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REVIEW ARTICLE

The Impact of Mobile Monitoring Technologies on Glycosylated Hemoglobin in Diabetes: A Systematic Review

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Abstract

Background:

A new development in the field of telehealth is the use of mobile health technologies (mhealth) to help patients record and track medical information. Mhealth appears particularly advantageous for conditions that require intense and ongoing monitoring, such as diabetes, and where people are of working age and not disabled. This review aims to evaluate the evidence for the effectiveness of mhealth interventions in diabetes management on glycosylated hemoglobin.

Method:

A comprehensive search strategy was developed and applied to eight electronic databases to identify studies that investigated the clinical effectiveness of mobile-based applications that allowed patients to record and send their blood glucose readings to a central server. The eligibility of 8543 papers was assessed against the selection criteria, and 24 papers were reviewed. All studies reviewed were assessed for quality using a standardized quality assessment tool.

Results:

Results for patients with type 1 and type 2 diabetes were examined separately. Study variability and poor reporting made comparison difficult, and most studies had important methodological weaknesses. Evidence on the effectiveness of mhealth interventions for diabetes was inconsistent for both types of diabetes and remains weak.

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Introduction

Telemonitoring refers to the recording and tracking of medical data by patients and health care professionals (HCPs) at a distance. This method of care may be particularly relevant for the management of chronic conditions, such as diabetes, which require intensive daily monitoring and behavioral adjustment. Diabetes self-management includes

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Abbreviations: (BG) blood glucose, (CHO) carbohydrate, (HbA1c) glycosylated hemoglobin, (HCP) health care professional, (RCT) randomized controlled trial, (SMBG) self-monitoring of blood glucose

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self-monitoring of blood glucose (SMBG) readings, taking medication, exercise, dietary management, and foot care. Evidence suggests that SMBG alone may be of limited clinical effectiveness. This may be because patients are unable to interpret results and hence make adjustments to self-care.[1,2] By providing patients with the tools needed to review, interpret data, and receive feedback, telemonitoring could facilitate self-management.

In the past, telemonitoring applications relied on home-based technologies, but with mobile devices, patients can transmit data in real time, at any time and in any place. This also means feedback can be received when it is most relevant. The ubiquitous nature of these wireless technologies is an important development, with potential to impact diabetes management.

A number of systematic reviews have examined the use of telehealth in diabetes, looking at a range of technologies, including fixed and mobile equipment.[3–5] Where reviews focused only on mobile platforms, a variety of interventions were included; for example, interventions aiming to increase peer support, educate, or remind patients of appointments or self-care activities.[6–9] Some reviewed both pediatric and adult samples, despite their differences in the management of diabetes and use of technology. Inclusive reviews are useful to gain a better understanding of ongoing research in the field. When looking at clinical effectiveness, however, reviews that focus on specific interventions or intervention components are needed for conclusions to be precise and reliable.

This review aims to examine the evidence for the clinical effectiveness [glycosylated hemoglobin (HbA1c)] of mobile telemonitoring to support diabetes management in adult patients. It focuses on interventions including the transfer of data to a Web server to receive feedback.

Methods

Search Strategy

Six electronic databases were searched in August 2009, with a subsequent update in January 2012. The search combined diabetes and mobile platform terms: "HbA1c," "metabolic control," "glycemic control," "glycosylated hemoglobin," "glycated hemoglobin," "diabetes complications," "blood glucose," "hypoglycemia," "plasma glucose," "insulin," "mobile phone," "cell phone," "PDA," "personal digital assistant," "personal smart assistant," "pocket computer," "pocket PC," "short message service," "SMS," "text messaging," "wireless," "iPhone," "smartphone," "electronic diary," "real-time," and "pager."

Inclusion and Exclusion Criteria

Studies included for review investigated the clinical effectiveness of interventions requiring patients to transmit blood glucose (BG) readings to an online server via a mobile device. Studies involving an adult population (>18 years) with type 1 or type 2 diabetes were eligible. Glycosylated hemoglobin had to be a clinical outcome. Case studies, papers with simulated HbA1c data, devices designed for use by HCPs, and studies with a sample consisting of more than 20% insulin pump users were excluded. Only English language papers were reviewed.

Data Extraction

A data extraction form was developed, piloted, and used by Justine Baron to extract data. Authors were contacted for clarification when needed.

Quality Assessment

An adapted version of the McMaster University quality assessment tool[10] was used to assess papers. Using the tool and its dictionary, studies were rated as poor, moderate, or strong. Ten areas were covered: selection bias, research objectives, study design, power, blinding, data collection methods, withdrawals and dropouts, intervention integrity, suitability of analyses, and suitability of interpretation of findings. Studies that were not randomized controlled trials (RCTs) or controlled trials were assessed against nine of these areas, as blinding was not relevant. To achieve a "strong" rating, RCTs and controlled trials had to be rated "strong" in at least 6 of the 10 areas and have no areas rated "weak." Other study designs required five or more strong ratings out of nine and no weak ratings.

Results

Study Selection

Paper selection was conducted independently by two of the authors. Disagreements were resolved through discussion until consensus was reached. **Figure 1** illustrates stages of the paper selection process for the 2009 search and 2012 update. Titles and abstracts were screened, leading to the review of a total of 146 full texts. A total of 24 publications matched the selection criteria. Three additional papers[11–13] were used for data extraction purposes; they provided no additional clinical data but further information on the methodology or intervention tested in two of the reviewed studies.

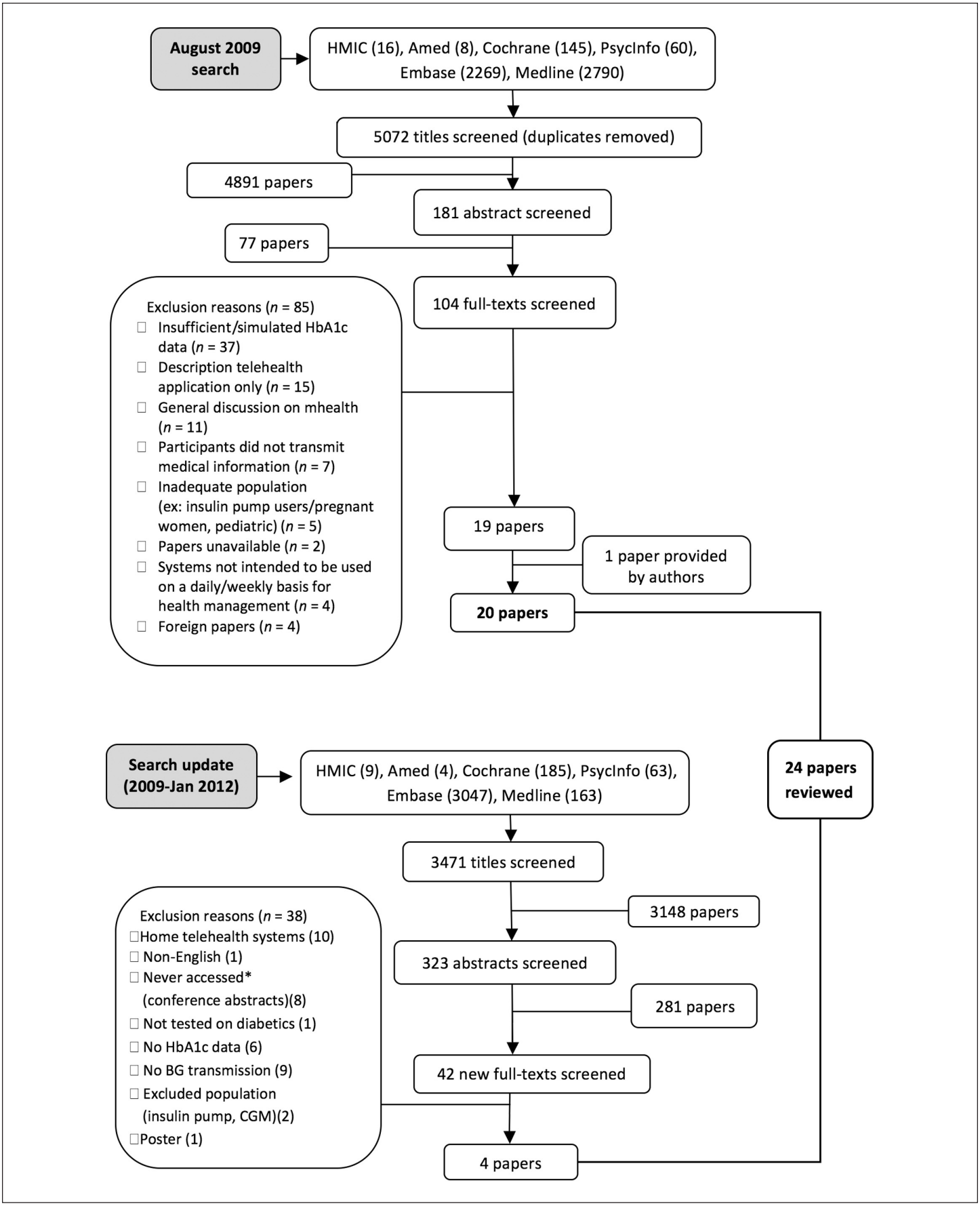

Figure 1. Study selection process for the 2009 search and 2012 update.

The 24 identified publications described 20 studies. Seven papers[14–20] published by the same group of authors evaluated the same intervention with some appearing to describe the same sample. The seven papers were independently examined by two authors and divided into three different studies. One study (2 papers[18,20]) focused on an intervention delivered to obese patients. A second study (4 papers[15–17,19]) evaluated the same intervention in a population not restricted to obese patients. Each of these 4 articles presented different follow-up periods, and 1 paper presented a subgroup analysis based on baseline HbA1c. Finally, a third study (1 paper[14]) used a single group before and after design. In this review, all papers referring to what was defined earlier as one study are grouped.

Description of Included Studies

Papers were published between 2002 and 2011. Studies were conducted in Asia (n = 8), Europe (n = 8), and the United States (n = 3); one was a multinational trial. Seven studies involved a population with type 1 diabetes, 11 with type 2. Two studies included a mixed population,[21,22] but as the percentage with type 1 diabetes was minimal (8% and 16%), they were grouped with studies on type 2 diabetes.

Tables 1 and **2** summarize intervention components. **Tables 3** and **4** summarize study and participant characteristics; they include the quality assessment results. These results suggest that overall quality was poor. Sixteen studies were rated weak, three moderate, and one strong.

Of the 20 studies, 12 were RCTs of which 1 was a four-group cluster RCT, 1 was a controlled trial, 2 were crossover studies, and 5 were single before and after designs. Of the 15 two-group studies, 9 evaluated mhealth compared with standard care and 6 with another intervention. This was either another mhealth intervention, a Web- or fax/phone-based intervention, pedometer monitoring, or diabetes education. A four-group RCT compared both mhealth with standard care and different mhealth groups with varying HCP access to patient data.

The mhealth interventions evaluated were similar across type 1 and type 2 diabetes, with the exception of dietary interventions, which occurred in type 1 diabetes. Three[23–25] of the type 1 diabetes studies had a specific focus on dietary management. The purpose of these

Table 1.
Intervention Components of Studies on Type 1 Diabetes

Reference, first author	Control group	Intervention group				
		Mobile platform	Data inputted	Recommended frequency of data input	Type and nature of feedback	Frequency of HCP feedback
Dietary interventions						
Tsang[23]	Standard care	Personal digital assistant	Meal content BG readings	2x per week	Automated text: CHO daily intake, proteins, calories, fat	Not applicable
Rossi[24]	Standard care (education on CHO counting)	Mobile phone	Meal content BG readings Insulin dose Exercise	2–3x per day	Automated text feedback: CHO daily intake, proteins, calories, fat, suggested insulin dose HCP feedback (behavioral advice)	Not reported
Rossi[25]	Not applicable					
Nondietary interventions						
Gómez[26]	Standard care	Personal digital assistant	BG readings Free text	At least 1x fortnightly	HCP feedback to patients with out-of-range BG readings or queries Graphical feedback for different time periods	24 h
Kollman[27]	Not applicable	Mobile phone	BG readings Medication Exercise Wellbeing	2–4x per day	Color-coded graphical feedback	Not applicable
Farmer[28]	Mobile-phone intervention with minimal feedback (no HCP feedback + non-color-coded graphical feedback for one time period only)	Mobile phone	BG readings Exercise Medication CHO	2–3x per day	HCP feedback and color-coded graphical feedback for different time periods	Fortnightly
Vähätalo[29]	Standard care	Mobile phone	BG readings	Not reported	HCP feedback to all patients whether changes needed to be made to regimen or not	Weekly during first month then biweekly

Table 2.
Intervention Components of Studies on Type 2 Diabetes[a]

Reference, first author	Control group	Intervention group				
		Data inputted	Recommended frequency of data input	Reminders and exclusions	Type and nature of feedback	Frequency of HCP feedback
Cho[30]	Web/personal computer transmission of medical data (BG readings, lifestyle, hypoglycemic events, medication, blood pressure, weight, free text) with HCP and graphical feedback + diabetes education	BG readings	Not reported	Exclusions after 3 weeks of nontransmission	HCP feedback: treatment recommendations, corrections to lifestyle factors, encouragements, reminders[b]	Fortnightly
Faridi[31]	Standard care + pedometer	BG readings	Daily	Not reported	Automated feedback: text message tailored to the BG readings and selected from a bank of predetermined messages	Not applicable
Kim[14]	Not applicable	BG readings, diet, medication, exercise	Daily	Reminders after 1 week of nontransmission Exclusion after nontransmission for 4 weeks	HCP feedback Graphical feedback	Weekly
Kim[16] Kim[17] Hee-Sung[15] Yoon[19]	Standard care	BG readings, CHO, medication, exercise	Daily	Reminders after 1 week of nontransmission, Exclusion after nontransmission for 4 weeks	HCP feedback Graphical feedback	Weekly
Istepanian[21]	Standard care + 2 h diabetes education course	BG readings	Personalized (4–9x/week)	Reminders when personalized monitoring schedule not respected	Automated feedback: letters sent through the post to HCPs and patients with amalgamated readings and treatment recommendations[b]	Not applicable
Kim[18] Kim[20]	Standard care	BG readings Medication, diet, exercise	Daily	Reminders after 1 week of nontransmission Exclusion after nontransmission for 4 weeks	HCP feedback	Weekly
Kwon[22]	Not applicable	BG and blood pressure readings, Weight	Not reported	Not reported	HCP feedback Graphical feedback	Not reported
Quinn[32]	Faxing/phoning in BGs until stable	BG readings, Medication, CHO	Not reported	Not reported	Automated feedback for patients within range BG values HCP feedback for those with troubling BG values	Not reported
Rodríguez-Idígoras[33]	Standard care	BG readings	Not reported	Not reported	HCP feedback to those patients signaled by the system	When signaled
Larsen[34]	Not applicable	BG readings, blood pressure, weight	Not reported	Reminders after 3 days of non-transmission	HCP feedback + graphical feedback	Data reviewed every 2–3 days
Kim[35]	Standard care + 1 h 20 diabetes education	BG readings	3x/week	Exclusion if less than 3 fasting readings in 20 days	Daily automated feedback messages on insulin adjustment[b]	Not applicable

Continued →

Table 2. Continued

Yoo[36]	Standard care	BG and blood pressure readings, weight, and exercise	Daily	Not reported	Automated feedback: text messages to encourage/ remind/motivate	Not reported
Quinn[37]	Standard care	3 active treatment groups transmitted BG and blood pressure readings, weight, medication	Not reported	Not reported	The three treatment groups received automated feedback: action plan to support diabetes self-management sent electronically every 2.5 months HCP feedback	Min. 1x/2–3 months, max. 4x/ month, depending on patient risk status

[a] In all the studies on type 2 diabetes, the mobile platform in the intervention group was a mobile phone.
[b] The intervention group received the same diabetes education as the control group.

Table 3.
Study and Participant Characteristics and Outcomes (Type 1 Studies)

Reference, first author	Design and quality	Research groups	Duration (months)	Recruited/ completed (*n*)	Age mean (standard deviation)	Gender (males, %)	Clinical outcomes (HbA1c)		
							Baseline	% change at last follow-up (except for crossover trials)	
								Baseline to 3 months	3 to 6 months
Tsang[23]	Crossover (pilot)[a]	(1) Standard care then transmission via personal digital assistant versus (2) Transmission via Personal digital assistant then standard care	6 (2x3)	20/19	32.5 ± 8.2	63.2%	(1): 8.76% (2): 8.56%	(1): -0.05% (2): -1.01%[b]	(1): +0.36% (2): +0.29%
Rossi[24]	Multinational RCT[c]	(1) Standard CHO education versus (2) shortened version + Mobile phone transmission	6	130/119	35.7 ± 9.4	43%	(1): 8.4% (2): 8.2%	1: -0.5%[b] 2: -0.4%[b]	
Rossi[25]	Single-group pre and post (pilot)[a]	Mobile phone transmission	9	41/Not reported[d]	31.6 ± 11.9	61%	7.6%	-0.33%	
Gómez[26]	Crossover (pilot)[a]	(1) Standard care followed by transmission via personal digital assistant (2) Transmission via personal digital assistant followed by standard care	12 (2x6)	10/Not reported	Not reported	Not reported	(1) 8.10%[d] for control study (2) 8.4% for mhealth study	(1) 8.15% for control study (2) 7.9% for mhealth study	
Kollman[27]	Single-group pre and post[a]	Mobile phone transmission	3	10/10	36.6 ± 11.0	60%	7.9%	-0.4%[b]	
Farmer[28]	RCT[a]	Mobile phone transmission with (1) nurse + graphical feedback (2) Graphical feedback trial only	9	93/81	23.8 ± 4.2	59.1%	(1): 9.2% (2):9.3%	(1): -0.6%[b] (2): -0.4%[b]	
Vähätalo[29]	Controlled trial (pre and post)[a]	(1) Standard care versus (2) mobile phone transmission	12	203/Not reported	42.9 ± 12.5	55.7%	(1): 7.7% (2): 7.9%	(1): +0.45% (2): +0.35%	

[a] Poor quality rating.
[b] Significant within group difference.
[c] Moderate quality rating.
[d] Pre and post HbA1c values reported are medians. No percentage change presented.

Table 4.
Study and Participant Characteristics and Outcomes (Type 2 Studies)

Reference, first author	Design and quality	Research groups	Duration (months)	Recruited/ completed (*n*)	Age (mean, standard deviation)	Gender (males, %)	Clinical outcomes (HbA1c)	
							Baseline	% change at last follow-up
Cho[30]	RCT[a]	(1) Mobile phone transmission versus (2) Computer/Web-based transmission	3	69/63	48.1 ± 12.5	78.3%	(1): 8.3% (2): 7.6%	(1): -0.7%[b] (2): -1.2%[b]
Faridi[31]	RCT[a]	(1) Standard care + pedometer versus (2) Mobile phone transmission + pedometer	3	30/Not reported	56.45 ± 9.6	36.6%	(1): 6.5% (2): 6.4%	(1): +0.3% (2): -0.1%
Kim[14]	Single-group pre and post[a]	Mobile phone transmission	3	45/33	43.5 ± 12.6	42.4%	8.1%	-1.1%[b]
Kim[16] Kim[17] Hee-Sung[15] Yoon[19]	RCT[c]	(1) Standard care versus (2) Mobile-phone transmission	12	60/51	47.1 ± 8.9	43.1%	(1): 7.59% (2): 8.09%	(1): +0.81% (2): -1.32%[b,d]
Istepanian[21]	RCT[a]	(1) Standard care + 2h diabetes education course versus (2) Mobile phone transmission + 2h diabetes education	9	137/87	58.6 ± 12.5	Not reported	(1): 8.1% (2): 7.9%	(1): +0.1% (2): 0%
Kim[18] Kim[20]	RCT[a]	(1) Standard care versus (2) Mobile phone transmission	12	40/34	46.9 ± 8.6	52.9%	(1): 7.66% (2): 8.16%	(1): +0.53% (2): -1.49%[b,d]
Kwon[22]	Single-group pre and post[a]	Mobile phone transmission	3	185/Not reported	42.4 (4–79)	28.1	7.5%	-0.5%[b]
Quinn[32]	RCT[a]	(1) Faxing/phoning in BGs until stable versus (2) Mobile phone transmission	3	30/26	51.04 ± 11.03	65%	(1): 9.05% (2): 9.51%	(1): -0.68% (2): -2.03%[d]
Rodríguez-Idígoras[33]	RCT[e]	(1) Standard care versus (2) Mobile phone transmission	12	328/297	63.9 ± 0.60	51.5%	(1): 7.41% (2): 7.62%	(1): -0.09% (2): -0.22%[b] At 6 months,[d] not at 12 months
Larsen[34]	Single-group pre and post[a]	Mobile phone transmission	6	23/Not reported	57.6 ± 12	80%	9.5%	-0.66%[b]
Kim[35]	RCT[a]	(1) Standard care + 1 h 20 diabetes education versus (2) Mobile phone transmission + 1 h 20 diabetes education	3	100/92	48.4 ± 7.46	50%	(1): 9.8% (2): 9.8% Overall: 9.8%	(1): -2.0% (2): -2.4%[d] Overall: -2.2%[b]
Yoo[36]	RCT[a]	(1) Standard care versus (2) Mobile phone transmission	3	123/111	58.2 ± 8.73	58.5%	(1): 7.4% (2): 7.6%	(1): +0.29%[b] (2): -0.4%[b]
Quinn[37]	4-group cluster RCT[c]	(1) Standard care versus (2, 3, 4) mobile phone transmission with increasing levels of HCP access to data	12	163/163	52.8 ± 8.66	49.7%	(1): 9.2%[f] (2): 9.3% (3): 9.0% (4): 9.9%	(1): -0.7% (2): -1.6%[d] (3): -1.1% (4): -2.0%[d]

[a] Poor quality rating.
[b] Significant difference within group.
[c] Moderate quality rating.
[d] Significant difference between groups.
[e] Strong quality rating.
[f] Group 1 receiving standard care is the reference group. Between group differences calculated by Quinn in relation to the reference group.

mhealth systems was to provide patients with support in calculating the appropriate insulin dose to match food consumed. Participants were required to transmit information on meal content and received automated feedback on protein, carbohydrate (CHO), calorie, and fat intake. An algorithm-based insulin dose was suggested in two of these studies. Of these, one study investigated whether the use of such a system could reduce the amount of hours usually spent on CHO-counting education; the mhealth group received a shortened version of the standard CHO education and used the device while the control group received the full version.

In the remaining studies on both type 1 and type 2 diabetes, participants transferred a combination of one or more of the following to a Web server: BG readings, blood pressure readings, weight, exercise, diet, medication, free text, and/or their level of wellbeing. Reminders to transmit were part of the intervention protocol in seven studies. Of these, two[27,29] were on type 1 diabetes; in one,[29] patients were reminded to transmit when there were too few readings for clinical judgment, and in another,[27] patients were reminded to transmit if less than three readings were sent daily. In some studies on type 2 diabetes, patients who did not transmit sufficient data were withdrawn.[14–20,30,35]

Health care professional feedback was provided in the majority of studies and included treatment recommendations, encouragements, reminders, advice, and corrections to lifestyle. In some cases, only patients with an out-of-range BG reading or high-risk profiles were contacted, while in others, all participants received feedback regardless of their BG values. Automated feedback was an intervention component in nine studies and was delivered via text message, on an accompanying patient Web portal, or via letter. Graphical feedback was provided in seven studies and was a representation, sometimes color-coded, of BG values over time. This was offered in addition to HCP feedback in five studies. Only one study included both automated text and HCP feedback. It suggests that providing automated text feedback is considered as a good alternative to HCP feedback when resources are limited.

Clinical Effectiveness of Studies on Type 1 Diabetes

For studies evaluating a diet-focused intervention, results were mixed. The single-group trial,[25] which was rated poor quality, failed to find any significant change in HbA1c post-intervention. The sample size remained small (n = 41), making the generalizability of the findings limited, and authors failed to report the number of participants completing the study. In addition, the frequency at which HCPs reviewed patient data and provided feedback was not specified. When the mhealth technology plus a short version of standard CHO education was compared with standard CHO education in the multinational RCT,[24] no difference was found between groups, but significant reductions in HbA1c were observed at 6 months in both groups. Although results are useful in suggesting mhealth could effectively replace part of the standard CHO-counting education, this study was rated of moderate quality. Little detail was provided on the content of the education sessions, which makes it difficult to identify which intervention components are necessary for intervention effectiveness. Authors also failed to report outcome differences between countries, although variations in dietary habits and intervention delivery (despite efforts to standardize) might have influenced results. Finally, the remaining dietary intervention compared twice-weekly transmission of BG and diet information with feedback from a HCP to standard care in a crossover trial.[23] A significant reduction in HbA1c was reported only in the group with a significantly shorter diabetes duration (5.3 versus 11.8 years), suggesting this tool might be particularly useful for patients recently diagnosed. This study, however, was also rated as poor quality. It included only 20 participants, and there was no washout period between study periods to avoid carry-over effects.

Results of studies on non-dietary interventions were inconclusive with two[27,28] of the four studies supporting the effectiveness of mhealth. Monitoring patients via mhealth led to significant improvements in HbA1c after 3 months in a before-and-after study[27] involving submission of data via mobile phone and access to graphics via a Web portal. Participants were sent a reminder to transfer every day on which less than three BG readings had been transmitted. This particularly intensive protocol for reminders may have ensured high use of the equipment and contributed to success of the intervention. This study, however, was rated poor in quality, a sample size of 10 being the major issue. A RCT[28] comparing mhealth with either intensive graphical feedback and nurse support or minimal graphical feedback only found significant improvements in HbA1c in both groups at months 4 and 9. This suggests that significant changes can occur regardless of the intensity of the graphical feedback provided and that HCP input may not be an essential ingredient to intervention success. Although the study had a larger sample size than many of the studies reviewed, it was slightly below the

number of participants required for adequate power. Authors also failed to report if outcome assessors were blinded. Interestingly, the response rate in this study was relatively low (52%) despite recruiting an age group (18–30 years) that may be keen to use technology. Finally, no significant clinical changes were observed in the two remaining studies examining transfer of BG readings via personal digital assistant and mobile phone plus HCP and graphical feedback.[26,29] Unlike the majority of studies reviewed, patients were limited to transferring BG readings only in these two studies. Asking patients to transfer more information may increase awareness and understanding of the relationship between BG readings and lifestyle factors, making it possible for patients to act upon them in an effective way. In addition, Gómez and colleagues[26] asked patients to transmit BG readings fortnightly, which is considerably less frequent than other studies. Research regarding optimal transmission frequency is, however, lacking. In terms of methodological quality, intervention participants in the study by Vähätalo and associates[29] received twice as many testing strips as control participants, thus enabling increased monitoring and thereby introducing bias. In addition, the trend toward HbA1c deterioration in both groups was linked to the calibration differences between the machines used to test HbA1c. This suggests lack of methodological rigor in the conduct of the study, potentially biasing results.

Clinical Effectiveness of Studies on Type 2 Diabetes

In the studies published by the same group of authors, the intervention included transmission of BG readings by mobile phone and weekly text message recommendations. In the 12-week program using a single-group design,[14] a significant pre-to-post reduction in HbA1c was found. Although the reduction from baseline to follow-up was clinically significant (1.1%), the sample size was small. With 26% (n = 12) of the sample excluded from the analysis, it would have been particularly relevant to investigate differences between patients who did not engage with the equipment or dropped out and those who completed the research. However, such analyses were not reported by the authors, nor were reasons for nontransmission of patient data. When applied to patients with a body mass index >23,[18,20] this intervention led to a significant improvement in HbA1c in the intervention group compared with the control group. Following a group of participants longitudinally,[15–17,19] significant differences between the intervention and control groups were found at 3, 9, and 12 months. In a subgroup analysis,[15] significant improvements in HbA1c were observed at 3 months for intervention group participants with a baseline HbA1c of ≥7% but not for the control group participants with the same baseline HbA1c. As might have been expected, however, no significant improvement was noted in intervention group participants already well controlled at baseline (HbA1c <7%). In fact, these participants maintained good glycemic control, whereas participants in the control group starting the study with a HbA1c of <7% deteriorated significantly. These results suggest that mhealth is effective for people with poorly controlled diabetes while also being more effective than standard care in helping people with well-controlled diabetes maintain glycemic control.

Of the 10 remaining studies, 7 found mhealth to be significantly more effective than other telehealth interventions and standard care. Two single-group studies[22,34] led to similar and significant improvements in HbA1c at 3 and 6 months, particularly so for those with a baseline HbA1c of ≥7.0%.[31] In a trial[35] evaluating a system that provided patients with an insulin dose adjustment based on fasting BG readings, overall, a clinically significant reduction in HbA1c was observed, but the reduction was significantly greater in the intervention group. Three RCTs[32,33,36] found significant reductions in HbA1c for the mhealth group. One compared the mhealth intervention to a fax- or telephone-based intervention.[32] In this study, however, the control group phoned or faxed in their BG readings fortnightly until these were stable. It was unclear whether HCP feedback was provided to this group, and no criteria defined a stable BG readings pattern. The two other RCTs[33,36] compared mhealth with standard care. In one of them,[33] improvements were significant at 6 months but were not at 12 months, therefore suggesting only short-term effectiveness. Finally, the four-group RCT[37] found significantly greater reductions in HbA1c at 12 months in two of the three active treatment groups compared with the control group after controlling for baseline HbA1c. Unlike Rodríguez-Idígoras and coworkers,[33] these between-group differences were still significant at 12 months. Interestingly, there were no significant differences between the three active treatment groups, although these differed in the level of access HCPs had to patient data. Similar to Farmer and colleagues,[28] in type 1 diabetes, it appears the key and active driver to success may be the transmission of patient data, regardless of whether those data are reviewed by HCPs or used to provide feedback.

The remaining three[21,30,31] RCT studies failed to find mhealth to be more effective than standard care or other telehealth interventions. These included mhealth

and pedometer monitoring compared with standard care with pedometer monitoring,[31] HCP feedback via letter including amalgamated readings and treatment recommendations to standard care,[21] and a computer versus mhealth intervention.[30] For Faridi and associates,[31] this is unsurprising considering the low levels of adherence to protocol among 15 intervention group patients. Only 2 patients were completely adherent and transmitted readings daily, while 9 patients were found to either transmit only for a week (n = 4) or not at all (n = 5) and the remaining four only for 1–2 months out of 3. Important methodological issues led to this study being rated as poor. For example, the control group wore pedometers as part of the objective assessment of physical activity. Although this was not intended as an intervention, reviewing daily step counts could have influenced participants' levels of exercise and biased results. Istepanian and coworkers[21] found mhealth to be ineffective in reducing HbA1c with patients receiving feedback in a letter format. Unfortunately, authors did not report the frequency at which letters were sent to patients or the type of treatment recommendations made. The immediacy of feedback displayed via mobile platforms as a result of data transmission may be more likely to facilitate data interpretation and promote active and prompt reactions to physiological states. The third RCT[30] did find significant improvements in HbA1c for both mhealth and a computer-based Web monitoring intervention; however, differences between groups were not significant. Both groups improved significantly and similarly despite the computer group being able to transfer considerably more diabetes-related information than the mobile phone group. The portability of the device, which may act as a reminder and prompt to self-care, may therefore be as effective as being able to provide more information. The behavioral mechanisms involved in fixed and mobile technology may differ and require further examination.

Discussion

This systematic review summarizes the evidence base for the clinical effectiveness of mhealth interventions in which patients transmit diabetes-related information to receive automated text, graphical, and/or HCP feedback. Systematic searching found 13 studies on type 2 diabetes and 7 on type 1 diabetes. None of the studies reviewed found mhealth to be harmful. Overall, the findings from the studies reviewed are somewhat mixed but do appear to be more consistently positive for studies in type 2 diabetes as was reported by Azar and Gabbay.[38] Ten of the 13 studies in type 2 diabetes and 4 of 7 studies on type 1 diabetes found mhealth to lead to benefits. Studies without HCP feedback led to improved HbA1c, suggesting HCP feedback might not be necessary for intervention success. The recording and tracking of data could be the key factor for increasing patients' awareness, understanding, and motivation to self-manage. Knowledge that the data are accessible to HCPs may also be an incentive to adhere to a regimen. The graphical and automated text feedback might also be an effective incentive to engage patients. It may help patients identify relationships between their lifestyle and BG patterns. Future research needs to determine which patients benefit most from HCP feedback and which patient characteristics predict intervention effectiveness. This will guide future mhealth deployment tactics and increase cost-effectiveness.

The methodological quality of the reviewed studies was poor, with many involving small sample sizes, no power calculations, and poor study designs. Many studies excluded patients who failed to engage with the devices from the analysis; this implies they assessed intervention efficacy and not effectiveness. If a "per-protocol analysis" rather than an intention-to-treat analysis is presented, as might be the case especially with studies with smaller sample sizes, this should be supplemented by an analysis of differences between completers and those who dropped out or were withdrawn along with a discussion on the possible implications and effects of the missing participants. Some of these criticisms reflect the observations made by Whitten and colleagues[39] in their review of the methodology adopted in telehealth research In addition, poor reporting in these studies made interpretations difficult; additional papers, Web pages, or diagrams should be made available to ensure transparency. The CONSORT-eHealth guidelines[40] for the reporting of telehealth interventions are available for researchers to use.

Finally, the costs incurred in the delivery and running of these telemonitoring interventions was not discussed in this review. Without this information, it remains impossible to know whether implementing such services is cost-effective.

This systematic review has limitations. It does not consider research exclusively on specific subgroups such as pregnant women or insulin pump users. Non-English language papers were not reviewed, and a publication bias could have occurred since grey literature was not searched.

In view of the considerations raised earlier and their implications on the interpretation of study results, this review cannot reliably conclude on the clinical effectiveness of mhealth interventions for diabetes management. Results do show potential for beneficial change, but higher-quality studies with better standard of reporting are urgently needed and will provide a strong evidence base for policy makers.

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