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The impact of mobile monitoring technologies on HbA1c in diabetes: a systematic review

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Abbreviations: (BG) blood glucose, (BMI) Body Mass Index, BP (blood pressure), Carbohydrate (CHO), (HbA1c) glycosylated haemoglobin, HCP (health care professional), PC (personal computer), (PDA) personal digital assistant, (RCT) randomized controlled trial.

Keywords: diabetes, glycaemic control, mobile health, monitoring, self-management

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Abstract

Background: A new development in the field of telehealth is the use of mobile health technologies (mhealth) to assist patients in the recording and tracking of 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 haemoglobin (HbA1c).

Methods: A comprehensive search strategy was developed and applied to eight electronic databases to identify studies investigating the clinical effectiveness of mobile-based applications allowing 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.

Introduction

Telemonitoring refers to the recording and tracking of medical data by patients and health care professionals (HCPs) at a distance. For the management of chronic conditions such as diabetes that require intensive daily monitoring and behavioural adjustment, this method of care may be particularly relevant. Diabetes self-management includes self-monitoring of blood glucose (SMBG) readings, medication taking, exercise, dietary management, and foot care. Evidence suggests 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.

Until recently, 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 upon 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 equipment³⁻⁵. Where reviews focused only on mobile

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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^{6,7,8,9}. Some reviewed both paediatric 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 reviews aims to examine the evidence for the clinical effectiveness (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, mobile platform terms: "HbA1c", "metabolic control", "glycaemic control", "glycosylated haemoglobin", "glycated haemoglobin", "diabetes complications", "blood glucose", "hypoglycaemia", "plasma glucose", "insulin", "mobile phone", "cell phone", "PDA", "personal digital assistant", "personal smart assistant", "pocket computer",

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“pocket PC”, “short message service”, “SMS”, “text messaging”, “wireless”, “iphone”, “smartphone”, “electronic diary”, “real-time”, “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 haemoglobin (HbA1c) 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 to extract data by JB. Authors were contacted for clarification when needed.

Quality assessment

An adapted version of the McMaster University quality assessment tool¹⁰ 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,

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blinding, data collection methods, withdrawals and dropouts, intervention integrity, suitability of analyses and of interpretation of findings. Studies that were not 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 six of the ten 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 papers¹¹⁻¹³ were used for data extraction purposes; they provided no additional clinical data but further information on the methodology or intervention tested in 2 of the reviewed studies.

The 24 identified publications described 20 studies. Seven papers¹⁵⁻²¹ published by the same group of authors evaluated the same intervention with some appearing to describe the same sample. The 7

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papers were independently examined by two authors and divided into three different studies. One (2 papers^{19,21}) focused on an intervention delivered to obese patients. A second (4 papers^{16-18,20}) evaluated the same intervention in a population not restricted to obese patients. Each of these four articles presented different follow-up periods and one paper presented a subgroup analysis based on baseline HbA1c. Finally, a third study (1 paper¹⁵) used a single group before and after design. In this review, all papers referring to what was defined above 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 US (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, but as the percentage with type 1 was minimal (8% and 16%) they were grouped with studies on type 2.

Table 1 and table 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.

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Of the 20 studies 12 were randomized controlled trials (RCT) of which one 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, nine evaluated mhealth compared to standard care, and six with another intervention. This was either another mhealth intervention, a web, or a fax/phone based intervention, pedometer monitoring or diabetes education. The four group RCT compared both mhealth to 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. Three of the type 1 diabetes studies had a specific focus on dietary management. The purpose of these 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 proteins, carbohydrates (CHO), calories 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 whilst the control group received the full version.

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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 well-being. Reminders to transmit were part of the intervention protocol in seven studies. Of these two²⁵ were on type 2 diabetes; in one²⁵ patients were reminded to transmit when there were too few readings for clinical judgement, and in another if less than three readings were sent daily (REF Kollman). In some studies patients who did not transmit sufficient data were withdrawn(ref).

HCP 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, whilst 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 colour-coded, of BG values over time. This was offered in addition to HCP feedback in 5 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.

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Clinical effectiveness of studies on type 1 diabetes

For studies evaluating a diet focused intervention results were mixed. The single group trial²⁷ 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 to standard CHO education in the multinational RCT²⁸ 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 trial²⁹. A significant reduction in HbA1c was reported only in the group with a significantly shorter diabetes

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duration (5.3 years versus 11.8), 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 2^{22,30} of the 4 studies supporting the effectiveness of mhealth.

Monitoring patients via mhealth led to significant improvements in HbA1c after 3 months in a before and after study²² involving submission of data via mobile phone and access to graphics via a web portal. Participants were expected to transmit data at least 3 times daily; the inclusion criteria however did not require patients to have this monitoring pattern at the time of enrolment. Hence, improvements in HbA1c may be the result of changes in self-monitoring patterns. A RCT³⁰ comparing mhealth with either intensive graphical feedback and nurse support or minimal graphical feedback only, found significant improvements in HbA1c in both groups at 4 and 9 months. This suggests significant changes can occur regardless of the intensity of the graphical feedback provided and 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

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an age group (18-30 years) who maybe keen to use technology.

Finally, no significant clinical changes were observed in the two remaining studies examining transfer of BG readings via PDA and mobile-phone plus HCP and graphical feedback^{25,31}. 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 Gomez and colleagues (2002) 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 Vahatelo et al (2004) received twice as many testing strips as control participants; this enabling increased monitoring and thereby introducing bias. In addition the trend towards HbA1c deterioration in both groups was linked to the calibration differences between the machines used to test HbA1c. This suggests lack of methodological rigour 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

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a single group design¹⁵ 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 non-transmission of patient data. When applied to patients with a BMI >23^{19,21} this intervention led to a significant improvement in HbA1c in the intervention group compared to the control group. Following a group of participants longitudinally^{16-18,20} significant differences between the intervention and control groups were found at 3, 9 and 12 months. In a sub-group analysis¹⁶ significant improvements in HbA1c were observed at 3 months for intervention group participants with a baseline HbA1c of $\geq 7\%$ but not for the control group participants with the same baseline HbA1c. As might have been expected however, no significant improvement was noted in those already well controlled (HbA1c < 7%). In fact these participants maintained good glycaemic control, whereas participants in the control group starting the study with a HbA1c of < 7% deteriorated significantly. These results suggest mhealth is effective for people with poorly controlled diabetes, whilst also being more effective than standard care in helping people with well controlled diabetes maintain glycaemic control.

Of the 10 remaining studies seven found mhealth to be significantly more effective than other telehealth interventions and standard care. Two single group studies^{14,37} led to similar and significant improvements in HbA1c at 3 and 6 months, particularly so for those with a baseline HbA1c of $\geq 7.0\%$ ³⁷. In a trial²⁶ 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. Two RCTs³³⁻³⁵ found significant reductions in HbA1c for the mhealth group. One compared the mhealth intervention to a fax or telephone based intervention. 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 other RCT compared mhealth to standard care³³. Improvements were significant at six months, but were not at 12 months. therefore, suggesting only short term effectiveness.. Finally, the 4 group RCT³⁶ found significantly greater reductions in HbA1c at 12 months in 2 of the 3 active treatment groups compared to the control group after controlling for baseline HbA1c. Unlike Rodriguez-Idigoras et al (2009) 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 (2005) in type 1 diabetes, it appears the key and active driver to success may

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be the transmission of patient data, regardless of whether that data is reviewed by HCPs or used to provide feedback.

The remaining 3^{23,24,32} RCT studies failed to find mhealth to be more effective than standard care or other telehealth interventions.

These included mhealth and pedometer monitoring compared to standard care with pedometer monitoring³², HCP feedback via letter including amalgamated readings and treatment recommendations to standard care²⁴, and a computer versus a mhealth intervention²³. For Faridi et al (2008)³², this is unsurprising considering the low levels of adherence to protocol amongst 15 intervention group patients. Only 2 patients were completely adherent and transmitted readings daily, whilst 9 patients were found to either transmit only for a week (n=4) or not at all (n=5) and the remaining 4 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 colleagues²⁴ 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

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and promote active and prompt reactions to physiological states. The third RCT²³ 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 behavioural 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 colleagues³⁹. Ten of the thirteen studies in type 2 diabetes and four of seven studies on type 1 found mhealth to lead to benefits. Studies without HCP feedback led to improved HbA1c, suggesting HCP feedback might not

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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 is 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 that dropouts 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 in their review of the methodology adopted in telehealth research⁴⁰. In addition, poor reporting in these studies made interpretations difficult; additional

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paper, web pages, or diagrams should be made available to ensure transparency.

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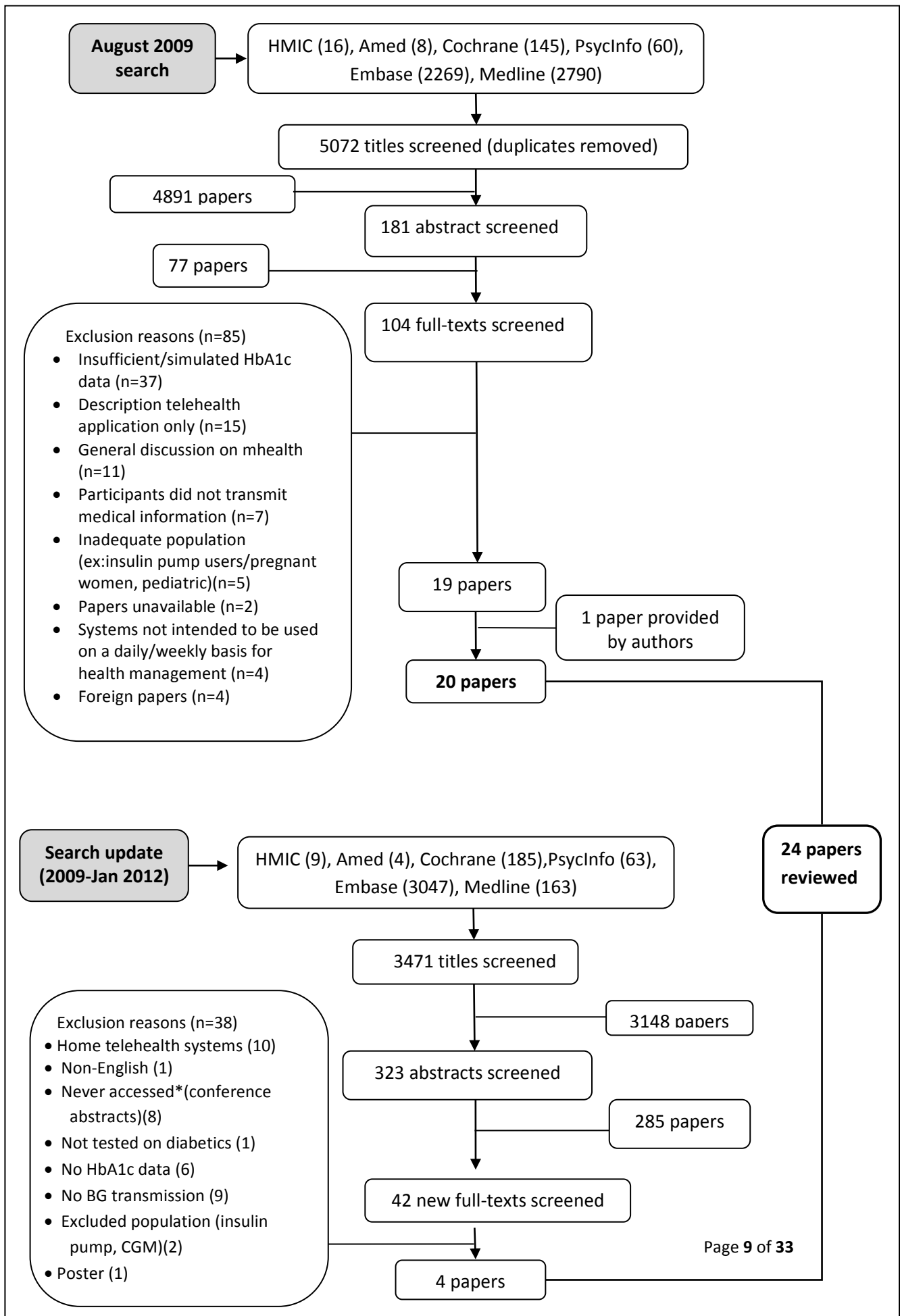
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Figure 1. Study selection process for the 2009 search and 2012 update



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Table 1. Intervention components of studies on type 1 diabetes

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 ²²	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

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 ²⁰	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	Forthnightly
Farid ²¹	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 (4-6x/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 ²²	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
Rodriguez-Idgoras ²²	Standard care	BG readings	Not reported	Not reported	HCP feedback to those patients signaled by the system	When signaled
Larsen ²⁴	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 ²⁵	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

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Table 2. Continued						
Yoo ²⁶	Standard care	BG and blood pressure readings, weight, and exercise	Daily	Not reported	Automated feedback: text messages to encourage/ remind/motivate	Not reported
Quinn ²⁷	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 2.6 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.						

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Table 3. Study and participant characteristics (type 1 studies)

Papers	Design and Quality	Groups compared	Duration (months)	Recruited/ Completed (n=)	Age Mean (SD)	Gender (males, %)	Clinical outcomes (HbA1c)	
							Baseline	% change at last follow-up
Tsang et al,2001 ²⁹	Cross-over (pilot)*	(1)Standard care then PDA transmission (2) PDA transmission then standard care	6 2x3	20/19	32.5 ±8.2	63.2%	(1): 8.76% (2): 8.56%	(1): -0.36% (2): -1.01%†
Rossi et al,2010 ²⁸	Multinational RCT**	(1) Standard CHO education versus shortened version + (2)mobile phone transmission	6	130/119	35.7 ±9.4	43%	(1): 8.4% (2): 8.2%	1: -0.5%† 2: -0.4%†
Rossi et al,2009 ²⁷	Single group pre and post (pilot)*	NA	9	41/NR	31.6 ±11.9	61%	7.6%	-0.33%
Gomez et al,2002 ³¹	Cross-over (pilot)*	Standard care versus transmission via PDA	12 2x6	10/NR	NR	NR	8.10% (median) for control study 8.4% (median) for mhealth study	8.15% (median) for control study 7.9% for mhealth study
Kollman et al,2007 ²²	Single group pre and post*	NA	3	10/10	36.6 ±11.0	60%	7.9%	-0.4%†
Farmer et al,2005 ³⁰	RCT*	(1) Mobile-phone transmission with nurse+ (2) graphical feedback versus graphical only	9	93/81	23.8 ±4.2	59.1%	(1): 9.2% (2):9.3%	(1): -0.6%† (2): -0.4%†
Vähätalo et al,2004 ²⁵	Controlled (pre and post)*	(1) Standard care versus (2) mobile-phone transmission	12	203/NR	42.9 ±12.5	55.7%	(1): 7.7% (2):7.9%	(1):+0.45% (2):+0.35%

Table 4. Study and participant characteristics (type 2 studies)

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 ²⁰	RCT ^a	(1) Mobile phone transmission versus (2) Computer/Web-based transmission	3	69/63	48.1 ± 12.6	78.3%	(1): 8.3% (2): 7.6%	(1): -0.7% ^b (2): -1.2% ^b
Farid ²¹	RCT ^a	(1) Standard care + pedometer versus (2) Mobile phone transmission + pedometer	3	30/Not reported	68.46 ± 9.8	38.6%	(1): 8.6% (2): 8.4%	(1): +0.3% (2): -0.1%
Kim ¹⁴	Single-group pre and post ^a	Mobile phone transmission	3	46/33	43.6 ± 12.8	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	60/61	47.1 ± 8.9	43.1%	(1): 7.69% (2): 8.09%	(1): +0.81% (2): -1.32% ^{b,d}
Istapanlian ²¹	RCT ^a	(1) Standard care + 2h diabetes education course versus (2) Mobile phone transmission + 2h diabetes education	9	137/87	68.8 ± 12.6	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	48.9 ± 8.8	62.9%	(1): 7.88% (2): 8.18%	(1): +0.63% (2): -1.49% ^{b,d}
Kwon ²²	Single-group pre and post ^a	Mobile phone transmission	3	156/Not reported	42.4 (4-79)	28.1	7.6%	-0.6% ^b
Quinn ²²	RCT ^a	(1) Faxing/phonng in BGs until stable versus (2) Mobile phone transmission	3	30/28	61.04 ± 11.03	66%	(1): 9.06% (2): 9.61%	(1): -0.88% (2): -2.03% ^d
Rodriguez-Irigoras ²³	RCT ^c	(1) Standard care versus (2) Mobile phone transmission	12	328/297	63.9 ± 0.80	61.6%	(1): 7.41% (2): 7.62%	(1): -0.09% (2): -0.22% ^b At 6 months, ^d not at 12 months
Larsen ²⁴	Single-group pre and post ^a	Mobile phone transmission	6	23/Not reported	67.8 ± 12	80%	9.6%	-0.68% ^b
Kim ²⁵	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 ± 7.48	60%	(1): 9.8% (2): 9.8% Overall: 9.8%	(1): -2.0% (2): -2.4% ^d Overall: -2.2% ^b
Yoo ²⁶	RCT ^a	(1) Standard care versus (2) Mobile phone transmission	3	123/111	68.2 ± 8.73	68.6%	(1): 7.4% (2): 7.8%	(1): +0.29% ^b (2): -0.4% ^b
Quinn ²⁷	4-group cluster RCT ^b	(1) Standard care versus (2, 3, 4) mobile phone transmission with increasing levels of HCP access to data	12	183/183	62.8 ± 8.88	49.7%	(1): 9.2% ^f (2): 9.3% (3): 9.0% (4): 9.6%	(1): -0.7% (2): -1.8% ^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.