Evaluation of a mobile phone telemonitoring system for glycaemic control in patients with diabetes

Robert SH Istepanian*, Karima Zitouni*, Diane Harry†, Niva Moutosammy†, Ala Sungoor*, Bee Tang* and Kenneth A Earle†

*Mobile Information and Network Technologies Centre, Kingston University, London; †St George's Hospital NHS Trust, London, UK

Summary

We conducted a randomized controlled trial using mobile health technology in an ethnically diverse sample of 137 patients with complicated diabetes. Patients in the intervention group ($n = 72$) were trained to measure their blood glucose with a sensor which transmitted the readings to a mobile phone via a Bluetooth wireless link. Clinicians were then able to examine and respond to the readings which were viewed with a web-based application. Patients in the control arm of the study ($n = 65$) did not transmit their readings and received care with their usual doctor in the outpatient and/or primary care setting. The mean follow-up period was 9 months in each group. The default rate was higher in the patients in the intervention arm due to technical problems. In an intention-to-treat analysis there were no differences in HbA_{1c} between the intervention and control groups. In a sub-group analysis of the patients who completed the study, the telemonitoring group had a lower HbA_{1c} than those in the control group: 7.76% and 8.40%, respectively ($P = 0.06$).

Introduction

It is now well established that a policy of intensive management to lower blood sugar reduces the incidence of diabetes complications.[1,2] However, translation of these research findings into routine practice remains a challenge for the health-care community. Technological developments allow remote monitoring of patients and improve diabetes care. However, although systematic reviews have confirmed the feasibility of remote monitoring, questions remain regarding its efficacy in long-term diabetes control.[3,4]

Mobile and wireless communication for health care (m-health) represent the evolution of telemedicine from desktop to wearable technologies.[5] In the case of diabetes management, m-health might improve the accessibility to, and ability of patients to engage in treatment intensification. Only a few studies have evaluated m-health in randomized trials. One study of 93 patients with type 1 diabetes and another of 30 patients with type 2 diabetes showed no benefit of the m-health intervention on haemoglobin A_{1c} (HbA_{1c}) compared with controls.[6,7] We have evaluated an m-health system against usual care in an unselected population of patients with mainly type 2 diabetes.

Correspondence: Dr K A Earle, Department of Cellular and Molecular Medicine, St George's Hospital NHS Trust, London SW17 ORE, UK (*Fax: +44 20 8725 1353*; *Email: k.earle@sgul.ac.uk*)

Methods

Patients were invited to take part in a randomized, parallel group study which was based at the Thomas Addison Diabetes Unit of St George's Hospital between December 2006 and July 2007. The local population has a diverse ethnic mix, with 22% of residents belonging to a non-white minority ethnic group and is characterised by high levels of social deprivation relative to the rest of England.

Ambulant patients aged over 18 years with diabetes were eligible for the study. Approximately one third of the 9000 patients with diabetes in the district were canvassed to take part in this study. Exclusion criteria were a physical inability to self-monitor blood glucose, pregnancy, severe life-threatening or terminal illness or an inability to provide written informed consent.

At the baseline clinic visit, a standardised diabetes dataset was collected for each patient. Diabetic retinopathy was assessed using digital fundal photography after pupil dilatation and was recorded as present (background, pre-proliferative or proliferative) or absent. Fasting venous blood was taken for the measurement of HbA_{1c}, total cholesterol and creatinine.

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All patients took part in a two-hour education session in which the diabetes research nurse gave instruction in general diabetes care and self-blood glucose monitoring. Randomization to usual care or the telemonitoring arm of the study was by computer-generated random numbers. The study was approved by the appropriate ethics committee and all patients provided written informed consent.

Telemonitoring

Patients in the telemonitoring arm were trained to self-measure capillary blood sugar (One Touch Ultra Glucose Meter, Lifescan, CA, USA). The monitor was adapted to transmit their recordings wirelessly by Bluetooth to a mobile phone (Motorola A-100, FL, USA). We allowed a run-in period of four weeks for patients to familiarise themselves with the system before transmitting readings according to a personalised monitoring schedule agreed with the research nurse. The mobile phone alerted the patient when a measurement was due.

Data were sent from the patient's mobile phone to a server at St George's Hospital. The research clinicians reviewed the recordings via a web-based application (Figure 1). Letters were sent from the clinician to the patients and their general practitioners with details of the amalgamated readings and treatment recommendations. Patients could also use the mobile phones free of charge to contact the research team for clinical and technical support.

Patients in the control group did not use a mobile phone to transmit data. They received their care from the diabetes centre and/or the local practitioners and were free to contact the research team if they wished.

Statistics

The primary outcome measure was HbA_{1c}. We aimed to evaluate 70 patients in each group over 9 months which would give the study 80% power to detect a difference of 0.72% in HbA_{1c}. The data were analysed on an intention-to-treat basis with imputation of carry-over data for patients defaulting or lost to follow-up. Analyses between or within the groups were performed using SPSS 16.0 for Windows (Chicago, USA).

Results

We randomized 137 patients to the telemonitoring ($n = 72$) and control ($n = 65$) groups. They were well matched according to their demographic and baseline clinical data (Table 1). The prevalence of diabetes complications and treatment regimens were similar in each group (Table 2).

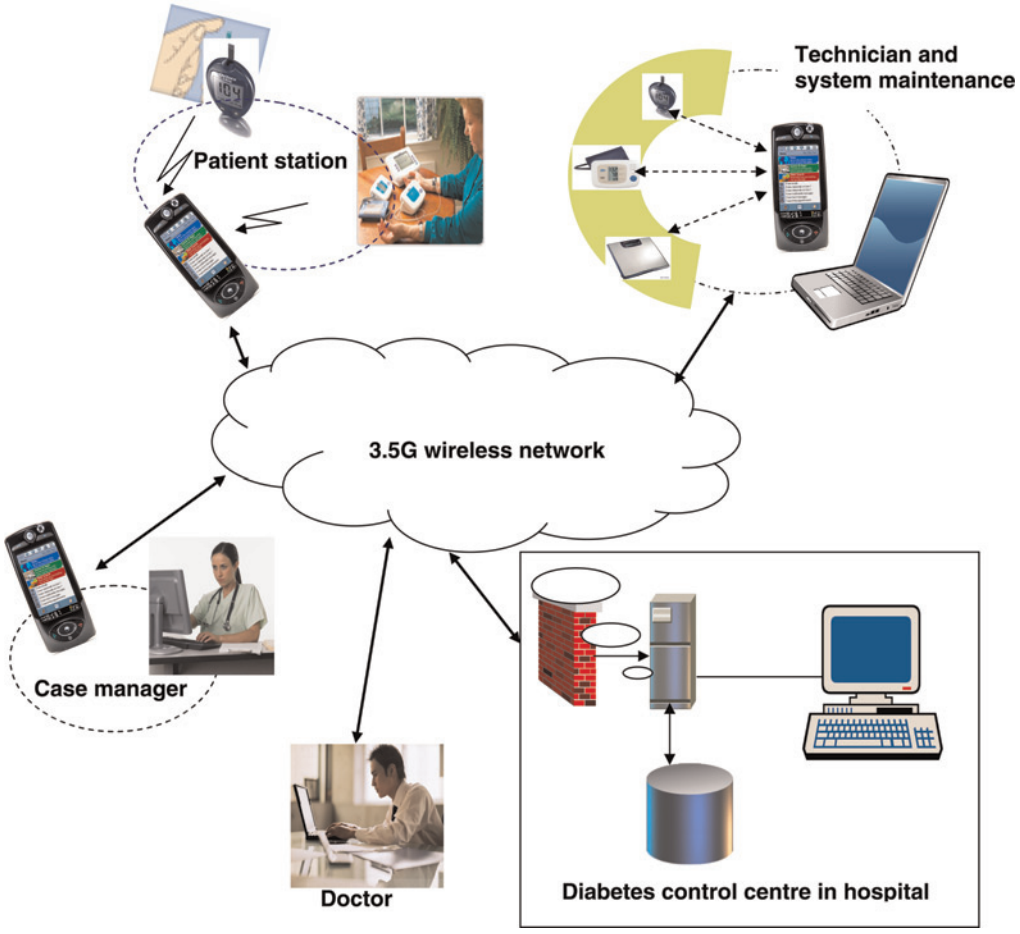

Figure 1 Information flow in the m-health system

Table 1 Baseline demographic, clinical and biochemical data of patients

	Telemonitoring	Control	*P*
Number of patients	72	65	
Age, years (SD)	60 (12)	57 (13)	0.25
Duration of diabetes, years (SD)	13.3 (8.6)	11.7 (8.0)	0.27
Type 1 diabetes, n (%)	6 (8)	5 (8)	0.85
Type 2 diabetes, n (%)	66 (92)	60 (92)	
Weight, kg (SD)	79.7 (17.9)	80.1 (20.1)	0.91
Ethnic group, n (%)			
Caucasian	26 (36)	21 (32)	0.79
African-Caribbean	24 (33)	18 (28)	
Indo-Asian	21 (29)	21 (32)	
Other	1 (1)	5 (7)	
HbA_{1c}, % (SD)	7.9 (1.5)	8.1 (1.6)	0.40
Total cholesterol, mmol/l (SD)	4.3 (1.1)	4.4 (1.2)	0.76
Plasma creatinine, μmol/l (SD)	111 (102)	93 (43)	0.21

Table 2 Complications and treatment regimens of patients

	Telemonitoring	Control
Background/maculopathy/pre-proliferative/ laser therapy, n	18/9/0/2	16/6/4/3
Nephropathy, n	31	35
Cardiovascular disease history positive, n	14	10
Diet therapy alone, %	5	5
Insulin alone, %	26	25
Oral hypoglycaemic agents (OHA), %	47	56
Combination of OHA and insulin, %	22	11

Insulin-treated patients had a significantly higher HbA_{1c} than those on oral hypoglycaemic agents only: 8.8% and 7.7%, respectively ($P = 0.005$).

The mean follow-up period was 9 months in each group. Thirty-two patients in the telemonitoring group and 55 patients in the control group completed the study. There were no differences in HbA_{1c} between the telemonitoring and the control groups: 7.9% and 8.2%, respectively ($P = 0.17$).

In a sub-group analysis of the patients who completed the study, the telemonitoring group had a lower HbA_{1c} than those in the control group: 7.76% and 8.40%, respectively ($P = 0.06$).

Discussion

The present study represents the largest randomized trial of m-health in an ethnically diverse sample of patients with complicated diabetes in the UK. The intention-to-treat analysis was negative, implying that this method did not have an advantage over usual diabetes care in these patients. However, in the patients who completed the study there was a biologically relevant 0.64% difference in favour of the m-health intervention. This is of note given the importance and difficulty of reducing an individual's HbA_{1c} level to below 7%.

The drop-out rate from the intervention arm in the study was higher than the 10–15% we predicted would occur. Patients cited technical issues related to operating the equipment as the main reason behind the protocol violations. Similar rates of failure and patient difficulty with such technology have been reported in other studies of telemedicine in diabetes.[7] This observation may also reflect the current controversies about blood glucose monitoring in patients with type 2 diabetes. There are conflicting studies of the benefit of self-blood glucose monitoring in patients with type 2 diabetes on long-term diabetes control.[8,9] Moreover, patients who perform self-blood glucose monitoring may score highest on scales that assess depression.[10]

The outcomes of this and other studies imply that the size of any possible beneficial effect of current telemonitoring on long-term diabetes control is likely to be small. In our analysis, patients completing the study tended to have lower HbA_{1c} values suggesting that patients with poorer control could be targeted for this intervention. On the other hand, patients who had a lower HbA_{1c} may have been more motivated to persist with such an intervention in order to achieve even better long-term control. Although the groups were well matched, the study did not have sufficient power to test this assertion.

The achievement of lower HbA_{1c} in the landmark diabetes treatment intensification trials involved considerable patient-clinician contact.[1,2] The level of human contact may have been a weakness in our study. A recent qualitative analysis of the diabetes patient's perspective of using telemedicine concluded that its potential depends on consistent, supportive interactions with health-care providers.[11] A quality of life analysis of our study is currently in progress which will help to evaluate the potential of m-health telecare in diabetes.

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References

1 The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med* 1993;**329**:977–86
2 UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). *Lancet* 1998;**352**:854–65
3 Montori VM, Helgemoe PK, Guyatt GH, *et al.* Telecare for patients with type 1 diabetes and inadequate glycemic control: a randomized controlled trial and meta-analysis. *Diabetes Care* 2004;**27**:1088–94
4 Farmer A, Gibson OJ, Tarassenko L, Neil A. A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes. *Diabet Med* 2005;**22**:1372–78
5 Istepanian RSH, Laxminarayan S, Pattichis CS, eds. *M-Health: Emerging Mobile Health Systems*. London: Springer, 2006
6 Farmer AJ, Gibson OJ, Dudley C, *et al.* A randomized controlled trial of the effect of real-time telemedicine support on glycemic control in young adults with type 1 diabetes (ISRCTN 46889446). *Diabetes Care* 2005;**28**:2697–702

7 Faridi Z, Liberti L, Shuval K, Northrup V, Ali A, Katz DL. Evaluating the impact of mobile telephone technology on type 2 diabetic patients' self-management: the NICHE pilot study. *J Eval Clin Pract* 2008; **14**:465–9
8 Franciosi M, Pellegrini F, De Berardis G, *et al*. The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients: an urgent need for better educational strategies. *Diabetes Care* 2001;**24**:1870–77
9 Farmer A, Wade A, Goyder E, *et al*. Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial. *BMJ* 2007;**335**:132–6
10 O'Kane MJ, Bunting B, Copeland M, *et al*. Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial. *BMJ* 2008;**336**:1174–7
11 Trief PM, Sandberg J, Izquierdo R, *et al*. Diabetes management assisted by telemedicine: patient perspectives. *Telemed J E Health* 2008;**14**:647–55