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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, selfmanagement

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Figures and tables: 1 figure, 2 tables

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 realtime, 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 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^{6,7,8,9}. 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",

"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,

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

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.

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.

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.

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 guality 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

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 ifoutcome assessors wereblinded. Interestingly the response rate in this study was relatively low (52%) despite recruiting

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

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 longitudinally¹⁶ ^{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

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 colleagues ²⁴ 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 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

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

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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Disclosures: None

References

1.Davidson MB. Counterpoint: Self-monitoring of blood glucose in type 2 diabetic patients not receiving insulin: a waste of money, Diabetes Care, 2005, 28(6): 1531-1533.

2.Clar C, Barnard K, Cummins E, Royle P, Waugh N. Self-monitoring of blood glucose in type 2 diabetes: systematic review, Health Technol Assess, 2010, 14 (12): 42-43.

3.Montori VM, Helgemoe PK, Guyatt GH, Dead DS, Leung TW, Smith SA, et al. Telecare for patients with type 1 diabetes and inadequate glycaemic control, A randomized controlled trial and meta-analysis, Diabetes Care, 2004, 27(5): 1088-1094.

4. Farmer AJ, Gibson O, Tarassenko PM. A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes, Diabet Med, 2005, 22 (10): 1372-1378.

5.Krishna S, Boren AS. Diabetes self-management care via cell phone: a systematic review, J Diabetes Sci Technol, 2008, 2 (3): 509-517.

6.Russell-Minda E, Jutai J, Speechley M, Bradley K, Chudyk A, Petrella
R. Health technologies for monitoring and managing diabetes: a
systematic review, J Diabetes Sci Technol , 2009, 3 (6): 1460-1467.

7.Tatara N, Arsand E, Nilsen H, Hartvigsen G. A review of mobile terminal-based applications for self- management of patients with diabetes, Proceedings of the International Conference on eHealth, Telemedicine, and Social Medicine, 2009 Feb 1-7, Cancun, Mexico. IEEE Computer Society.

8.Liang X, Yang X, Cao J, Mo X, Huang J, Wang L, et al. Effect of mobile phone intervention for diabetes on glycaemic control: a metaanalysis, Diabet Med, 2011, 28 (4): 455-463.

 9. Holtz B and Lauckner C, Diabetes management via mobile phones: a systematic review, [published online ahead of print February 22nd
 2012], Telemed J E Health, 2012, 18 (3).

10. Effective Public Health Practice Project (1998), Quality Assessment Tool For Quantitative Studies, Available from *http://www.ephpp.ca/tools.html*, last accessed 18 January 2012.

11. Istepanian RSH et Sungoor A, Earle KA. Technical and compliance considerations for mobile health self-monitoring of glucose and blood pressure for patients with diabetes, Conf Proc IEEE Eng Med Biol Soc. 2009:5130-3.

12. Earle et al, Mobile telemonitoring for achieving tighter targets of blood pressure control in patients with complicated diabetes: a pilot study, 2010. Diabetes Technol Ther, vol 12(7).

13. Quinn CC, Gruber Baldini AL, Shardell M, Weed K, Clough SS, Peeples M, et al. Mobile diabetes intervention study: testing a personalized treatment/behavioural communication intervention for blood glucose control, 2009. Contemp Clin Trials, 30 (4), 334-346.

14.Larsen ME, Turner J, Farmer A, Neil A, Tarassenko L. Telemedicine-supported insulin optimisation in primary care, J Telemed Telecare, 2010, 16 (8): 433-440.

15.Kim HS, Kim NC, Ahn SH. Impact of a nurse short message service intervention for patients with diabetes, J Nurs Care Qual, 2006, 21 (3): 266- 271.

 Hee-Sung K. Impact of Web-based nurse's education on glycosylated haemoglobin in type 2 diabetic patients, J Clin Nurs, 2007, 16 (7): 1361-1366.

17. Kim HS. A randomized controlled trial of a nurse short-message service by cellular phone for people with diabetes, Int J Nurs Stud, 2007, 44 (5): 687-692.

18.Kim HS, Jeong HS. A nurse short message service by cellularphone in type-2 diabetic patients for six months, J Clin Nurs, 2007, 16(6): 1082-1087.

19.Kim HS, Song MS, Technological intervention for obese patients with type 2 diabetes, Appl Nurs Res, 2008, 21 (2): 84-89.

20.Yoon KH, Kim HS, A short message service by cellular phone in type 2 diabetic patients for 12 months, Diabetes Res Clin Pract, 2008, 79 (2): 256-261.

21.Kim SI, Kim HS, Effectiveness of mobile and internet intervention in patients with obese type 2 diabetes, Int J Med Inform, 2008, 77 (6): 399-404.

22.Kollmann A, Riedl M, Kastner P, Schreier G, Ludvik B. Feasibility of a mobile phone-based data service for functional insulin treatment of type 1 diabetes mellitus patients, J Med Internet Res, 2007, 9 (5): e36.

23.Cho JH, Lee HC, Lim DJ, Kwon HS, Yoon KH, Mobile communication using a mobile phone with a glucometer for glucose control in Type 2 patients with diabetes: as effective as an Internetbased glucose monitoring system, J Telemed Telecare, 2009, 15 (2): 77-82.

24.Istepanian RS, Zitouni K, Harry D, Moutosammy N, Sungoor A, Tang B, Earle KA, Evaluation of a mobile phone telemonitoring system for glycemic control in patients with diabetes. J Telemed Telecare, 2009, 15 (3): 125-128.

25.Vähätalo MA, Virtamo HE, Viikari JS, Rönnemaa T. Cellular phone transferred self blood glucose monitoring: Prerequisites for positive outcome, Practical Diabetes Int, 2004, 21 (5): 192-194

26.Kim CS, Park SY, Kang JG, Seong JL, Sung HI, Moon GH, et al. Insulin Dose Titration System in diabetes Patients Using a short message service automatically produced by a knowledge matrix, Diabetes Technol Ther, 2010, 12 (8): 663-669.

27. Rossi MCE, Nicolucci A, Pellegrini F, Bruttomesso D, Bartolo PD, Marelli G, et al. Interactive diary for diabetes: A useful and easy-touse new telemedicine system to support the decision-making process in type 1 diabetes, Diabetes Technol Ther, 2009, 11 (1), 19-24.

28. Rossi MC, Nicolucci A, Di Bartolo P, Bruttomesso D, Girelli A, Ampudia FJ, Kerr D, et al. « Diabetes Interactive Diary » (DID): a new telemedicine system enabling flexible diet and insulin therapy while improving the quality of life: an open label, international, multicentre, randomized study, Diabetes Care, 2010, 33 (1): 109-115. 29.Tsang MW, Mok M, Kam G, Jung M, Tang A, Chan U, Chu CM, et al. Improvement in diabetes control with a monitoring system based on a hand-held, touch-screen electronic diary, J Telemed Telecare, 2001, 7 (1): 47-50.

30. Farmer AJ, Gibson OJ, Dudley C, Bryden K, Hayton PM, Tarassenko L, et al. A randomized controlled trial of the effect of realtime telemedicine support on glycemic control in young adults with type 1 diabetes, 2005, Diabetes Care, 28 (11): 2697-2702.

31.Gomez EJ, Hernando ME, Garcia A, Del Pozo F, Cermeno J, Corcoy R, et al. Telemedicine as a tool for intensive management of diabetes: The DIABTel experience, 2002, Comput Methods Programs Biomed, 2002, 69 (2): 163-177.

32.Faridi Z, Liberti L, Shival K, Northrup V, Ali A, Katz D, Evaluating the impact of mobile telephone technology on type 2 diabetic patients' self-management: the NICHE pilot study, J Eval Clin Pract, 2008, 14 (3): 465-469.

33.Quinn CC, Clough SS, Minor JM, Lender D, Okafor MC, Gruber-Baldini A, WellDoc mobile diabetes management randomized controlled trial: change in clinical and behavioral outcomes and patient

and physician satisfaction, Diabetes Technol Ther, 2008, 10 (3): 160-168.

34.Rodríguez-Idígoras MI, Sepúlveda-Muñoz J, Sánchez-Garrido-Escudero R, Martínez-González JL, Escolar-Castelló JL, Paniagua-Gómez IM, et al. Telemedicine influence on the follow-up of type 2 diabetes patients, Diabetes Technol Ther, 2009, 11 (7): 431-437.

35.Yoo HJ, Kim TN, Yang SJ, Cho GJ, Hwang TG, et al. A ubiquitous chronic disease care system using cellular phones and the internet, 2009, Diabet Med, vol 26: 628-635.

36. Quinn CC, Shardell M, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioural intervention for blood glucose control, 2011, Diabetes Care, 34 (9): 1934-1942.

37.Kwon HS, Cho JH, Kim HS, Lee JH, Song BR, Oh JA, et al.
Development of web-based diabetic patient management system
using short message service (SMS), Diabetes Res Clin Pract, 2004,
66 (Suppl 1): 133-137.

38. Azar M, Gabbay R., Web-based management of diabetes through glucose uploads: Has the time come for telemedicine?, Diabetes Research and Clinical Practice, 2009, 83 (1): 9-17.

40.Whitten P, Johannessen LK, Soerensen T, Gammon D, Mackert M,

A systematic review of research methodology in telemedicine studies, J

Telemed Telecare, 2007, 13 (5): 230-235

41.Kerkenbush JL, Lasome CEM, The Emerging Role of Electronic

Diaries in the Management of Diabetes Mellitus, AACN Clinical Issues,

2003, 14 (3): 371-376.

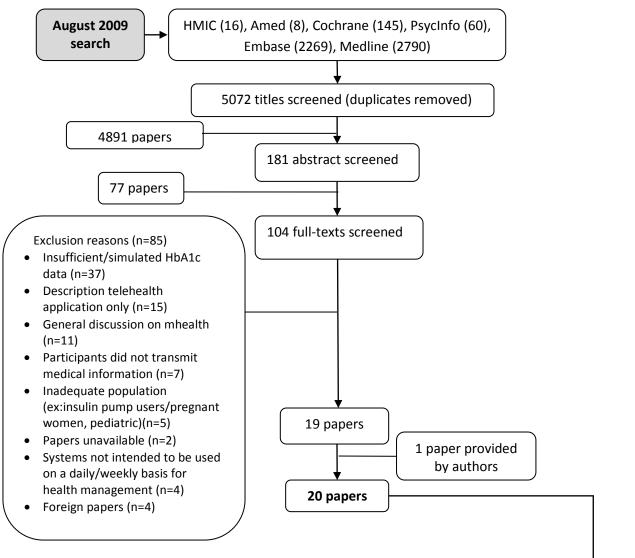


Figure 1. Study selection process for the 2009 search and 2012 update

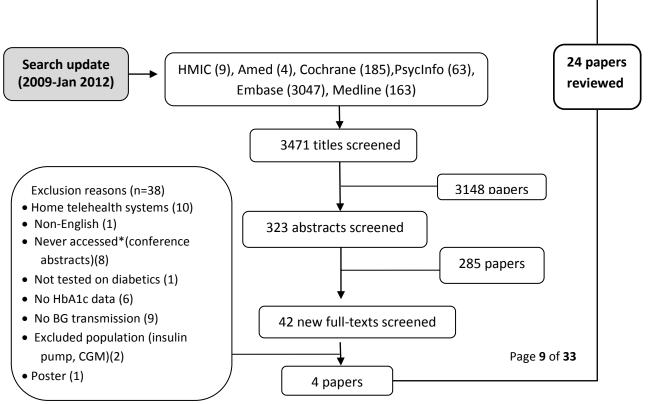


Table 1. Intervention components of studies on type 1 diabetes

		Intervention group							
Reference, first author	Control group	Mobile platform	Data Inputted	Recommended frequency of data input	Type and nature of feedback	Prequency of HCP feedback			
Dietary Inter	ventions								
Tsang ²³	Standard care	Personal digital assistant	Meal content BG readings	2x perweek	Automated text: CHO daily intake, proteins, calories, fat	Not applicable			
Rossi ^{al}	Standard care (education on CHO counting)	Mobile phone	Meal content BG readings Insulin dose	2-3x perday	Automated text feedblack: CHO daily intake, proteins, calories, fat, suggested insulin dose	Not reported			
Rossi ²⁵	Not applicable	01303 204	Exercise		HCP feedback (behavioral advice)				
Noncletary In	nterventions								
Gómez∞	Standard care	Personal digital assistant	BG readings Pree text	At least 1x fortnigh1y	HCP feedback to patients with out- of-range BG readings or queries Graphical feedback for different time periods	24 h			
Kollman⊅	Not applicable	Mobile phone	BG readings Medication Exercise Wellbeing	2-4x per day	Color-coded graphical feedback	Not applicable			
Farmer ^{as}	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 perday	HCP feedback and color-coded graphical feedback for different time periods	Fortnightly			
Vähätalo ²³	Standard care	Mobile phone	8G 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 stu	udies on type 2 diabetes
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Table 2. Intervent	ion Components of Studi	es on Type 2 Di	abetes ^d			
				Intervention grou	up .	
Reference, first author	Control group	Data Inputted	Recommended frequency of data input	Reminders and exclusions	Type and nature of feedback	Prequence of HCP feedback
Cho ²⁰	Web.p ersonal computer transmission of medical data (BG readings, lifestyle, hypoglycemic events, medication, blood pressure, weight, free text) with HCP and graphical feedback + diabletes education	8G readings	Not reported	Exclusions after 3 weeks of nontransmission	HCP feedblack: treatment recommendations, corrections to lifestyle factors, encouragements, reminders ⁶	Fortnight
Farl d ^{ai}	Standard care + pedometer	8G readings	Daily	Not reported	Automated feedblack: text message tailored to the 8G readings and selected from a blank of predetermined messages	Not applicable
Kimit	Not applicable	BG readings, diet, medication; exercise	Dally	Reminders after 1 week of nontransmission Exclusion after nontransmission for 4 weeks	HCP feedback Graphical feedback	Weekly
Kim ^{is} Kim ⁱ⁷ Hee-Sung ^{is} Yoon ^{is}	Standard care	BG readings, CHO, medication, exercise	Daily	Reminders after 1 week of nontransmission, Exclusion after nontransmission for 4 weeks	HCIP feedback Graphical feedback	Weekly
istep anlan ²¹	Standard care + 2 h diabetes education course	BG readings	Personalized (4-9x/week)	Reminders when personalized monitoring schedule not respected	Automated feedblack: letters sent through the post to HCPs and patients with amalgamated readings and treatment recommendations ⁶	Not applicable
Kim™ Kim™	Standard care	BG readings Medication, diet, exercise	Daily	Reminders after 1 week of nontransmission Exclusion after nontransmission for 4 weeks	HCP feedback	Weekly
Kwonz	Not applicable	BG and blood pressure readings, Weight	Not reported	Not reported	HCP feedback Graphical feedback	Not reported
Quinn≇	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- Idigoras ⁷²	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∞	Standard care + 1 h 20 diabetes education	8G readings	3x/week	Exclusion if less than 3 fasting readings in 20 days	Daily automated feedback messages on insulin adjustment ^e	Not applicable

Y0038	Standard care	BG and blood pressure readings, weight, and exercise	Dally	Not reported	Automated feedback: text messages to encourage/ remind/motivate	Not reported
Quinn#	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

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

0	Design and	Completed		Age Mean	Gender	Clinical outcomes (HbA1c)		
Papers	Quality		(months)	(n=)	(SD)	(males, %)	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 <u>mhealth</u> study	8.15% (median) for control study 7.9% for <u>mhealth</u> 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 an	d Participant	Characteristics and Ou	tcomes (Type 2 Stu	dies)			
	1.000 Mar 1.000 Mar			Recruited/	Age (mean,		Clinical outo	omes (HbA1c)
Reference, first author	Design and quality	Research groups	Duration (months)	completed	standard deviation)	Gender (males, %)	Baseline	% change a last follow-u
Cho ^{ao}	RCT ⁴	(1) Mobile phone transmission versus (2) Computer/Web-based transmission	3	69/63	48.1 ± 12.6	78.3%	(1): 8.3% (2): 7.8%	(1): -0.7% ⁶ (2): -1.2% ⁶
Faricial	RCT ⁴	(1) Standard care + pedometer versus (2) Mobile phone transmission + pedometer	3	30/Not reported	58.45 ± 9.8	38.6%	(1): 6.5% (2): 6.4%	(1): +0.3% (2): -0.1%
Юти	Single-group pre and post ⁴	Mobile phone transmission	3	45/33	436 ± 12.8	42.4%	8.196	-1.1.96 ⁰
Kim ^{is} Kim ⁱ⁷ Hee-Sung ^{is} Yoon ⁱ⁹	RCT ⁶	(1) Standard care versus (2) Mobile-phone (2) mobile common transmission	12	60/61	471 ±8.9	43.1%	(1): 7.6994 (2): 8.0996	(1): +0.8196 (2): -1.3296 ⁸ /
istepanian ²¹	RCT ⁴	(1) Standard care + 2h diabetes education course versus (2) Mobile phone transmission + 2h diabetes education	9	137/87	68.8 ± 12.5	Not reported	(1): 81% (2): 7.9%	(1): +0:196 (2): 096
Kim™ Kim™	RCT ⁴	(1) Standard care versus (2) Mobile phone transmission	12	40/34	48.9 ± 8.8	52.9 %	(1): 7.66% (2): 8.16%	(1): +0.83% (2): -1.49% ^{8,}
Kwon ²²	Single-group pre and post ^a	Mobile phone transmission	83	186/Not reported	42,4 (4-78)	28.1	7.696	-0.5% ⁸
Quinn ³²	RCT ^e	(1) Faxing/phoning in BGs unti stable versus (2) Mobile phone transmission	3	30/26	61.04 ± 11.03	66%	(1): 9.05% (2): 9.61%	(1): -0.88% (2): -2.03%
Rodriguez- Idigoras ²³	RCT ^e	(1) Standard care versus (2) Mobile phone transmission	12	328/297	63.9±0.60	<u>ଟ</u> ା ୫%	(1): 7.4196 (2): 7.8296	(1): -0.09% (2): -0.22% ⁶ At 6 months, not at 12 months
Larsen®	Single-group pre and post ^e	Mobile phone transmission	6	23/Not reported	67.8 ± 12	8096	9.5%	-0.88%
ĸm≖	RCT ⁴	 (1) Standard care + 1 h 20 diabletes education versus (2) Mobile phone transmission + 1 h 20 diabletes education 	3	100/92	48.4 ± 7.48	80 %	(1): 9.8% (2): 9.8% Overall: 9.8%	(1): -2.0% (2): -2.4% ^d Overall: -2.2% ⁶
Y0 0 25	RCT ^a	(1) Standard care versus (2) Mobile phone transmission	3	123/111	68.2 ± 8.73	58.596	(1): 7,496 (2): 7,896	(1): +0.29% ⁶ (2): -0.4% ⁶
Quinn ^æ	4-group cluster RCT ^o	(1) Standard care versus (2, 3, 4) mobile phone transmission with Increasing levels of HCP access to data	12	163/163	52.5 ± 8.66	487%	(1): 9.2% (2): 9.3% (3): 9.0% (4): 9.8%	(1): -0.796 (2): -1.896 ^d (3): -1.196 (4): -2.096 ^d

Table 4. Stud	y and partici	pant characteris	stics (type 2 studies)
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⁶ Significant difference within group.
 ⁶ Moderate quality rating.
 ⁷ Significant difference between groups.
 ⁶ Strong quality rating.
 ⁷ Strong quality rating.
 ⁷ Group 1 receiving standard care is the reference group. Between group differences calculated by Quinn in relation to the reference group.