



# Digital health technology and mobile devices for the management of diabetes mellitus: state of the art

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## Abstract

Diabetes mellitus is a disease that can be difficult to manage and requires high levels of health literacy and numeracy, self-monitoring and frequent contact with clinicians. If not optimally controlled, diabetes can lead to kidney failure, blindness and cardiovascular complications, which, in turn, contribute to increasing healthcare costs. Although not yet widely used, mobile health (mHealth) tools have enhanced diabetes management and prevention and are likely to play an increasing role with the growth of smartphone ownership and medical device innovations. Recent mHealth interventions targeting type 1 and type 2 diabetes are diverse in their goals and components, and include insulin management applications, wearable blood glucose meters, automated text messages, health diaries and virtual health coaching. In this paper, we review the modalities and components of various impactful interventions for insulin management, diabetes education, self-management and prevention. More work is needed to investigate how individual demographic, socioeconomic, behavioural and clinical characteristics contribute to patient engagement and the efficacy of mHealth tools for diabetes.

**Keywords** Diabetes · Digital health · Glucose monitoring · HbA<sub>1c</sub> · mHealth · Precision medicine · Review · Self-monitoring · Smartphones · Wearables

## Abbreviations

CE	Conformité Européenne
DID	Diabetes Interactive Diary
FDA	Food and Drug Administration
FTA	Few Touch Application
mHealth	Mobile health
mDPP	Mobile Diabetes Prevention Program
MITI	Mobile Insulin Titration Intervention
rtCGM	Real-time continuous glucose monitoring

SMBG	Self-monitored blood glucose
SMS	Short message service

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## Introduction

The growing field of mobile health (mHealth) has been applied to numerous areas, including health promotion, behaviour change support and self-management of chronic diseases. The US Food and Drug Administration (FDA) defines mHealth as the delivery of health services and improvement of health outcomes via mobile and wireless devices. mHealth interventions often employ modalities such as short message service (SMS) text messaging, smartphone applications ('apps') and wearable technology. mHealth is a subset of digital health or electronic health (eHealth), which also includes health information technology, telemedicine and personalised medicine [1]. Digital platforms can be adapted to changing medical guidelines and translated across different conditions. They can also be quickly scaled to reach thousands of people and potentially increase access to healthcare. In 2018, approximately 66% of the world's population

owned a smartphone, including up to 80% in Western European countries and 77% in the USA [2, 3]. Consumer technology companies, such as Apple, Google and Fitbit, have entered the healthcare market, and thousands of health or fitness mobile apps are in the Apple App Store and Google Play, though only a small proportion have been approved by entities such as the FDA [4].

The management of diabetes mellitus is challenging for both patients and clinicians. To successfully self-manage diet, exercise, medications and insulin doses, patients must have high levels of health literacy and numeracy. Clinicians often motivate behaviour change, interpret blood glucose trends and adjust medication doses within brief clinic visits, sometimes engaging with patients who may have a limited understanding of their condition or treatment plan.

mHealth is well-suited to diabetes management, as it can provide frequent contact with patients and timely dissemination of health information, facilitate glycaemic control and guide self-management. A 2011 meta-analysis of 1657 individuals with type 1 or type 2 diabetes using SMS messages to send self-monitored blood glucose (SMBG) values and receive self-management information revealed a 0.5% (5.5 mmol/mol) decrease in HbA<sub>1c</sub> over 6 months in mHealth intervention groups compared with control groups, with a greater effect size in patients with type 2 diabetes than in those with type 1 diabetes [5]. A 2017 meta-analysis of 13 studies on mobile apps for diabetes suggested overall efficacy in reducing HbA<sub>1c</sub>, with a mean 0.44% (4.8 mmol/mol; 95% CI 0.29%, 0.59%) decrease in intervention compared with control, as well as increased perception of self-care among mobile app users [6]. Nevertheless, of the numerous commercially available mobile apps for diabetes, only 14 have clinical outcomes published in peer-reviewed literature or with regulatory clearance from the FDA or the Conformité Européenne (CE) mark, according to a 2016 review [7].

Initial results demonstrate the potential value of mHealth in diabetes. The field is rapidly expanding and the components of existing evidence-based interventions are heterogeneous. In this narrative review, we explore aspects of mHealth interventions for the management of diabetes, highlighting the various components of recent interventions.

## Insulin management

The technical and computational challenges of calculating insulin boluses, counting carbohydrates, and titrating insulin make mHealth interventions for type 1 diabetes and insulin-dependent type 2 diabetes particularly valuable (Table 1).

Studied in patients with type 1 diabetes, Diabeo (Voluntis) [8] and Diabetes Interactive Diary (DID, Meteda) [9, 10] both consist of a mobile app that incorporates SMBG recording and an insulin bolus calculator. The bolus calculators use algorithms that consider SMBG values, carbohydrate intake and physical activity, as well as clinician-set parameters for the insulin/carbohydrate ratio, correction factor and basal insulin dose. The systems also recommend changes to these parameters if postprandial or fasting SMBG levels are off target. These systems differ in their telemedicine components and efficacy. While Diabeo offers biweekly telephone consultations with healthcare professionals, DID sends recorded data to clinicians via SMS messaging, and recommended changes in treatment or behaviours can be texted back to the patient [8, 10]. A three-arm RCT found a 0.91% (9.9 mmol/mol) greater HbA<sub>1c</sub> reduction at 6 months in the Diabeo plus telemedicine arm compared with usual care ( $p < 0.001$ ), with no difference in hypoglycaemia [8]. Diabeo is commercially available in Europe [7], and a larger-scale RCT evaluating Diabeo with telemedicine support is underway in France to confirm the prior results [11]. In contrast, DID has been evaluated in two multicentre RCTs [9, 10], both of which did not demonstrate efficacy in HbA<sub>1c</sub> reduction. However, the DID group had an 86% lower incidence rate of moderate–severe hypoglycaemia episodes and improved quality of life scores [10]. DID is commercially available in Italy and has been given the CE mark in Europe [7].

The pilot randomised Mobile Insulin Titration Intervention (MITI) trial [12] aimed to streamline insulin glargine titration among low-income, ethnically diverse type 2 diabetes patients via text messaging. Patients texted SMBG values, and a nurse provided algorithm-based insulin glargine titration advice via weekly phone calls. A higher proportion of patients in the intervention arm reached an optimal insulin glargine dose within the 12 week study (88% in the MITI arm, 37% in the control arm,  $p < 0.001$ ), reducing frequent clinic visits for titration [12]. However, cost savings for the patient are offset by the need for uncompensated clinician intervention, as telemedicine reimbursements in the USA are currently limited. Generalisability is also limited, as MITI was designed for a specific patient population to integrate with a single clinic workflow; nevertheless, the simplicity and relative ease of set-up suggest that a texting intervention to meet a specific need is impactful and can be adapted for other uses.

## Connected and wearable blood glucose meters

Many mobile apps incorporate connected blood glucose meters and are often developed by the device manufacturers.

**Table 1** mHealth interventions for insulin management

Study, setting	Sample characteristics	Modality	Components of intervention	Clinical outcomes
Charpentier et al, 2011 [8] TeleDiab 1 Study, Diabeo (Voluntis) Multicentre RCT: 17 hospitals in France	T1DM adults, on basal-bolus insulin regimen. Age: $33.8 \pm 12.9$ years. Baseline HbA <sub>1c</sub> : $9.07 \pm 1.07\%$ ( $76 \pm 11.7$ mmol/mol) $n = 59$ Diabeo + teleconsultation $n = 60$ Diabeo alone $n = 60$ Paper SMBG log-book and usual care	Mobile app, telephone calls	Insulin bolus calculator: based on SMBG, carbohydrate counts and physical activity. Suggests adjustments for insulin/carbohydrate ratio and basal insulin dose if SMBG off-target. Teleconsultations with physicians: every 2 weeks for SMBG log-book review, insulin-dose adjustments and motivational support.	Diabeo only group had 0.67% (7.3 mmol/mol) greater reduction in HbA <sub>1c</sub> at 6 months than control ( $p < 0.001$ ). Diabeo + teleconsultation had 0.91% (9.9 mmol/mol) greater HbA <sub>1c</sub> reduction at 6 months ( $p < 0.001$ ). No difference in frequency of hypoglycaemic episodes between groups.
Rossi et al, 2010 [9] Diabetes Interactive Diary (DID, Meteda) Multicentre RCT: Italy, England, Spain	T1DM adults, on any insulin regimen except for soluble regular or NPH insulin, no previous education on carbohydrate counting. Age: $35.4 \pm 9.5$ years in DID group, $36.1 \pm 9.4$ years in control group. Baseline HbA <sub>1c</sub> : $8.2 \pm 0.8\%$ ( $66 \pm 8.7$ mmol/mol) in DID group, $8.4 \pm 0.7\%$ ( $68 \pm 7.7$ mmol/mol) in control group $n = 67$ DID intervention $n = 63$ Usual care	Mobile app, SMS	Insulin bolus calculator: based on SMBG, carbohydrate counts, physical activity, and insulin/carbohydrate ratio. Recommends daily carbohydrate intake. Suggests basal insulin dose adjustments. SMS communication with physicians: recorded data are regularly sent to physicians; therapeutic recommendations are texted to patients.	No difference in HbA <sub>1c</sub> reduction; both groups reduced HbA <sub>1c</sub> by $\sim 0.5\%$ (5.5 mmol/mol) at 3 months, maintained at 6 months. DID group had significantly improved diabetes-related quality-of-life scores.
Rossi et al, 2013 [10] DID (Meteda) Multicentre RCT: Italy	T1DM adults, on 1 daily dose insulin glargine + 3 doses insulin glulisine, no previous education on carbohydrate counting. Age: $38.4 \pm 10.3$ years in DID group, $34.3 \pm 10.0$ years in control group. Baseline HbA <sub>1c</sub> : $8.4 \pm 0.1\%$ ( $68 \pm 1.1$ mmol/mol) in DID group, $8.5 \pm 0.1\%$ ( $69 \pm 1.1$ mmol/mol) in control group $n = 63$ DID intervention $n = 64$ Usual care	Mobile app, SMS	Same as above	No difference in HbA <sub>1c</sub> reduction; both groups reduced HbA <sub>1c</sub> by $\sim 0.50\%$ (5.5 mmol/mol) at 6 months. DID group had 86% lower incidence rate of moderate–severe hypoglycaemic episodes and improved quality-of-life scores.
Levy et al, 2015 [12] Mobile Insulin Titration Intervention (MITI) Single-centre RCT: USA	Low-income T2DM patients taking insulin glargine in a clinic primarily serving uninsured or Medicaid patients. Age: $46.70 \pm 10.75$ years. Baseline HbA <sub>1c</sub> : $11.72 \pm 1.83\%$ ( $104 \pm 20.0$ mmol/mol) $n = 33$ MITI $n = 28$ Usual care	SMS, telephone calls	Glucose monitoring: patients received texts requesting their fasting SMBG values. Remote management: the clinic's diabetes nurse educator reviewed the SMBG responses for alarm values, consulted titration algorithm and called patient to adjust insulin dose if needed.	Percentage of patients who achieved optimal insulin glargine dose within 12 weeks was higher in the MITI arm (88%) than in the usual care arm (37%, $p < 0.001$ ).
Bolinder et al, 2016 [16] FreeStyle Libre (Abbott) Multicentre RCT: Sweden, Austria, Germany, Spain, Netherlands	T1DM adults, well controlled on insulin therapy. Age: 42 years (IQR 33–51) in intervention group, 45 years (IQR 33–57) in control group. Baseline HbA <sub>1c</sub> : $6.7 \pm 0.5\%$ ( $50 \pm 5.5$ mmol/mol) in intervention group, $6.7 \pm 0.6\%$ ( $50 \pm 6.6$ mmol/mol) in control group $n = 119$ Flash glucose monitoring $n = 120$ Usual care with finger-stick SMBG	Flash glucose testing	Glucose monitoring: interstitial glucose concentrations captured on a skin-worn sensor; scanning with reader device displays current glucose level and 8 h trends. Data can be uploaded from the reader to device software to generate reports. Patients otherwise managed diabetes according to usual care.	Time in hypoglycaemia ( $< 3.9$ mmol/l) decreased by 1.24 h/day more in the intervention than control group at 6 months ( $p < 0.0001$ ). No difference in 6-month HbA <sub>1c</sub> reduction between groups. Treatment satisfaction favoured intervention.
Haak et al, 2017 [17] FreeStyle Libre (Abbott) Multicentre RCT: France, Germany, UK	T2DM adults on insulin therapy. Age: $59.0 \pm 9.9$ years in intervention group, $59.5 \pm 11.0$ in control group. Baseline HbA <sub>1c</sub> : $8.74 \pm 0.97\%$ ( $72 \pm 10.6$ mmol/mol) in intervention group, $8.88 \pm 1.04$ ( $74 \pm 11.3$ mmol/mol) in control group $n = 149$ Flash glucose monitoring $n = 75$ Usual care with finger-stick SMBG	Flash glucose testing	Same as above.	Time in hypoglycaemia ( $< 3.9$ mmol/l) decreased by 0.47 h/day more in intervention than control at 6 months ( $p = 0.0006$ ). No difference in 6 month HbA <sub>1c</sub> change between groups. Treatment satisfaction favoured intervention.

T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus

For example, the commercially available Accu-Chek Connect app (Roche) receives SMBG results from the Accu-Chek Connect blood glucose meter and includes an insulin bolus calculator and photographic food diary to aid in carbohydrate counting [7]. The ease of data flow from connected blood glucose meters allow glucose patterns to be efficiently presented to patients for self-management and to clinicians for treatment adjustments.

The inconvenience and pain of obtaining finger-stick blood samples from traditional blood glucose meters can contribute to poor adherence to self-monitoring and is one barrier to optimal glucose control. Real-time continuous glucose monitoring (rtCGM) and intermittently scanned flash glucose monitoring are increasingly used as adjuncts and alternatives to finger-stick glucose tests for making diabetes treatment decisions. Both use a wearable sensor that measures interstitial fluid glucose concentrations, which are transmitted to a reader device. Although rtCGM has been available for some time, flash glucose monitoring is a newer alternative to SMBG that can be used without calibration with a finger-stick test [13]. The FreeStyle Libre flash glucose monitor (Abbott) obtained FDA approval in 2017 and the CE mark in 2018 [14, 15] and is now available by prescription. The factory-calibrated disk-like sensor is worn on the upper arm for up to 14 days. By passing a reader device over the sensor, the patient can obtain real-time glucose levels and trends, and hypo- and hyperglycaemia alarms are available in some countries [15]. Large multicentre RCTs of the FreeStyle Libre sensor vs finger-stick SMBG demonstrated lower time in hypoglycaemia in type 1 diabetes patients [16] and in type 2 diabetes patients on insulin therapy [17]. Although studies have not shown decreased 6 month HbA<sub>1c</sub> levels, the device promoted increased monitoring frequency (mean 8–15 scans per day with FreeStyle Libre vs <1 SMBG per day), with higher treatment satisfaction [16, 17].

Flash glucose monitoring and rtCGM are useful when higher frequency data are needed, for example, to generate a remotely viewed glucose log after making therapy adjustments, so clinicians can see if the changes were effective. Although these devices are increasingly common, the high costs (depending on insurance coverage) prohibit more widespread use. Despite concerns regarding the accuracy of interstitial fluid measurements, particularly at low glucose values and with equilibration delay between vascular and interstitial compartments, these methods have generally good concordance with SMBG [18]. The increased adherence to self-monitoring and higher patient satisfaction with flash glucose monitoring highlight the importance of the user experience in promoting self-management of diabetes.

Manufacturers such as Dexcom and Abbott have developed mobile apps supporting the rtCGM and flash glucose monitoring devices to enhance monitoring of glucose data. For example, the LibreLink (Abbott) mobile app allows a smartphone to replace the reader device, using near field communication to scan the sensor and read glucose data, displaying ambulatory glucose profile and estimated HbA<sub>1c</sub> [13]. Additionally, carers of diabetic patients can use an app on their own smartphones to remotely monitor patients' glucose levels [13]. However, RCTs have focused on evaluating the safety and accuracy of the flash glucose monitoring devices exclusively, and studies describing the real-world use of the supporting mobile apps are lacking.

## Diabetes education, self-management and lifestyle modifications

Clinicians often direct patients to attend in-person diabetes self-management classes, which may be burdensome, and this may be partly responsible for the low attendance rates [19]. Thus, mHealth interventions to support self-management and diabetes education can potentially expand care delivery. Unlike interventions specifically designed for glucose monitoring or insulin dosing, mHealth interventions for education and self-management generally provide holistic content, are targeted towards patients with type 2 diabetes, and are informed by behavioural change theories, such as the Information-Motivation-Behavioral Skills Model [20], social cognitive theory [21, 22], theory of planned behaviour [21] or motivational interviewing [23]. Patients are encouraged to self-monitor glucose, diet and exercise, and these data may be used to tailor feedback messages. Message content includes diabetes education, health promotion, motivational messages, reminders for medications and SMBG, or specific behavioural changes to implement, which are usually sent automatically according to an algorithm [20–22, 24–26]. The content of educational messages should be credible and evidence-based. Some interventions use expert-generated content; others are adapted from published national curriculums, such as the Diabetes Prevention Program [27], ADA's Diabetes Self-Management Education [25], or the National Diabetes Education Program [22] (Table 2).

**Mobile applications with comprehensive features** Several studies of smartphone applications have shown promising results in self-management of type 2 diabetes [20, 24, 28]. The BlueStar mobile diabetes coach (WellDoc) [24, 28] became the first type 2 diabetes app available on prescription [4] and a non-prescription version was approved by the FDA in 2017. BlueStar provides real-time automated educational and behavioural messages sent in response to

**Table 2** mHealth interventions for education, self-management and prevention of diabetes

Study, location	Sample characteristics	Modality	Components of intervention	Clinical outcomes
Bloek et al, 2015 [21] Alive-PD (NutritionQuest). Single-centre RCT: USA	Adults with prediabetes by HbA <sub>1c</sub> (5.7–6.4% [39–46 mmol/mol]) or fasting plasma glucose (5.55–6.94 mmol/l) and BMI $\geq 27$ kg/m <sup>2</sup> . Age: 55 ± 8.9 years. Baseline BMI: 31.1 ± 4.4 kg/m <sup>2</sup> . Fasting glucose: 6.1 ± 0.5 mmol/l. HbA <sub>1c</sub> : 5.6 ± 0.3% (38 ± 3.3 mmol/mol) <i>n</i> = 163 Intervention <i>n</i> = 176 Usual care (wait-list group who received intervention after 6 month delay)	Mobile app, website, email, interactive voice response calls	<ul style="list-style-type: none"> <li>• <b>Self-monitoring:</b> track weight, diet, physical activity.</li> <li>• <b>Behavioural coaching:</b> tailored behaviour support messages for physical activity, diet, weight loss, stress and sleep. No personal contact or human coaching.</li> <li>• <b>Goal setting:</b> weekly emails recommending personally relevant small-step goals for participants to select.</li> <li>• <b>Social support:</b> virtual teams, option to share on social media, messaging among participants.</li> <li>• <b>Gamification:</b> points system for monetary rewards, team competitions.</li> </ul>	At 6 months: fasting glucose decreased by 0.41 mmol/l in intervention vs 0.12 mmol/l in control group ( <i>p</i> < 0.001). HbA <sub>1c</sub> decreased by 0.26% (2.8 mmol/mol) in intervention vs 0.18% (2.0 mmol/mol) in control group ( <i>p</i> < 0.001), weight decreased by -3.26 kg in intervention vs -1.26 kg in control group ( <i>p</i> < 0.001).
Fukuoka et al 2015 [27] Mobile phone-based Diabetes Prevention Program (mDPP). RCT: multiple primary care clinics, USA	Adults over 35 years with BMI $\geq 25$ kg/m <sup>2</sup> at risk for diabetes, or prediabetic by HbA <sub>1c</sub> , fasting plasma glucose or OGTT. Age: 55.2 ± 9.0 years. Baseline HbA <sub>1c</sub> : 5.83 ± 0.31% (40 ± 3.4 mmol/mol) in intervention group, 5.70 ± 0.27% (39 ± 3.0 mmol/mol) in control group. BMI: 33.3 ± 6.0 kg/m <sup>2</sup> <i>n</i> = 30 Intervention (mobile app + pedometer) <i>n</i> = 31 Control (pedometer only)	Mobile app, pedometer	<ul style="list-style-type: none"> <li>• <b>Health education:</b> 6 in-person sessions, reinforced by daily motivating messages, video clips and quizzes. Adapted from Diabetes Prevention Program curriculum.</li> <li>• <b>Self-monitoring:</b> electronic diary for recording weight, activity, steps and energy intake.</li> <li>• <b>Goal-setting:</b> automatically set individual short-term activity goals based on average daily step counts.</li> <li>• <b>Gamification:</b> quizzes with content on weight loss and prediabetes.</li> </ul>	Weight loss at 5 months was greater in intervention group (-6.2 kg, SD 5.9) than control (+0.3 kg, SD 3.0; <i>p</i> < 0.001). Percentage of participants achieving clinically significant weight loss of 7% reduction was higher in intervention (43% vs 0%, <i>p</i> < 0.001).
Holmen et al 2014 [23] Few Touch Application (FTA), Norwegian Centre for Integrated Care and Telemedicine). Multicentre RCT: Norway	T2DM with HbA <sub>1c</sub> $\geq 7.1$ % Age: 57 ± 12 years. Baseline HbA <sub>1c</sub> : 8.2 ± 1.1% (66 ± 12.3 mmol/mol) <i>n</i> = 51 FTA only <i>n</i> = 50 FTA + health counselling <i>n</i> = 50 Usual care	Mobile app, blood glucose meter, telephone calls	<ul style="list-style-type: none"> <li>• <b>Self-monitoring:</b> blood glucose meter with automatic wireless data transfer, diet manual, physical activity recording, personal goal setting.</li> <li>• <b>Telephone coaching:</b> diabetes nurse provided counselling via telephone calls for first 4 months.</li> </ul>	HbA <sub>1c</sub> at 1 year decreased in all groups with no difference between groups.
Orsama et al 2013 [20] Monica. Single-centre RCT: Finland	T2DM, use of oral glucose-lowering drugs. Age: 62.3 ± 6.5 years in intervention group, 61.5 ± 9.1 years in control group. Baseline HbA <sub>1c</sub> : 6.86 ± 1.56% (51 ± 17.1 mmol/mol) in intervention group, 7.09 ± 1.51% (54 ± 16.5 mmol/mol) in control group <i>n</i> = 27 Monica intervention <i>n</i> = 29 Usual care	Mobile app, web portal, EHR integration	<ul style="list-style-type: none"> <li>• <b>Self-monitoring:</b> manual entry of BP, weight, steps and SMBG using study-provided measurement devices.</li> <li>• <b>Behavioural coaching:</b> reported measurements triggered automated feedback message containing information, motivation and tips to support behaviour change. Graphs display uploaded data and target values.</li> <li>• <b>Patient web portal:</b> displays medical records and data from Monica.</li> </ul>	Intervention group had 0.40% (4.4 mmol/mol) HbA <sub>1c</sub> reduction at 10 months vs 0.036% (0.39 mmol/mol) HbA <sub>1c</sub> increase in control, <i>p</i> = 0.022. Intervention group had greater weight loss of -2.1 kg in vs -0.4 kg in control group, <i>p</i> = 0.021.
Quinn et al 2011 [24] Mobile Diabetes Intervention Study, BlueStar (WellDoc). Cluster-randomised trial: 26 primary care practices in USA	T2DM, excluded insulin pump users and uninsured or Medicaid/Medicare. Age: 53.2 ± 8.4 years in usual care group (all four groups similar). Baseline HbA <sub>1c</sub> : mean 9.4% (79 mmol/mol), range 7.5–15.5% (58–146 mmol/mol)	Mobile app, web portal, physician reports	<ul style="list-style-type: none"> <li>• <b>Self-monitoring:</b> patients entered SMBG values, carbohydrate intake and medications.</li> <li>• <b>Self-management coaching, personalised messages:</b> real-time, automated, educational and motivational feedback messages.</li> </ul>	Maximal intervention group had 1.9% (20.8 mmol/mol) HbA <sub>1c</sub> reduction at 1 year compared with 0.7% (7.7 mmol/mol) reduction in control, <i>p</i> < 0.001.

**Table 2** (continued)

Study, location	Sample characteristics	Modality	Components of intervention	Clinical outcomes
Arora et al, 2014 [22] TEXT-MED. Single-centre RCT: USA	Low-income English and Spanish speakers with T2DM who have used a safety-net emergency department. Age: 50.7 ± 10.2 years. Baseline HbA <sub>1c</sub> : 10.1 ± 1.7% (87 ± 18.6 mmol/mol) <i>n</i> = 64 Texting intervention <i>n</i> = 64 Control	SMS	<ul style="list-style-type: none"> <li>• <b>Website portal</b>: displays self-monitored data, educational material, diabetes-related health information (laboratory values, eye exams, foot exams). Patients could send secure messages to clinical diabetes educators, who intermittently reviewed the portal.</li> <li>• <b>Electronic ‘action plans’</b>: given to patients to serve as pre-visit summaries for office visits.</li> <li>• <b>Clinical decision support tool</b> summarises patient data with evidence-based recommendations.</li> <li>• <b>Health education</b>: educational and motivational messages based on National Diabetes Education Program content areas (blood glucose, blood pressure, controlling diabetes, cholesterol, foot care, healthy eating, heart disease, physical activity, recipes, social support)</li> <li>• <b>Self-management</b>: general reminders to take medications.</li> </ul>	No difference in secondary outcomes of lipids levels, blood pressure, diabetes symptoms and distress.  No significant difference in HbA <sub>1c</sub> reduction at 6 months between groups. Among 92 Spanish speakers, 6-month HbA <sub>1c</sub> was lower by −0.80% (8.7 mmol/mol) in intervention than control ( <i>p</i> = 0.025).
Dobson et al, 2018 [26] SMS4BG. Multicentre RCT: New Zealand	Individuals 16 years and older with poorly controlled T1DM or T2DM. Age: 47 ± 15 years in intervention and control groups. Baseline HbA <sub>1c</sub> : 86.4 ± 17.83 mmol/mol (10.1 ± 1.6%) in intervention, 83.30 ± 14.80 mmol/mol (9.8 ± 1.4%) control <i>n</i> = 183 SMS4BG intervention <i>n</i> = 183 Control	SMS	<ul style="list-style-type: none"> <li>• <b>Gamification</b>: healthy-living challenges, trivia.</li> <li>• <b>Health education</b>: text messages provided information, support, motivation and reminders related to diabetes self-management and lifestyle behaviours.</li> <li>• <b>Personalised messages</b>: Messages were tailored by duration, timing, names of support people, individual goals, and culture/ethnicity (Maori/Pacific). Individuals could opt in to additional messages including smoking cessation, foot care and insulin.</li> </ul>	Intervention group had mean 8.85 ± 14.84 mmol/mol (0.81 ± 1.4%) reduction in HbA <sub>1c</sub> at 9 months vs mean 3.96 ± 17.02 mmol/mol (0.36 ± 1.6%) reduction in control, <i>p</i> = 0.007.
Fortmann et al, 2017 [25] Dulce Digital Multicentre RCT: USA	Spanish- and English-speaking Hispanic adults, uninsured or Medicaid-enrolled, with poorly controlled T2DM. Age: 48.43 ± 9.80 years. Baseline HbA <sub>1c</sub> : 9.5 ± 1.3% (80.3 ± 14.2 mmol/mol) <i>n</i> = 63 Dulce Digital intervention <i>n</i> = 63 Usual care	SMS	<ul style="list-style-type: none"> <li>• <b>Health education</b>: motivational and educational messages based on a culturally-informed version of ADA’s Diabetes Self-Management Education curriculum.</li> <li>• <b>Self-management</b>: general reminders to take medications, reminders to check blood glucose and text values back. Messages were <i>not</i> personalised to medication regimen or SMBG values.</li> </ul>	Lower HbA <sub>1c</sub> at 6 months in intervention (8.5 ± 1.2%, 69 ± 13.1 mmol/mol) than control (9.4 ± 2.0%, 79 ± 21.8 mmol/mol) after controlling for baseline HbA <sub>1c</sub> ( <i>p</i> = 0.03). Inverse association between number of SMBG values reported and 6 month HbA <sub>1c</sub> .

EHR, electronic health record; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus

patient-reported data (including SMBG values, diabetes medications and lifestyle behaviours). In addition, patients securely message clinical diabetes educators through a web-based portal, and the patients' clinicians receive reports synthesising self-monitored data with treatment guidelines [24]. In a study from Finland, the Monica app sent automated patient-specific feedback messages in response to self-reported glucose, blood pressure, weight and steps. However, it did not provide any tools to support decision making by the clinician, despite having electronic health record integration and alerts to clinicians for concerning data [20]. Although RCTs for both interventions demonstrated reductions in HbA<sub>1c</sub>, BlueStar had a larger study population, involved multiple intervention arms and resulted in a larger effect (1.2% [13.1 mmol/mol] difference in HbA<sub>1c</sub> reduction between maximal intervention arm and control,  $p < 0.001$ ), while the Monica results were less clinically significant (0.436% [4.8 mmol/mol] difference in HbA<sub>1c</sub> reduction between intervention and control,  $p = 0.022$ ) [20, 24]. However, the BlueStar RCT excluded patients who were uninsured or had Medicaid/Medicare insurance [24], limiting its generalisability. The Few Touch Application (FTA, Norwegian Centre for Integrated Care and Telemedicine) [23], a similar intervention, did not demonstrate any improvement in HbA<sub>1c</sub>. Although FTA promoted self-monitoring through a food and exercise diary and a wirelessly connected blood glucose meter, it did not incorporate real-time feedback messages, opting instead for monthly telephone coaching by a diabetes nurse accessing patient-reported data [23].

In patients at risk for diabetes, the Alive-PD (NutritionQuest) [21] behavioural change intervention and the Mobile Diabetes Prevention Program (mDPP) [27] were two important studies demonstrating the use of mobile apps to promote lifestyle modifications. Alive-PD is fully automated and consists of a mobile app and website for tracking physical activity, diet, weight loss, stress and sleep, with weekly emails to set individually tailored goals [21]. Unlike Alive-PD, the mDPP included six in-person sessions to deliver the curriculum. The mobile app reinforced content from the in-person sessions and allowed diet and step count tracking [27]. Full automation is more sustainable and scalable, but some patients may be more motivated and engaged with in-person sessions. Both interventions demonstrated efficacy in reducing body weight. Participants who received the mDPP intervention lost a mean 6.5 kg more than those in the control group ( $p < 0.001$ ), while the Alive-PD intervention resulted in a mean 2 kg greater weight loss than control ( $p < 0.001$ ) [21, 27]. mDPP did not affect HbA<sub>1c</sub>, a secondary outcome, while in Alive-PD, the reduction of 0.26% (2.8 mmol/mol) in the intervention group vs 0.18% (2.0 mmol/mol) in the control group ( $p < 0.001$ ) is of uncertain clinical significance.

**SMS-based diabetes education** Simpler SMS-based interventions for diabetes self-management have been studied, including the recent Self Management Support for Blood Glucose (SMS4BG) study [26]. In this study, patients with poorly controlled type 1 or type 2 diabetes who were randomised to the treatment arm received educational and motivational text messages on self-management and lifestyle modifications, which were tailored by timing, duration, names of support people, individual goals and culture/ethnicity, with optional messages on smoking cessation, foot care and insulin management [26]. This relatively large study found a 4.89 mmol/mol (0.45%) greater decrease in HbA<sub>1c</sub> in participants who received the intervention vs those given usual care. Despite this relatively modest effect, the study demonstrated that technology as straightforward as text messaging can be tailored in a sophisticated way.

SMS interventions are more accessible than smartphone applications, as they only require a basic cell phone without cellular data or WiFi; thus, these types of interventions may be more feasible in underserved populations. TExT-MED [22] and Dulce Digital [25] are two important US studies conducted among low-income, uninsured or Medicaid-enrolled English and Spanish speakers with type 2 diabetes. Both studies used non-personalised SMS messages to deliver culturally informed educational and motivational content, with reminders to take medications and check blood sugar. Although TExT-MED found no significant difference in HbA<sub>1c</sub> improvement for the group as a whole, they found a significant and larger effect of the intervention among the 92 Spanish speakers enrolled, while Dulce Digital did find a significantly lower HbA<sub>1c</sub> in the intervention group compared with the control group [22, 25]. The results suggest that the potential to lower HbA<sub>1c</sub> through mHealth-delivered diabetes education may be greater in underserved populations, who may have lower health literacy and access to care at baseline.

## Access to remote clinicians

Diabeo, DID, BlueStar and MITI all provide patients access to a remote clinician, which may contribute to efficacy but limit scaling, reproducibility and sustainability. For example, the insulin bolus calculator Diabeo is paired with teleconsultations for review of glucose logs, insulin dose adjustments and motivational support [8], while DID sends patient-reported data to physicians every 1–3 weeks and allows texting between patients and physicians [9, 10]. However, data from Diabeo and DID are presented to clinicians without decision support tools, which may slow workflow due to data overload. Alternatively, MITI

relies on a nurse-managed insulin titration algorithm to adjust therapy [12], while BlueStar provides clinicians with summaries of glycaemic control, self-reported medication adherence, and lifestyle behaviours alongside relevant evidence-based guidelines in a clinical decision support tool [24]. Of note, the intervention arm with the BlueStar app plus clinical decision support produced a 1.9% (20.8 mmol/mol) decrease in HbA<sub>1c</sub> at 1 year [24]. In these studies, involving the patient's own clinicians for feedback, motivation and treatment adjustments may enhance efficacy. For interventions to be applicable in the real world, integration with clinicians from the start of development is crucial to ensure the mHealth tool does not impede the existing workflow, and collaborations with payers and healthcare systems are necessary to ensure proper reimbursements for clinicians providing remote intervention. Indeed, reimbursements for telemedicine and remote patient monitoring have advanced but are still limited in scope in both France [29], where Diabeo was studied, and the USA, where MITI was studied.

## Patient engagement

Patient engagement with technology, educational content and self-care behaviours influence outcomes of mHealth interventions. Thus, it is important to tailor the intervention in a patient-centred way and to evaluate user satisfaction. For example, although the DID intervention did not improve HbA<sub>1c</sub>, patients who used the app reported improved quality of life, including decreased 'fear of hypoglycaemia,' and improved 'social relations' [10]. In a satisfaction survey, 93.6% of patients who received the TExT-MED intervention enjoyed the programme and believed it was a good way to learn about diabetes [22].

Going beyond questionnaires, Quinn and colleagues performed a mixed-methods analysis of the messages that 107 BlueStar users sent to clinical diabetes educators via a web portal [30]. Patients who sent any messages during the 1 year study were significantly older and more likely to be white than those who did not send any messages. Most patients who never sent messages had a high school or lower level of education, perhaps indicating lower health literacy. Patient engagement was highest for more 'medical' topics, such as glucose monitoring and medications, and lower for 'lifestyle' topics, such as physical activity and healthy coping. Sending messages on any topic was associated with a 0.75% (8.2 mmol/mol; 95% CI 0.01%, 1.08%) lower HbA<sub>1c</sub> compared with sending no messages [30]. Similarly, the Dulce Digital study found that the number of SMBG values sent by patients significantly correlated with lower 6 month HbA<sub>1c</sub> values [25]. These results underscore the effect of patient engagement on outcomes and suggest that demographics and health literacy should be considered when designing

interventions. However, contrary to the common belief that age is a barrier to mHealth adoption, older age does not necessarily impede engagement with technology [23, 30].

Some features designed to promote engagement include personalisation of messages, integration of social support and gamification, i.e. incorporating elements of game design into real-life concepts for non-gaming purposes, but there are no consistent methods of evaluating these features. Although personalised messaging may have been a component of success in BlueStar [24, 30], SMS4BG [26], Monica [20], and Alive-PD [21], results from the TExT-MED and Dulce Digital studies [22, 25] suggest that personalisation is not a requirement for efficacy or user satisfaction. The Alive-PD intervention promoted social support by creating virtual teams using a participant messaging system and the option to share content on social media [21]. Gamification methods include healthy-living challenges [22, 31], team competitions, a points system with monetary rewards [21], trivia questions [22] and quizzes [21, 27]. Engagement may also be promoted with enhanced media, including video messages [27, 32] and voice recognition [33]. Despite the intuitive appeal of such features, more research is needed to specifically evaluate their impact on engagement outcomes, and to explore which features are most effective for which types of individuals.

## Future research needs

The design of mHealth interventions should incorporate both patient and clinician feedback on lifestyle or workflow integration, respectively, as well as usability and content. Access to a remote provider, via teleconsultations or text messages, may enhance clinical efficacy and patient accountability, but more research is needed to establish the optimal balance between increasing patient–clinician interaction while preserving scalability. In addition, more research is needed to assess how clinicians currently incorporate patient-facing mHealth tools into their practice and the prevalence of mHealth use in various healthcare systems. In high-resource settings, CGMs are relatively common, but comprehensive mobile apps and SMS-based interventions may be less common, possibly reflecting individual and systemic barriers to more widespread mHealth adoption. Cost is one barrier to adoption and sustainability that should be characterised in economic analyses, both in terms of limited reimbursement for remote clinicians and in cost to the patient for devices.

The sample sizes in the RCTs presented vary widely, with the largest being SMS4BG, which enrolled 183 patients per arm [26]. Although these numbers may be sufficient to detect significant change in HbA<sub>1c</sub>, larger studies are needed to allow stratification to assess outcomes by individual characteristics or usage patterns, and to assess hard cardiovascular outcomes.



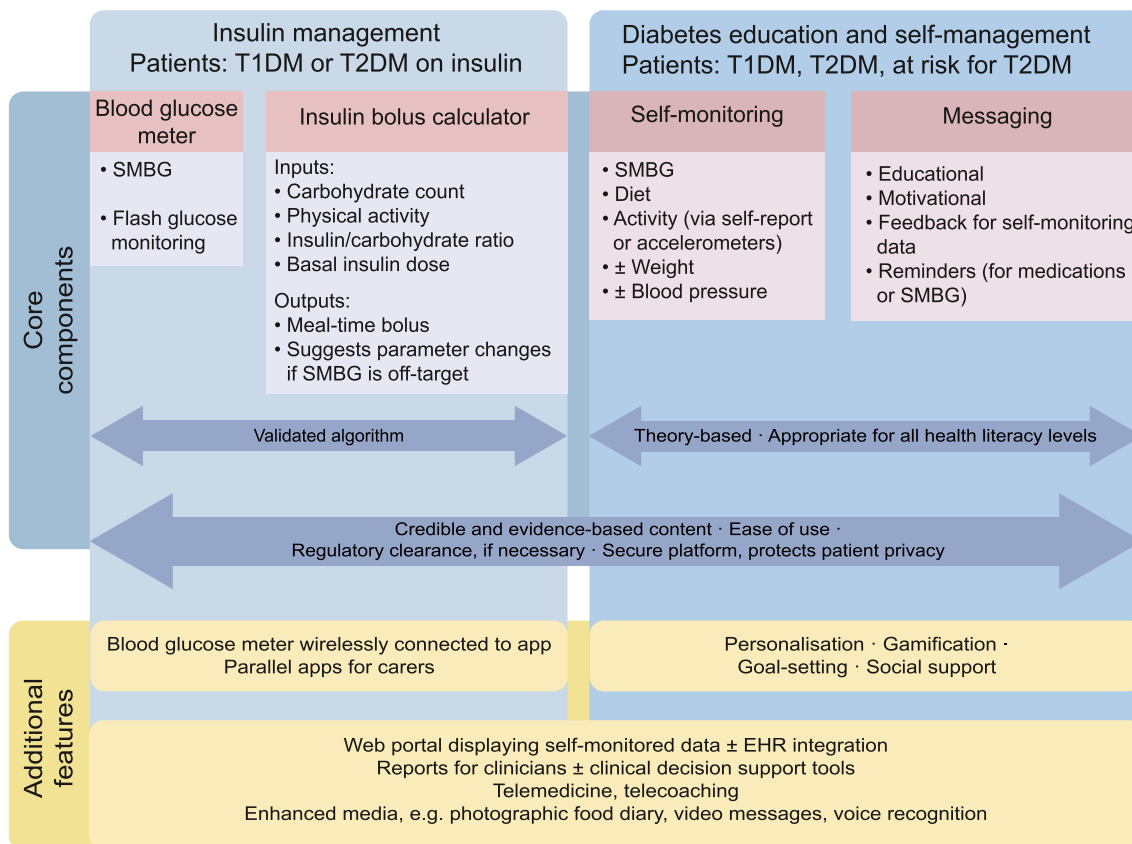
Furthermore, mHealth is capable of delivering precision medicine, as it allows personalisation for different patients and collects frequent physiological and usage data to inform individualised analyses [34]. Future studies should investigate which patients would benefit most from the intervention, how they could be identified, and how their engagement could be enhanced. Of the studies discussed, follow-up duration ranged from 3 to 12 months, which is enough to detect initial changes in HbA<sub>1c</sub>, but studies with longer follow-up are needed to assess the sustainability of outcomes and retention of use.

mHealth has the potential to promote health equity by expanding access to care. Future studies should continue to evaluate interventions tailored for underserved populations, as MITI [12], TExT-MED [22], Dulce Digital [25], and SMS4BG [26] demonstrated that mHealth interventions are well accepted, feasible and efficacious in low-income ethnically diverse populations. Underserved populations have much to benefit from mHealth, as they have high rates of cell phone ownership, are more likely to depend on smartphones for internet access [35] and are disproportionately affected by diabetes and its complications [36].

Medication adherence is an important component of diabetes management that requires additional research.

Some studies, such as SMS4BG [26], TExT-MED [22], and BlueStar [24], included general reminders to take medications as part of diabetes coaching and education, but measuring medication adherence is a challenge. TExT-MED found an improvement in the self-reported Morisky Medication Adherence Scale with the SMS intervention [22], but there are obvious limitations to self-reported adherence. A few interventions have targeted medication adherence in type 2 diabetes [37–39], using methods such as electronic blisters, electronic pill dispensers and daily SMS reminders. However, results are mixed, and the studies relied on different methods of measuring adherence, such as pill counts or pharmacy refills.

Given the varying degrees of efficacy of the interventions presented, which are generally modest in scope, more work is needed to determine what factors would improve the efficacy of mHealth tools. While interventions addressing medication adherence and lifestyle modifications will remain relevant in a patient-managed disease, insulin management tools such as connected blood glucose meters may become less relevant as better closed-loop systems become readily accessible.



**Fig. 1** Summary of key components and features of mHealth interventions for diabetes. EHR, electronic health record; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus. This figure is available as a [downloadable slide](#)

## Conclusion

All the mHealth interventions presented (Table 1 and Table 2) were studied in RCTs, with most interventions (eight out of 13) demonstrating clinically and statistically significant efficacy, while five interventions had null results or achieved less than 0.5% (5.5 mmol/mol) difference in HbA<sub>1c</sub> reduction between intervention and control. These interventions vary from insulin bolus calculators and innovations in glucose monitoring to health education and lifestyle modifications. Their components include educational content, self-monitoring and automated messages providing motivation, education and feedback, as well as contact with a remote clinician through a telemedicine model (Fig. 1). Some features that may enhance patient engagement include personalised content, social support and gamification, but these have been inadequately studied. To allow more thoughtful personalisation of mHealth, more studies are needed to assess how individual factors, such as health literacy, culture, socioeconomic status, behaviours and treatment plan, impact patient engagement with mHealth tools and clinical outcomes.

## Summary

- mHealth interventions for diabetes are heterogeneous and clinical effects are generally modest
- Barriers to adoption include cost, sustainability and integration with healthcare systems
- mHealth has particular potential to expand access to healthcare in underserved populations and to deliver precision medicine
- More work is needed to assess which features promote clinical efficacy and patient engagement
- Future work in diabetes should focus on medication adherence and lifestyle modifications
- Closed-loop systems may replace the need for insulin management mHealth tools

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