

# CLINICAL EVALUATION OF A MOBILE PHONE TELEMEDICINE SYSTEM FOR THE SELF-MANAGEMENT OF TYPE 1 DIABETES

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**Abstract – A mobile phone system for the self-management of Type 1 diabetes was tested in a clinical randomized controlled trial. Both intervention and control groups used the system, but the intervention group had extra feedback and proactive nurse support. Both groups showed improvements in blood glucose control, as measured by HbA1c, although the difference in HbA1c change between groups was not statistically significant. The difference in compliance between groups was highly significant, however, showing the importance of targeted support from healthcare professionals in the use of such systems.**

## I. INTRODUCTION

Type 1 diabetes mellitus is caused by the destruction of insulin-producing beta cells in the pancreas. Patients inject insulin to reduce blood glucose (BG) levels, adjusting the dose to account for diet, exercise and their current BG level, which they can measure using an electronic meter. An intensive therapy (typically four insulin injections per day) has been shown to delay long-term complications caused by excessively high BG levels [1]. In conventional care, patients discuss their BG control at three-monthly clinics without access to computer-based BG data or visualisations. Overall BG control during the past 90 days is also assessed at clinics by measuring the proportion of haemoglobin A1c (HbA1c) in the blood.

## II. TECHNICAL INFORMATION

A telemedicine system was developed to assist patients in the self-management of Type 1 diabetes. A mobile phone (Motorola) was interfaced to a blood glucose meter (LifeScan Inc) using a custom-built cable containing an embedded microcontroller to interface between the two devices. Custom Java software on the phone gathered readings from the meter and asked the patient questions about their diet, exercise levels and the insulin dose they had chosen to inject. This information was then transmitted via the General Packet Radio Service (GPRS) to a server. A graph of recent blood glucose readings was displayed on the phone screen, and secure web pages allowed both patients and healthcare professionals to view the data graphically.

In comparison to previous telemedicine systems in the literature [2], this system offers immediate transmission of data with graphical feedback from a portable device which can be easily integrated into a patient's lifestyle. The phone software was designed to be very quick to use; only three questions were asked on every occasion (about insulin dose, diet and exercise), although patients could choose to enter additional detailed information on particular foods consumed and other factors affecting blood glucose, if they wished.

The system was used in a 9-month randomized controlled trial, in which 93 patients from the Oxford Young Adult Clinic were recruited. Both the intervention and control groups used the phone system as described above, but the intervention group additionally had more intensive feedback: proactive nurse support via telephone and an extra histogram display of recent BG readings (in the last two weeks) on the phone. The patients in the trial were young (age 18-30 years) and had sub-optimal BG control (indicated by HbA1c levels of 8% to 11%) at the start of the trial.

## III. RESULTS

### *Blood glucose control*

There was a statistically significant reduction in HbA1c in each group: in the intervention group from 9.2% to 8.6% ( $p=0.001$ ) and in the control group from 9.3% to 8.9% ( $p=0.04$ ). The difference in HbA1c change between the groups was not statistically significant ( $p=0.3$ ).

The proportion of patients with HbA1c  $\leq 8\%$  increased during the trial in the intervention group from 10.6% to 46.8% and in the control group from 19.6% to 23.9%. This difference between groups was statistically significant ( $p<0.0001$ ).

Figure 1 shows the distributions of BG readings taken by each group during the trial; the difference in median BG between groups was statistically significant (intervention: 8.9 mmol/l, control: 10.3 mmol/l,  $p<0.0001$ ).

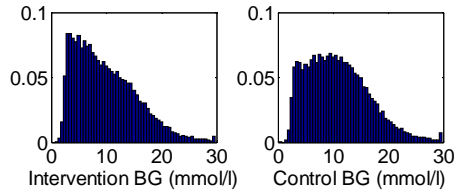


Figure 1. Distributions of all BG readings received from each group during the trial, scaled to have the same area.

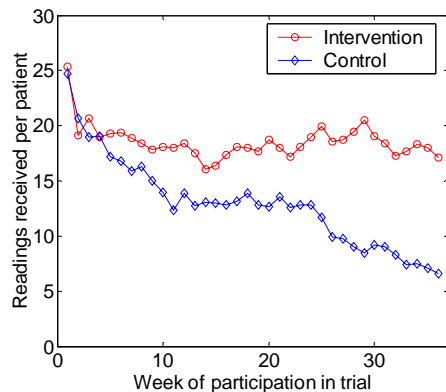


Figure 2. Mean number of readings received from patients in each group, during each week of their participation in the trial.

### Compliance

The mean number of weeks in which no BG measurement was received was significantly different between the intervention group (3.9 weeks) and control group (11.4 weeks):  $p < 0.0001$ . The difference in compliance between the two groups can be seen in the readings received per patient in each week of their participation in the trial (Figure 2).

## IV. DISCUSSION

Blood glucose control improved in both trial groups who used the telemedicine system to support their self-management, although the between-group change in HbA1c was not significantly different. There is a clear difference between the distributions of the BG readings from the two groups (Figure 1): a greater proportion of readings from the intervention group lie in the “non-diabetic” range of approximately 4 - 7 mmol/l, and the median BG is also significantly lower. These measures indicate that proactive support by healthcare professionals (using the data immediately available from the web site) has some impact on blood glucose readings.

The proactive nurse support also appears to be essential in maintaining compliance in taking a reasonable frequency of BG readings. Figure 2 shows that the number of readings received per patient each week decreased

during the trial in the control group, but was sustained in the intervention group. Similarly, the significant between-group difference in the number of weeks for which no readings were received implies that nurse support discourages patients from stopping their use of the system altogether.

Technical reliability appears to have been important in this trial; in particular, the cable connecting the phone to the meter was vulnerable to damage and often required replacement. In the next version of the system, this cable has been replaced by a wireless Bluetooth link, improving reliability.

## V. CONCLUSION

The trial has demonstrated the use of a novel mobile phone-based telemedicine system to assist patients in the self-management of Type 1 diabetes. Over 55,000 BG readings were transmitted during the trial, and blood glucose control improved significantly in both groups of patients using the system. The inclusion of feedback and proactive nurse support is clearly very important to maintain compliance in BG testing and use of the system.

The large data set collected during the trial allows automatic algorithms to be developed for prioritising patients for intervention by healthcare professionals (for example, by identifying patients with sub-optimal blood glucose control or specific problems such as low blood glucose overnight). These should allow the time of healthcare professionals to be targeted to improve outcomes without substantial increases in resources.

## ACKNOWLEDGEMENTS

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