

Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial

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ABSTRACT

Objectives To assess the effect of self monitoring of blood glucose concentrations on glycaemic control and psychological indices in patients with newly diagnosed type 2 diabetes mellitus.

Design Prospective randomised controlled trial of self monitoring versus no monitoring (control).

Setting Hospital diabetes clinics.

Participants 184 (111 men) people aged <70 with newly diagnosed type 2 diabetes referred to the participating diabetes clinics. Major exclusion criteria were secondary diabetes, insulin treatment, previous self monitoring of blood glucose.

Interventions Participants were randomised to self monitoring or no monitoring (control) groups for one year with follow-up at three monthly intervals. Both groups underwent an identical structured core education programme. The self monitoring group received additional education on monitoring.

Main outcome measures Between group differences in HbA_{1c}, psychological indices, use of oral hypoglycaemic drugs, body mass index (BMI), and reported hypoglycaemia rates.

Results 96 patients (55 men) were randomised to monitoring and 88 (56 men) to control. There were no baseline differences in mean (SD) age (57.7 (11.0) in monitoring group v 60.9 (11.5) in control group) or HbA_{1c} (8.8 (2.1)% v 8.6 (2.3)%, respectively). Those in the monitoring group had a higher baseline BMI (34 (7) v 32 (6.2)). There were no significant differences between groups at any time point (12 months values given) in HbA_{1c} (6.9 (0.8)% v 6.9 (1.2)%, P=0.69; 95% confidence interval for difference -0.25% to 0.38%), BMI (33.1 (6.4) v 31.8 (6.0); adjusted for baseline BMI, P=0.32), use of oral hypoglycaemic drugs, or reported incidence of hypoglycaemia. Monitoring was associated with a 6% higher score on the depression subscale of the well-being questionnaire (P=0.01).

Conclusions In patients with newly diagnosed type 2 diabetes self monitoring of blood glucose concentration has no effect on glycaemic control but is associated with higher scores on a depression subscale.

Trial registration ISRCTN 49814766.

INTRODUCTION

Although self monitoring of blood glucose concentrations is widely advocated by healthcare professionals for patients with type 2 diabetes mellitus who do not require insulin, there is conflicting evidence as to its value.¹ We investigated the effect of self monitoring on glycaemic control and attitudes and satisfaction with treatment in patients with newly diagnosed type 2 diabetes.

METHODS

The ESMON study was a randomised control trial of self monitoring of blood glucose concentration (intervention) versus no monitoring (control). Patients aged <70 with newly diagnosed type 2 diabetes were recruited from the outpatient diabetes services at four hospitals between 2002 and 2005. See bmj.com for exclusion criteria.

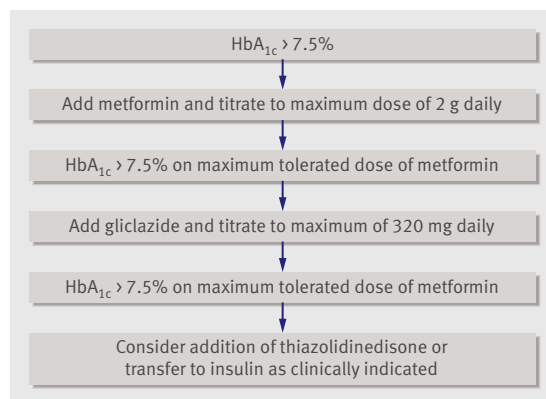
Outcomes

Pre-designated primary end points were differences between groups in HbA_{1c}, psychological indices, and incidence of hypoglycaemia. Secondary end points were differences between groups in body mass index and use of oral hypoglycaemic drugs.

Randomisation

Participants were recruited from among those patients with newly diagnosed type 2 diabetes referred to the hospital diabetes clinics. Eligible patients were randomised into intervention (self monitoring of blood glucose) or control (no monitoring) groups.

Those in the self monitoring group were all provided with a glucose monitor, and asked to monitor four fasting and four postprandial capillary blood glucose measurements each week. They were advised on appropriate responses to high or low readings (for example, dietary review or exercise). At each clinic visit, concordance with the self monitoring regimen was verified by downloading meter readings. Patients in the no monitoring group (control) were asked not to acquire a meter or perform monitoring for the duration of the study.



Treatment algorithm for oral hypoglycaemic agents

Both groups underwent an identical structured education programme. All patients were reviewed by the doctor, diabetes nurse practitioner, and dietitian at three monthly intervals for one year. At each visit all aspects of diabetes care were reviewed including indices of glycaemic control. Patients in the self monitoring group received ongoing advice in the interpretation of and response to their capillary glucose results.

We used an identical treatment algorithm for dietary and pharmacological management of glycaemia for both groups based on HbA_{1c} targets (figure). Blood concentrations of HbA_{1c}, lipids, and electrolytes were measured at or before each clinic and results were discussed with patients in the context of the treatment targets.

At each three monthly visit patients completed a questionnaire incorporating the diabetes treatment satisfaction questionnaire,² a modified version of the diabetes attitude scale,³ and the well-being questionnaire.⁴

Analysis

The study was powered to detect a 1% (1 unit) difference in HbA_{1c} (2 SD) between the groups at the 0.05 level (two tailed *t* test) with a power in excess of 90%. We used three predetermined time invariant predictors: sex, age, monitoring status. Compliance was defined as a monitoring frequency of >80% of that requested. We introduced the number of medications being taken for the control of HbA_{1c} as a time varying covariate. See bmj.com.

RESULTS

Of 212 consecutive participants approached between January 2003 and July 2005, 195 were recruited and 184 (86.7% of those approached) proceeded to randomisation (96 to self monitoring). Four participants (two in each group) failed to complete the study. There was no significant difference in baseline HbA_{1c}, age, or sex between the groups, although participants in the self monitoring group had a higher baseline body mass index (BMI) (mean (SD) 34 (7) *v* 32 (6.2)). Of the 96 participants in the self monitoring group, 63 carried

out over 80% of the requested blood glucose monitoring (that is, four fasting and four postprandial readings a week).

Outcome measures

Although HbA_{1c} fell within each group, there were no significant differences between the groups at any time point, with mean (SD) values at 12 months of 6.9 (0.8)% *v* 6.9 (1.2)% for the self monitoring versus control groups. The 95% confidence interval for the difference at 12 months in HbA_{1c} between groups was -0.25% to 0.38%.

The measures of depression and anxiety were scored on a 100 point scale with the measure at the final time point regressed on to the baseline measure, monitoring status, and sex. All models provided an adequate description of the data. Participants in the self monitoring group were more depressed, scoring 6 points higher (that is, 6%) on the depression subscale of the well-being questionnaire at 12 months, and there was a trend towards increased anxiety (table). There were no significant (0.05 level) differences between groups on any of the other subscales, in the mean scores on treatment satisfaction, or on any of the diabetes attitude subscales. There were no differences between groups in the incidence of reported hypoglycaemia at any time points or in use of oral hypoglycaemic drugs. Although there was a difference in BMI between groups at randomisation, after correction for the baseline value there were no significant differences at subsequent time points.

DISCUSSION

In this cohort of patients with newly diagnosed type 2 diabetes we were unable to identify any significant effect of self monitoring over one year on HbA_{1c}, BMI, use of oral hypoglycaemic drugs, or reported incidence of hypoglycaemia. Furthermore, monitoring was associated with a 6% higher score on the well-being depression subscale.

Strengths of study

All patients were newly diagnosed with type 2 diabetes, and were therefore new to monitoring. We randomised a high proportion of eligible participants (86.7%), suggesting that the cohort was representative of newly presenting patients in the community. The drop-out rate was low (2.2%) and concordance with the monitoring regimen in the intervention group was

Analysis of covariance for effect of monitoring on psychological variables (baseline and end point), adjusted for sex

Item	β coefficient* (SE)	P value
Depression	6.05 (2.37)	0.011
Anxiety	5.86 (3.19)	0.07
Positive wellbeing	4.16 (2.88)	0.15
Energy	-0.84 (2.83)	0.77

*All variables scored on 100 point scale and therefore β coefficient corresponds to % change associated with monitoring.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Self monitoring of blood glucose concentration in type 2 diabetes is widely advocated as an adjunct to achieving good glycaemic control

Randomised trials on self monitoring have given conflicting results, have been limited to patients with established diabetes, and have rarely considered quality of life

WHAT THIS STUDY ADDS

Self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes did not result in improved glycaemic control but was associated with a 6% higher score on a depression index

high. We used a structured drug treatment algorithm based on HbA_{1c} targets for both groups. The core diabetes educational programme was identical to that administered under standard care, although education on monitoring was provided to those randomised to the monitoring group only. The starting HbA_{1c} was high (8.8% and 8.6% in self monitoring and control groups, respectively) and both groups attained a satisfactory HbA_{1c} level of 6.9%. We therefore think that the results of this study have general applicability.

Comparison with other studies

Previous studies have used a range of designs. This reflects the difficulty of isolating the effect of a single home intervention in a condition in which patients' motivation, self management behaviour, and concordance with a prescribed drug regimen play a central role in effective treatment.

The ROSSO study found that self monitoring was associated with a reduction in both fatal and non-fatal events over a mean review period of 6.5 years.⁵ The non-randomised retrospective study design, however, makes it difficult to exclude the possibility that more motivated patients opt to monitor and monitoring might be a marker of generally beneficial self management behaviour.

The small number of randomised controlled trials have varied in quality and provided conflicting results, though a meta analysis suggested a non-significant 0.39% (95% confidence interval 0.21% to 0.56%) reduction in HbA_{1c} in favour of monitoring, which would equate to 14% reduction in risk of microvascular complications.^{6,7} Educational interventions often differ between the self monitoring and control group, making it difficult to isolate the effect of self monitoring.^{8,9} The ASIA study found significant reductions in HbA_{1c} from baseline in both self monitoring and control groups with a 0.3% reduction between groups in favour of monitoring at 24 weeks.⁸ The study had a high drop-out rate, which limits the general applicability of the findings. In contrast, the DIGEM trial found no benefit of self monitoring (with or without structured education) in patients with established and well controlled type 2 diabetes,¹⁰ although the mean starting HbA_{1c} was low (7.5%), which would have reduced the sensitivity for detecting an effect of monitoring.

An important difference between these trials and the present study is that ours included a rigorous treatment

algorithm for the management of glycaemic control based on the target HbA_{1c}. The success of this algorithm is shown by the reduction in mean HbA_{1c} in both groups to the satisfactory level of 6.9% at 12 months. The use of an effective and uniformly applied treatment regimen possibly minimises any potential benefit conferred by monitoring.

All studies to date have included people with established diabetes, and it is unclear to what extent results could be extrapolated to newly presenting patients. Recruitment protocols in such studies generally excluded those who were already actively monitoring or who had recently monitored, introducing a potential selection bias. We removed any such potential bias by recruiting only those patients with a new diagnosis of diabetes and who had not previously performed self monitoring of blood glucose.

Anecdotal and other evidence suggests that some patients consider monitoring uncomfortable, intrusive, and unpleasant.^{11,12} Our study found that monitoring was associated with a 6% higher score on a depression subscale and a trend towards increased anxiety, although satisfaction with treatment was unchanged. Others have also found higher levels of distress, depressive symptoms, and anxiety in patients who self monitored.^{13,14} The negative effect might relate less to feelings of powerlessness in the face of high blood glucose readings than to the enforced discipline of regular monitoring without any tangible gain.

The ESMON Study Group comprises Vivien Coates, Margaret Copeland, Brendan Bunting (University of Ulster); Maurice O'Kane, Sandra McConnell, Kenneth Moles, Sharon Patton (Altnagelvin Hospitals Health and Social Services Trust); Michael Ryan, Fergal Tracey, Mary Glass, Lesley Hamilton (Causeway Hospital Trust); Randal Hayes, Pooler Archbold, Sharon Martin, Margaret Devlin, Sonia Cambridge (Belfast City Hospital Trust); and Roy Harper, Moira Campbell, Lynne Thomas (Ulster Hospital and Community Trust). The executive committee comprises Vivien Coates, Brendan Bunting, Mary Glass, Sharon Martin, Roy Harper, Maurice O'Kane, and Margaret Copeland.

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Cost effectiveness of self monitoring of blood glucose in patients with non-insulin treated type 2 diabetes: economic evaluation of data from the DiGEM trial

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ABSTRACT

Objective To assess the cost effectiveness of self monitoring of blood glucose alone or with additional training in incorporating the results into self care, in addition to standardised usual care for patients with non-insulin treated type 2 diabetes.

Design Incremental cost utility analysis from a healthcare perspective. Data on resource use from the randomised controlled diabetes glycaemic education and monitoring (DiGEM) trial covered 12 months before baseline and 12 months of trial follow-up. Quality of life was measured at baseline and 12 months using the EuroQol EQ-5D questionnaire.

Setting Primary care in the United Kingdom.

Participants 453 patients with non-insulin treated type 2 diabetes.

Interventions Standardised usual care (control) compared with additional self monitoring of blood glucose alone (less intensive self monitoring) or with training in self interpretation of the results (more intensive self monitoring).

Main outcome measures Quality adjusted life years and healthcare costs (sterling in 2005-6 prices).

Results The average costs of intervention were £89 (€113; \$179) for standardised usual care, £181 for less intensive self monitoring, and £173 for more intensive self monitoring, showing an additional cost per patient of £92 (95% confidence interval £80 to £103) in the less intensive group and £84 (£73 to £96) in the more intensive group. No other significant cost difference was detected between the groups. An initial negative impact of self monitoring on quality of life occurred, averaging -0.027 (95% confidence interval -0.069 to 0.015) for the less intensive self monitoring group and -0.075 (-0.119 to -0.031) for the more intensive group.

Conclusions Self monitoring of blood glucose with or without additional training in incorporating the results into self care was associated with higher costs and lower quality of life in patients with non-insulin treated type 2 diabetes. In light of this, and no clinically significant differences in other outcomes, self monitoring of blood glucose is unlikely to be cost effective in addition to standardised usual care.

Trial registration Current Controlled Trials ISRCTN47464659.

INTRODUCTION

Self monitoring of blood glucose has been shown to be the largest single component of management costs associated with implementing more intensive glycaemic control in the UK.¹ Improvements in haemoglobin A_{1c} levels are associated with reduced rates of long term complications from diabetes. Although these improvements may lead to gains in quality adjusted life expectancy and generate savings within the healthcare system, self monitoring has opportunity costs as funds could be used to finance other aspects of managing non-insulin treated type 2 diabetes. We carried out an economic evaluation of self monitoring of blood glucose using data from the diabetes glycaemic education and monitoring (DiGEM) trial.²

METHODS

The diabetes glycaemic education and monitoring trial was an open, randomised study of 453 patients with non-insulin treated type 2 diabetes who had haemoglobin A_{1c} levels of 6.2% or more and were self monitoring not more than once a week.² These patients were allocated to either standardised usual care (control, n=152), a blood glucose meter with advice for participants to contact their doctor for