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HEALTH CARE DELIVERY SYSTEMS AND IMPLEMENTATION IN DIABETES (ME MCDONNELL AND AR SADHU, SECTION EDITORS)

mHealth Interventions for Disadvantaged and Vulnerable People with Type 2 Diabetes

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Abstract

Background Mobile- and Internet-delivered (collectively, digital) interventions are widely used by persons with diabetes (PWD) to assist with self-management and improve/maintain glycemic control (hemoglobin A1c [A1c]). However, evidence concerning the acceptance and benefits of such interventions among disadvantaged/vulnerable PWD is still quite limited.

Purpose of Review We reviewed studies published from 2011–April 2019 evaluating the impact of diabetes self-management interventions delivered via mobile device and/or Internet on glycemic control of disadvantaged/vulnerable adults with type 2 diabetes (T2D). Included studies reported ≥ 50% of the sample having a low socioeconomic status and/or being a racial/ethnic minority, or living in a rural setting or low-/middle-income country (LMIC). We identified 21 studies evaluating a digital intervention among disadvantaged/vulnerable PWD.

Recent Findings Although many digital interventions found within-group A1c improvements (16 of 21 studies), only seven of the seventeen studies with a control group found between-group differences in A1c. Three studies found reductions in emergency room (ER) visits and hospitalizations. We synthesize this information, and provide recommendations for increasing access, and improving the design and usability of such interventions. We also discuss the role of human support in digital delivery, issues related to study design, reporting, economic value, and available research in LMICs.

Summary There is evidence suggesting that digital interventions can improve diabetes control, healthcare utilization, and healthcare costs. More research is needed to substantiate these early findings, and many issues remain in order to optimize the impact of digital interventions on the health outcomes of disadvantaged/vulnerable persons with diabetes.

Keywords Type 2 diabetes · HbA1c · Technology interventions · Mobile · Lifestyle intervention · Disparities · Disadvantaged

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Introduction

Diabetes is responsible for 12% of the global health expenditure and is the world's fifth leading cause of death [1]. The human and economic burden of diabetes is growing rapidly, with 415 million adults currently affected and a projected increase to 642 million by 2040 [1]. Self-management (e.g., medication adherence, physical activity, maintaining a healthy diet, and self-monitoring of blood glucose) optimizes glycemic control, which can prevent complications associated with diabetes [2]. However, marked disparities persist in diabetes prevalence, self-management, and outcomes [3–5].

Disadvantaged/vulnerable populations can include people with low socioeconomic status (SES), members of a racial/ethnic minority group, persons with limited health literacy or numeracy skills (i.e., the inability to understand and apply basic written or numerical information to make health decisions [6]), and/or persons living in rural areas or a low-/middle-income country (LMIC). These populations with type 2 diabetes (T2D) have higher rates of suboptimal glycemic control [7–9], diabetes-related hospitalizations [10] and complications [9, 11], and pre-mature mortality [12] compared to more advantaged, less vulnerable populations. Causes underlying these disparities are multifactorial and multilevel, including patient-level factors (e.g., less adherence to self-management [13–16], lower participation in diabetes education [17]), community-level factors (e.g., limited access to healthy foods and places for physical activity [18, 19]), healthcare-level factors (e.g., disparities in healthcare delivery [20], provider bias [21, 22]), and system-level factors (e.g., lower rates of health insurance [23], differential access to medical care [24], and health and social policies [25]).

Mobile phones and Internet browsers are delivering health education, motivating messages, prompts, coaching, reinforcements, and/or skills training to people around the world. Interventions delivered with these technologies can also accommodate different learning styles, literacy levels, and user-specific needs and preferences (e.g., cultural/linguistic background) [26]. For example, automated calls recorded in multiple languages benefitted PWD who either spoke non-dominant languages or reported literacy barriers [27]. According to multiple reviews, digitally delivered interventions can improve the self-management [28, 29] and clinical outcomes [29, 30] of populations with chronic health conditions, including diabetes [30–33].

However, knowledge on efficacy and acceptance of these interventions among disadvantaged and vulnerable PWD is limited [30–32, 34, 35], but must be studied rigorously to avoid generating or widening disparities [36]. In the USA, the "digital divide" between racial/ethnic minorities has narrowed somewhat in recent years [37, 38], but socioeconomic disparities in ownership of Internet and Internet-enabled devices (i.e., smartphones, tablets, personal computers) persist [39]. Thus, focusing interventions solely on Internet-delivered programs could subsequently widen health disparities [40]. Internet access, even on smartphones, remains unavailable to segments of the population [38] who cannot afford such services [41], do not live in areas with access [42], or do not have the requisite skills to use them [43]. In contrast, basic mobile phones are now ubiquitous across sociodemographic strata [44] and geographic regions [44–46], increasing the potential reach of health promotion content and messages. However, few studies of digital interventions include underserved/vulnerable populations, and some factors which work well in high-resource setting may be inaccessible and ineffective for these patients [31]. Therefore, in May 2019, we reviewed studies published in the past 8 years evaluating digital (mobile and Internet) interventions among disadvantaged/vulnerable adults with T2D.

Methods

We searched studies published from Jan 2011 to April 2019 evaluating a digital intervention with disadvantaged/vulnerable persons with T2D which measured A1c as an outcome. We searched PubMed and Medline electronic databases with the following terms and key words: "mobile intervention," or "mobile program," or "Internet intervention," or "Internet program," or "web intervention," or "web program," or "cell phone intervention," or "cell phone program" and "self-care," or "self-management," or "behavior" and "type 2 diabetes." Next, we hand-searched five relatively recent systematic reviews [31, 47–51] on digital interventions among PWD to identify any studies meeting our inclusion criteria not identified in our original search.

Included studies were (1) published as original research articles (excluding review articles and meta-analyses), (2) written in the English language, (3) sampled people with T2D defined as $\geq 50\%$ of the sample (excluding those with samples $> 50\%$ having type 1 diabetes, gestational diabetes, or prediabetes), (4) employed a randomized control trial (RCT), non-randomized quasi-experimental design, or a one-arm pre-post design, (5) included hemoglobin A1c (A1c) as an outcome, and (6) sampled people with low SES or racial/ethnic minorities defined as $\geq 50\%$ of the sample, or sampled people from rural areas or LMICs. We extracted key attributes of the study and then performed a narrative synthesis of these articles with commentary and recommendations.

Results

We identified and screened 205 articles and excluded 184 of them; 13 were not original research studies, 1 was not in English, 90 included a study sample with $< 50\%$ T2D, 26 did not meet study design criteria, 31 did not include A1c as an outcome, and 23 did not include a sample with at least 50% vulnerable or disadvantaged PWD. The remaining 21 studies met our inclusion criteria.

The characteristics of identified studies are presented in Tables 1 and 2. The average age of participants was approximately 55 years and two-thirds of the studies were conducted in the USA. Because vulnerable/disadvantaged was operationalized in various ways across the studies, Tables 1 and 2 show reasons for this classification for each study. Of the 21 identified studies, fourteen included ≥ 50% racial/ethnic minorities (primarily African Americans and Latinos), eight included ≥ 50% persons with low SES (i.e., low education, income and/or uninsured/publicly insured), two included persons from rural areas, and two were conducted in LMICs (Bangladesh and Iraq). Most interventions were "patient-facing," although some included a "provider-facing" component such as a dashboard for clinicians (e.g., electronic medical record alerts/reminders, clinical encounter forms to document diet and exercise behaviors, or educational resources) [72], clinical support for nursing staff [56], teleconferencing between nurses and participants [66], and/or support for community health workers (CHWs) [68]. Most mobile interventions used text messaging. In general, few studies reported user satisfaction but those that did [52, 53••, 55••, 69, 73] were well-received, even among programs with low engagement [70].

Most studies (76%; 16 of 21) reported A1c improved within the intervention group [52, 53, 54•, 55, 56, 58•, 61•, 62•, 64–69, 70•, 71, 72]. Seventeen studies had a control group [52, 53••, 55••, 56••, 57••, 59, 61•, 62•, 65•, 66•, 67••, 68••, 69••, 71••, 72], of which seven [54•, 57••, 59••, 61, 66, 67••, 72] reported between-group differences favoring the intervention. In addition to A1c improvements, interventions improved a range of secondary outcomes, including diabetes distress [68, 71–73], diabetes knowledge [58, 68, 69], diabetes self-efficacy [68, 73], diabetes self-management behaviors [53••, 59, 63, 66, 68••, 69, 73], body mass index [65•, 66], and quality of life [73]. Interventions also reduced emergency room (ER) visits [53••, 60] and hospitalizations [60, 73].

Discussion and Recommendations for Future Research

We identified notable patterns and important considerations for future digital program development and related research with disadvantaged/vulnerable PWDs. We summarize these recommendations in Table 3 and describe in detail below, drawing examples from studies included in this review.

Access Issues

Among identified studies, disadvantaged/vulnerable PWDs used Internet-dependent interventions less than text messaging interventions. For example, utilization was modest in the HEAT-IT-UP [70] Internet intervention study, despite investigators giving participants extensive technical and financial support. Mobile interventions requiring text messaging [29, 58•, 62•, 74] (vs. data plans or Internet access) may have had more utilization. Adding Internet-enabled features or requirements to existing mobile phone-delivered interventions can enhance their functionality, but may leave some users behind. For instance, Bell et al. [54•] sent video messages requiring broadband via text message; one-third of the intervention group never viewed the videos or viewed them only briefly. Agboola et al. [52] reported that requiring computers with Internet access contributed directly to attrition.

Among the studies in this review, it was common to accommodate users' limited access to certain types of devices (e.g., computers) and/or the Internet. Several Internet-dependent interventions [66, 67••, 68••, 69] relied on people (e.g., providers, CHWs, research staff) bringing the device (e.g., tablet) to, or using it with, participants. Other studies paid for Internet/mobile phone service [54•, 57, 65•, 70•, 75], provided devices in clinics [69] or directly to participants [57••, 61•, 65•, 66•, 76], or compensated participants extra to cover these costs [60]. For instance, Ryan et al. [70] supplied free desktop computers, Internet access, computer literacy training, telephonic technology support, glucometers and supplies, and staff support to participants. Carter et al. [66] found participants in an urban setting often lived in "dead zones" where broadband access was unavailable or insufficient, and supplied participants with both laptops and wireless broadband cards to support teleconferencing with nurses and accessing a portal.

The cost of access to a technology can be a substantial barrier to initial intervention use, ongoing engagement, and the ability to evaluate effects. Although paying for service plans and/or providing devices facilitates tests efficacy, it does not tell us if disadvantaged/vulnerable PWD would use the intervention and benefit from it on their own. Choosing to appropriately compensate for research participation (e.g., data collection), but not pay for or provide the technology or service, would accelerate our understanding of an intervention's real-world reach and impact, and encourage studies to examine interventions using technologies patients already have and use (e.g., text messaging).

Program Design and Usability

Several studies attempted to make interventions culturally appropriate either by tailoring an intervention to self-reported personal data (e.g., diabetes barriers [52], psychosocial

Table 1 Included mobile phone intervention studies

First author, year	Study design & duration	Sample characteristics	Vulnerable/ disadvantaged classification	Intervention characteristics	Intervention tailoring	Control group	Glycemic control
Agboola, 2016 [52]	Two-arm randomized control trial 6 months.	126 English- or Spanish-speaking patients with T2D ($n = 64$ intervention, $n = 62$ control) from four health centers in MA, USA. Mean age 51 years, 52% female, with baseline A1c 8.7%.	50% high school education/GED or less	Text to Move incorporates physical activity monitoring and coaching to provide automated and personalized text messages to help patients with T2D achieve their physical activity goals.	Text messages tailored to participant preferred language goal, demographic, and behavioral information including stages of change	Received pedometers and usual care.	A1c decreased by 0.43% in the intervention group ($p = .01$) compared to 0.21% ($p = .29$) in the control group, but the between-group difference was not significant.
Arora, 2014 [53]	Two-arm randomized controlled trial 6 months.	128 patients with T2D ($n = 64$ intervention, $n = 64$ control) from a safety-net hospital in Los Angeles, CA, USA. Mean age 51 years, 82% female, with baseline A1c 10.1%.	87% Latino, 9% African American	TExT-MED sends unidirectional daily text messages delivering education/motivation, medication reminders, healthy living challenges, and trivia questions with answers sent 1 h after these messages.	None	Usual care	A1c decreased by 1.05% in the intervention group compared to 0.60% in the control group (Δ 0.45; 95% CI -0.27 to 1.17), but the between-group difference was not significant. Among Spanish-speaking patients ($n = 92$), the intervention group improved (1.20%) significantly more than the control group (0.40%; Δ 0.80).
Bell, 2012 [54]	Two-arm randomized controlled trial 6 months. (tracked change for 1 year)	65 patients with T2D or T1D ($n = 32$ intervention, $n = 33$ control) from a military medical center in Washington, D.C., USA; Mean age 58 years, 45% female, with baseline A1c 9.3%.	58% African American	Intervention sends daily, asynchronous unidirectional 30- to 60-s videos (out of 540 videos) in random order to broadband-enabled mobile phones. Videos covered diabetes self-care topics (e.g., health eating, being active, monitoring), and could be viewed multiple times for 24 h upon receipt.	Videos sent at user-determined time of day	Usual care	A1c decreased more in the intervention group compared to the control group (0.02% difference over 12 months., $p < .01$), especially in the first 3 months. The rate of decline was greatest among people who received and viewed >10 videos per month.
Capozza, 2015 [55]	Two-arm randomized controlled trial 6 months.	93 patients with T2D ($n = 58$ intervention, $n = 35$ control) from primary care clinics in Salt Lake City, UT, USA. Mean age 53 years, 61% female, with baseline A1c 9.1%.	65% of participants recruited from clinics serving mostly low-income patients	Care4Life sends 1–7 daily unidirectional and bi-directional text messages written at the 5th grade reading level related to diabetes education and health improvement, and access to a web-based portal for viewing trends in biometric and behavioral bi-directional text messages responses.	Type, timing, and frequency of texts; option to turn off texts any time by texting “stop”	Usual care	A1c decreased in the intervention group and in the control group (reductions/p values not provided). There were no between-group differences at 3 or 6 months.
Cho, 2011 [56]	Two-arm randomized controlled trial 3 months.	71 patients with T2D ($n = 36$ intervention, $n = 35$ control) from Chung-ju City, South Korea. Mean age 64 years, 61% female, with baseline A1c 8.0%.	100% rural	Nurses measure blood glucose with personal data assistant glucometers and upload these values along with patients’ diet, exercise, and medications for remote physician review and individualized self-care prescription delivered face-to-face by the nurse.	Individualized self-care prescription and drug modification based on blood glucose values and current self-care behaviors.	Nurse measures blood glucose with personal data assistant glucometer and provides general diabetes education, but does not send glucose values to the physician for individualizing the self-care prescription	A1c decreased in the intervention group by 0.50% ($p < .01$) at 3 months. A1c did not decrease in the control group. Between-group differences not presented.

Table 1 (continued)

First author, year	Study design & duration	Sample characteristics	Vulnerable/ disadvantaged classification	Intervention characteristics	Intervention tailoring	Control group	Glycemic control
Fortmann, 2017 [57]	Two-arm randomized control trial 6 months.	126 patients with T2D ($n = 63$ intervention, $n = 63$ control) from San Diego, CA, USA. Mean age 48 years, 75% female, with baseline A1c 9.5%.	100% Latino 75% uninsured	Dulce Digital sends text messages to participants containing educational messages, medication reminders, and blood glucose monitoring prompts. Blood glucose monitoring texts encouraged participants to text message in their next observed value	Texts tailored for language.	All participants viewed an educational video and received a blood glucose meter, testing strips, and instructions on use. Control group also received usual care	Dulce Digital intervention group exhibited greater improvement in A1c across time compared with control group ($p = 0.03$).
Haddad, 2014 [58]	Non-experimental pre-post design 6 months.	50 newly-diagnosed patients with T2D from a teaching hospital in Basra, Iraq. Of the 42 patients who completed the study, mean age 51 years, 71% female, with baseline A1c 9.3%.	100% LMIC	Intervention sends one weekly, unidirectional text messages reminding users about one of five aspects of diabetes management: diet, medications, complications, blood glucose monitoring, and clinic attendance.	Text messages sent at user-determined day/time of the week.	N/A	A1c decreased in the intervention group by 0.70% ($p < .001$).
Islam, 2015 [59]	Two-arm randomized control trial 6 months.	236 patients with T2D from Bangladesh Institute of Health Sciences in Dhaka, Bangladesh. Mean age 48 years, 54% female, with baseline A1c 8.4%.	100% LMIC	Intervention group received daily text messages based on the principles of behavioral learning theory.	None.	Usual care	A1c decreased by 0.85% for intervention group and 0.18% for the control group ($p < 0.001$).
Katz, 2012 [60]	Non-experimental pre-post design 12 months.	32 patients with T2D from a community health center in Washington, D.C., USA. Mean age 39 years, 97% female, with baseline A1c 8.0%.	100% African American	WellDoc is an interactive platform for patients and healthcare providers to track blood glucose and receive real-time feedback and diabetes information. Case managers monitor patients' dashboards and send weekly personalized messages.	Case managers send weekly personalized messages based on blood glucose uploads.	N/A	Success in receiving a standard-of-care A1c test declined over the study period, regardless of level of intervention engagement. Because blood testing was not required at the end of the study, A1c change could not be examined.
Lim, 2016 [61]	Two-arm randomized controlled trial 6 months.	100 patients with T2D ($n = 50$ intervention, $n = 50$ control) from Seoul National University Bundang Hospital in South Korea. Mean age 65 years, 25% female, with baseline A1c 8.0%.	53% < high school education	U-healthcare uses a glucometer and physical activity monitor worn at the waist. Each connects to a public switched telephone network via Bluetooth to transfer results to a server in the u-healthcare center. Tailored messages are automatically sent to users' mobile phones in response to results. Participants were recommended to measure their blood glucose level at least 8 times per week and wear the physical activity monitoring device.	Feedback text messages tailored to results of self-monitoring of blood glucose levels and physical activity data relative to each participant's recommended activity level set by an exercise physiologist.	Both groups received diabetes education for 1 h each at baseline, 3 and 6 months. Control group participants were recommended to measure their blood glucose level at least 8 times per week and wear a non-connected physical activity monitoring device.	A1c was significantly decreased in the intervention group, as compared to the control group, at 3- and 6-month follow-up ($p < .05$). At 6 months, decreases were 0.7% in the intervention group as compared to 0.2% in the control group. A greater proportion of intervention group participants had A1c < 7.0% (26% vs. 12%, $p < .05$).
Nundy, 2014 [62]	Pre-post quasi-experimental design 6 months.	348 patients with T2D or T1D ($n = 74$ intervention, $n = 274$ control) from an academic medical center in Chicago, IL, USA Mean age 53 years, 52%	66% African American	CareSmarts is a theory-driven mobile intervention that sends unidirectional and bi-directional text messages to educate about diabetes, prompt self-care, and	The contents of the messages users receive are modified through software every 2 weeks as needed, based	Usual care	A1c decreased in the intervention group by 0.70% ($p < .01$) at 6 months. A1c did not decrease in the control group.

Table 1 (continued)

First author, year	Study design & duration	Sample characteristics	Vulnerable/ disadvantaged classification	Intervention characteristics	Intervention tailoring	Control group	Glycemic control
		female, with baseline A1c 7.6%.		ask about self-care needs structured in two-week modules that users can experience at their own pace. Nurses monitor and respond to users' text message responses.	on users' interactions with the system.		Between-group differences not presented.
Ratanawongsa, 2014 [63]	Four-arm stepped wedge design ~6 months. (27 weeks)	252 patients with T2D or T1D ($n = 127$ intervention, $n = 125$ control) from San Francisco, CA, USA. Mean age 56 years, 74% female, with baseline A1c 7.0%.	Recruited from publicly funded clinics 61% Asian/Pacific Islander 63% ≤ $20 K income	Automated telephone self-management support and health coaching intervention. Out-of-range responses triggered callbacks within 3 days from language-concordant health coach, for collaborative goal-setting to form patient-centered action plans.	Automated calls tailored for language (English, Spanish, or Cantonese), literacy, and culture.	Usual care	No significant changes in A1c, within or between groups.
Wayne, 2014 [64]	Non-experimental pre-post design 6 months.	21 patients with T2D from a community health center in Toronto, Canada. Mean age 56 years, 57% female, with baseline A1c 7.6%.	14% Latino, 14% African, 14% Caribbean, 14% South Asian	Health Coach app supports multi-channel communications between users, health coaches, and supportive family members, and supports tracking health behaviors (e.g., exercise, diet) and self-monitoring health data (e.g., blood glucose, mood, and energy).	A human health coach and patient collaboratively create a personalized wellness plan based on electronic monitoring entries and physician and dietician medication and dietary guidelines, respectively.	N/A	A1c decreased in the intervention group by 0.28% ($p = 0.05$) at 6 months. Patients with uncontrolled baseline A1c (n = 12) experienced the greatest A1c improvement (0.43%, $p = .04$).
Wayne, 2015 [65]	Randomized control trial 6 months.	97 patients with T2D ($n = 48$ health coaching with mobile phone support, $n = 49$ health coaching without mobile phone support) from two health centers in Toronto, Canada. Mean age 53 years, 72% female, with baseline A1c 8.8%.	5% African, 40% Caribbean, 9% Hispanic	With health coach assistance, clients determined health-related goals and monitored daily progress. The health coach monitored participant's mobile phone input and directed immediate attention to episodes of desirable progress, relapse, and resistance. Intervention group could track/monitor their meals, exercise, blood glucose, and mood and communicate with the coach any time through the platform.	A human health coach and patient create a personalized wellness plan based on electronic monitoring entries.	Both groups had access to a health coach; however, control group did not have smartphone interaction. Both groups also had access to decision support and action support through the health coach, as well as had access to the Exercise Education Program. Control group participated in verbal discussion of meals, exercise, blood glucose, and mood.	A1c decreased in the intervention group by 0.84% ($p = .001$) and in the control group by 0.81% ($p = .001$) over 6 months. No significant between-group changes. Intervention group did achieve an accelerated A1c reduction, leading to a significant between-group difference at 3 months ($p = .03$).

Table 2 Included Internet intervention studies

First author, year	Study design & duration	Sample characteristics	Vulnerable/ disadvantaged classification	Intervention characteristics	Intervention tailoring	Control group	Glycemic control
Carter, 2011 [66]	Two-arm randomized controlled trial 9 months.	47 patients with T2D ($n = 26$ intervention, $n = 21$ control) from a primary care practice in Washington, DC. Mean age 51 years, 64% female, with baseline A1c 8.9%.	100% African American	Home visit by study staff to provide laptops with webcam and broadband wireless card and provide a tutorial on how to use the portal, followed by bi-weekly self-management teleconferencing with a nurse, and access to a health education module and a social networking module where participants could interact with one another. Intervention participants also received a wireless scale, a blood pressure cuff, and a glucometer to measure weight, blood pressure, and glucose throughout the study period.	Each participant had a "culturally competent action plan based on the treatment plan provided by the patient's healthcare provider." The nurse tailored each interactive session to the patient's individual needs and preferences.	Usual care	Participants in the intervention group were 4.6 times more likely to achieve A1c ≤ 7.0% than those in the control group ($p < .05$).
Egede, 2017 [67]	Two-arm randomized control trial 6 months.	113 patients with T2D ($n = 54$ intervention, $n = 59$ control) from SC, USA. Mean age 54 years, 81% female, with baseline A1c 10.1%.	Recruited from federally qualified health centers 75% African American	Technology-assisted Case Management intervention group used a telehealth system to link a case manager to patients in real time. Patients provided daily measurements on blood glucose and blood pressure using the telehealth system, which were reviewed by the nurse case manager who made weekly medication adjustments accordingly.	None.	Usual care.	Between-group difference in A1c was 0.99% ($p = 0.02$) at 6 months. The rate of decline in levels of A1c over time was significantly faster for intervention participants compared to the control group (−0.16, $p = 0.04$).
Heisler, 2014 [68]	Two-arm randomized controlled trial 2 h. (3-month follow-up assessment)	188 patients with T2D ($n = 93$ iDecide intervention, $n = 95$ print intervention) from community health centers in Detroit, MI, USA. Mean age 52 years, 71% female, with baseline A1c 8.3%.	57% Latino & 52% Spanish-speaking, 37% African American 60% < 15 K incomes	iDecide is an individually tailored, Web-based, tablet computer-delivered tool supporting diabetes medication decision making designed for community health workers (CHW) to deliver on tablet computers via 3G wireless access.	Presentation of materials is targeted to patients with low literacy. An assessment helps participants identify personally salient concerns, which they then explore. Personal information from the baseline assessment (e.g., A1c, current medications, personal values, social support, adherence, reported barriers) is used to tailor intervention content throughout.	Control group received the same information as the intervention group, delivered by a CHW with non-tailored, paper-based materials.	A1c decreased in the intervention group by 0.40% ($p = .001$). A1c decreased in the control group by 0.30% ($p = .01$) at 3-month follow-up. No between-group differences.
McIlhenny, 2011 [69]	Pre-post quasi-experimental design 6 months.	98 patients with T2D ($n = 48$ MyHERO portal intervention, n = 50 print intervention) from rural health clinics in PA, USA. Mean age 64 years, 51% female, with baseline A1c 7.3%.	100% rural	MyHERO is a web portal designed to provide reliable, evidence-based health information. Patients at the intervention site received one-on-one healthcare education ~ every 6 weeks and training in how to use the MyHERO portal from a nurse educator.	Patient education selected based on nursing assessment and patient request. Patients could attend education sessions in-person or via phone.	Control group received access to MyHERO, traditional instructions by their provider, and an instructional handout with step-by-step instructions and screenshots to access MyHERO.	No changes in A1c.
Ryan, 2013 [70]	Non-experimental pre-post design 13 months.	21 patients with T2D from an urban community clinic in Miami, FL, USA. Mean age 54 years, 67% female, with baseline A1c 7.5%.	78% African American 78% no health insurance	HEAT-IT-UP is a web-based suite of applications, collectively designed to be a "relationship management tool" aimed at improving diabetes self-management and clinical outcomes via improvements in working alliance, health-related quality of live, and self-efficacy for diabetes management. Participants were asked to upload blood glucose	Upon logging-in, patients receive feedback in the form of educational and motivational messages tailored to their uploaded blood glucose data, and positive feedback or instructions based on uploaded blood glucose results. Content targeted to culture and low literacy. Applications provided support for	N/A	A1c decreased by 0.6% ($p = .04$).

Table 2 (continued)

First author, year	Study design & duration	Sample characteristics	Vulnerable/ disadvantaged classification	Intervention characteristics	Intervention tailoring	Control group	Glycemic control
				results daily and log-in every other day.	communication with providers and peers.		
Welch, 2011 [71]	Two-arm randomized controlled trial 12 months.	46 patients with T2D ($n = 25$ intervention, $n = 21$ control) from an urban community health center in Springfield, MA, USA. Mean age 56 years, 65% female, with baseline A1c 8.8%.	100% Latino	The Comprehensive Diabetes Management Program is an Internet-based diabetes care program focusing on clinical management, psychosocial health, and lifestyle modification provided by certified diabetes educators to patients in-person during 7 visits.	None.	Control group received 7 1-h visits over 12 months with bilingual clinic staff using paper diabetes education materials.	A1c reductions in the intervention group were greater than reductions in the control group (− 1.6% ± 1.4% versus − 0.6% ± 1.1%; $p = .01$). Between-group difference was not significant.
Welch, 2015 [72]	Two-arm randomized controlled trial 6 months.	399 adults with T2D ($n = 199$ intervention, $n = 200$ control) from urban community health centers in Western Massachusetts, USA. Mean age 55 years, 60% female, with baseline A1c 9.0%.	100% Latino	The Comprehensive Diabetes Management Program is an Internet-based diabetes dashboard management tool used by clinicians in-person with patients during 5 visits.	Providers tailored sessions on clinical data from medical records and patient-reported behaviors, barriers, and psychosocial challenges. Also tailored to preferred language (Spanish or English), literacy level, desire to include family members, and preference for alternative medicine.	Control group received usual care, which included individual patient visits with education content, access to lifestyle and diabetes self-management support groups run by peer volunteers and clinical staff, with no use requirements.	A1c decreased in the intervention group by 0.8% ($p < .001$). More intervention participants than the control group participants achieved A1C < 7.0% (15.8% vs. 7.0%, $p = .01$). Intervention was more effective among patients with baseline A1C > 8.0% (45.2% vs. 25.3% achieved A1C < 7.0%, $p < .001$).

challenges [72], personal values and social support [68], glucose and physical activity data [52, 61•, 65•]), by modifying content to languages and/or cultures [52, 57••, 63, 70••], or by utilizing personnel familiar with the study population (e.g., health coaches [63, 64, 65•], CHWs [68], case managers [60], or nurses [66, 70, 73]).

Only 14% of studies reported the literacy or numeracy status of the study sample [63, 68, 72]. Sensitivity to literacy and numeracy concerns are especially important in the design of digital interventions and their content, as both are prevalent barriers to understanding and acting on health information. Lower literate and numerate persons often struggle with evaluating and trusting online health information [77], and often rely on verbal communication about their health [78]. Lower numerate persons disproportionately have difficulty navigating online patient portals [79], and interpreting A1c test results presented in a patient portal-like format [80]. Some of the studies factored in *computer* literacy/usability considerations [52, 68, 70] or the piloting of an intervention in previous work [53••, 72, 73], suggesting a responsiveness to the understandability (of function and/or content) for end users.

We recommend study authors be more explicit about the process used to develop and/or adapt intervention content and technical functionality for disadvantaged/vulnerable PWD. Existing standards [78, 81] outline key design principles to improve accessibility and better meet the needs of digital users with limited literacy. Similarly, given the numeracy demands of diabetes self-management tasks (e.g., self-monitoring of blood glucose, insulin titration, A1c interpretation), existing numeracy-friendly print materials [82] could be adapted for digital use. There should be short summaries of this process in manuscripts evaluating the impact of these interventions, in addition to citing publications with more lengthy descriptions and/or lessons learned during feasibility/usability studies.

Despite heterogeneity in intervention utilization, disadvantaged/vulnerable PWD had high rates of satisfaction with the full range of intervention platforms [52, 53••, 55••, 69, 73]. This may reflect a strong desire on the part of users, particularly disadvantaged/vulnerable populations who disproportionately report negative healthcare experiences, to feel supported and "cared for" by their healthcare team [21, 22, 83]. Given this possibility, satisfaction data alone may be insufficient to assess the acceptability and adoption of an intervention. The addition of usability data (e.g., how often/how much users engaged with the intervention and how easy/how helpful they found it to be) or data on reach and sustained use would provide a more comprehensive assessment.

The Human Element

CHWs, patient navigators, and case managers often provide an important cultural bridge between disadvantaged/ vulnerable populations and the rest of the healthcare team

Table 3 Key recommendations for the design and research of mobile and Internet interventions for disadvantaged and vulnerable persons with diabetes

Access issues	Use technology patients already access and use
	Compensate for participation, but do not pay for technology to understand potential real-word use and sustainability
	If providing/paying for technology, consider cost analyses to determine sustainability
Program design and usability	Tailor content on the individual level (e.g., person-reported personal data)
	Apply existing standards to make digital design acceptable to persons of all health literacy and numeracy levels
	Consider literacy and numeracy when designing content *and* functionality; report how design accommodates all levels
	For now, disparities in internet access persist, so consider non-internet-dependent technology
	Test interventions for usability with the target population; report usability data (not just self-reported satisfaction)
The human element	Utilize personnel familiar with/known to the study population (e.g., community health workers)
	Trained personnel can tailor to individuals' needs and experiences with the technology and may help overcome mistrust
	Systematically evaluate when and how humans can and should be used to improve the reach or effectiveness of digital interventions
Understand the user population	Report data on socioeconomic status (e.g., income, education, insurance status), health literacy and numeracy of study samples or study catchment populations to inform next steps for interventions
	When possible, examine differential effects by socioeconomic status, health literacy status
	When possible, examine differential engagement with the intervention by socioeconomic and/or health literacy status
Use more agile science	Focus on comparative effectiveness/superiority trials, pragmatic trials and cost analyses rather than efficacy trials with a treatment-as-usual control group
	Studies with an active comparison are more likely to engage disadvantaged/vulnerable persons with diabetes
	Use adaptive study designs to address the need for continued quality improvement and rapid iteration
Long-term evaluation	Studies with interventions lasting longer than 3 or 6 months are needed
	Studies with post-intervention follow-up periods are needed
Economic evaluations	Make efforts to understand costs and savings associated with digital interventions to determine if effects are "worth" costs associated with the technologies
	Consider cost analyses in two ways: (1) without providing/paying for technology, (2) evaluating whether providing/paying for technology is cost-effective in light of savings associated with improvements in health outcomes
Conduct studies in low-/middle-income countries	More studies in low-/middle-income countries are needed
	Develop interventions specifically for the population or describe rigorous efforts to adapt existing interventions to the context

[84–87]. They can often address patient barriers of mistrust in providers and health systems [24, 88], literacy barriers [89], and language and cultural discordance [90, 91]. Several interventions utilized CHWs [68], health coaches [63, 64, 65•], or case managers [60, 67••] as integral components alongside the technical elements. Nurses [66, 70, 73] were also used in this capacity. Trained CHWs or other healthcare team members can tailor information to cultural values/context [66, 92, 93], literacy and numeracy abilities [90, 91], and/or personal beliefs and concerns [66, 92] in real time, thereby increasing the applicability of a technology to different types of populations [84, 93].

Digital interventions *alone* are likely insufficient to address the full range of self-management support needs of disadvantaged/vulnerable populations with T2D. Automated interventions that act *in concert* with human capital may have more potential for success among disadvantaged/vulnerable PWD than stand-alone digital interventions. To fully realize this potential, we must first identify ways to leverage the functions of healthcare personnel and CHWs (whose time and associated costs limit scalability) with the advantages of technologies (e.g., potential for scale, rapid dissemination, and real-time interactions).

The User Population

Many studies did not report data on patient income, insurance status, and/or education level [52, 54•, 55, 58, 59, 61, 72, 76]. Not reporting participants' SES creates barriers to the effective translation of interventions. If a study reports efficacy, but pertinent characteristics of the sample are absent, the next steps are unclear (i.e., additional tailoring for specific user subgroups vs. readiness for broader dissemination and implementation). To minimize such uncertainty, interventions should report information about a sample's race/ethnicity, income, education, insurance status, health literacy, and/or numeracy. Alternatively, when person level data is unavailable, studies should report on clinic- or population-level data. Differential intervention effects and engagement by users' SES and/or literacy/numeracy status should also be pursued when possible.

Scientific Methods

Typically, researchers study an intervention's impact in terms of depth (i.e., improved individual outcomes) and breadth (i.e., impact across the entire group). Highly controlled RCTs limit our understanding of the depth and breadth of interventions in real-world conditions in which vulnerable populations live. We call for innovative research designs to evaluate digital interventions, particularly among disadvantaged and vulnerable PWD. Research efforts focusing on comparative effectiveness, how to maximize the reach of a digital intervention (vs. focusing only on the depth of intervention effects), or pragmatic trials (i.e., using technology to supplement existing improvement efforts) may be more informative and useful. We also echo calls for more agile and iterative approaches to develop, improve, and evaluate digital interventions [94] to ensure that the pace of development and research keeps with the pace of technology and patient expectations.

In addition, we need more studies evaluating costs and healthcare utilization, in order to maximize our understanding of the impact of digital interventions, and to identify the most cost-effective "real-world" interventions. Nundy et al. [73] found an 8.8% reduction in health plan costs for diabetes care and improvements in healthcare utilization in a 6-month trial of their mobile program CareSmarts. Two other studies [53••, 60] reported reductions in hospitalizations and/or ER visits. As mentioned previously, comparative effectiveness, equivalency, and superiority trials can illuminate the added value of automated versus traditional print (i.e., generally lower cost) or in-person (i.e., generally higher cost) interventions. Cost-effectiveness studies can then determine if any identified differential effects are worth the investment. We recommend studies look at the "cost-efficacy" of interventions in two ways. First, evaluate an intervention's reach in real-world settings (i.e., without studies paying for devices or Internet/mobile phone service). Second, if studies do provide or pay for devices/services, economic analyses are needed [95] to evaluate whether providing devices/services is cost-effective, taking into consideration any cost savings associated with improvements in health outcomes. Healthcare systems or communities may adopt plans to support use of digital interventions once cost savings associated with their use have been established.

One example of a pragmatic randomized trial was Arora et al.'s [53••] TExT-MED intervention that sent text messages twice daily to resource-poor PWD recruited from an ER, which found that TExT-MED improved medication adherence and reduced the ER utilization [53••] among users in the intervention group [53••]. Because TExT-MED relied on the technical capabilities of the target audience, and reached PWD who recently used the ER, there is generalizability for broader implementation of this intervention.

Intervention studies with disadvantaged/vulnerable populations must be careful about using usual care control groups, because of ethical challenges arising from such study designs in resource-poor settings. Disadvantaged/vulnerable persons have disproportionately more barriers (e.g., inflexible work schedules [57••, 64], inaccessible or unreliable transportation [57••], longer distances to clinics or study sites [96]) to research participation than advantaged persons, and may be less inclined to participate if assigned to a usual care control [64]. The use of active controls (e.g., waitlist controls, alternative interventions) that give all PWD access to some type of intervention, versus inactive controls (i.e., a confirmatory trial), can address the ethical issues and support retention in the control groups. Several studies used an active comparator in their randomized trials (i.e., a superiority trial). For example, Welch et al. used certified diabetes educators (nurses and dieticians) to deliver 7 h of diabetes care visits for the intervention group, while the attention control participants received 7 h of visits with trained clinic support staff to review diabetes education materials prepared by the American Diabetes Association (ADA) [71]. Offering an alternative intervention to ensure control group retention may produce greater effects for all, but may dampen the ability to detect between-group effects [97]. On the other hand, active comparator studies may engage clinics in research partnerships, engage and improve outcomes for all participants, and—if designed correctly—help parse out the effects of individual intervention components and make decisions about scalability.

Long-Term Evaluation

Although several interventions noted a faster initial rate of A1c decline in the intervention group relative to controls [54•, 65•, 67••], there was little attention paid to long-term effects. Most interventions lasted 6 months or less, with a few notable exceptions. Only one mobile phone intervention was 12 months; it used a pre-post design [60] and was unable to assess within-group improvements in A1c due to incomplete data. Three Internet-delivered [66, 70, 71] interventions lasted longer than 6 months, and found improvements in diabetes control at 9, 12, and 13 months. Only one study had a post-intervention follow-up period; Bell et al. [54•] tracked participants for 6 months (after a 6-month intervention period), and found a between-group difference in A1c at 12 months. More work should focus on examining long-term efficacy of interventions as well as post-intervention (sustained) effects.

Studies in LMICs

Three quarters of the world's diabetes population live in low to middle-income countries [LMICs] [1], but there is limited evidence on the effect of mobile and Internet interventions on diabetes control in LMICs. Only two of the 21 studies in our review were conducted in a LMIC (i.e., Iraq [58] and Bangladesh [59]). Both showed clinically meaningful improvements in diabetes control (i.e., A1c). To advance the field and improve the health of PWD in LMICs, we recommend more digital self-management interventions be developed for and tested with PWD in LMICs, and that studies measure and report on the clinical outcomes of these users. Consistent with our above recommendations, such interventions must be appropriately adapted and contextualized to the language, culture, literacy and numeracy skills, local context, health systems, and the access and availability of the Internet and digital devices in these countries.

Summary and Conclusions

Technology can offer access to information, support, and healthcare providers to improve diabetes health outcomes of disadvantaged/vulnerable patients, communities, regions, and countries. Technology can also automate the delivery of health information and support, with relatively limited demand on healthcare system resources. The rapid adoption of mobile devices throughout the world is redefining how healthcare is delivered and how PWD manage their disease. This is particularly true in LMICs [95], where mobile devices can be used to engage populations who have been historically difficult to reach via traditional healthcare delivery or communication channels. Although evidence on the acceptability, use, efficacy, and cost-effectiveness of digital interventions is increasing, traditional study designs and measures are becoming inadequate for addressing the questions needed to optimize the effects of digital interventions on disadvantaged and vulnerable PWD.

To address the challenges outlined in this review, the research community needs new approaches to the design, implementation, and evaluation of mobile and Internet interventions for disadvantaged and vulnerable PWD. First, we need to better address the accessibility and usability of technology interventions for disadvantaged/vulnerable PWD by leveraging in-place technologies and rigorously applying best practice standards to ensure digital content sufficiently meets the needs and desires of these populations. Meaningful implementation of design standards and user-centered design approaches, with rigorous reporting, should be a priority. The research community also needs more dynamic approaches and adaptive study designs to address the need for continued quality improvement and rapid iteration [35]. According to Mohr et al. [97], traditional evaluation methods are fundamentally incompatible with mobile and Internet-delivered interventions, where technological advances and consumer expectations change quickly, necessitating rapid changes in program content and delivery. Adopting our recommendations will require even more transdisciplinary approaches to evaluation that strongly emphasize evaluation of the user experience, engagement, and "real-world" value and costs.

To move the field forward and enhance the public health significance of these interventions, we recommend that future studies explore (a) *how* we digitally present and deliver information, support, and skills to disadvantaged and vulnerable PWD, (b) what is the *reach* relative to traditional forms of intervention delivery, and (c) what is the *cost-efficacy* relative to other interventions and/or relative to the cost savings associated with improvements in outcomes. Pursuing between-group A1c improvement via traditional confirmatory/efficacy RCTs may be less innovative or informative than using comparative or cost-effectiveness designs or performing equivalency or superiority trials. Thus, the question is not *whether* technology can improve the health of PWD, but how to best design intervention studies to *maximize* these effects to improve health for all, especially high-risk and vulnerable patients.

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Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

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