

RAPID APPRAISAL

Name of Trial: Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial.

Reference: BMJ. 2007; published online 25 June. Doi:10.1136/bmj.39247.447431.BE

Question: Is self monitoring of blood glucose, with or without instruction in incorporating the results into self care, more effective than usual care in improving glycaemic control in non-insulin-treated patients with type 2 diabetes?

Summary: The data from this trial suggest that self-monitoring of blood glucose does not improve glycaemic control compared to usual care in reasonably well-controlled non-insulin-treated type 2 diabetic patients. Routine self-monitoring of blood glucose is not required if patients are well-controlled on non-insulin therapy (including oral treatment, diet and exercise control). Regular HbA_{1c} measurements should be used to monitor blood glucose control. Self-monitoring of glucose levels can be important at diagnosis when used as part of a patient education programme. However, health professionals must ensure that patients clearly understand the purpose and frequency of self-monitoring and should clarify with patients how readings should be interpreted and applied to goals for lifestyle changes.

Did the study ask a clearly focussed question?

Yes – This study was designed to evaluate whether self monitoring of blood glucose, compared with standardised usual care, can improve glycaemic control in patients with non-insulin-treated diabetes.¹ The primary outcome was the glycosylated haemoglobin (HbA_{1c}) level at 12 months. Secondary outcomes included blood pressure control, weight, total cholesterol level, total cholesterol to high density lipoprotein (HDL) ratio, and body mass index.

Was the study design appropriate?

Yes – The diabetes glycaemic education and monitoring (DiGEM) study was a four-year open, randomised, parallel-group trial set in UK general practices. Eligible patients had type 2 diabetes, were aged 25 years and over at diagnosis, were managed with diet or oral hypoglycaemic agents alone, had an HbA_{1c} level \geq 6.2% at assessment, and were independent in activities of daily living. Overall, 453 patients were randomly assigned to one of three treatment groups:

- Standardised usual care with measurements of HbA_{1c} levels by health professionals every three months (control group, n = 152).
- Use of a blood glucose meter (three readings twice per week), with advice for participants to contact their doctor for interpretation of results (less intensive self-monitoring, n = 150).
- Use of a blood glucose meter (three readings twice per week), with training on self interpretation and application of the results to diet, physical activity, and drug adherence (more intensive self-monitoring, n = 151).

The study was funded by the NHS and the National Institute for Health Research health technology assessment programme. Abbott Diabetes Care (Maidenhead, UK) provided Optium[®] blood glucose meters.

Were participants appropriately allocated to intervention and control groups?

Yes – Randomisation was conducted using a computerised partial minimisation procedure to balance three important covariates collected at baseline: duration of diabetes, HbA_{1c} level, and current treatment (diet, oral monotherapy, or oral combination therapy). Baseline personal and clinical characteristics appear well balanced among the groups, although no statistical analyses are presented.

Were participants, staff and study personnel 'blind' to participants study group?

No – Due to the nature of the interventions blinding was not possible. However, randomisation was conducted independently of the nurses who managed recruitment and carried out the assessment visits. The treatment allocation was also concealed from laboratory staff.

Were all of the participants who entered into the trial accounted for at its conclusion?

Yes – The analysis was conducted on an intention-to-treat basis. In total, 57 patients (12.6%) were lost to follow-up, which did not differ significantly between groups. HDL measurements were not obtained for 39 patients. At follow-up, HbA_{1c} measurements were not collected for two patients, blood pressure for five, cholesterol levels for 10,

and HDL levels for 15. Eight patients in the control group started self-monitoring of blood glucose.

Were the participants followed up and data collected in the same way?

Yes – Follow-up visits were scheduled at three, six, and nine months, and differed in content according to the allocated intervention in line with usual practice. Patients in the control group had HbA_{1c} levels measured two weeks before their scheduled visit, the result of which was fed back to them as an indication of the impact of their self-care activities on their glycaemic control. Blood glucose values were reviewed at the scheduled visit for those allocated to self-monitoring, and patients were told to seek advice from their doctor if values were persistently > 6 mmol/L. Patients in each arm of the study received feedback on glycaemic control, and this was used to explore the success of goals and to set new targets. Participants' doctors were notified of all HbA_{1c} results and requested to consider changes in drug therapy in line with NICE diabetes guidance.²

Was the study large enough?

Yes – The study was designed to have a 90% power to detect a difference of 0.5% in HbA_{1c} levels as the primary endpoint at a two-sided significance level of $p < 0.05$. The standard deviation (SD) of HbA_{1c} levels was estimated to be 1.5% based on a previous trial of patients with type 2 diabetes, and assumed a loss to follow-up of 10%. This required a total of 630 patients to achieve the specified statistical power. However, baseline data on HbA_{1c} levels in the first 245 randomised patients indicated that the SD for HbA_{1c} levels had been overestimated in the original power calculations and was therefore revised to 1.25%. The recruitment target was subsequently revised to 450 patients, retaining a 10% dropout rate and a 90% power.

How are the results presented and what is the main results?

Primary endpoint.

At 12 months no difference was found in HbA_{1c} levels between groups after adjustment for baseline HbA_{1c} levels ($p = 0.12$). The difference in unadjusted mean change in HbA_{1c} from baseline to 12 months between the control and less intensive self-monitoring group was -0.14% (95% confidence interval (CI) -0.35% to 0.07%), and between the control and more intensive self-monitoring group was -0.17% (95% CI -0.37% to 0.03%).

Secondary endpoints.

There were significant differences in the change in total cholesterol levels from baseline to 12 months between the groups ($p = 0.010$). The mean

difference in the changes from baseline (4.6 to 4.7 mmol/L) were -0.06 mmol/L (95% CI -0.26 to 0.14) between the control group and the less intensive self-monitoring group, and -0.23 mmol/L (95% CI -0.43 to -0.04) between the control group and the more intensive self-monitoring group. No significant differences were found in any other secondary outcome measure.

Hypoglycaemia.

During the study one or more grade 2 hypoglycaemic events were experienced by 14 patients in the control group, 33 in the less intensive self-monitoring group, and 43 in the intensive self-monitoring group ($p < 0.001$). However, the proportion of patients prescribed an increase in antidiabetic drugs between baseline and 12 months did not differ among the groups (30%, 29% and 32%, respectively).

Use of the blood glucose meter.

Patients allocated to less intensive self-monitoring were significantly more likely to persist with the use of the meter than those allocated to the more intensive self-monitoring (67% vs. 52% continued to use the meter at least twice per week for the 12 months of the study, $p = 0.012$). Among those who continued to use the meter, the mean number of readings taken over 12 months was significantly higher in the more intensive monitoring group compared to the less intensive monitoring group ($p = 0.022$).

How precise are the results?

This was a small, well conducted and accurately documented study. The baseline characteristics of the three groups were well balanced. Although recruitment targets were revised after baseline data revealed that the SD for HbA_{1c} levels had been overestimated, the investigators did not change the proposed power or significance levels for the study. Participants in this study had reasonably well-controlled diabetes and although the majority were not using a meter some had had experience of their use; both these factors may have limited the scope for further improvements in glycaemic control.

Can the results be applied to the local population?

Probably – The trial was conducted in non-insulin-treated patients with type 2 diabetes. The study was conducted across 48 general practices in Oxfordshire and South Yorkshire. The median duration of diabetes was three years, mean HbA_{1c} level was 7.5%, and the mean age 65.7 years. NICE recommends that patients with type 2 diabetes should have HbA_{1c} levels measured at two to six monthly intervals depending on the level and stability of glucose control, and/or change in therapy.² Six-monthly measurements should be

made if the blood glucose level and therapy are stable.² Self-monitoring of glucose should be taught if the need/purpose is clear and agreed with the patient, but should not be considered as a stand-alone intervention.² The participants in this study are representative of reasonably well-controlled non-insulin-treated type 2 diabetic patients in whom self-monitoring of blood glucose may not be routinely warranted.

Is self-monitoring of blood glucose more effective than standardised usual care in improving glycaemic control in non-insulin treated patients with type 2 diabetes?

No – The data from this trial suggest that self-monitoring of blood glucose, with or without instruction in incorporating the results into self-care does not improve glycaemic control compared to

usual care in reasonably well-controlled non-insulin-treated type 2 diabetic patients. Routine self-monitoring of blood glucose is not required if patients are well-controlled on non-insulin therapy (including oral treatment, diet and exercise control),³ regular HbA_{1c} measurements should be used to monitor blood glucose control.² Self-monitoring of glucose levels can be important at diagnosis when used as part of a patient education programme. However, to maximise the benefit of self-monitoring, health professionals must ensure that patients clearly understand the purpose and frequency of self-monitoring and should clarify with patients how readings should be interpreted and applied to goals for lifestyle changes. Self-monitoring does not replace the need for regular laboratory assessment.

Further information is available in the RDTC Drug Update No.50; Self-monitoring of blood glucose.⁴

REFERENCES

1. 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;bmj.39247.447431.BE. (RCT)
2. NICE. Management of type 2 diabetes: management of blood glucose - inherited clinical guideline G. September 2002. (G)

3. Owens D. Blood glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus. *Diabetes and Primary Care* 2004;6:8-16. (R)
4. Regional Drug and Therapeutic Centre. Drug Update No. 50: Self-monitoring of blood glucose. January 2007. http://www.nyrdtc.nhs.uk/docs/dud/DU_50_Self%20Monitoring%20RDTC.pdf. (R)

KEY: RCT - randomised controlled trial, G – guidelines, R – review.

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