

**The impact of automated brief messages promoting lifestyle changes delivered via mobile devices to people with type 2 diabetes: a systematic literature review and meta-analysis of controlled trials**

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## **ABSTRACT**

### **BACKGROUND**

Brief automated messages have the potential to support self-management in people with type 2 diabetes, but their effect compared with usual care is unclear.

### **OBJECTIVES**

To examine the effectiveness of interventions to change lifestyle behavior delivered via automated brief messaging in patients with type 2 diabetes.

### **METHODS**

A systematic literature review of controlled trials examined the impact of interventions, delivered by brief messaging and intended to promote lifestyle change in people with type 2 diabetes, on behavioral and clinical outcomes. Bibliographic databases searched included Medline, Embase, CINAHL, PsycINFO, and ISI WoK. Two reviewers independently screened citations. We extracted information on study risk of bias, setting (high versus low- and middle-income countries) and intervention characteristics (including use of theory and behavior change techniques). Outcome measures included acceptability of the interventions and their impact on: i) determinants of lifestyle behavior (knowledge about diabetes, self-efficacy, attitudes towards self-management), ii) lifestyle behavior (diet, physical activity) and, iii) clinical and patient-reported outcomes. Where possible, we pooled data using random-effects meta-analyses to obtain estimates of effect size of intervention compared to usual care.

## **RESULTS**

We identified 15 trials (15 interventions). Most interventions were delivered via short-message-service text-messaging (n=12) and simultaneously targeted diet and physical activity (n=11). Nine interventions consisted of unidirectional messages, whereas six consisted of bidirectional messages, with patients receiving automated tailored feedback based on self-reported data. The acceptability of the interventions and their impact on lifestyle behavior and its determinants was examined in a low proportion of trials, with heterogeneous results being observed. In 13 trials (1155 patients) where data were available there was a difference in glycated hemoglobin of -0.53% (95%CI, -0.59% to -0.47%) between intervention groups compared to usual care. In five trials (406 patients) there was a non-significant difference in body mass index of -0.25 kg/m<sup>2</sup> (95%CI, -1.02 to 0.52). Interventions based on unidirectional messages produced similar effects in the outcomes examined than those based on bidirectional messages. Interventions conducted in low- and middle- income countries showed a greater impact than those conducted in high-income countries. In general, trials were not free of bias and did not use explicit theory.

## **CONCLUSIONS**

Automated brief messages strategies can improve health outcomes in people with type 2 diabetes. Larger, methodologically robust trials are needed to confirm these positive results.

## **KEY WORDS**

Diabetes mellitus, type 2; mobile health; text messaging; systematic review; diet; physical activity; self-care.

## INTRODUCTION

The number of people with type 2 diabetes worldwide is currently estimated to be 387 million, and is expected to increase to 592 million by 2035 [1]. This imposes a substantial burden of disease, mainly due to life-long multi-organ complications [2], leading to increased disability and premature deaths in low and middle income as well as high income countries [3].

Available evidence suggests that better control of blood glucose, blood pressure and cholesterol levels would delay the onset of complications, and thereby prevent premature deaths among those already diagnosed with diabetes [4]. Lifestyle modification focusing on healthy diet is an accepted component of management [5] alongside promotion of physical activity [6]. However, patients with diabetes do not always follow advice about recommended changes in diet and physical activity, and therefore do not achieve optimal control of risk factors. Reasons for this are multifactorial, including psychological, social and health care related factors [7, 8].

Recommendations for supporting diabetes self-management are now widely incorporated in clinical practice guidelines [9, 10]. However, strategies for providing effective continuing support and motivation are not well developed, and facilitating sustained behavior change remains an important challenge. Emerging evidence suggests that mHealth interventions may improve cardiovascular-related lifestyle behaviors and disease management [11]. Interventions based on brief messages delivered via mobile device technologies (such as Short Message Service technology) are one of the most studied types of mHealth interventions, and available evidence suggests it may contribute to behavior change

[11, 12]. Messages can be readily delivered at a wide-scale and at a low cost. They can be used to provide information through one-way (unidirectional) systems but also to facilitate two-way communication (interactive or bi-directional). In contrast to more resource intensive one-to-one clinician-patient contacts in clinics, the use of brief messages can be attractive for patients in terms of convenience, acceptability and user-friendliness [13, 14]. This type of interventions could address non-adherence to lifestyle recommendations by providing frequent reminders, motivational support and prompts to action as well as timely access and feedback to relevant health information while making patient-provider communication much easier [15]. Although their impact in different resource settings is still unclear, automated messaging technologies could be especially relevant in low-resource settings, given their ubiquity, low cost and to potential to underpin a developing healthcare infrastructure, for example in relation to electronic medical records systems. All these features are leading to an increasing interest in the use of brief messages as part of public health interventions.

There are a number of systematic reviews providing evidence for the effectiveness of mobile-phone based interventions on self-management of long term conditions [11, 16-19]. However, so far no study has specifically reviewed the potential impact of automated brief messages on promoting lifestyle modifications in patients with type 2 diabetes. In addition, the theoretical basis for this type of intervention is not well established, and the extent to which basing messages on established behavior change techniques is helpful is not known. This may partly be due to inadequate characterization of the techniques being used, which prevents the identification of those that might be helpful.

The primary objective of this systematic review was to examine the effectiveness of brief messages in improving glycemic control through promoting healthy eating and

increasing physical activity, compared to usual care. We focused specifically on interventions delivered via mobile devices in people with type 2 diabetes. Secondary objectives included, i) examining the extent to which interventions have used explicit theory; ii) examining the behavior change techniques used; iii) examining the acceptability of the interventions; iv) examining their impact on lifestyle change behavior and its determinants; v) examining their impact on other clinical (blood pressure, lipids, and weight) and patient-reported outcomes; vi) comparing the impact of Eligible interventions targeted healthy eating, physical activity unidirectional vs bidirectional messages; and vii) exploring the specific impact of the interventions in high-income countries (HIC) and low- and middle-income countries (LMIC).

## **METHODS**

The study was planned, conducted, and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [20]. The review protocol was registered in the PROSPERO International prospective register of systematic reviews (registration number CRD42015024302).

### **Data Sources and Searches**

Specific search strategies were designed for the following databases (Appendix Table 1): Medline, Embase, Cumulative Index of Nursing and Allied Health (CINAHL), PsycINFO, Cochrane Central Register of Controlled Trials (CENTRAL) and Science Citation Index & Conference proceedings Citation Index (ISI Web of Knowledge). To ensure the identification of relevant studies carried out in LMIC, we also searched the following databases: African Index Medicus, Index Medicus for the Eastern Mediterranean Region, Index Medicus for South-East Asia Region, Inter-Science Latin American and Caribbean Health Sciences Literature, Western Pacific Region Index Medicus and World Health Organization Library Database (all accessed via the Global Health Library).

The search strategy combined MeSH terms and free-text keywords (Appendix Table 2). Databases were searched from inception to April 2015 and no language restriction was applied. In addition, potentially relevant studies were identified using a snowball technique initiated by the examination of 52 previous systematic reviews on the broader area telehealth and diabetes. A bibliographical database was created using EndNote X7™, and used to store and manage the references.

## Study Selection

We included controlled trials examining the impact of interventions intended to promote lifestyle changes on diet and physical activity among people with type 2 diabetes, delivered by brief messaging using mobile devices, on behavioral and clinical outcomes, compared to usual care.

Eligible interventions had as their main component the provision of information via brief messaging systems characterized by automated messages, including computer-generated messages following an algorithm, tailored or custom-made, personalized messages, or bulk messages. Messages had to be received via devices using mobile technology, such as mobile phones, smart-phones or hand-held computers. Messaging systems were those using the following technologies: short message service (SMS), automated email, or software applications ("apps"). These systems could be used to provide information through one-way (unidirectional) messages or to facilitate two-way communication (interactive or bi-directional). Unidirectional messages were conceptualized as messages sent from the providers or researchers to the participants. Bidirectional messages were conceptualized as those involving a two-way communication around self-monitoring data that was sent by the participants, who in return received real-time automated brief messages providing tailored feedback. Eligible interventions targeted healthy eating, physical activity, or both.

Inclusion criteria for study design were controlled clinical trials, including randomized controlled trials (RCTs), cluster RCTs, non-randomized controlled trials, and crossover studies. Only studies with control or comparator arms that consisted of patients receiving usual (standard) clinical care, or a minimal intervention (i.e. an intervention that is



unlikely to produce any effect, such as sending non-health related messages, but allow blinding participants to condition allocation) were eligible for inclusion. Eligible studies included adult (at least 18 years old) patients with type 2 diabetes mellitus (with or without comorbid conditions) and had to be set in the community or in any primary, secondary or tertiary care setting.

Studies reporting at least one of the following outcome measures were included: acceptability by recipients; determinants of change in lifestyle (namely knowledge, attitudes and self-efficacy on lifestyle modifications), lifestyle behaviors that impact on diabetic control (diet and physical activity); and clinical outcomes (HbA1c, BMI or body weight, lipids, blood pressure and waist circumference).

Trials were excluded if they i) examined the use of messages created by a clinician based on a clinical judgement of a patient's disease status (i.e., not automated); ii) had a proportion of patients with type 2 diabetes lower than 90%, iii) evaluated a multifaceted intervention in which brief messages were not the main component of the intervention, or iv) were published only in the form of conference abstracts. No language restrictions were applied.

A preliminary screen for eligibility was followed by retrieval and assessment of full texts of the selected articles. Those that met the inclusion criteria were included for data extraction. All citations were independently screened by two reviewers. Any disagreements were solved by consensus with a third reviewer.

## Data Extraction and Quality Assessment

Structured forms were used to extract data about the trial design, trial setting (HIC vs LMIC - according to the World Bank classification [21]), number of participants in each group, length of follow-up, key elements of the intervention, type of comparison group, and acceptability of the intervention. In addition the impact on determinants of change in lifestyle, diet and physical activity behavior, and clinical outcomes were recorded.

The extent to which the trials used theory explicitly in the development and evaluation of the interventions was assessed using an established coding-scheme which contains 19 items assessing whether a theory was mentioned, how theories were used in intervention design and in the selection of intervention techniques, how intervention evaluations tested theory, and the implications of the results for future theory development [22]. The behavior change techniques used in each intervention were classified using an established taxonomy [23].

We used the Cochrane Collaboration's tool for risk of bias assessment [24]. Two reviewers independently extracted all the information and assessed the risk of bias and the use of theory. Disagreements were discussed with a third reviewer until consensus was reached.

## Data Synthesis and Analysis

We examined and synthesized the acceptability of the interventions, and their impact on: i) determinants of change in lifestyle, ii) behavior (diet and/or physical activity) and, iii) clinical outcomes. Outcomes in all the studies were examined and classified as measuring one of these domains. Variables that measured other domains were not included in the analysis. For

all the pooled outcomes we used subgroup analyses to examine potential differences between types of messages (unidirectional vs bidirectional) and settings (HIC vs LMIC).

We extracted from each study the mean (standard deviation (SD)) of HbA1c levels and BMI, contacting study authors when the information was not available. We transformed this information into weighted mean difference (95% CI), and pooled the data using random-effects models. Where SD of the change between intervention and control group for an outcome was not provided, we derived them from baseline and final SDs, assuming a correlation of 0.5 [25]. A sensitivity analysis was undertaken using different values of correlation to determine whether the overall result of the analysis were robust to the use of imputed correlation coefficients. Heterogeneity was quantified by the  $I^2$  statistic, where  $I^2 > 50\%$  was considered evidence of substantial heterogeneity [26]. Publication bias was examined with funnel plots and presence of asymmetry tested with Begg [27] and Egger tests [28]. Meta-analyses were conducted with Stata, version 12.0. We set a threshold of  $P=0.05$  to accept statistical significance.

## RESULTS

### Trial identification

Search results are summarized in the PRISMA flow diagram (Figure 1). The initial search identified a total of 2,096 unique citations. Title and abstract screening of these citations resulted in the inclusion of 169 citations for further review. Following full text screening, 19 articles [29-47] reporting on 15 separate trials (evaluating 15 separate interventions) were finally included.

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FIGURE 1 ABOUT HERE

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### Characteristics of trials and interventions

Each trial assessed only one intervention. Thirteen trials used an RCT design, whereas the remaining two used a cluster-RCT [39, 40] and a crossover design [44]. The average (SD) number of participants per trial was 92 (52), ranging from 19 to 215. Nine of the trials (60%) were conducted in HIC, whereas six were conducted in LMIC (Table 1).

Table 1. Characteristics of the identified trials and interventions

Reference/ Country/ Setting	Study design/ Comparator/ Duration (months)	Messages (Type/ Format/ Content)	Messages (Frequency <sup>a</sup> / Timing <sup>b</sup> )	Mobile devices and applications	Use of theory	Behavior change techniques
Tsang et al. 2001 [44] China Hospital care	Cross over Usual care 6	Bidirectional Image (graphs) Diet	2 per week/ Not reported	Hand-held electronic diary with a touch-screen (CV8300, Vtech, Hong Kong)	Not reported	Provide feedback on performance
Yoo et al. 2009 [47] South Korea University and community healthcare center	RCT Usual care 3	Bidirectional Text (SMS) Physical activity+ diet + other	3 per day/ Not reported	Mobile phone (LG- SV280; LGElectronics, Seoul, Korea)	Not reported	Provide information on consequences; Provide instruction; Provide feedback on performance; Provide contingent rewards; Prompt practice; Time management
Noh et al. 2010 [37] South Korea Hospital care	RCT Minimal intervention 7	Unidirectional Text (website) Physical activity+ diet + other	Not reported	Web-based ubiquitous information system (SK telecom [Seoul, Republic of Korea]). All mobile phones using the International Mobile Telecommunication -2000 system could connect to the system.	Not reported	Stress management
Lim et al. 2011 [36] South Korea Hospital care	RCT Usual care 6	Bidirectional Text (SMS) Physical activity+ diet + other	Variable ( at least 8 per week)/ Not reported	Glucometers specifically devised for ubiquitous healthcare service (GlucoDr Supersensor, AGM- 2200, Allmedicus, Korea).The glucometer transferred the tested data and stored it in a remote server.	Not reported	Provide feedback on performance; Prompt practice
Quinn et al. 2011 [39, 40] US Primary care	Cluster RCT Usual care 12	Bidirectional Text (SMS) Physical activity+ diet + other	Variable (depending on patients' needs)/ Not reported	One Touch Ultra 2 glucose meter (LifeScan, Milpitas, CA), mobile phones, and a diabetes management software.	Trans- theoretical model	Provide instruction; Provide feedback on performance

Shetty et al. 2011 [42] India Primary care	RCT Usual care 12	Unidirectional Text (SMS) Physical activity+ diet + other	2 per week/ Not reported	Mobile phone	Not reported	Provide information on consequences; Prompt self- monitoring of behavior; Prompt practice
Bell et al. 2012 [31] US Specialized care	RCT Usual care 12	Unidirectional Video Physical activity+ diet + other	1 per day/ Variable (participants were allowed to view the video multiple times throughout the 24-hour period before the next video was sent)	Broadband-enabled cell phone	Not reported	Provide information about behavior-health link; Provide information on consequences; Provide instruction; Stress management; Time management
Goodarzi et al. 2012 [34] Iran Community	RCT Usual care 3	Unidirectional Text (SMS) Physical activity+ diet + other	4 per week/ Not reported	Patients' mobile phone	Not reported	Provide information on consequences; Prompt intention formation; Provide instruction
Abebe et al. 2013 [29]/ Capozza et al. 2015 [33] US Primary care	RCT Usual care 6	Unidirectional Text (SMS) Physical activity+ diet + other	Variable (between one and seven messages per day, depending on participants' preference)/ Sent at convenient timing for participants	Patients' mobile phone	Not reported	Prompt intention formation; Prompt self- monitoring of behavior; Provide feedback on performance; Provide contingent rewards; Prompt practice; Stress management
Orsama et al. 2013 [38] Finland Community	RCT Usual care 10	Bidirectional Text (SMS) Physical activity+ diet + other	Not reported	Mobile telephone, software application, and assessment devices	Information- motivation- behavioral skills model	Provide information on consequences; Provide instruction; Provide feedback on performance
Arora et al. 2014 [30]/ Burner et al. 2014 [32] US Hospital care	RCT Usual care 6	Unidirectional Text (SMS) Physical activity+ diet + other	2 per day/ 9 am and 5pm	Patients' mobile phone	Not reported	Provide information on consequences; Prompt intention formation; Provide instruction
Tamban et al. 2014 [43] Philippines Unclear	RCT Usual care 6	Unidirectional Text (SMS) Physical activity+ diet + other	3 per week/ Sent at convenient timing for participants	Patients' mobile phone	Not reported	Provide information about behavior-health link; Provide

						information on consequences; Provide instruction; Prompt specific goal setting; Prompt self-monitoring of behavior; Provide feedback on performance
Islam et al. 2014 [35]/ Islam et al. 2015 [41] Bangladesh Hospital care	RCT Usual care 6	Unidirectional Text (SMS) Physical activity+ diet + other	1 per day/ Not reported	Patients' mobile phone	Behavioral learning theory and trans-theoretical model of behavioral change	Provide information about behavior-health link; Provide information on consequences; Provide instruction; Stress management
Waki et al. 2014 [45] Japan Hospital care	RCT Usual care 3	Bidirectional Text (SMS) Physical activity+ diet	Not reported	Smartphone (NEC, Tokyo, Japan: MEDIAS WP N-06C), NFC-enabled glucometer (Terumo, Tokyo, Japan: MS-FR201B), BP monitor (Omron, Kyoto, Japan: HEM-7081-IT), pedometer (Omron HJ-720IT), and scale (Omron HBF-206IT).	Not reported	Prompt barrier identification; Provide feedback on performance
Yarahmadi et al. 2014 [46] Iran Specialized care	RCT Unclear 2	Unidirectional Text (SMS) Physical activity+ diet + other	3 per week/ Not reported	Patients' mobile phone	Not reported	Unclear

a: Number of messages sent per week.

b. Time of the day when the messages were sent.

RCT, randomized controlled trial; SMS, short message service;

On average, interventions lasted seven months (SD=4). The majority of them (n=12) used SMS technology to deliver the messages, whereas the rest were based on graphical information presented to the patients [44], texts available in a website [37], or brief video-messages [31]. About three quarters of the interventions (n=11) addressed both diet and physical activity. Nine interventions consisted of unidirectional messages and six of

bidirectional messages. Bidirectional messages were usually initiated by the study participants, who were instructed to use a specific devices to conduct the glucose (and in some interventions blood pressure) measurements and transmit the results using their mobile devices to the study database. Other systems used by patients to transmit self-management information included a hand-held electronic diary that allowed participants to describe their meals by selecting the food ingredients [44], or a SMS-based system that allowed them to record their physical activity [47]. In all these interventions for each reported measurement, the patient received automated, real-time educational, behavioral, and motivational messaging specific to the entered data, on the basis of a decision support algorithm.

Twelve behavior change techniques were used in total. Most interventions used multiple techniques. Most frequently used techniques consisted of: (i) providing information about the consequences of inaction; (ii) providing instructions about how to perform a behavior; and iii) providing feedback on performance – each of which were used in eight interventions. Whereas all the studies examined the impact of the interventions on clinical outcomes, behavior change was only measured in six of them, with a wide range of instruments being used.

### Risk of bias

Only a minority of the trials presented low risk of bias, and none was completely free of bias (Appendix Figures 1 and 2). Most frequent biases were related to blinding of participants and personnel to the interventions (eight trials with high risk of bias), and “other sources of bias” (seven trials), which were mostly related to small sample sizes that did not allow the detection of clinically meaningful differences.



## Acceptability of the interventions

Five trials examined whether unidirectional messaging interventions were acceptable to participants. Three [29, 30, 32, 33, 42] reported high acceptability and satisfaction. However, one [29, 33] reported moderate usability, with 40% of the participants requesting to stop receiving the messages before the end of the intervention. Another trial, in which messages were available through a website, reported low acceptability due to the lack of a user-friendly interface and inexperience with mobile web use [37]. In a trial evaluating the use of video-messages [31] it was observed that 47% of the participants in the intervention group did not view videos at all or did so only briefly at the beginning of their participation and then stopped in the first two months.

Four trials examined participants' acceptability of bidirectional messaging interventions, consistently observing high acceptability in terms of easiness to use systems, usefulness, and general satisfaction [38, 44, 45, 47].

## Effectiveness of the interventions

### 1. Impact on determinants of behavior change

The impact of unidirectional messages on behavior change determinants was only examined by two trials. One of them observed significant improvement in diabetes knowledge and self-efficacy, but not in self-management attitudes [34], whereas the other observed no effect on knowledge or self-efficacy [30, 32]. None of the trials evaluating bidirectional messages examined the potential impact on determinants of behavior change (Table 2).

Table 2. Main results of the studies identified

Reference/ Type of messages	Acceptability	Knowledge/ Attitudes/ Self-efficacy	Behavior change (diet/physical activity)	Clinical and patient reported outcomes
Noh et al. 2010 [37]/ Unidirectional	Low acceptability due to the lack of a user-friendly interface and inexperience with mobile web use	Not reported	Not reported	<u>Glycemic control</u> : No statistical difference in between groups at 6 months ( $7.5\% \pm 0.4\%$ vs. $8.1 \pm 0.3\%$ ). <u>Lipids</u> : Statistically significant improvement in LDL-cholesterol (but not in TG or HDL-cholesterol) in the intervention group, whereas no differences were observed in the control group. <u>Blood pressure</u> : No statistically significant improvement in the intervention group. <u>Weight</u> : No differences observed
Shetty et al. 2011 [42] /Unidirectional	Highly acceptable to the patients, as seen from the number of messages and their frequency requested by the patients	Not reported	<u>Physical activity</u> : Marginal improvement (not statistically significant) in the intervention group. <u>Diet</u> : No statistically significant changes	<u>Glycemic control</u> : The proportion of patients with HbA1c<8% significantly increased in the intervention group (from 30.8% to 55.1%) whereas no changes were observed in the control group. <u>Lipids</u> : No differences observed in total and LDL-cholesterol. <u>BMI</u> : No differences observed
Bell et al. 2012 [31] / Unidirectional	11 participants did not view videos at all or did it briefly at the beginning of their participation and then stopped in the first 2 months; 2 participants viewed the videos throughout the active intervention but <10/month; 10 participants viewed more than 10 videos/month	Not reported	Not reported	<u>Glycemic control</u> : No statistically significant differences observed. <u>Blood pressure</u> : No differences observed. <u>Weight</u> : No differences observed
Goodarzi et al. 2012 [34] / Unidirectional	Not reported	<u>Knowledge</u> : significant improvement/ <u>Attitudes</u> : no significant improvement/ <u>Self-efficacy</u> : significant improvement	<u>Physical activity</u> : statistically significant improvement in the intervention group. <u>Diet</u> : statistically significant improvement in the intervention group	<u>Glycemic control</u> : significant improvement in HbA1C for the experimental group. <u>Lipids</u> : significant change in cholesterol for the experimental group but not in LDL, triglycerides, or HDL.
Abebe et al. 2013 [29] & Capozza et al. 2015 [33] / Unidirectional	High satisfaction. Moderate usability (40% of the participants requested stop receiving the messages before the end of the intervention)	Not reported	Not reported	<u>Glycemic control</u> : No statistically significant differences between the intervention and control groups
Arora et al. 2014 [30] & Burner et al. 2014 [32] /	Subjects rated satisfaction with the TExT-MED program very highly. No patients opted out of the	<u>Knowledge</u> : Not statistically significant improvement in	<u>Physical activity</u> : No statistically significant effect observed. <u>Diet</u> : No statistically	<u>Glycemic control</u> : The primary outcome of median HbA1c decreased by 1.05% in the TExT-MED group compared with 0.60%

Unidirectional	program	the intervention group (mean=-0.7 (95%CI= -1.5 to 0.1))/ <u>Self-efficacy</u> : Not statistically significant improvement in the intervention group (mean=0.1 (95%CI= 0.2 to 0.4))	significant effect observed.	in the control group (difference not statistically significant). <u>Patient reported outcomes</u> : No statistically significant improvement in diabetes related emotional distress (PAID questionnaire) in the intervention group
Tamban et al. 2014 [43] / Unidirectional	Not reported	Not reported	<u>Physical activity</u> : Statistically significant improvement in physical activity (number of minutes) is seen after 6 months, favoring the SMS group. <u>Diet</u> : statistically significant improvement in the intervention group	<u>Glycemic control</u> : Statistically significant reduction in HbA1c in the intervention (-0.82%) when compared to the control group (-0.52%). <u>BMI</u> : significant reduction in the intervention when compared with control group
Islam et al. 2014 [35]/ Islam et al. 2015 [41]/ Unidirectional	Not reported	Not reported	Not reported	<u>Glycemic control</u> : Statistically significant HbA1c reduction in the intervention (-0.82%) when compared to the control group (0.18%)
Yarahmadi et al. 2014 [46] / Unidirectional	Not reported	Not reported	Not reported	<u>Glycemic control</u> : Higher reduction in HbA1c in the intervention (-0.65%) when compared to the control group (-0.12%)
Tsang et al. 2001 [44] / Bidirectional	<u>Acceptability</u> : 95% patients found the device easy to operate while 63% found it useful	Not reported	<u>Diet</u> : 35% of the patients were consuming the recommended carbohydrate portions as stated in their meal plan. 60% had a tendency to over-consume, 5% under-consume	<u>Glycemic control</u> : Use of the system was associated with a significant reduction of HbA1c concentration compared with the control period (mean HbA1c difference between control and intervention group = -0.83%)
Yoo et al. 2009 [47] / Bidirectional	Participants did not find the system difficult to use. They were satisfied with the continuous care of their chronic disease	Not reported	Not reported	<u>Glycemic control</u> : significant improvements in HbA1c in the intervention group (-0.5%) compared with the control group (0.1%). <u>Lipids</u> : Total cholesterol and LDL-cholesterol levels were significantly decreased after 3 months in the intervention group compared with the control group <u>Blood pressure</u> : Significant reduction in the systolic and diastolic blood pressure only in the intervention group. <u>Weight and waist circumference</u> : No differences observed

Lim et al. 2011 [36] / Bidirectional	Not reported	Not reported	Not reported	<p><u>Glycemic control</u>: The proportion of patients that achieved HbA1c&lt;7.0% without hypoglycemia (primary end point of the study) was significantly higher in the intervention than in the control group (30.6% vs 14.0%).</p> <p><u>Lipids</u>: significant reduction in LDL-cholesterol in the intervention group when compared to the control group.</p> <p><u>Weight and BMI</u>: significant reduction in the u-healthcare group compared with control group</p>
Quinn et al. 2011 [39, 40] / Bidirectional	Not reported	Not reported	Not reported	<p><u>Glycemic control</u>: significant reduction of HbA1c in the intervention group (-1.9% in comparison with the control group (-0.7%).</p> <p><u>Lipids</u>: Reduction in the intervention group in total cholesterol, triglycerides, HDL-cholesterol, and LDL-cholesterol, but differences were only statistically significant for total cholesterol.</p> <p><u>Blood pressure</u>: No statistically significant differences.</p> <p><u>Patient reported outcomes</u>: No significant differences in "Diabetes Distress Scale", "Diabetes Symptom Inventory", and depression (PHQ-9)</p>
Orsama et al. 2013 [38] / Bidirectional	100% of intervention participants regarded the mobile telephone application, as “very easy” or “quite easy” to use. More than 90% reported that making health parameter measurements and reporting them was “very useful” or “quite useful,” and approximately 82% regarded the automatic feedback they received as “very useful” or “quite useful.”	Not reported	Not reported	<p><u>Glycemic control</u>: Intervention participants achieved, compared with controls, a significantly greater mean reduction in HbA1c (-0.40% vs 0.04%).</p> <p><u>Blood pressure</u>: No statistically significant improvement in the intervention group.</p> <p><u>Weight</u>: significant reduction in the u-healthcare group (-2.1 kg) compared with control group (-0.4 kg)</p>
Waki et al. 2014 [45] / Bidirectional	Usability: participants were comfortable with the use of the equipment.	Not reported	<p><u>Physical activity</u>: No statistically significant effect observed/  <u>Diet</u>: No statistically significant effect observed</p>	<p><u>Glycemic control</u>: HbA1c decreased an average of 0.4% compared with an average increase of 0.1% in the control group (statistically significant differences observed).</p> <p><u>Lipids</u>: no differences observed in LDL, HDL and TG.</p> <p><u>Blood pressure</u>: No differences observed</p>

				<u>BMI</u> : significant reduction in the intervention when compared with control group
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BMI, body mass index; CI, confidence interval; HbA1c, glycemic hemoglobin; HDL, high density lipoprotein;

LDL, low density lipoprotein; PHQ, Patient Health Questionnaire; TG, triglycerides.

## 2. Impact on behavior change

Four trials examined the impact of unidirectional messages on diet and physical activity. Two of them reported no effects [30, 32, 42], whereas the remaining two reported statistically significant improvements in both diet and physical activity [34, 43]. Only one examined the impact of bidirectional messages on behavior change [45], reporting no effects.

## 3. Impact on clinical outcomes

Data from thirteen trials reporting the impact of the interventions on HbA1c [29-41, 43, 45-47] were pooled in a meta-analysis (Figure 2). The trials included thirteen comparisons assessing the impact of unidirectional and bidirectional messages. The weighted HbA1c mean difference between intervention (n=583) and control group (n=572) was -0.53% (95%CI – 0.59% to -0.47%). There was no observed heterogeneity in HbA1c among the trials ( $I^2=0\%$ ). Very similar effects were produced by unidirectional messages (-0.53% (-0.60% to -0.47%)) compared with bidirectional (-0.52% (-0.69% to -0.34%)).

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FIGURE 2 ABOUT HERE

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A second meta-analysis examined the impact of the interventions on BMI. Five trials [36, 37, 43, 45, 47] with a total of 406 participants were included. The BMI mean difference between the intervention and control group was -0.25 kg/m<sup>2</sup> (-1.02 to 0.52) and not statistically significant (Appendix Figure 3). There was no observed heterogeneity among the trials ( $I^2=0\%$ ). Unidirectional messages produced a smaller effect than bidirectional messages

(0.08 [-1.76 to 1.93] vs -0.32 [-1.16 to 0.53], respectively), but the difference was not statistically significant.

For both meta-analyses sensitivity analyses confirmed that the overall results were robust to the use of imputed correlation coefficients, and Egger and Begg tests indicated absence of publication bias.

Other clinical outcomes were too heterogeneous to pool. Unidirectional messaging interventions led to significant reductions of blood pressure in one of the two trials examining this outcome [31, 37], and in one [47] of the four bidirectional messages based trials [38-40, 45, 47]. Improvement in lipids was reported for two [29, 37] out of three unidirectional messaging interventions, and for three [36, 39, 40, 47] out of four bidirectional messaging interventions. Patient reported outcomes (diabetes related distress, diabetes symptoms and depression) did not significantly improve in either of the two trials that examined them [30, 32, 39, 40].

#### 4. Differences in impact between high and low- and middle- income countries

The proportion of trials reporting positive effects was consistently higher for trials carried out in LMIC than for HIC in all the domains examined, including acceptability of the interventions (100% in LMIC vs 57% in HIC), impact on determinants of behavior change (100% vs 0%), on physical activity and diet (67% vs 0%) and on clinical outcomes (100% vs 55%) (Appendix Figure 4). Subgroup meta-analysis showed a similar reduction in HbA1c in HIC (-0.53 (-0.60; -0.47)) than in LMIC (-0.53 (-0.69 to -0.37)).

### Use of theory in included studies

The extent to which the trials explicitly used theory in relation to a number of criteria is reported in Appendix Table 3. In general, theory was not used extensively. Only three trials [35, 38-41] explicitly reported that the interventions were based on theory. Two interventions [35, 39-41] were based on the transtheoretical model of behavioral change [48] (one of them [35, 41] in conjunction with the behavioral learning theory [49]), whereas the remaining intervention [38] was based on the information-motivation-behavioral skills model [50, 51].

Where theory was explicitly mentioned, two trials [35, 38, 41] used theory to develop the intervention techniques. Only one of them [38] mentioned the targeted construct that the intervention was hypothesized to change, and linked the theoretical constructs to at least one intervention technique. None of the trials measured theory-relevant constructs, used adequate measures of behavior change, carried out a mediational analysis of constructs, or used their results to refine theory.



## DISCUSSION

This systematic review identified 15 controlled trials examining the effectiveness of interventions to promote healthy eating and physical activity in people with type 2 diabetes, delivered via automated brief messaging sent to mobile devices. The interventions predominantly used SMS technology, addressed both diet and physical activity, and were not based on theoretical models of behavior change. Our meta-analysis showed that automated brief messaging produced a clinically important and statistically significant effect on glycemic control (pooled effect on HbA1C:  $-0.53\%$ ,  $P<0.001$ ), but not on weight loss ( $\text{BMI}=-0.25 \text{ kg/m}^2$ ,  $P=0.53$ ). In general, interventions based on the use of unidirectional messages produced similar effects than those based on bidirectional messages. Interventions conducted in LMIC generally showed a more positive impact than those conducted in HIC.

### Strengths and limitations of the review

This is the first systematic review specifically examining the impact of automated brief messages on self-management behavior in people with type 2 diabetes. Additional novel aspects of this review include an assessment of the extent to which interventions were based on theory; an assessment of the behavioral change techniques used; and an examination of the relative impact of this type of interventions in countries with different levels of economic development. Relevant trials were identified using a comprehensive search strategy and a large number of bibliographic sources.

In terms of limitations, our meta-analyses were restricted to glycemic control and BMI. Although we intended to conduct meta-analyses on other relevant outcomes (namely diabetes knowledge, attitudes toward diabetes self-management, and change in diet and physical activity related behaviour) they were seldom measured, which represents a gap in

evaluations to date. Finally, although formal tests on publication bias seemed to exclude its presence, we cannot completely rule out its existence.

### Comparison with previous reviews and implications

The positive findings observed in our diabetes specific review are consistent with findings from reviews looking at a wide range of conditions. For example, a recent meta-analysis observed that SMS messages produced a small, positive, significant effect ( $g = 0.29$ ) on a broad range of healthy behaviors in patients with different types of long-term conditions [12]. A recent study reviewed 15 systematic reviews and meta-analyses observing that the majority of published text-messaging interventions were effective when addressing weight loss, physical activity, smoking cessation, and medication adherence for antiretroviral therapy [52].

The estimated 0.53% reduction in HbA1c observed in our meta-analysis is clinically important, as evidence suggests that every percentage point decrease in HbA1c over 10 years is associated with a risk reduction of 21% for deaths related to diabetes, 14% for myocardial infarctions, and 37% for microvascular complications [53]. Our result is consistent with findings from a previous systematic review of computer-based interventions to improve diabetes self-management, which showed that interventions based on the use of mobile phone (although not specifically text messages) produced the largest HbA1c reductions (-0.5%) [19]. We deliberately focused this review on interventions to improve physical activity and healthy diet. Medication adherence is also a key aspect of diabetes self-management, and adherence behavior can also be targeted by messaging interventions. We examined the impact of brief messages to improve adherence to diabetes medication in a separate

systematic review, which provided evidence that messages produced a moderate positive effect on medication adherence and clinical outcomes [17].

Interventions based on the use of one-way messages produced a very similar effect to those based on two-way messages, which can be more tailored and usually require more complex technology and are more resource intensive. This is also consistent with findings from a recent trial evaluating text messages to improve treatment adherence in people with hypertension. It is also consistent with findings from our systematic review on messages to improve adherence to diabetes medication, which observed that interventions exclusively based on brief messages produced a similar effect than more complex interventions combining messaging with monitoring strategies [17].

More than half of the trials did not include measures of behavior change, and those that did reported mixed results. Previous systematic reviews also reported mixed results. For example, Cassimatis et al [54] observed that only five out of eight trials examining the effects of type 2 diabetes behavioral telehealth interventions showed significant improvements in dietary adherence and physical activity. Cotter et al [55] observed that only two out of nine studies based on Internet interventions to support lifestyle modification for type 2 diabetes management demonstrated improvements in diet or physical activity.

Although we did not observe a statistically significant reduction in BMI, we cannot exclude a small reduction. Since the text messages specifically targeted diet and physical activity behavior, we expected a greater effect. However, there were only a low number of trials reporting BMI as an outcome. Evidence from previous systematic reviews looking at

the impact of text messages on weight reduction is mixed, with some of them suggesting lack of consistent effects [56, 57] and others reporting significant weight loss [58].

The interventions seem to have been acceptable to the recipients. There are many features related to mobile technology that may engage patients with the intervention. Some of these features include; being easy to use, convenience (e.g. messages need not be retrieved immediately), mobility (e.g. read at home or away), and frequent reinforcement (e.g. can read more than once). However, measures of acceptance and usability of the interventions assessed in the review were not obtained using a validated tool.

Our results suggested that the interventions were more effective in LMIC than in HIC. As far as we know, this is the first study comparing the impact of automated brief messages on long-term condition self-management between countries with different levels of economic development. Two recent reviews evaluated the impact of mobile health interventions in patients with long-term conditions living in LMICs, concluding that they are cost-effective and can produce a positive impact on clinical outcomes, health-related quality of life [59], and treatment adherence [60]. Increasing evidence suggests that mobile health interventions are a useful tool to address healthcare system constraints in developing countries, namely limited healthcare workforce, limited financial resources, high burden of disease, and difficulties in providing healthcare to hard-to-reach populations [61]. This may partially explain the more positive impact in LMIC observed in our review.

#### Limitations of available evidence and future research needs

The studies in our review consistently supported the use of brief messages to promote healthier lifestyle behavior in patients with type 2 diabetes. However available evidence is

limited by several factors. First, most of the trials presented moderate or high risk of bias, mainly due to small sample sizes and inadequate blinding. To confirm the positive findings observed in our review, methodologically robust trials of greater size are very much needed. Second, although all the interventions specifically aimed to improve lifestyle behavior, behavior change was measured in less than half of the studies. Where measured, a wide range of instruments were used - most of them designed *ad hoc* and not meeting adequate standards for validity or reliability. Third, only a small fraction of trials reported use of explicit behavior change theory. Where it was mentioned, theory was used to design the intervention, but not to examine process measures that might indicate effect, or to refine theory subsequently. There is a current debate about whether or not the evidence base for behavior change interventions can be enhanced by applying relevant theory. It is suggested that doing so may focus attention on the mechanisms by which interventions are effective [62]. Four, interventions used a relatively narrow range of behavior change techniques, focusing on provision of information. Techniques such as those involving goal setting and planning how to enact behavior or elicit social support were seldom considered, despite evidence that such techniques are generally effective at increasing physical activity in people with diabetes or obese people [63, 64].

Additional research needs include to estimate the cost-effectiveness the interventions; examine their long-term impact; understand under what circumstances they work (what features of the underlying health system and target population are helpful, and what features mitigate against them working); assess their safety; and examine their potential contribution to more comprehensive, multifaceted interventions [65].

## Conclusions

Interventions based on the use of automated brief messages sent to mobile devices to promote lifestyle behavior can improve glycemic control in patients with type 2 diabetes both in developed and developing countries. Larger and methodologically robust trials are needed to confirm these positive findings.

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## **CONFLICTS OF INTEREST**

The authors report no conflict of interest.

## **ABBREVIATIONS**

BMI: body mass index

CI: confidence interval

HbA1c: glycated hemoglobin

HIC: high-income country

LMIC: low- and middle-income countries

mHealth: mobile health

RCT: randomized controlled trial

SD: standard deviation

SMS: short message service



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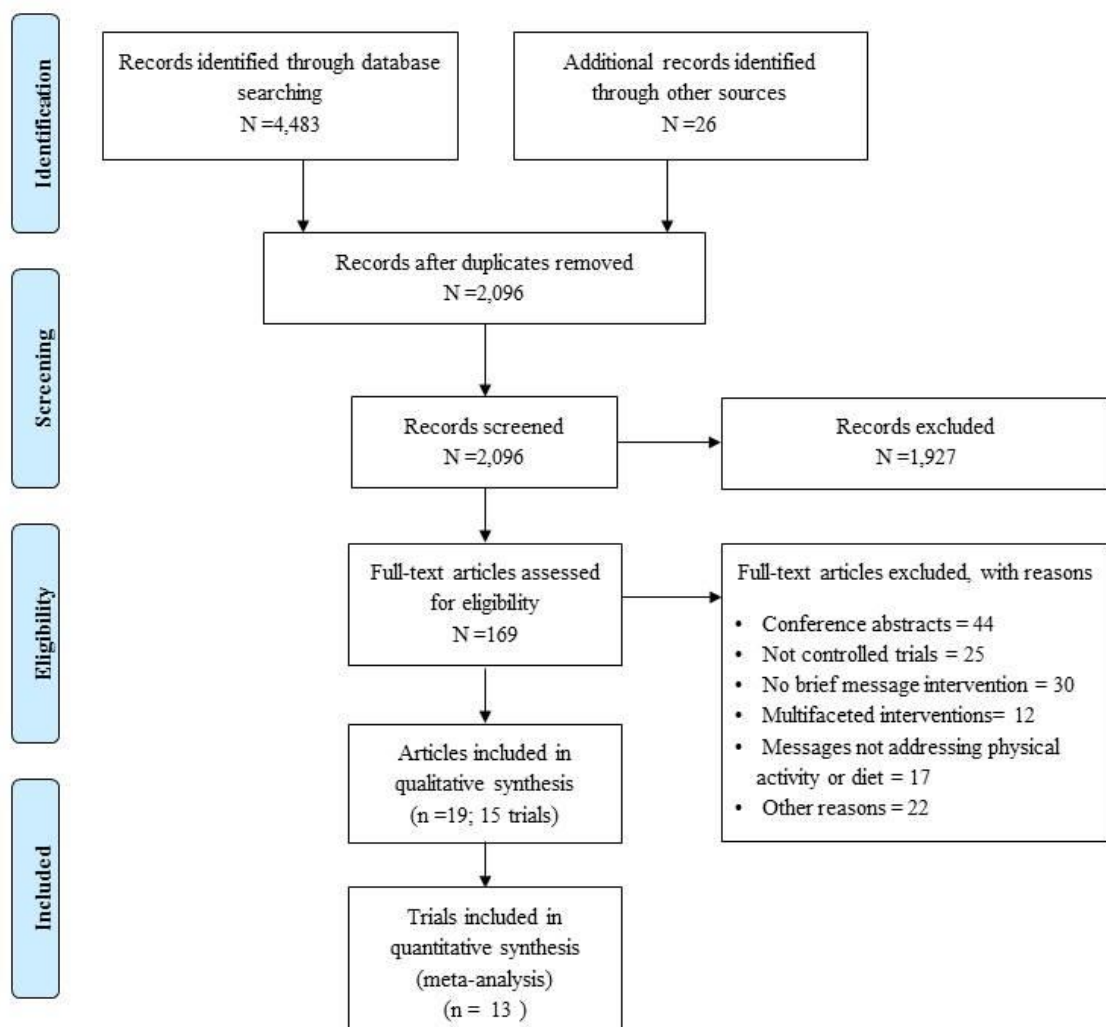
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**Figure 1. Flowchart of articles included at each stage of the screening process**



**Figure 2. Weighted mean difference in size of effect of intervention compared with “no treatment” for glycated hemoglobin.**

HbA1c, glycated hemoglobin; CI, confidence interval; N, number of participants; SD, standard deviation.

