benefits of the intervention among those who used and stuck with the product.

To date, mobile technologies have generally been evaluated in motivated individuals and selected settings. These idealized conditions also will lead to exaggerations of the typical effectiveness that might be seen had the product been evaluated in general community practice or among diverse or underserved populations. Most studies were also of short duration, resulting in lingering questions about the sustainability or “stickiness” of the products. In particular, the fields of obesity and physical activity interventions are littered with interventions that work over the short term but fail to support durable lifestyle change. Perhaps most challenging, studies to date have almost uniformly evaluated a single technology compared with standard care, and there have been almost no head-to-head studies comparing various technologies with each another.

Beyond consistent questions about product safety and effectiveness, our review of the field found almost no studies that analyzed how products worked or user input in its development. Specifically, formative work had not defined which components in an intervention are pivotal to success or whether the impact of the product varies depending on the mode of use or delivery. Without these data, it is difficult to anticipate whether a similar but slightly different mobile technology would also be likely to be effective. Finally, these reviews pointed out the need for more implementation studies evaluating how to best incorporate these technologies (once proven) into a broader collaborative model of care.

Until such information is available, mobile app developers will continue to face questions and doubts from the public, providers, and payers. As with any other product that claims to improve health, groups will want to answers to certain questions: Does the product work best when used in certain settings or among specific patient groups? Does the app duplicate or potentiate impact when it is combined with other traditional interventions (such as in-person counseling)? If a specific mobile technology is found to be effective, in what cases can these findings be generalized among similar technologies in the class? Are the effects seen durable, or does the impact of the intervention wane over time? Finally, are there any unintended consequences associated with the device and program in which it is used?

Producing this evidence must be a shared responsibility. In the future, manufacturers will likely come under increasing pressure from regulatory agencies to produce evidence of effectiveness before marketing. Insurers are also likely to demand proof of durable effectiveness before they are willing to cover these services. However, the responsibility for generating evidence should not fall solely only on the product developers. The research and clinical communities also must help to generate these needed data. Our review of the evidence to date, even with its flaws and limitations, clearly demonstrates the great potential that mobile technologies can have to aid in lifestyle modification. Thus, clinicians should



not conclude that mobile technologies are generally unproven and thus can be ignored. The current absence of evidence should not be used as evidence of an absence of effectiveness. Instead, we need to embrace the challenge of producing this needed evidence on how effective these new technologies are and how we can best adopt them in our practice to promote better patient health.

**Acknowledgments**

We would like to acknowledge the contribution of individuals who assisted with the literature review and development of this manuscript: Mary Lou Klem, PhD, Annabel Kornblum, MPH, and Heather Alger, PhD. This article was initiated by the Science Subcommittee on Behavior Change for Improving Health Factors, Councils on Epidemiology and Prevention and Lifestyle and Cardiometabolic Health.

**Disclosures**

**Writing Group Disclosures**

| Writing Group Member | Employment                                      | Research Grant   | Other Research Support | Speakers' Bureau/Honoraria | Expert Witness | Ownership Interest         | Consultant/Advisory Board | Other |
|----------------------|---|--|------------------------|----------------------------|----------------|----------------------------|---------------------------|-------|
| Lora E. Burke        | University of Pittsburgh                        | None   | None                   | None                       | None           | None                       | None                      | None  |
| Kristen M.J. Azar    | Palo Alto Medical Foundation Research Institute | None   | None                   | None                       | None           | None                       | None                      | None  |
| Gary G. Bennett      | Duke University                                 | None   | None                   | None                       | None           | Coeus Health†; Scale Down† | None                      | None  |
| Jun Ma               | Palo Alto Medical Foundation Research Institute | NIH†; Palo Alto Medical Foundation Research Institute† | None                   | None                       | None           | None                       | None                      | None  |
| Eric D. Peterson     | Duke Clinical Research Institute                | None   | None                   | None                       | None           | None                       | None                      | None  |
| Charlene C. Quinn    | University of Maryland School of Medicine       | None   | None                   | None                       | None           | None                       | Roche*                    | None  |
| William Riley        | NIH   | None   | None                   | None                       | None           | None                       | None                      | None  |
| Svati H. Shah        | Duke University Medical Center                  | None   | None                   | None                       | None           | None                       | None                      | None  |
| Bonnie Spring        | Northwestern University                         | NIH†   | None                   | None                       | None           | None                       | Actigraph*                | None  |
| Julia Steinberger    | University of Minnesota                         | Synageva Biopharma Corp*; NIH/NHLBI*                   | None                   | None                       | None           | None                       | None                      | None  |
| Janna Stephens       | Johns Hopkins                                   | None   | None                   | None                       | None           | None                       | None                      | None  |
| Brian Suffoletto     | Independent Contributor                         | None   | None                   | None                       | None           | None                       | None                      | None  |
| Tanya N. Turan       | Medical University of South Carolina            | None   | None                   | None                       | None           | None                       | None                      | None  |
| Yaguang Zheng        | University of Pittsburgh School of Nursing      | None   | None                   | None                       | None           | None                       | None                      | None  |

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.  
†Significant.



## Reviewer Disclosures

| Reviewer             | Employment                         | Research Grant  | Other Research Support     | Speakers' Bureau/Honoraria   | Expert Witness | Ownership Interest | Consultant/Advisory Board | Other                         |
|----------------------|------------------------------------|---|----------------------------|------------------------------|----------------|--------------------|---------------------------|-------------------------------|
| Deborah A. Greenwood | Sutter Health                      | Patient and provider engagement and empowerment through technology to improve health in diabetes mellitus, PICORI, UC Davis†; | Intel-GE Care Innovations† | Diabetes Technology Society* | None           | Welkin Health*     | None                      | None                          |
| Michael V. McConnell | Stanford University Medical Center | None  | None                       | None                         | None           | None               | openmhealth.org*          | None                          |
| Wendy Nilsen         | NIH                                | None  | None                       | None                         | None           | None               | None                      | None                          |
| Malinda M. Peeples   | WellDoc                            | None  | None                       | None                         | None           | WellDoc*           | None                      | WellDoc VP Clinical Advocacy† |

This table represents the relationships of reviewers that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all reviewers are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.

†Significant.

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KEY WORDS: AHA Scientific Statements ■ cardiovascular diseases  
■ consumer health information ■ electronic mail ■ lifestyle ■ mobile health  
■ prevention and control



# Circulation

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Prevention: A Scientific Statement From the American Heart Association**

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*Circulation*. published online August 13, 2015;

*Circulation* is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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