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REVIEW ARTICLE

# Health Technologies for Monitoring and Managing Diabetes: A Systematic Review

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## Abstract

***Background:***

The primary objective of this review was to determine the strength of evidence for the effectiveness of self-monitoring devices and technologies for individuals with type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) based on specific health-related outcome measures. Self-monitoring devices included those that assist patients with managing diabetes and preventing cardiovascular complications (CVCs). A secondary objective was to explore issues of feasibility, usability, and compliance among patients and providers.

***Methods:***

Study criteria included individuals ≥14 years and youth (7–14 years) with T1DM or T2DM, intervention with a self-monitoring device, assessment of clinical outcomes with the device, literature in English, and ≥10 participants. Relevant published literature was searched from 1985 to 2008. Randomized controlled trials and observational studies were included. Data were extracted for clinical outcomes, feasibility and compliance methods, and results. Selected studies were independently evaluated with a validated instrument for assessing methodological quality.

***Results:***

Eighteen trials were selected. Predominant types of device interventions included self-monitoring of blood glucose, pedometers, and cell phone or wireless technologies. Feasibility and compliance were measured in the majority of studies.

***Conclusions:***

Self-monitoring of blood glucose continues to be an effective tool for the management of diabetes. Wireless technologies can improve diabetes self-care, and pedometers are effective lifestyle modification tools. The results of this review indicate a need for additional controlled trial research on existing and novel technologies for diabetes self-monitoring, on health outcomes associated with diabetes and CVCs, and device feasibility and compliance.

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**Abbreviations:** (CVC) cardiovascular complication, (BMI) body mass index, (HbA1c) hemoglobin A1c, (HDL) high-density lipoprotein, (LDL) low-density lipoprotein, (PDA) personal digital assistant, (RCT) randomized controlled trial, (SMBG) self-monitoring of blood glucose, (SMS) short message service, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

**Keywords:** diabetes mellitus, health technologies, monitoring, systematic review

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## Introduction

Diabetes mellitus is a serious chronic disease that imposes substantial social and economic burdens around the world. The prevalence of diabetes for all age groups worldwide is estimated to be 2.8% and is expected to nearly double by 2030 (4.4%).[1] In the United States, the prevalence of diabetes is estimated to be 23.6 million people, roughly 7.8% of the population.[2] According to projected prevalence estimates, the number of people with diabetes in Canada will increase from approximately 1.4 million to 2.4 million, and estimated diabetes-related health care costs in Canada are projected to increase by 75% (for the years 2000–2016).[3] It is likely, however, that the true prevalence of diabetes is dramatically underestimated.[4] Diabetes is associated with a number of health-related complications, and the level of hyperglycemia and the duration of the disease are associated with an increased risk of developing macrovascular and microvascular complications such as neuropathy, nephropathy, retinopathy, myocardial infarction, and stroke.[5,6] One way to prevent the progression of these complications is through improved blood glucose (hemoglobin A1c [HbA1c]) control, as was shown in the UK Prospective Diabetes Study[7,8] and the Diabetes Control and Complications Trial.[9] The results from these trials also highlight the positive effects that increased contact with clinicians can have on improving patient glycemic control. However, health care provision deficits, physician shortages, and the inability of many patients to increase their clinic visits have prompted the clinical research community and individuals themselves to search for feasible solutions. This reality supports the need for effective self-management of the disease through self-monitoring of blood glucose (SMBG) and blood pressure, as well as increasing levels of exercise. Exercise programs have been shown to reduce blood pressure, improve glycemic control, and improve overall cardiovascular health.[10,11] Current self-management interventions for patients with type 2 diabetes mellitus (T2DM) who are at risk for cardiovascular complications (CVCs) include the use of devices that monitor blood glucose, blood pressure, heart rate, and physical activity. Although recent surveys indicate that patients are willing to become more actively involved in managing their own care,[12,13] it is unclear how much patients know about these self-monitoring techniques or how accessible and feasible they are to implement into daily life. The main objective of this systematic review, therefore, was to determine the strength of evidence for the effectiveness of any type of established or emerging self-monitoring device for improving key health outcomes (HbA1c, blood pressure, low-density lipoproteins [LDLs]) in adults and youth with diabetes (type 1 or type 2) who are at risk of developing CVCs. Secondary objectives were to critically examine the factors that may affect patient and provider adherence to these established or emerging self-monitoring devices and to assess the feasibility or usability of these technologies.

## Methods

### *Study Inclusion/Exclusion Criteria*

The population of interest included individuals ≥14 years and youth 7–14 years with type 1 diabetes mellitus (T1DM) or T2DM. Studies were included if there were measures of clinical outcomes, such as HbA1c, blood pressure, body mass index (BMI), LDL, or other related outcomes important for understanding the progression of CVCs. All types of self-monitoring devices and technologies were included in our search: SMBG devices, blood pressure devices, heart rate monitors, pedometers or accelerometers, wireless data technologies such as mobile messaging (e.g., short message service [SMS] and pagers), devices that use Web-enabled technologies, and global information systems. Research literature was also considered where there was an inclusion of measured outcomes related to the usability and feasibility of these technologies, both from the patient's or the clinician's perspectives. Literature in English was primarily considered for this review. All types of experimental study designs were included (randomized controlled trials [RCTs] and nonrandomized, observational studies) for possible evaluation. We excluded studies with <10 participants, cross-sectional data, primary interventions with medications, studies assessing accuracy of devices, telemedicine applications, continuous glucose monitoring devices, or where the self-monitoring device was not part of the main intervention being assessed. Studies scoring lower than 20 points on the Downs and Black instrument for assessing study quality[14] were excluded due to an inability to form strong conclusions with low-scoring studies (fair to poor quality levels). Downs and Black is a validated instrument for rating the methodological quality of both RCTs and non-RCTs[15] and is sensitive to key qualities of research design (see **Table 1**).

### *Search Strategy*

Topic-related online databases were searched from 1985 to May 2008 using a detailed search strategy: CINAHL, Cochrane Library, EMBASE, MEDLINE, PsycInfo,

SportDiscus, and Scirus. Relevant journals, health-related evidence-based practice centre Web sites, clinical guidelines, and unpublished literature sources were also searched. Two research assistants, Elizabeth Russell-Minda and Kaitlin Bradley, conducted the literature searches and organized the material in reference management software. Abstracts were reviewed by authors Elizabeth Russell-Minda, Jeffrey Jutai, Kaitlin Bradley, and Robert Petrella. See **Figure 1** for study flow and selection.

### *Study Selection, Review, and Assessment*

Three reviewers (Elizabeth Russell-Minda, Kaitlin Bradley, and Anna Chudyk) evaluated the selected studies using the Downs and Black instrument.[14] The highest possible score is 28 for RCTs and 25 for non-RCTs. Studies were assigned the following levels where applicable: RCT (I), cohort (II), case control (III), case series (IV), and expert opinion (V).[16] Downs and Black score ranges were given corresponding quality levels: excellent (26–28), good (20–25), fair (15–19), and poor (≤14). Only RCTs could be assigned a quality level of excellent. These quality levels were then mapped to strength of evidence levels and used to formulate results. In order to assess inter-rater reliability using Downs and Black, Pearson R correlations were conducted among three reviewers (Elizabeth Russell-Minda, Anna Chudyk, and Kaitlin Bradley). The results showed adequate inter-rater reliability among reviewers (range 0.71–0.90, statistically significant at the alpha level of $p < .05$). After a study was scored with the Downs and Black checklist, it was assigned an evidence level. This grading system is based on a hierarchical scale developed by the Centre for Evidence-Based Medicine (Oxford, UK),[17] where evidence levels provide grades of recommendation and assist with formulating evidence-based conclusions. In order to determine conclusions for the research evidence, Downs and Black score ranges were given corresponding quality levels based on a methodology used in other projects affiliated with the research team.[18,19] In conjunction with determining accepted scoring ranges, strength of evidence levels were then used to formulate conclusions. The following strength of evidence levels were based in part on methods used in other health care systematic reviews:[20,21] level 1a (very strong), the findings were supported by the results of two or more studies of at least excellent quality; level 1b (strong), the findings were supported by at least one study of excellent quality; level 2a (moderate), the findings were supported by two or more studies of at least good quality; level 2b (limited), the findings were supported by at least one study of good quality; level 2c (weak), the findings were supported by at least one study of fair or poor quality; level 3 (consensus), in the

**Table 1.**
**Summary of Downs and Black Instrument**

| |
|---|
| A 27-item checklist was used to assess the methodological quality of both randomized and nonrandomized studies of health care interventions. Answers are scored 0 or 1, except for one item in the reporting subscale, which is scored 0 to 2. The power item responses were collapsed from the original 0 to 5, to either 0 or 1. The total maximum score is 28. |
| **Reporting (10 items)**<br>Assesses whether the information provided in the paper was sufficient to allow the reader to make an unbiased assessment of the findings of the study. |
| **External Validity (3 items)**<br>Addresses the degree to which the findings from the study can be generalized to the population from which the participants were derived. |
| **Internal Validity—Bias (7 items)**<br>Addresses biases in the measurement of the intervention and the outcome. |
| **Internal Validity—Confounding (6 items)**<br>Addresses bias in the selection of study participants. |
| **Power (1 item)**<br>Addresses whether the negative findings from a study could be due to chance. |

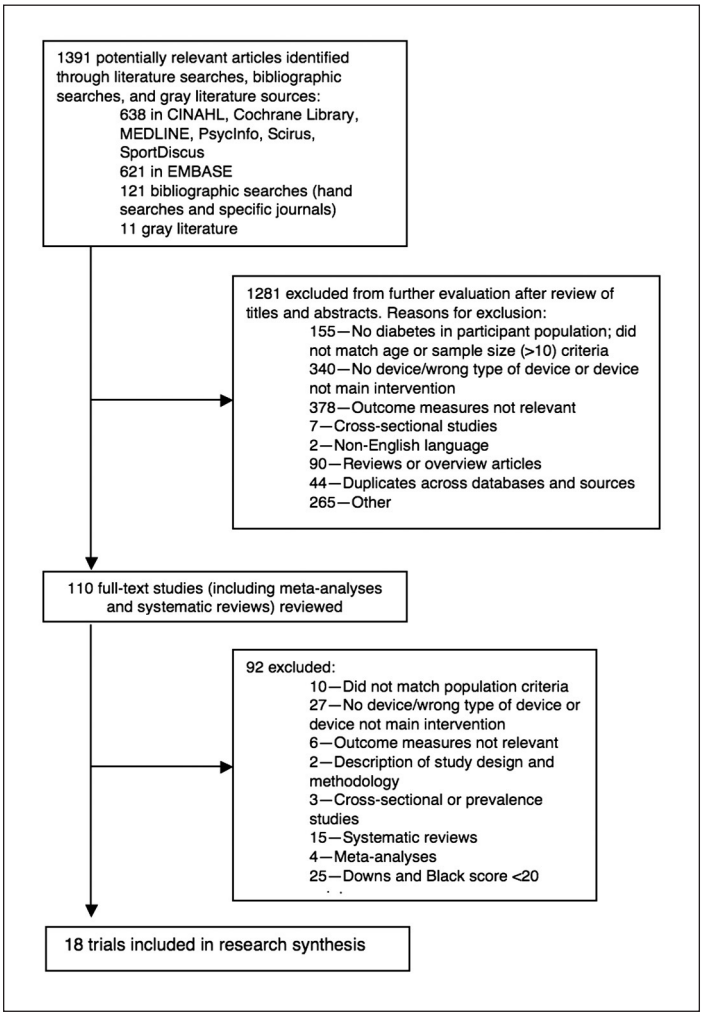


**Figure 1.** Study flow diagram.

absence of evidence, agreement by a group of experts on the appropriate treatment course—consensus opinion is regarded as the lowest form of evidence; and level 4 (conflicting), disagreement between the findings of at least two RCTs. Where there are more than four RCTs and the results of only one is conflicting, the conclusion is based on the results of the majority of the studies, unless the study with conflicting results was of higher quality.

## Results

Eighteen trials were selected and grouped according to the following major device categories: (1) SMBG, (2) pedometers, and (3) cell phone/wireless devices. Studies were from the following countries: United States (seven), France (three), South Korea (four), UK/Scotland (two), Canada (one), and Norway (one). Four meta-analyses, one Cochrane review, five systematic reviews, one health technology assessment, and one criteria-based review were reviewed but not evaluated with Downs and Black. The details of the selected studies and health outcomes results are listed in corresponding tables. Where studies included measures of usability, feasibility, compliance, and patient satisfaction, these are noted in the tables. Comprehensive evidence tables may be requested from the authors.

### *Self-Monitoring of Blood Glucose Devices*

Five trials using SMBG devices were selected for this systematic review (**Table 2**). The use of SMBG devices has been suggested as an effective way of maintaining healthy blood glucose levels in patients with T2DM. According to previous meta-analyses and systematic reviews on SMBG, there is some disagreement regarding the level of effectiveness of SMBG for patients with both insulin- and noninsulin-dependent forms of the disease.[6,22,23] In addition, there is a lack of consensus as to the recommended frequency of SMBG testing. Welschen and colleagues,[24] Coster and associates,[23] and Faas and coworkers[22] concluded that results showing positive effects of SMBG on glycemic control for patients with T2DM were inconclusive due to study heterogeneity and poor study designs.

Level 1b (strong) evidence based on results of one excellent (based on Downs and Black score) RCT[25] indicates that, when compared with usual care, the effectiveness of a less *versus* more intensive SMBG intervention for improving glycemic control is inconclusive. This trial included a sample size of 453 patients with noninsulin-treated T2DM and a primary outcome measure of HbA1c measured at 12 months. The "diabetes glycemic education and monitoring" intervention was conducted as a 4-year, open, randomized, three-arm, parallel group study. The primary goal was to determine if HbA1c levels at 12 months were different between patients with T2DM receiving one of the three allocations: (1) standardized usual care with measurements of HbA1c levels every 3 months (control group); (2) use of a blood glucose meter, with advice for patients to contact their provider to interpret the results (less intensive monitoring); and (3) use of a blood glucose meter, with training in self-interpretation and application of results to physical activity, diet, and drug adherence (more intensive monitoring). At 12 months, no difference was found in HbA1c levels between the groups (after adjusting baseline HbA1c levels) ($p$ = .12). The mean difference in change in HbA1c levels from baseline to 12 months between the controls and the less intensive intervention group was -0.14% (95% confidence interval -0.35% to 0.07%) and between the control group and more intensive intervention group was -0.17% (-0.37% to 0.03%). For secondary outcome measures, there was a significant difference found in the change in total cholesterol levels between the groups ($p$ = .010). Although Farmer and colleagues[25] scored relatively high on the Downs and Black instrument, there are several limitations of this study: the inclusion of patients with good metabolic control may have skewed their treatment plans, the intensified treatment was not detailed, and there was an overall inadequacy of adherence to self-monitoring.

Level 2a (moderately strong) evidence based on the combined results of four good quality RCTs[26–29] suggests that SMBG may be effective in improving glycemic control in patients with noninsulin-treated T2DM, but due to the heterogeneity of interventions and outcomes across the selected studies, it is difficult to compare study results adequately. Fontbonne and associates[27] and Davidson and coworkers[26] showed no statistically significant differences in the decrease of HbA1c between SMBG and control groups. In the Davidson *et al.*[26] trial, HbA1c decreased 0.8% in the SMBG group and 0.6% in the control group. For Fontbonne and associates,[27] HbA1c improved 0.4% in the SMBG group, compared to 0.1% and 0.5% in the self-monitoring of urine glucose and control groups. Guerci and colleagues[28] reported a statistically significant difference of 0.4% in HbA1c levels at the close of the study between SMBG and control groups. The results from Allen and associates[29] found that both groups (SMBG and self-monitoring of urine glucose) had lower HbA1c at the end of the study. No difference was detected between groups (both had a decrease of 2.0%). In summary, there is moderately strong evidence that SMBG is an effective tool for maintaining

stable metabolic control for both T1DM and T2DM, thus reducing the risk of developing additional microvascular and macrovascular complications. Self-monitoring of blood glucose remains an integral part of diabetes self-care. There may still be debate about the frequency of testing as well as the accuracy of the devices themselves.

### *Pedometers*

Regular physical activity and exercise can have positive effects on glycemic control, weight management, and insulin resistance in patients with T2DM.[30–33] Recommendations for exercise in adults from the Centers for Disease Control and the American College of Sports

**Table 2.**
**Health-Related Outcomes for Self-Monitoring of Blood Glucose Devices**

| Study details[a] | Intervention | Outcome measures | Health outcomes results[b] | Downs and Black score[c] |
|---|---|---|---|---|
| Farmer *et al.*[25]<br>England<br>I RCT | *N* = 453; SMBG (alone or with instruction) versus usual care (noninsulin-dependent T2DM) | • HbA1c level measured at 12 months (primary)<br>• Secondary measures:<br>» Blood pressure<br>» Weight<br>» Total cholesterol level<br>» Ratio of cholesterol to high-density lipoprotein (HDL) cholesterol<br>» BMI<br>» Patient persistence in use of blood glucose meter (diaries) | ↔ HbA1c levels ($p$ = .12)<br>+ Total cholesterol for all groups ($p$ = .010)<br>↔ No differences were found in the other secondary measures<br>+ Compliance ($p$ = .012) | 26 |
| Davidson *et al.*[26]<br>USA<br>I RCT | *N* = 89; effectiveness of SMBG improving HbA1c responses in noninsulin-dependent T2DM patients | • HbA1c, measured at entry and every 2 months | ↔ BMI and weight<br>+ HbA1c levels ($p$ < .001, control group $p$ = .05) | 24 |
| Fontbonne *et al.*[27]<br>France<br>I RCT | *N* = 208; SMBG versus usual care in noninsulin-dependent T2DM; duration of trial, 6 months | • HbA1c measured every 2 months<br>• Weight, measured every 2 months<br>• Number of reactive strips reported in diary, recorded every 2 months | ↔ HbA1c or weight reduction<br>– Compliance, based on number of strips used ($p$ < .01) | 24 |
| Guerci *et al.*[28]<br>France<br>I RCT | *N* = 689; SMBG (in addition to conventional laboratory work-up) with education on weight loss and physical activity versus conventional laboratory work-up based solely on lab measurement of HbA1c every 12 weeks; education on weight loss and physical activity | • Weight, systolic blood pressure, and diastolic blood pressure at baseline and 3 and 6 months<br>• HbA1c (determined using DCA analyzer and blood glucose); measured at baseline and 3 and 6 months<br>• Number of hypoglycemic episodes<br>• Diet and physical activity compliance | + HbA1c in SMBG group ($p$ = .012)<br>↔ Fasting blood glucose levels, weight, systolic blood pressure, or diastolic blood pressure between groups<br>↔ Diet and physical activity<br>78 patients reported at least one episode of hypoglycemia during the study (SMBG:10.4%; conventional: 5.2%). | 21 |
| Allen *et al.*[29]<br>USA<br>I RCT | *N* = 54; compared the effectiveness of SMBG to routine urine testing as part of standardized treatment program for patients with noninsulin-treated T2DM | • Fasting plasma glucose (monthly)<br>• HbA1c (initially and 3 and 6 months)<br>• Total cholesterol and HDL<br>• Weight (monthly)<br>• Compliance | + Fasting plasma glucose and HbA1c (within each group)<br>↔ Total cholesterol and HDL<br>+ Compliance in reporting (>90%)<br>+ Attendance at monthly visits (>98%). | 21 |

[a] Study details are listed according to level of evidence and in order of quality assessment score (Downs and Black). Study levels: I = RCT; II = cohort; III = case control; IV = case series.
[b] ↔ indicates no difference in health outcomes; + indicates improvements in health outcomes; and – indicates decline in health outcomes.
[c] Downs and Black score ranges were given corresponding quality levels: excellent (26–28) and good (20–25). Studies that scored either in the fair (15–19) or poor (≤14) ranges were excluded, except where it was the only available evidence.

Medicine include at least 30 min of moderate-intensity exercise during the week.[34] This can also be achieved by walking at least 10,000 steps per day, also in agreement with clinical recommendations.[35,36] A total of four trials with pedometer-based interventions were selected for this review (see **Table 3**). Two trials included some component or measurement of compliance with the pedometer-based intervention.[37,38] None of the selected studies on pedometer-based interventions assessed issues of feasibility or usability. One trial using an accelerometer-based exercise intervention was reviewed[39] but did not fit the inclusion criteria.

Level 2b (limited) evidence based on the results of one good quality RCT[40] indicates that pedometers do not increase walking (number of steps) or improve metabolic outcomes, based on results from a 6-month intervention. Level 2b (limited) evidence based on the results of one good quality RCT[37] suggests that the First Step Program increases daily physical activity (>3000 steps/day, $p < .0001$) and improves long-term health outcomes (no statistically significant difference between groups on cardiovascular fitness, glycemia, or lipid status). Relapses in activity indicate that reminder sessions are important for continued success. This is based on results from a16-week intervention with a 24-week follow-up. Level 2b (limited) evidence from one good quality RCT[38] suggests that using a pedometer may increase the number of daily accumulated steps, whether the person is involved in a structured or unstructured goal-setting program. A structured lifestyle-goal program may improve participant satisfaction with pedometer-based programs, based on the results from a 6-week intervention. There were no clinical outcomes measured in this study. Level 2c (weak) evidence from one fair quality RCT[41] indicates that use of a pedometer can increase step counts in patients with T2DM, based on the results of a 6-week intervention instructing participants to walk 10,000 steps/day on five or more days of the week. There is an absence of evidence on the effectiveness of using accelerometers for improving diabetes self-management and improving clinical outcomes.

### *Cell Phones and Wireless Devices*

Existing and emerging technologies such as wireless devices (cell phones) with email and text messaging (SMS) functionality, pagers, and the Internet can help facilitate patient self-management of diabetes. These types of devices are practical and cost-effective methods for monitoring clinical outcomes and increasing patient adherence to treatments.[42,43] Wireless technologies can be used as intermediary tools to facilitate the information between patient and provider and treatment advice between clinic visits. Results from studies incorporating the use of remote patient monitoring devices (cell phones and other wireless tools) have indicated significant decreases in HbA1c levels and improved health-related outcomes in diabetes.[43,44] The use of these devices may encourage patients to adhere to their monitoring regimens by acting as reminders to self-manage their disease. Nine trials using cell phones with SMS interventions for diabetes management were selected for this review (see **Table 4**) and are discussed below.

Level 2a (moderately strong) evidence from four good quality RCTs[45–49] suggests that the use of a cell phone with SMS and Internet (some with nurse-directed educational component) may help to lower HbA1c levels and improve 2 h postmeal glucose values in patients with T2DM. With this intervention, patients initially set up their data on a Web site including blood glucose values, drug information, kinds and dosages of insulin, and other information important for diabetes control. After reviewing the patient information on the Web site, the diabetes educator or researcher sent recommendations and reminders via SMS to the patient's cell phone on a weekly basis (e.g., "please decrease the long-acting insulin by two units" or "lack of exercise may be the cause of aggravated glucose level"). Among the studies, the intervention periods ranged from 3 to 12 months; however, there were no measures of adherence, quality of life, patient satisfaction, or feasibility of the technology. Level 2b (limited) evidence from one good quality RCT[49] suggests a text messaging support system (SweetTalk) may improve self-efficacy and adherence but does not improve glycemic control in children and adolescents (8–18 years) with T1DM. Level 2b (limited) evidence from one good quality RCT[50] suggests that long-term telemedicine-based follow-up of insulin-pump-treated patients using a cell phone, SMS, and Web-based platforms is safe and feasible, and may improve metabolic control. There was a nonsignificant reduction in HbA1c (-0.25 ± 0.94%, $p < .10$) and mean glucose values (-9.2 ± 25 mg/dl, $p = .06$) for the 6-month SMS period. Level 2b (limited) evidence from one good quality RCT[51] indicates that a self-managed wireless two-way pager able to send and receive text message reminders may improve metabolic control (average HbA1c decrease of 0.1%–0.3%). The primary outcome of this study was HbA1c, and secondary outcomes were blood pressure, patient perceptions of their disease and health care team, and if the pager system would improve their sense of well-being and adherence to the treatment plan. Level 2b (limited) evidence from one good quality RCT[52] suggests that the use

**Table 3.**
**Health-Related Outcomes in Studies Using Pedometers**

| Study details[a] | Intervention | Outcome measures | Health outcomes results[b] | Downs and Black score[c] |
|---|---|---|---|---|
| Bjørgaas *et al.*[40]<br>Norway<br>I RCT | *N* = 70; subjects with T2DM randomized pedometer or no-pedometer group to determine if pedometer increases walking or increases beneficial health-related effects; 6-month intervention | • Steps/day<br>• Oxygen uptake $VO_{2peak}$<br>• HbA1c, serum creatine, lipids<br>• Body weight<br>• Blood pressure<br>• Fasting plasma glucose<br>• Cholesterol, HDL, triglycerides | ↔ Steps/day, no increase ($p$ = .65)<br>↔ Oxygen uptake $VO_{2peak}$<br>+ Body weight, HbA1c, fasting blood glucose, triglycerides, and diastolic blood pressure<br>↔ HDL cholesterol (no improvement)<br>– Compliance, no diary or not enough data; mean number of pedometer days recorded per month varied between 5.4 and 5.9 | 22 |
| Tudor-Locke *et al.*[37]<br>Canada<br>I RCT | *N*=47; effectiveness of 16-week physical activity intervention (24-week follow-up): the First Step Program for adults with T2DM; examined if increased physical activity was related to improvements in cardiovascular health, glycemic control, and lipid profiles | • Steps/day<br>• BMI<br>• Heart rate and blood pressure<br>• Blood glucose<br>• Total cholesterol<br>• HDL/LDL cholesterol<br>• Triglycerides<br>• HbA1c | – Compliance; recording daily steps in calendars began at 100% and dropped to 88% when group meetings were discontinued, then stabilized at 58% during the last 4 weeks<br>+ First Step Program group, approximately 3000 steps/day from baseline ($p$ < .01)<br>↔ BMI and body weight (both groups)<br>+ Waist girth (improvement)<br>↔ Other indicators of cardiovascular fitness, glycemia or lipids (between groups) | 22 |
| Richardson *et al.*[38]<br>USA<br>I RCT (pilot) | *N* = 30 (35 randomized); T2DM; 6-week study comparing two goal-setting strategies: (1) lifestyle goals targeting total daily accumulated steps and (2) structured goals targeting bout steps defined as walking that lasts for 10 min or longer at a pace of 60 steps/min, to determine which strategy was most effective in increasing bout steps | • Increase in steps taken during previously defined bouts using automated Internet-based uploading-enhanced pedometers<br>• Satisfaction and adherence | + Daily bout steps (in both groups); across groups, the average daily bout steps increased by 1921 ± 2729<br>+ Satisfaction with the program (lifestyle goal group); all participants enjoyed tracking their steps with the pedometer<br>+ Adherence (lifestyle goal group more likely to use pedometer) | 21 |
| Araiza *et al.*[41]<br>USA<br>I RCT | *N* = 30; effectiveness of accumulation of daily steps (10,000/day) for improving metabolic outcomes in patients with T2DM; 6-week intervention; the active group (*N* = 15) instructed to walk at least 10,000 steps/day, 5 or more days/week for 6 weeks | • BMI, % body fat, waist circumference<br>• Blood pressure, resting energy expenditure<br>• HbA1c, fructosamine, fasting plasma glucose, insulin, and lipids<br>• Total radical antioxidant parameter, MDA[d], plasminogen activator inhibitor 1 (PAI-1), homocysteine, lipoprotein (a)<br>• Serum total cholesterol, HDL-C, triglycerides | + Active group increased steps/day ($p$ = .002).<br>↔ Control group, no change in activity levels ($p$ > .05)<br>↔ BMI, % body fat, HbA1c, blood pressure, or waist circumference, both groups ($p$ > .05)<br>+ Measured REE[d]; active group ($p$ = .014) | 19 |

[a] Study details are listed according to level of evidence and in order of quality assessment score (Downs and Black). Study levels: I = RCT; II = cohort; III = case control; IV = case series.
[b] ↔ indicates no difference in health outcomes; + indicates improvements in health outcomes; and – indicates decline in health outcomes.
[c] Downs and Black score ranges were given corresponding quality levels: excellent (26–28) and good (20–25). Studies that scored either in the fair (15–19) or poor (≤14) ranges were excluded, except where it was the only available evidence.
[d] MDA, malondialdehyde; REE, resting energy expenditure

**Table 4.**
**Health-Related Outcomes in Studies Using Cell Phones and Wireless Devices**

| Study details[a] | Intervention | Outcome measures | Health outcomes results[b] | Downs and Black score[c] |
|---|---|---|---|---|
| Franklin *et al.*[49]<br>Scotland<br>I RCT | *N* = 92; assessment of SweetTalk, a text-messaging support system to improve self-efficacy and adherence to intensive insulin therapy for youth (10–15 years) with T1DM | • HbA1c<br>• Series of validated psychological measures: self-efficacy for diabetes, diabetes knowledge score, and diabetes social support interview | + HbA1c for patients allocated to intensive therapy and SweetTalk ($p < .001$)<br>↔ HbA1c levels for conventional insulin therapy with or without SweetTalk<br>+ Improved self-efficacy and self-reported adherence<br>+ Diabetes self-management | 25 |
| Benhamou *et al.*[50]<br>France<br>I RCT | *N* = 30; randomized crossover trial of telecare for adults with T1DM under continuous subcutaneous insulin infusion, cell phone for transmission of retrospective data, and SMS for immediate feedback | • Assessment of metabolic efficacy<br>• Safety (low blood glucose episodes < 70 mg/dl)<br>• Quality of life<br>• Adherence to performing SMBG | ↔ HbA1c ($p < .10$) and mean blood glucose values ($p = .06$) during 6-month SMS sequence, compared to no-SMS period<br>↔ Safety issues (hypoglycemia and glucose variability)<br>↔ Adherence to SMBG<br>+ Diabetes quality of life global score and diabetes quality of life satisfaction with life subscale during SMS period | 23 |
| Leu *et al.*[51]<br>USA<br>I RCT | *N* = 42; T1DM and T2DM; effectiveness of a two-way pager for management of diabetes through medication, blood glucose testing reminders, and exercise reinforcement | • HbA1c levels (primary)<br>• Blood pressure (secondary)<br>• Patient attitudes and adherence to treatment plans via survey | ↔ HbA1c did not reach targeted goals of study<br>+ More patients in pager group were normotensive and felt care was better at end of study<br>+ 79% of participants enjoyed using pager and 68% desired to continue using system | 23 |
| Kim and Jeong[45]<br>South Korea<br>I RCT | *N* = 51; diabetes management via nurse SMS by cellular phone and Internet for T2DM patients | • HbA1c levels (pretest and 3 and 6 months)<br>• 2 h postmeal glucose levels | + HbA1c (decreased at 3 and 6 months for intervention group)<br>+ 2 HPMG[d] (decrease at 3 and 6 months for intervention group)<br>↔ Fasting plasma glucose (between the two groups or over time) | 22 |
| Kim and Kim[46]<br>South Korea<br>I RCT | *N* = 34; T2DM; decrease body weight and improve fasting plasma glucose levels through researcher recommendations via cell phone/SMS and Internet (Web site) | • HbA1c levels<br>• 2 h postprandial test<br>• Measurements taken at 3, 6, 9, and 12 months | + HbA1c (decreased for intervention group at all time points, $p < .05$)<br>+ HPPT[d] improved (decrease for intervention group at all time points, $p < .05$) | 22 |
| Yoon and Kim[47]<br>South Korea<br>I RCT | *N* = 51; educational intervention using cellular phone with SMS and Internet for glycemic control (HbA1c < 7%) in patients with T2DM | • Measures at pretest and 3, 6, 9, and 12 months:<br>• HbA1c<br>• Fasting plasma glucose<br>• 2 HPMG[d]<br>• Total cholesterol<br>• Triglycerides<br>• HDL-C | + HbA1c for intervention group, all time points ($p < .05$)<br>↔ Fasting plasma glucose levels did not differ significantly between groups or over time<br>+ 2 HPMG[d] for intervention group ($p < .05$)<br>↔ Total cholesterol, triglycerides, and HDL-C did not differ significantly between two groups over time | 22 |
| Kim[48]<br>South Korea<br>I RCT | *N* = 51; T2DM; weekly blood glucose based optimal recommendations via SMS | • Group 1 <7% pre–post Group 2 ≥7%<br>• HbA1c<br>• Fasting plasma glucose<br>• 2 HPMG[d] | + HbA1c (for patients with baseline <7.0%, controls) showed good control, mean percentage change 0.43 (6.71% pretest to 7.14% post-test, $p = .034$)<br>↔ HbA1c for intervention no change<br>↔ Fasting plasma glucose: patients with baseline HbA1c <7.0% (intervention) pretest to posttest<br>+ 2 HPG[d]: patients with baseline HbA1c <7.0% (intervention) improved<br>↔ Control group showed no significant change | 21 |

continued →

**Table 4. Continued**

| Study details[a] | Intervention | Outcome measures | Health outcomes results[b] | Downs and Black score[c] |
|---|---|---|---|---|
| Kumar *et al.*[52]<br>USA<br>I RCT | *N* = 40; wireless, portable diabetes management system for youth with T1DM and T2DM; feasibility of system assessed in addition to clinical outcomes | • HbA1c (baseline and 3 months)<br>• Frequency of entering insulin dosage and carbohydrate data<br>• Diabetes knowledge survey<br>• Feasibility and use of the system | – Frequency of hyperglycemia (game group)<br>+ HbA1c maintenance (game group)<br>+ Number of transmitted blood glucose values (78% game group, 68% control group)<br>↔ Insulin dosing and carbohydrate intake frequency (entered into PDA database)<br>+ Median carbohydrate intake lower for game group<br>+ Diabetes knowledge survey, improved knowledge scores (game group, $p < .005$; control group, $p = .09$)<br>+ Satisfaction with technologies: glucose monitor with infrared data transmission and PDA software (youth and parents) | 21 |
| Quinn *et al.*[53]<br>USA<br>I RCT (pilot) | *N* = 30; T2DM; impact on HbA1c levels via cell-phone-based diabetes management software system (Web-based data analytics and therapy optimization tools); examine health care provider adherence to prescribing guidelines and assessed health care provider's adoption of the technology | • HbA1c levels<br>• Summary of diabetes self-care activities questionnaire | + HbA1c for intervention group ($p < .02$)<br>+ 84% of intervention patients had medications modified (titrated) by providers, compared to controls ($p = .002$)<br>+ Physicians reported that the WellDoc system facilitated treatment decisions, reduced time to review logbooks, and organized data well | 21 |

[a] Study details are listed according to level of evidence and in order of quality assessment score (Downs and Black). Study levels: I = RCT; II = cohort; III = case control; IV = case series.
[b] ↔ indicates no difference in health outcomes; + indicates improvements in health outcomes; and – indicates decline in health outcomes.
[c] Downs and Black score ranges were given corresponding quality levels: excellent (26–28) and good (20–25). Studies that scored either in the fair (15–19) or poor (≤14) ranges were excluded, except where it was the only available evidence.
[d] HPG – 2-hour plasma glucose, HPMG – 2-hour post-meal glucose, HPPT – 2-hour post-prandial test

of a wireless personal digital assistant (PDA) with diabetes management software and an integrated motivational game (DiaBetNet) may assist youth 8–18 years with diabetes (type 1 and type 2) in managing their blood glucose levels. The use of the motivational game may also increase the frequency of monitoring and improve diabetes knowledge. Level 2b (limited) evidence based on the results of one good quality RCT[53] suggests that a cell-phone-based diabetes management system, in conjunction with Web-based analytics and therapy optimization tools (WellDoc system), may significantly improve HbA1c in patients with T2DM. The average decrease in HbA1c for the intervention group was 2.03%, compared to 0.68% ($p < .02$) for control patients. Both provider and patient satisfaction with this system was found to be clinically and statistically significant. Patients in the intervention group used a Bluetooth-enabled OneTouch Ultra blood glucose meter and a cell phone with WellDoc diabetes management software. Patients were given a satisfaction survey at the end of the study and asked to give feedback on the usability of the system. For all major survey questions, 91% of the WellDoc users reported being satisfied with the system. Patients using the WellDoc system reported having better control over their diabetes based on their knowledge of food choices (91% versus 50%), confidence (100% versus 75%), and physician receiving regular blood sugars (100% versus 36%).

## Discussion

According to the Canadian Diabetes Association Clinical Practice Guidelines for 2008,[4] the targets for glycemic control for both T1DM and T2DM include maintaining HbA1c levels of ≤7.0%, a fasting plasma glucose or preprandial plasma glucose level of 4.0–7.0 mmol/liter, and a 2 h postprandial plasma glucose level of 5.0–10.0 mmol/liter (5.0–8.0 if HbA1c targets are not being met). These levels are recommended in order to reduce the potential for developing microvascular and macro-

vascular complications. The Canadian Diabetes Association Clinical Practice Guidelines also state that glycated hemoglobin is a valuable indicator of treatment effectiveness and should be measured every 3 months when glycemic targets are not being met and when diabetes therapy is being adjusted.[4] Current Canadian Diabetes Association Clinical Practice Guidelines for diabetes and physical activity suggest that moderate to high levels of physical activity and cardiorespiratory fitness are associated with substantial reductions in morbidity and mortality in both men and women and in both T1DM and T2DM. Since many people with diabetes will develop hypertension, which can lead to CVCs, the recommended blood pressure targets are <130/80 mm Hg. The results from major trials indicate that both blood glucose as well as blood pressure should be adequately controlled to prevent further complications for individuals with diabetes.[8,54,55] The results of this systematic review found an absence of trials devoted to the assessment of home blood pressure monitoring as a way of managing or developing the complications found in diabetes.

Based on the results of the studies discussed in this review, there is moderately strong evidence that SMBG is an effective way to improve glycemic control in patients with noninsulin-treated T2DM. The recommended frequency of SMBG testing for effective blood glucose control has yet to be determined. Furthermore, SMBG alone has not yet been proven to directly affect the ability to maintain stable metabolic levels—it is evident that behavior and lifestyle changes must accompany the self-monitoring activity to adequately self-manage this disease.[56] The findings from this review compare positively with current clinical practice guidelines in terms of recommendations for SMBG, achieving targeted glycemic ranges, and increasing levels of physical activity. In addition to SMBG, regular monitoring of blood pressure and making lifestyle modifications such as increased exercise offer effective ways for patients to manage diabetes.

Although our research synthesis found limited levels of evidence supporting the effectiveness of pedometer-based interventions for improving overall fitness levels and metabolic control (based on our quality assessment methods), pedometers can still be an effective method of motivation for patients with diabetes to make these necessary lifestyle changes and increase their daily steps. Our review also uncovered an absence of trials involving the integration of diabetes self-management devices with blood pressure devices, heart rate monitors, and other emerging technologies. These are certainly areas where additional research is needed. Remote patient monitoring through the use of cell phones, smart phones, and other wireless technologies (Internet-based applications) are proving to be accessible, affordable methods for self-managing diabetes and adhering to exercise and diet regimens. These tools can be used in a home setting or while traveling at a minimal cost to the patient and the provider. Simple reminder schedules for self-monitoring can be established, and health care providers can oversee the progress via patient monitoring databases. Additional trials should be conducted that assess the effectiveness of remote patient monitoring on key health outcomes and lifestyle change (increased exercise or improved diet) for patients with diabetes.

Interventions and outcome measures related to feasibility, adherence, and satisfaction with diabetes self-management devices are frequently evaluated in the research; however, it is challenging to form solid conclusions as to the degree of feasibility or compliance with a particular device, as many of the trials used qualitative surveys or relied solely on the number of times a device was uploaded to a server to determine compliance with the device or intervention. Aside from calculating percentages of self-monitoring device or database usage, evaluating patient or provider compliance with statistically rigorous methods can pose challenges (difficult to assess usability or compliance in the patient's home, for example). In many cases, patients and their providers are generally satisfied with self-monitoring technologies, and adherence to self-management interventions is improved after using the device, perhaps due to increased motivation after learning how to use the technologies and receiving regular feedback. The impact of usability on device adherence is especially important in certain populations, such as younger patients with T1DM or T2DM who may need additional encouragement and support to use their devices and regulate their metabolic functions.

Systematic reviews aim to inform evidence-based practice and minimize bias by grouping and analyzing key research studies within an organized and rigorous framework. An important result of conducting systematic reviews is to close or locate gaps within healthcare research and highlight the need for additional studies to be conducted in the areas where they would be most beneficial. One limitation of this systematic review may be that our inclusion criteria for the population, the technologies, and the health-related outcomes were too broad. A consideration for a future review on diabetes monitoring technologies might be to conduct meta-analyses of the data on key health outcomes such as reduction in

HbA1c, blood pressure, and cholesterol levels; lifestyle change (improved or increased exercise); compliance; and usability—and to assess these outcomes using a single type of self-monitoring technology. This review found an absence of trials incorporating outcome measures for assessing the usability and feasibility of self-monitoring devices for diabetes, which indicates a need for these types of measures to be included in future studies. If the methods for measuring device feasibility and usability outcomes were further developed, this could produce valuable findings for both patients and providers. Evaluations of adherence, compliance, and persistence with self-monitoring devices should also continue to be measured in future trials. Current clinical guidelines and health-related economic policies or programs could be greatly enhanced with the inclusion of strong evidence-based findings for device usability, feasibility, and costs. If a self-monitoring device is useful, and if patients are motivated to use the technology, then the degree of impediment to managing diabetes with the technology may potentially be lessened. Health care providers may in turn discover that they have more reliable clinical information and improved communication with their patients through the usability feedback they might obtain as a result of patient self-monitoring technologies.

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