BMJ

RESEARCH

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

Maurice J O'Kane, consultant,[1] Brendan Bunting, professor,[2] Margaret Copeland, trial manager,[3] Vivien E Coates, professor,[3] on behalf of the ESMON study group

[1]Department of Clinical Chemistry, Altnagelvin Hospital, Western Health and Social Care Trust, Londonderry, Northern Ireland

[2]Psychology Research Institute, University of Ulster, Londonderry, Northern Ireland

[3]Institute of Nursing Research, University of Ulster, Coleraine, Northern Ireland

Correspondence to: M J O'Kane Maurice.OKane@westerntrust.hscni.net

doi:10.1136/bmj.39534.571644.BE

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] Self monitoring might contribute to management in two ways. Firstly, it might improve glycaemic control by reinforcing beneficial self management behaviours and compliance with medication. Secondly, the process of monitoring and the immediate feedback it provides on glycaemic control might affect patients' experience and determine attitudes to their diabetes and satisfaction with treatment.

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 controlled 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 Altnagelvin, Belfast City, Causeway, and the Ulster Hospitals (Northern Ireland) between 2002 and 2005. The decision to refer individual patients reflected the normal referral practice of the primary care doctor. Exclusion criteria included secondary diabetes, use of insulin, previous use of self monitoring of blood glucose, major illness within the previous six months, chronic kidney disease, chronic liver disease, and alcohol misuse.

Outcomes

Our pre-designated primary end points were differences between groups in HbA_{1c}, psychological indices, and incidence of hypoglycaemia. Our 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.

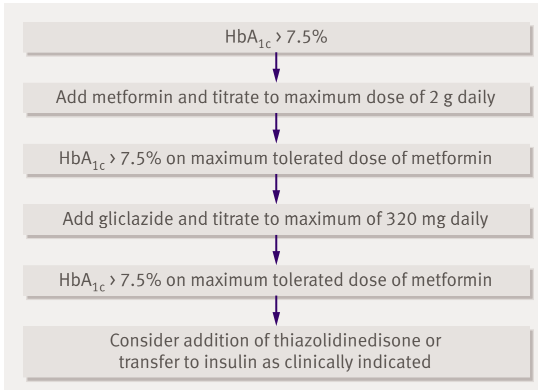

Fig 1 | **Treatment algorithm for oral hypoglycaemic agents**

After an initial assessment visit, eligible patients were randomised into intervention (self monitoring of blood glucose) or control (no monitoring) groups with a randomly generated allocation code in consecutively numbered sealed envelopes. The study diabetes nurse at each hospital site performed the treatment allocation.

Patients in the self monitoring group were all provided with a single glucose monitor (Lifescan OneTouch Ultra; Johnson and Johnson, Milpitas, CA) and instructed in its use. They were 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. Such advice included the need for dietary review or the suggestion of exercise (such as walking) in response to high readings. 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.

Patients in both groups underwent an identical structured education programme involving diabetes nurse practitioners, dieticians, podiatrists, and medical staff. All patients were reviewed by the doctor, diabetes nurse practitioner, and dietician at three monthly intervals for one year. At each visit all aspects of diabetes care were reviewed including indices of glycaemic control (HbA_{1c} for both groups and self monitoring results for the self monitoring group). Patients in the self monitoring group received ongoing advice and support in the appropriate 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 1). 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. Measurement of HbA_{1c} was performed in the local hospital laboratory with a diabetes control and complications trial (DCCT) aligned HbA_{1c} assay.[2] All laboratories participated in HbA_{1c} external quality assurance, which was satisfactory for the duration of the study. All other laboratory tests were also performed in the local hospital laboratory, where staff were blinded to treatment allocation.

At each three monthly visit patients completed a questionnaire survey incorporating the diabetes treatment satisfaction questionnaire,[3] a modified version of the diabetes attitude scale,[4] and the well-being questionnaire.[5] The diabetes attitude scale included three of the seven subscales: seriousness of type 2 diabetes, blood glucose control and its implications, and impact of diabetes on patients' lives.[4] The well-being questionnaire incorporated four subscales (depression, anxiety, energy, and positive wellbeing) and a total score of general wellbeing.

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%. (A 50% reduction in this standard deviation—that is, a narrowing of the HbA_{1c} distribution width as HbA_{1c} values converge on treatment targets—would detect a difference of 0.5% in HbA_{1c} with the above power.) We used Mplus univariate independent *t* tests for statistical analysis and checked the results against non-latent growth models with time variant and time invariant covariates.[6] We used three predetermined time invariant predictors: sex, age, monitoring status (that is, control or monitoring, with monitoring further broken down into two subgroups: patients who complied with the suggested monitoring regimen and patients who did not comply with the suggested monitoring regimen). Compliance was defined as a monitoring frequency of >80% of that requested. In addition, we introduced the number of medications being taken for the control of HbA_{1c} as a time varying covariate. The analysis was performed on an intention to treat basis, with missing data imputed through the use of full information maximum likelihood. Psychological indices were examined by analysis of covariance with the measurement models held invariant across time. Differences between groups in use of oral

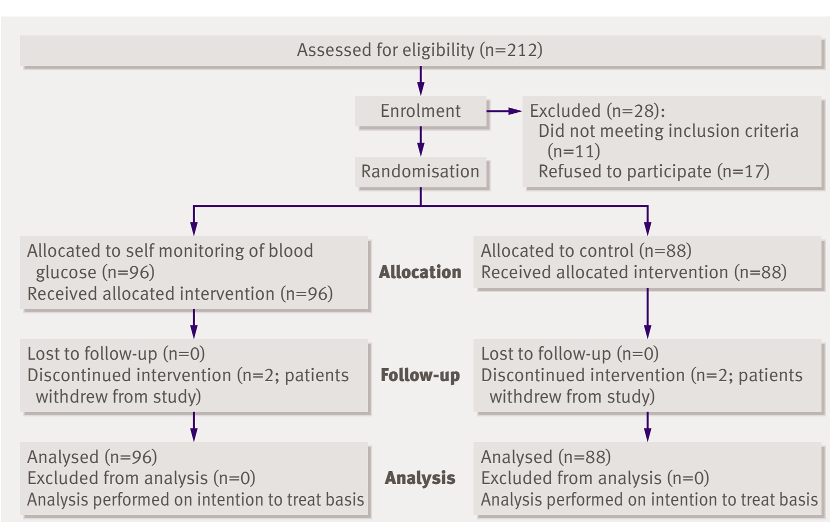

Fig 2 | **Flow of patients through study**

Table 1 | Baseline characteristics of patients with newly diagnosed diabetes according to self monitoring or no monitoring (control) of blood glucose. Figures are means (SD) unless stated otherwise

	Monitoring group	Control
No of patients (men/women)	96 (55/41)	88 (56/32)
Age (years)	57.7 (11.04)	60.9 (11.5)
Body mass index	34 (6.98)	32 (6.23)
% HbA_{1c}	8.8 (2.1)	8.6 (2.3)

hypoglycaemic drugs were assessed by Pearson's χ^2 test.

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) (fig 2). 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), table 1).

Of the 96 participants in the self monitoring group, 63 carried out more than 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 (table 2). 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 (P=0.01), and there was a trend towards increased anxiety (table 3). 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 (tables 4 and 5). 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 (table 6).

Table 2 | Mean (SD) HbA_{1c} in patients with newly diagnosed diabetes according to self monitoring or no monitoring (control) of blood glucose

Time (months)	Monitoring	Control	P value	Mean difference (95% CI)
0	8.8 (2.1)	8.6 (2.3)	0.68	−0.33 (−0.77 to 0.51)
3	7.2 (1.1)	7.1 (1.2)	0.50	0.18 (−0.47 to 0.23)
6	7.0 (0.9)	7.0 (1.1)	0.82	0.04 (−0.27 to 0.35)
9	6.9 (0.8)	7.1 (1.4)	0.30	0.19 (−0.16 to 0.54)
12	6.9 (0.8)	6.9 (1.2)	0.69	0.07 (−0.25 to 0.38)

DISCUSSION

Self monitoring of blood glucose concentrations might contribute in two ways to the management of type 2 diabetes: by improving glycaemic control or by improving the patients' experience of diabetes. 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

We investigated the role of self monitoring in a cohort of patients with newly diagnosed type 2 diabetes, all of whom 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 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 on the efficacy of self monitoring have varied in design and have included non-randomised trials (both prospective and retrospective) and randomised controlled trials.[7-19] The range of designs used in these studies reflects the difficulty of isolating the effect of a single home intervention in a condition in which

Table 3 | 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.

Table 4 | Number of patients who reported hypoglycaemia (total number of hypoglycaemia episodes reported) according to self monitoring and no monitoring (control) of blood glucose

Time (months)	Monitoring	Control
0	1 (3)	0 (0)
3	5 (10)	2 (8)
6	3 (5)	4 (8)
9	5 (9)	1 (6)
12	4 (4)	6 (14)

patients' motivation, self management behaviour, and concordance with a prescribed drug regimen play a central role in effective treatment.

The retrospective ROSSO study found that self monitoring was associated with a reduction in both fatal and non-fatal (microvascular and macrovascular) events in 3268 patients over a mean review period of 6. 5 years.[19] The non-randomised retrospective study design, however, makes it difficult to exclude the possibility that more motivated patients opt to monitor and the fact of monitoring might therefore simply be a marker of generally beneficial self management behaviour. Randomised controlled trials offer a more robust tool for the investigation of self monitoring.

The small number of such trials undertaken, however, 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.[20 21] There was clinical heterogeneity between the trials studied in both baseline characteristics and interventions.[18] Educational interventions often differ between the self monitoring and control group, making it difficult to isolate the effect of self monitoring.[11 12] Two recent large studies (ASIA and DIGEM) have provided differing results on the role of self monitoring.[11 13] The ASIA study of 689 patients with established type 2 diabetes found significant reductions in HbA_{1c} from baseline in both self monitoring (−0.88%) and control (−0.6%) groups with a 0.3% reduction between groups in favour of monitoring at 24 weeks.[11] The improvement in HbA_{1c} in the control group suggested that pre-existing management had been suboptimal and that management administered under the study protocol differed from usual care. Furthermore the ASIA study had a high drop-out rate (48% in the self monitoring group, 40% in the control), which limits the general applicability of the findings. In contrast, the well designed DIGEM trial of 453 patients found no benefit of self monitoring (with or without structured education) in patients with established and well controlled type 2 diabetes,[13] 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 randomised controlled trials and the present study is that our study 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, however, have included people with established diabetes, and it is unclear to what extent results could be extrapolated to newly presenting patients.[22] Recruitment protocols in such studies generally excluded those who were already actively monitoring or who had recently monitored. This introduced a potential selection bias by excluding patients who had found monitoring beneficial, and by including patients who may have had previous experience of monitoring but rejected it as unhelpful.[7-12] The effect of any such bias would be to underestimate the benefit of self monitoring. We removed any such potential bias by recruiting only those patients with a new diagnosis of diabetesandwho had not previously performed self monitoring.

Anecdotal and other evidence suggests that some patients consider monitoring uncomfortable, intrusive, and unpleasant.[23 24] An interesting finding of our study was 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. This supports the results of Franciosi et

Table 5 | Use of oral hypoglycaemic drugs in patients with newly diagnosed diabetes according to self monitoring or no monitoring (control) of blood glucose

	Monitoring	Control	P value*
At baseline†			
No drugs	86	78	0.67
1 drug	8	7	0.91
2 drugs	0	2	0.14
At 12 months‡			
No drugs	34	29	0.95
1 drug	44	40	0.62
2 drugs	11	6	0.36

*Pearson's χ^2 cross tabulation between monitoring and control by number of drugs.
†Data missing for two patients in monitoring group and one in control group.
‡Data missing for seven in monitoring group and 13 in control group.

Table 6 | Body mass index (mean* (SD) and predicted overall mean) at 3, 6, 9, and 12 months adjusted for baseline value in self monitoring or no monitoring (control) groups

Time (months)	Monitoring	Control	P value	Predicted overall mean (95% CI†)
0	34.0 (7.0)	32 (6.2)	0.04	—
3	33.0 (6.5)	31.5 (6.1)	0.56	31.83 to 32.93 (32.38)
6	33 (6.3)	31.4 (6.1)	0.75	31.71 to 32.86 (32.28)
9	33.1 (6.3)	31.7 (6.1)	0.49	31.99 to 33.19 (32.59)
12	33.1 (6.4)	31.8 (6.0)	0.32	32.09 to 33.29 (32.69)

*Raw score standard deviations.
†Confidence interval based on overall predicted mean score.

al,[16] who also found higher levels of distress, depressive symptoms, and anxiety in patients who self monitored, and the qualitative findings of Peel et al.[25] This possible negative effect of monitoring might be important and merits further investigation. Given that glycaemic control rapidly improved to satisfactory levels during the study, 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. This possibility should be considered when patients with a new diagnosis of diabetes are introduced to monitoring.

The value of self monitoring in patients with a new diagnosis is an important practical issue given that in UK clinical practice patients are often introduced to monitoring at an early stage after diagnosis.[22 23] Our results suggest it is not associated with any improvement in glycaemic control in such patients and might be associated with reduced wellbeing.

The ESMON Study Group comprises Vivien Coates, Margaret Copeland, Brendan Bunting (University of Uster); 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.

Contributors: MJO'K and VEC had the original idea for the study and wrote the protocol with BB in conjunction with members of the ESMON study group. BB was the study statistician. VEC and MC managed the study. MJOK, BB, MC, and VEC analysed and interpreted the study data. MJO'K wrote the first draft of the manuscript. All members of the study executive committee reviewed the final draft of the manuscript. VEC is guarantor.

Funding: Northern Ireland research and development office. MC was employed as a research associate as part of the funding allocation. The blood glucose meters were supplied free of charge by Johnson and Johnson, Milpitas, CA.

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

Competing interests: None declared.
Ethical approval: University of Ulster ethics committee.
Provenance and peer review: Not commissioned; externally peer reviewed.

1 IDF Clinical Guidelines Taskforce. Global guidelines for type 2 diabetes: recommendations for standard, comprehensive and minimal care. *Diabet Med* 2006;23:579-93.
2 Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long term complications of insulin dependent diabetes mellitus. *N Engl J Med* 1993;329:977-86.
3 Bradley C. Diabetes treatment satisfaction questionnaire [DTSQ]. In: Bradley C, ed. *The handbook of psychology and diabetes; a guide to psychological measurement in diabetes research and practice*. Chur, Switzerland: Harwood Academic Publishers, 1994:111-32.
4 Anderson RM, Donnelly MB, Dedrick RF. Measuring the attitudes towards diabetes and its treatment. *Patient Educ Couns* 1990;16:231-45.
5 Bradley C. The well-being questionnaire. In: Bradley C, ed. *The handbook of psychology and diabetes; a guide to psychological measurement in diabetes research and practice*. Chur, Switzerland: Harwood Academic Publishers, 1994:89-109.
6 Muthén LK, Muthén BO. *Mplus user's guide*. 4th ed. Los Angeles: Muthén & Muthén, 2006.
7 Fontbonne A, Billault B, Acosta M, Percheron C, Varenne P, Besse A, et al. Is glucose self-monitoring beneficial in non-insulin treated patients? Results of a randomized comparative trial. *Diabetes Metab* 1989;15:255-60.
8 Allen BT, DeLong ER, Feussner JR. Impact of glucose self-monitoring on non-insulin treated patients with type 2 diabetes mellitus. *Diabetes Care* 1990;13:1044-50.
9 Muchmore DB, Springer J, Miller M. Self-monitoring of blood glucose in overweight type 2 diabetic patients. *Acta Diabetol* 1994;31:215-9.
10 Schwedes U, Siebolds M, Mertes G. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care* 2002;25:1928-32.
11 Guerci B, Drouin P, Grange V, Bougneres P, Fontaine P, Passa P, et al. Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the auto-surveillance intervention active [ASIA] study. *Diabetes Metab* 2003;29:587-94.
12 Davidson MB, Castellanos M, Kain D, Duran P. The effect of self-monitoring of blood glucose concentrations on glycated haemoglobin levels in diabetic patients not taking insulin. *Am J Med* 2005;118:422-5.
13 Farmer A, Wade A, Goyder E, Yudkin P, French D, Craven A, 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.
14 Gallichan MJ. Self-monitoring by patients receiving oral hypoglycaemic agents: a survey and comparative trial. *Practical Diabetes* 1994;11:28-30.
15 Miles P, Everett J, Murphy J, Kerr D. Comparison of blood or urine testing by patients with newly diagnosed type 2 diabetes: patient survey after randomised crossover trial. *BMJ* 1997;315:348-9.
16 Franciosi M, Pellegrini F, De Beradis G, Belfiglio M, Calviere D, Di Nardo B, 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;24:1870-7.
17 Karter AJ, Ackerson LM, Darbinian JA, D'Agostino RB Jr, Ferrara A, Liu J, et al. Self monitoring of blood glucose levels and glycemic control: the Northern California Kaiser Permanente diabetes registry. *Am J Med* 1996;100:157-63.
18 Soumerai SB, Mah C, Zhang F, Adams A, Barton M, Fajtova V, et al. Effects of health maintenance organization coverage of self-

monitoring devices on diabetes self-care and glycaemic control. *Arch Intern Med* 2004;164:645-52.

19 Martin S, Schneider B, Heineman L, Lodwig V, Kurth H-J, Kolb H, et al. Self-monitoring of blood glucose in type 2 diabetes and long term outcome: an epidemiological cohort study. *Diabetologia* 2005;49:271-8.

20 Welschen LMC, Bloemendal E, Nijpels G, Dekker JM, Heine RJ, Stalman WAB, et al. Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin. *Diabetes Care* 2005;28:1510-7.

21 Stratton IM, Adler AI, Neil HA, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ* 2000;321:405-12.

22 Heller SR. Self monitoring of blood glucose in type 2 diabetes. *BMJ* 2007;335:105-6.

23 Gulliford M, Latinovic R. Variations in glucose self-monitoring during oral hypoglycaemic therapy in primary care. *Diabet Med* 2004;21:685-90.

24 Watkins KW, Connell CM, Fitzgerald JT, Klem L, Hickey T, Ingersoll-Dayton B. Effect of adults' self regulation of diabetes on quality of life issues. *Diabetes Care* 2000;23:1511-5.

25 Peel E, Douglas M, Lawton J. Self monitoring of blood glucose in type 2 diabetes: longitudinal qualitative study of patients' perspectives. *BMJ* 2007;335:493.

Accepted: 21 March 2008