

## Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial

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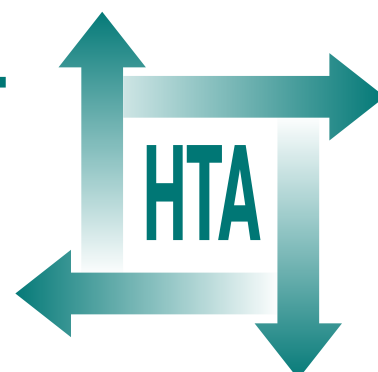
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### *Executive summary*

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## Executive summary

### Introduction

Self-monitoring of blood glucose (SMBG) is a technology that is frequently incorporated into self-management interventions of diabetes, but has been separately evaluated in only a limited number of trials. Despite this lack of evidence, guidance is given to both support and discourage its use. Self-monitoring was used to guide insulin dose adjustment among individuals with type 1 diabetes in the Diabetes Control and Complications Trial (Epidemiology of Diabetes Interventions and Complications Study Research Group 2005). This trial demonstrated conclusively that tight glycaemic control reduced the risk of long-term complications. However, among non-insulin-treated patients with type 2 diabetes it is unclear whether self-monitoring is useful in providing personal feedback about the impact of changes in eating patterns and physical activity to support self-management. Self-monitoring of blood glucose is now widely accepted as part of the management of people with type 2 diabetes (European Diabetes Policy Group 1999, Blonde *et al.* 2002). The use of self-monitoring in this group of patients and the cost to health systems of the consumable test strips has become a major and increasing proportion of health-care budgets (Farmer and Neil 2004, Davidson 2005). We therefore set out to establish the benefit and cost-effectiveness of SMBG in the Diabetes Glycaemic Education and Monitoring (DiGEM) study.

### Objectives

We report here the results of the DiGEM study – a trial designed to test whether self-monitoring of blood glucose, used with or without instruction in incorporating findings into self-management, can improve glycaemic control in non-insulin-treated diabetes compared with standardised usual care.

### Methods

The DiGEM study was an open, parallel group randomised trial with an economic analysis, examination of impact on beliefs and self-reported

behaviour, and a qualitative study to explore patient experiences. Participants were recruited from 48 general practices in Oxfordshire and South Yorkshire and were eligible if they had type 2 diabetes managed with diet or oral hypoglycaemic agents alone, were aged  $\geq 25$  years and had a glycosylated haemoglobin (HbA1c)  $\geq 6.2\%$ . Patients were randomised to (1) standardised usual care with 3-monthly HbA1c (control); (2) SMBG with patient training focused on clinician interpretation of results in addition to usual care (less intensive self-monitoring); and (3) SMBG with additional training of patients in interpretation and application of the results, to enhance motivation and maintain adherence to a healthy lifestyle (more intensive self-monitoring).

An intention-to-treat analysis was performed with the primary outcome of HbA1c at 12 months. Blood pressure, lipids, episodes of hypoglycaemia and quality of life measured with the EuroQol 5 dimensions (EQ-5D) were secondary measures. Further questionnaires were used to measure well-being, beliefs about use of SMBG and self-reports of medication taking, dietary and physical activities, and health-care resource use.

### Results

Four hundred and fifty-three patients were randomised, with mean (standard deviation) HbA1c 7.5% (1.1). The differences in 12-month HbA1c between the three groups (adjusted for baseline HbA1c) were not statistically significant ( $p = 0.12$ ). The difference in unadjusted mean change in HbA1c from baseline to 12 months between the control and less intensive self-monitoring groups was  $-0.14\%$  [95% confidence interval (CI)  $-0.35$  to  $0.07$ ] and between the control and more intensive self-monitoring groups was  $-0.17\%$  (95% CI  $-0.37$  to  $0.03$ ). No evidence was found of a significantly different impact of self-monitoring on glycaemic control when comparing subgroups of patients defined by duration of diabetes, therapy, diabetes-related complications and EQ-5D score.

Self-monitoring of blood glucose was found to be significantly more expensive than standardised usual care, by £92 and £84 for the less intensive SMBG and the more intensive SMBG groups respectively. There appears to be an initial negative impact of SMBG on quality of life measured on the EQ-5D. The potential additional lifetime gains in quality-adjusted life-years, resulting from the lower levels of risk factors achieved at the end of trial follow-up, were outweighed by the initial negative impacts for both SMBG groups compared with standardised usual care. Results of the extrapolation also suggest that the incremental lifetime savings in diabetes complications did not offset the additional intervention costs. The cost-utility analysis showed that it is unlikely that either investigated form of SMBG is cost-effective compared with standardised usual care.

In-depth interviews identified groups of patients who used SMBG to monitor impact of different lifestyle choices and motivate adherence to these choices. However, there were also patients who were not clear about the relationship between behaviour and test results or who experienced no improvement in test results after changing behaviour. Questionnaires about health-related beliefs did not identify an increase in perceived control over diabetes, but did find an increase in perceived seriousness of diabetes in the group carrying out more intensive self-monitoring.

## Conclusions

We have found no convincing evidence to recommend routine use of SMBG by reasonably well-controlled, non-insulin-treated patients with type 2 diabetes. The specific advantages of monitoring identified by patients need to be placed in the context of a decline in compliance in the more intensive monitoring group and, at best, a small reduction in HbA1c. Neither the within-trial economic analysis nor the long-term modelling supports SMBG as a cost-effective intervention for all non-insulin-treated patients with type 2 diabetes. However, a clinically important benefit for specific subgroups of patients in initiating good glycaemic control cannot be excluded without further research.

## Implications for practice

1. This trial does not provide convincing evidence to support the routine use of SMBG for non-insulin-treated patients with type 2 diabetes. However, our trial does not negate the established benefits of SMBG in insulin-treated patients, although further work is required to optimise its use.
2. Our in-depth interviews suggest that some individuals may benefit from SMBG use. However, with our present knowledge, we cannot clearly identify these patients, and clinical judgement is required to make this assessment in discussion with patients.
3. Our trial cannot exclude the possibility that SMBG may be helpful in non-insulin-treated type 2 diabetes patients with symptoms of hypoglycaemia; in those motivated to make alterations to behaviour that lead to consistent changes in blood glucose; and where there is strong patient preference.
4. If support for self-management training is available within usual care, then 3-monthly HbA1c management may be the optimum strategy. However, if HbA1c remains above 8%, then self-monitoring may provide motivation for medication adherence and lifestyle measures, as insulin therapy may be required in this group.

## Research priorities

We have identified the following research priorities:

1. The qualitative element of the trial identifies a group of patients who consider that use of SMBG provides them with motivation to adopt and maintain behaviours that lead to better diabetes control. Further work is required to characterise those who gain most benefit in terms of glycaemic control and to determine whether this is related to use of the procedure.
2. Our results suggest that routine use of SMBG may not be appropriate for reasonably well-controlled patients; however, its role in the management of patients with less well-controlled diabetes is not clear. A pragmatic strategy of self-management education with HbA1c monitoring and intensifying drug

therapy may be appropriate in the first instance. If glycaemic control is not then achieved, SMBG may be appropriate, first to explore any potential motivating effect, and second because insulin treatment is likely to be required. Exploration of the utility of this strategy may be useful.

3. There is an increased rate of hypoglycaemia reported among self-monitoring individuals. Further exploration of the data is needed to establish whether these differences are likely to result from biochemical differences or greater awareness of hypoglycaemia as a cause of symptoms.

## Trial registration

This trial is registered as ISRCTN47464659.

## Publication

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