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## Research: Care Delivery

# Self-monitoring of blood glucose versus self-monitoring of urine glucose in adults with newly diagnosed Type 2 diabetes receiving structured education: a cluster randomized controlled trial

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## Abstract

**Aims** To compare the effectiveness and acceptability of self-monitoring of blood glucose with self-monitoring of urine glucose in adults with newly diagnosed Type 2 diabetes.

**Methods** We conducted a multi-site cluster randomized controlled trial with practice-level randomization. Participants attended a structured group education programme, which included a module on self-monitoring using blood glucose or urine glucose monitoring. $HbA_{1c}$ and other biomedical measures as well as psychosocial data were collected at 6, 12 and 18 months. A total of 292 participants with Type 2 diabetes were recruited from 75 practices.

**Results** $HbA_{1c}$ levels were significantly lower at 18 months than at baseline in both the blood monitoring group [mean (SE) −12 (2) mmol/mol; −1.1 (0.2) %] and the urine monitoring group [mean (SE) −13 (2) mmol/mol; −1.2 (0.2)%], with no difference between groups [mean difference adjusted for cluster effect and baseline value = −1 mmol/mol (95% CI −3, 2); −0.1% (95% CI −0.3, 0.2)]. Similar improvements were observed for the other biomedical outcomes, with no differences between groups. Both groups showed improvements in total treatment satisfaction, generic well-being, and diabetes-specific well-being, and had a less threatening view of diabetes, with no differences between groups at 18 months. Approximately one in five participants in the urine monitoring arm switched to blood monitoring, while those in the blood monitoring arm rarely switched (18 vs 1% at 18 months; $P < 0.001$).

**Conclusions** Participants with newly diagnosed Type 2 diabetes who attended structured education showed similar improvements in $HbA_{1c}$ levels at 18 months, regardless of whether they were assigned to blood or urine self-monitoring.

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## Introduction

Self-monitoring of blood glucose is a core component of effective self-management of Type 1 diabetes, and of Type 2 diabetes for people using insulin or sulphonylureas [1,2]. However, the benefit is less clear for people with Type 2 diabetes using diet or oral agents that do not increase the risk of hypoglycaemia. Systematic reviews [3–7] and meta-analyses have generally reported little improvement in biomedical outcomes for self-monitoring of blood glucose in people with non-insulin-treated Type 2 diabetes. The lack of clarity in results is in part because the trials were heterogeneous, differing in trial design, in population recruited and in how the use of self-monitoring was implemented. The one exception appears to be studies where the approach to monitoring is 'structured', with participants following clearly defined monitoring schedules and receiving regular and detailed feedback and advice from trained healthcare professionals. Where this has been the case, clinically relevant improvements in glycaemic control have been observed [8–11]; however, this 'structured' approach does not represent current routine care in the UK, where people with Type 2 diabetes who start self-mon-

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**What's new?**

- This is the first pragmatic trial comparing blood glucose monitoring with urine glucose monitoring within an established and widely available structured education course delivered in a primary care setting.
- Equivalent improvements in $HbA_{1c}$ and other biomedical outcomes were seen regardless of the mode of monitoring, although participants showed a slight preference for blood monitoring.
- Promoting urine monitoring as the method of choice in structured education programmes for people newly diagnosed with diabetes might lead to substantial savings without impairing outcomes. Those who find blood monitoring more useful should be permitted to use this method, but the results suggest they might be more likely to benefit if they received ongoing advice and support for this approach from their primary care team.

itoring soon after diagnosis may receive minimal support from their healthcare provider and sometimes choose to start self-monitoring without seeking help.

Few studies have examined self-monitoring of blood glucose in people with newly diagnosed Type 2 diabetes [12,13] or compared it with other forms of glucose monitoring (e.g. urine monitoring), which might be provided at less cost [14–16]. We hypothesized that, for adults with newly diagnosed Type 2 diabetes attending group structured education, the use of self-monitoring of urine glucose would be as effective as blood glucose monitoring in terms of improving and sustaining glycaemic control over 18 months. We tested this hypothesis in a primary care setting with all participants attending the Diabetes Education Self-Management for Ongoing and Newly diagnosed Diabetes (DESMOND) structured education programme [17], thus ensuring that participants in both study arms experienced similar structured education in self-management.

## Methods

The study design and protocol have been described previously [18]. In brief, the study was an 18-month multi-site cluster-randomized controlled trial with participants in different practices randomized to one of two arms. All participants attended a DESMOND structured education programme [17], which included a module on either blood or urine self-monitoring. Follow-up data were collected at 6, 12 and 18 months after delivery of the education programme. Ethical approval was received from a Research Ethics Committee (07/H0304/129) and local research governance approval was obtained from participating health trusts.

### Setting and participants

Sixty-five general practices (including those in inner city and rural settings) in England referred adults with Type 2 diabetes to the study within 12 weeks of diagnosis. Participants were excluded if they were aged < 18 years, using insulin, had severe and enduring mental health problems, were not primarily responsible for their own care, were unable or unwilling to participate in a group programme or were taking part in another research study. Participants were required to attend the DESMOND programme within 6 months of diagnosis and were not eligible if they had already started regular self-monitoring of blood glucose.

### Randomization

The study was cluster-randomized, with randomization at practice level, after stratification for site and practice list size. The study was unblinded, but practices agreed to participate before randomization took place and were not informed of their study arm allocation. It is likely, however, that clinicians at each practice became aware of the arm allocation over time as participants attended the practice for ongoing clinical support and repeat prescriptions for monitoring resources. Practice staff were instructed to refer participants without telling them which arm they had been allocated to and participants were not informed of their study arm allocation until they had given informed consent.

### Study intervention

Participants attended the DESMOND 'Newly Diagnosed' programme [17]. This is delivered by two trained and accredited educators as a single 6-h session or two 3-h sessions 1 week apart, and usually includes a 20-min session covering both urine and blood self-monitoring. For the study, the time spent discussing self-monitoring was extended to 100 min, and the course was delivered in two sessions, 1 week apart. The development, content and piloting of the new self-monitoring modules are described in the protocol paper [18]. The approach to self-monitoring was non-directive, but promoted the practice of self-monitoring as a tool to support decision-making with regard to lifestyle changes and medication use. Participants were encouraged to discover when and how often to monitor, as well as how to interpret results and explore options for change. Although participants were allocated to blood or urine self-monitoring, they were free to change their method of monitoring or to stop monitoring at any time. During the study, they obtained further monitoring supplies by requesting a prescription from their practice. Most participants were exempt from prescription charges and the small number who were liable to pay were refunded any charges they incurred. Practices were also refunded the prescribing costs to prevent cost being a barrier to self-monitoring or to participation in the trial.

The primary outcome was mean $HbA_{1c}$ level at 18 months. The secondary outcomes included biomedical and psychosocial variables, measured at 6, 12 and 18 months. Biomedical measures included lipid profile, blood pressure, body weight and waist circumference. Psychosocial processes and outcomes were measured using questionnaires covering various aspects of diabetes and self-monitoring. Satisfaction with treatment was assessed using the Diabetes Treatment Satisfaction Questionnaire [19], which measures: 1) total treatment satisfaction; 2) perceived frequency of hyperglycaemia; and 3) perceived frequency of hypoglycaemia. Psychological well-being was measured using the 28-item Well-Being Questionnaire (W–BQ28) [19], from which two 12-item constructs were produced: 1) generic well-being and 2) diabetes-specific well-being. Perceptions of diabetes were measured using a diabetes-specific version of the Brief Illness Perceptions Questionnaire [20]. For all measures, a higher score indicates more of the construct being measured.

The trial was designed as a non-inferiority trial with the aim of demonstrating a mean equivalence in $HbA_{1c}$ level at 18 months of within 5 mmol/mol (0.5%). Assuming, at 18 months, a conservative standard deviation of 16 mmol/mol (1.5%) [21], 80% power and 5% significance, 142 participants were required per arm, increasing to 163 per arm to allow for clustering, assuming an intra-cluster correlation of 0.05 and mean cluster size of four. Assuming 20% non-consent and a 20% drop-out rate, the numbers required were 254 referrals and 204 consenting participants per arm.

Baseline characteristics were summarized by group at each follow-up point, as was the monitoring method that the participant reported using. For each outcome and follow-up, the mean (SE) change from baseline at each follow-up was estimated by arm and compared using generalized estimating equations adjusted for baseline value and a term that accounted for the practice-level clustering. These equations assumed an exchangeable correlation matrix, robust SE values and a normal distribution for the data, except for the reported monitoring method, which used a binomial distribution. The primary analyses followed the intention-to-treat principle and data were analysed according to randomization arm, regardless of whether participants continued to use that monitoring method or provided follow-up data. Missing data were replaced using multiple imputation, which accounted for the clustering as far as possible except where this meant that the model would not converge (waist circumference, systolic and diastolic blood pressure, HDL and LDL cholesterol and W–BQ28 generic well-being, because the models that accounted for site did not converge).

Analyses were repeated in two key subsets: 1) only those with complete data available, i.e. with no imputation of missing data and 2) only those who were using their randomized monitoring method at the follow-up time point of interest. The latter is analogous to a per protocol analysis in an individually randomized trial and, thus, is referred to as 'per protocol' hereafter, for ease of understanding. All $P$ values were two-sided and statistical significance was assessed at the 5% level. Analyses were conducted in STATA 12.1. Data are presented as estimate (95% CI).

## Results

A flow chart for study participants is shown in Fig. 1. A total of 75 general practices were recruited and randomized: 37 to blood monitoring and 38 to urine monitoring. The blood monitoring practices referred 253 people, of whom 140 (55%) consented to join the study. The urine monitoring practices referred 275 people, of whom 152 (55%) consented to join the study (Fig 1). The main reasons for non-participation were no further interest in taking part, booking but not attending, inability to arrange a suitable date and inability to contact participants. The baseline characteristics of those who participated are shown in Table 1. There was no significant difference within randomization groups in age, gender or baseline $HbA_{1c}$ between those who did and did not provide biomedical data at 18 months. Participants who did not complete the questionnaire at 18 months were younger than respondents in both arms (blood monitoring: $P < 0.001$; urine monitoring: $P = 0.05$) but did not differ in terms of $HbA_{1c}$ (blood monitoring: $P = 0.45$; urine monitoring: $P = 0.74$) or gender (blood monitoring: $P = 0.12$; urine monitoring: $P = 0.71$).

Results for the biomedical outcomes are shown in Table 2. There were significant reductions in mean (SE) $HbA_{1c}$ from baseline in the blood monitoring group of 13 (2) mmol/mol [1.2 (0.2)%] at 6 months, 12.0 (2) mmol/mol [1.1 (0.2)%] at 12 months, and 12.0 (2.2) mmol/mol [1.1 (0.2)%] at 18 months. Likewise, there were significant reductions in the urine monitoring group of 15.0 (2) mmol/mol [1.4 (0.2)%] at 6 months, 14 (2) mmol/mol [1.3 (0.2)%] at 12 months and 13.0 (2) mmol/mol [1.2 (0.2)%] at 18 months. There were no significant differences between groups in terms of $HbA_{1c}$ change at each follow-up (Table 2).

There were similar improvements from baseline in BMI, waist circumference, weight, systolic and diastolic blood pressure, and total and LDL cholesterol in both monitoring groups at each follow-up (most of which were statistically significant, with no significant differences between groups at each follow-up; Table 2). Sensitivity and per protocol analyses showed no significant differences between the two groups for any of the biomedical outcomes (Table S1).

In both groups, there were improvements from baseline in total treatment satisfaction, generic well-being and diabetes-specific well-being, and diabetes was perceived as less threatening. Most of these improvements were statistically significant (Table 3). There were no significant changes in perceived frequency of hyper- or hypoglycaemia. The only significant difference between the groups was that at

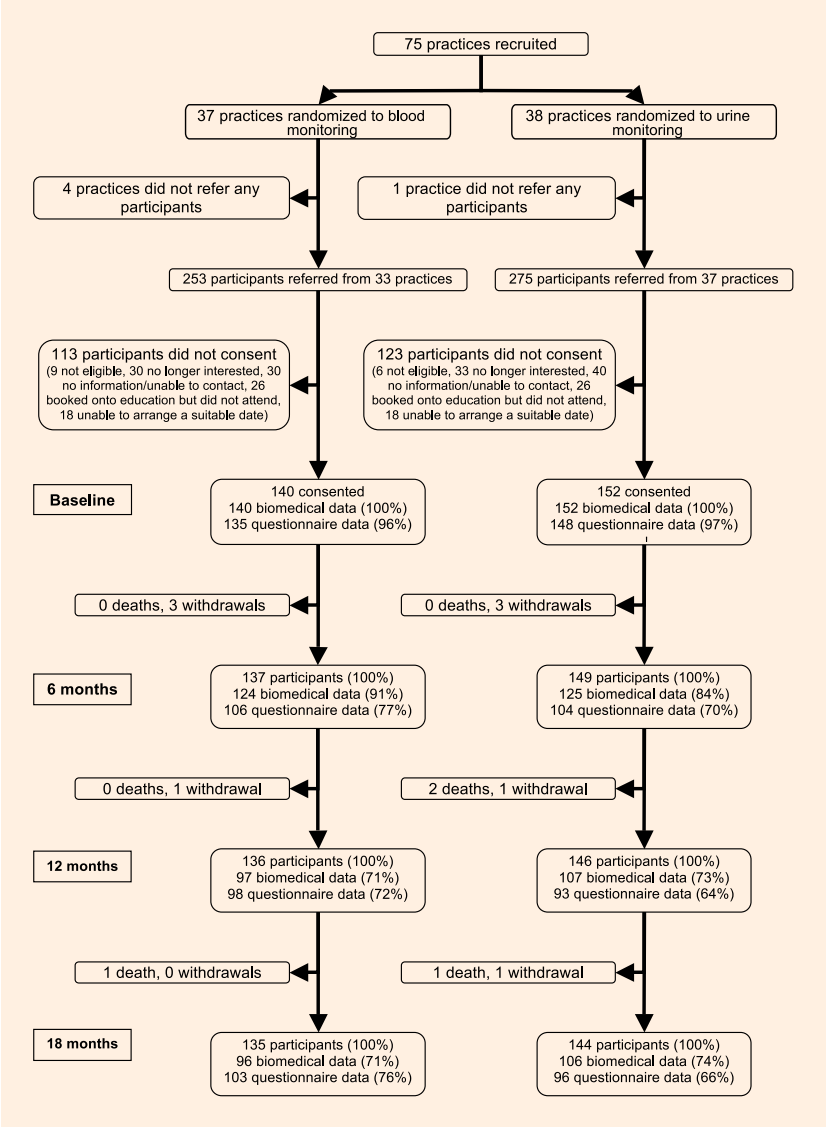


**FIGURE 1** CONSORT diagram showing flow of patients through the trial.

6 months, people randomized to urine monitoring perceived diabetes as less threatening than those randomized to blood monitoring (difference = −2.8; 95% CI = −5.3, −0.3).

Sensitivity and per protocol analyses (Table S2) show that many of the previously nonsignificant differences between groups strengthened and became statistically significant. When only complete data were analysed (i.e. missing data not imputed), the urine monitoring group were less satisfied with their treatment, had better generic and diabetes-specific well-being, and a less threatening view of diabetes, for at least one follow-up time point. In per protocol analyses, the urine monitoring group reported lower perceived frequency of hyperglycaemia and a less threatening view of diabetes at 6 months.

Participants randomized to blood monitoring were more likely to be using their randomized monitoring method than participants randomized to urine monitoring at 6 months (86 vs 74%; $P = 0.04$), 12 months (85 vs 69%; $P = 0.01$) and 18 months [79 vs 59%; $P < 0.01$ (Fig 2)], but the proportion of participants who did not monitor at all was not significantly different between the groups (6 months:12 vs 8%, $P = 0.14$; 12 months:12 vs 14%, $P = 0.70$; 18 months:17 vs 20%, $P = 0.58$). Those initially randomized to urine monitoring tended to switch to blood monitoring whilst those initially randomized to blood monitoring almost never switched method (6 months: 12 vs 1%, $P = 0.01$; 12 months:11 vs 0%, $P < 0.001$; 18 months: 18 vs 1%, $P < 0.01$). In both groups, participants who were monitoring were most likely to be doing so 1–3 times per week (data not shown). Half of the participants were prescribed metformin during the study. This usually happened at diagnosis (48% by 6 months) with small increases in prescription rates

**Table 1** Baseline characteristics of study participants stratified by monitoring group

| Variable | Blood monitoring $N = 140$ | Urine monitoring $N = 152$ |
|---|---|---|
| Demographic factors | | |
| Women, *n* (%) | 69 (49.3) | 65 (42.8) |
| White European, *n* (%) | 124 (93.9) | 121 (87.1) |
| Mean (SD) age, years | 57.1 (11.3) | 59.4 (11.6) |
| Biomedical measures, mean (SD) | | |
| $HbA_{1c}$, mmol/mol | 65 (22) | 66 (23) |
| $HbA_{1c}$, % | 8.1 (4.2) | 8.2 (4.3) |
| Total cholesterol, mmol/l | 5.3 (1.2) | 5.3 (1.4) |
| HDL cholesterol, mmol/l* | 1.2 (0.4) | 1.2 (0.3) |
| LDL cholesterol, mmol/l* | 3.0 (1.1) | 3.1 (1.1) |
| Systolic blood pressure, mm/Hg | 135.5 (15.1) | 136.2 (15.6) |
| Diastolic blood pressure, mm/Hg | 81.5 (10.1) | 81.4 (12.1) |
| Weight, kg | 94.4 (20.2) | 91.8 (18.5) |
| Waist circumference, cm* | 107.3 (16.1) | 106.1 (15.6) |
| BMI, $kg/m^2$ | 34.2 (10.8) | 32.8 (7.9) |
| Psychosocial measures, mean (SD) | | |
| DTSQ | | |
| Total treatment satisfaction * (score range: 0–36) | 25.8 (8.0) | 24.5 (8.4) |
| Perceived frequency of hyperglycaemia* (score range: 0–6) | 1.8 (1.9) | 1.6 (1.8) |
| Perceived frequency of hypoglycaemia* (score range: 0–6) | 0.9 (1.4) | 0.9 (1.3) |
| W-BQ28 | | |
| 12-item generic well-being (score range: 0–36) | 21.7 (6.7) | 23.2 (6.6) |
| Diabetes-specific well-being (score range: 0–36) | 23.9 (7.2) | 24.8 (7.1) |
| BIPQ | | |
| Threatening view of diabetes* (score range: 0–80) | 35.1 (12.8) | 33.8 (12.1) |

DTSQ, Diabetes Treatment Satisfaction Questionnaire; W-BQ28, 28-item Well-Being Questionnaire; BIPQ, Brief Illness Perceptions Questionnaire.
*More than 20% of the data for these variables were missing. For all variables, missing values were imputed before data analysis (see Methods).

occurring over time (50 and 54% at 12 and 18 months, respectively). There were no differences in levels of metformin prescription between the two arms.

## Discussion

Both groups showed significant improvements in $HbA_{1c}$ levels and other biomedical and psychosocial outcomes during the study, but there were no significant differences in changes between the groups, indicating that blood monitoring provided no additional benefit when compared with urine monitoring.

The present study had a robust, multi-site cluster design, to prevent contamination between groups, and a clinically relevant follow-up period of 18 months. It was conducted in a primary care setting, with broad inclusion criteria and involved attending a structured group education intervention that is delivered widely in the UK. Participants were recruited using a standard referral pathway. The pragmatic study design therefore embeds it in the real world and provides good external validity. Validated generic and diabetes-specific questionnaires were used in the evaluation. The two groups were well matched, and the fact that both received the same amount of education enabled us to control for the effects of education. Although eligibility for referral did not include a minimum $HbA_{1c}$ level, the mean value at baseline of 65 mmol/mol (8.1%) was high enough to show improvement. This has been a weakness of other studies where a low baseline $HbA_{1c}$ may have caused a 'floor effect' [13,22,23].

The study limitations include a consent rate lower than anticipated (although rates were identical in each arm), which resulted in not recruiting to target; however, sample size calculations were based on a predicted standard deviation in $HbA_{1c}$ at the end of the study of 16 mmol/mol (1.5%), but the actual standard deviation [11 mmol/mol (1.0%)] was lower than this. Substituting the observed standard deviation into the sample size calculation and keeping other assumptions the same, the required sample size would be 73 participants per arm, indicating that the study was adequately powered to meet its primary objective. The low consent rate was attributable to logistical problems that commonly occur in standard clinical pathways (e.g. difficulty contacting patients, cancellation and non-attendance). The level of data return dropped from 91% at 6 months to 71% at 18 months; however, there were no significant differences at baseline in age, gender or $HbA_{1c}$ between those who did and did not provide follow-up data, and sensitivity analysis suggests that level of data return did not have a large impact on results. The information and support that participants received for self-monitoring was almost exclusively from the DESMOND course. Although healthcare professionals in participating practices received a training visit before the trial [18], and were asked to provide impartial support and advice on self-monitoring during the study, their input was unlikely to have been large. Furthermore some participants in the qualitative sub-study reported a lack of support from healthcare professionals with interpreting results and in some cases disapproval of the method [24]. Thus, the full potential of blood monitoring to effect changes in self-management may have been limited.

Systematic reviews have generally reported little benefit in clinical outcomes in people with non-insulin-treated Type 2 diabetes [3–7]. More recent studies where the approach to monitoring is 'structured' have shown benefits [8–11], but

**Table 2** Mean changes from baseline for biomedical outcomes by monitoring group ($N$ = 292)

| Variables | Mean (SE) change from baseline | | Difference (95% CI) between monitoring groups[†] |
|---|---|---|---|
| | Blood monitoring | Urine monitoring | |
| $HbA_{1c}$, mmol/mol | | | |
| 6 months | 13 (2)*** | 15 (2)*** | 0 (−3, 2) |
| 12 months | 12 (2)*** | 15 (2)*** | 0 (−3, 2) |
| 18 months[‡] | 12 (2)*** | 13 (2)*** | −1 (−3, 2) |
| $HbA_{1c}$, % | | | |
| 6 months | −1.20 (0.16)*** | −1.40 (0.19)*** | −0.01 (−0.23, 0.22) |
| 12 months | −1.08 (0.18)*** | −1.33 (0.20)*** | −0.02 (−0.27, 0.24) |
| 18 months[‡] | −1.13 (0.21)*** | −1.20 (0.20)*** | −0.05 (−0.28, 0.18) |
| BMI, $kg/m^2$ | | | |
| 6 months | −1.28 (0.21)*** | −1.03 (0.29)*** | 0.17 (−0.49, 0.82) |
| 12 months | −1.04 (0.34)** | −0.86 (0.23)*** | 0.38 (−0.34, 1.10) |
| 18 months | −0.80 (0.43) | −1.06 (0.42)* | −0.64 (−1.59, 0.31) |
| Waist circumference, cm | | | |
| 6 months | −1.99 (1.15) | −2.87 (0.96)** | −0.54 (−2.42, 1.33) |
| 12 months | −2.97 (2.88) | −1.80 (1.73) | −0.55 (−3.96, 2.86) |
| 18 months | −3.07 (3.42) | −2.98 (1.52) | 0.01 (−2.58, 2.61) |
| Weight, kg | | | |
| 6 months | −3.59 (0.70)*** | −2.97 (0.73)*** | 0.02 (−1.87, 1.92) |
| 12 months | −2.86 (0.95)** | −2.80 (0.65)*** | −0.17 (−2.29, 1.94) |
| 18 months | −1.45 (1.28) | −3.62 (1.25)** | 0.12 (−3.09, 3.33) |
| Systolic blood pressure, mmHg | | | |
| 6 months | −2.49 (1.67) | −4.11 (1.68)* | −0.96 (−4.41, 2.49) |
| 12 months | −4.39 (2.22) | −4.20 (2.06)* | 1.05 (−2.13, 4.24) |
| 18 months | −1.60 (2.30) | −3.98 (1.83)* | −0.41 (−3.36, 2.55) |
| Diastolic blood pressure, mmHg | | | |
| 6 months | −3.32 (1.10)** | −3.54 (0.93)*** | −0.75 (−2.55, 1.05) |
| 12 months | −4.88 (1.22)*** | −3.37 (1.18)** | 0.53 (−1.52, 2.59) |
| 18 months | −2.56 (1.52) | −3.63 (2.63) | −0.63 (−3.07, 1.81) |
| Total cholesterol, mmol/l | | | |
| 6 months | −0.77 (0.13)*** | −0.98 (0.13)*** | −0.20 (−0.46, 0.06) |
| 12 months | −1.04 (0.15)*** | −0.99 (0.14)*** | −0.12 (−0.35, 0.12) |
| 18 months | −1.02 (0.14)*** | −0.97 (0.15)*** | −0.07 (−0.27, 0.12) |
| HDL cholesterol, mmol/l | | | |
| 6 months | −0.02 (0.05) | 0.03 (0.03) | 0.02 (−0.04, 0.08) |
| 12 months | 0.07 (0.03)* | 0.14 (0.10) | 0.03 (−0.07, 0.14) |
| 18 months | 0.02 (0.03) | 0.01 (0.03) | 0.00 (−0.05, 0.06) |
| LDL cholesterol, mmol/l | | | |
| 6 months | −0.57 (0.12)*** | −0.69 (0.15)*** | 0.03 (−0.28, 0.22) |
| 12 months | −0.90 (0.18)*** | −0.83 (0.16)*** | 0.01 (−0.19, 0.21) |
| 18 months | −0.67 (0.19)** | −0.57 (0.17)** | −0.01 (−0.17, 0.15) |

*$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.
[†]Adjusted for baseline value and cluster effect. Analyses follow the intention-to-treat principle and so missing data were imputed.
[‡]$HbA_{1c}$ at 18 months is the primary outcome defined in the study protocol. All other outcomes are secondary outcomes.

such studies are efficacy trials and cannot be compared closely with the present trial, which was pragmatic, conducted in primary care and involved a single session of group education with relatively little input from healthcare professionals at practice level. The DiGEM study [23] which was conducted in a similar setting to that of the present study (primary care in the UK) reported no difference in $HbA_{1c}$ level at 12 months in participants with established Type 2 diabetes randomized to a control group (no monitoring) or one of two blood monitoring groups of which one received education and feedback from trained practice nurses.

Only two recent trials have evaluated self-monitoring of blood glucose in people with newly diagnosed Type 2 diabetes [12,13] and these showed conflicting results. In the ESMON study [12], there were large but similar improvements in $HbA_{1c}$ over 12 months in both groups [21 mmol/mol (1.9%) in those who used blood monitoring and 19 mmol/mol (1.7%) in those who did not monitor], while in the St Carlos Study [13], the group using self-monitoring showed greater 'remission' and 'regression' compared with the group that did not monitor. In both studies, referral took place in hospital clinics and the interventions included substantial amounts of one-to-one education with trained healthcare professionals as well as quarterly $HbA_{1c}$ tests, which were used to inform changes in medication. Fundamental differences in design therefore make it difficult to compare the results of these trials with our own. One of the limitations in studying newly diagnosed patients is that even limited input on the part of the healthcare professionals might result in improved glycaemic control; however, since

**Table 3** Mean changes from baseline for psychosocial outcomes by monitoring group ($N$ = 292)

| Variables | Mean (SE) | | Difference (95% CI) between monitoring groups[†] |
|---|---|---|---|
| | Blood monitoring | Urine monitoring | |
| DTSQ: Total treatment satisfaction | | | |
| 6 months | 4.18 (0.96)*** | 3.12 (0.96)** | −1.23 (−2.86, 0.41) |
| 12 months | 3.19 (0.87)*** | 1.41 (0.77) | −1.24 (−2.69, 0.21) |
| 18 months | 4.58 (0.98)*** | 3.12 (0.89)*** | −1.09 (−3.35, 1.18) |
| DTSQ: Perceived frequency of hyperglycaemia | | | |
| 6 months | 0.12 (0.23) | −1.61 (1.41) | −1.15 (−3.56, 1.27) |
| 12 months | 0.21 (0.27) | −1.77 (1.44) | −1.30 (−4.13, 1.54) |
| 18 months | −0.38 (0.25) | −0.24 (0.20) | −0.08 (−0.47, 0.30) |
| DTSQ: Perceived frequency of hypoglycaemia | | | |
| 6 months | 0.18 (0.16) | −3.06 (2.11) | −1.33 (−4.60, 1.95) |
| 12 months | −0.03 (0.17) | −1.43 (1.53) | −0.50 (−2.95, 1.95) |
| 18 months | 0.11 (0.17) | −1.63 (1.58) | −0.45 (−2.76, 1.87) |
| W-BQ28: Generic well-being | | | |
| 6 months | 1.13 (0.44)* | 1.62 (0.58)** | 0.49 (−1.09, 2.07) |
| 12 months | 0.30 (0.47) | 0.76 (0.70) | 0.68 (−0.58, 1.95) |
| 18 months | 0.64 (0.54) | 1.86 (0.64)** | 0.78 (−0.68, 2.25) |
| W-BQ28 Diabetes-specific well-being | | | |
| 6 months | 2.32 (0.55)*** | 3.48 (0.61)*** | 1.04 (−0.44, 2.53) |
| 12 months | 2.23 (0.61)*** | 2.43 (0.59)*** | 0.34 (−0.82, 1.50) |
| 18 months | 3.14 (0.65)*** | 3.39 (0.68)*** | 0.66 (−0.64, 1.97) |
| BIPQ Threatening view of diabetes | | | |
| 6 months | −1.71 (1.16) | −6.25 (1.29)*** | −2.78 (−5.26, −0.31)* |
| 12 months | −2.90 (1.31)* | −4.67 (1.23)*** | −2.04 (−5.09, 1.01) |
| 18 months | −3.35 (1.32)* | −4.84 (1.33)*** | −0.00 (−2.54, 2.53) |

DTSQ, Diabetes Treatment Satisfaction Questionnaire; W-BQ28, 28-item Well-Being Questionnaire; BIPQ, Brief Illness Perceptions Questionnaire.
*$P$ < 0.05, **$P$ < 0.01, ***$P$ < 0.001.
[†]Adjusted for baseline value and cluster effect. Analyses follow the intention-to-treat principle and so missing data were imputed.

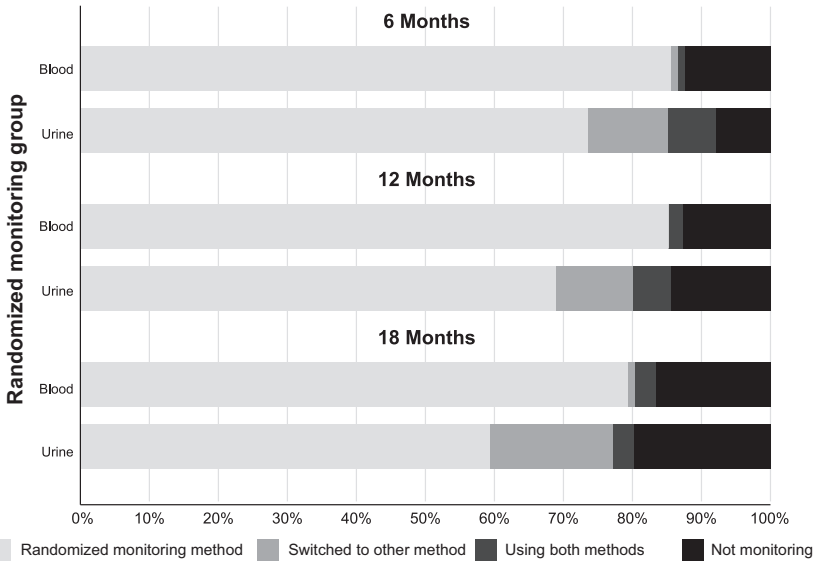


**FIGURE 2** Reported monitoring method at each time point among participants who provided questionnaire data.

the aim of our pragmatic trial was to compare two methods of self-monitoring, we believe that our study design was appropriate.

In the present study, the proportion switching methods or stopping monitoring altogether was greater in the urine monitoring group who tended to report less satisfaction with their treatment. Our qualitative sub-study has helped explain this: interviewees reported blood monitoring as accurate, convenient and useful in a practical sense for managing their diabetes, while many initially positive views of urine

monitoring lessened over time as interviewees came to find it inaccurate [24]. This is supported by previous qualitative work which reported a perception of urine monitoring as inconvenient and unhygienic [25].

With regard to psychosocial outcomes, those randomized to urine monitoring in the present study had a tendency to have better generic and diabetes-specific well-being at follow-up, consistent with trials reporting that emotional well-being may be adversely affected by blood monitoring, including increased anxiety [12,26] and depressive symptoms [12,27]. In addition, those using urine monitoring in the present study reported a less threatening view of diabetes (at 6 months). Our qualitative sub-study suggested that urine monitoring provided insufficient visibility of diabetes to interviewees, leading some to question their diagnosis [24]. By contrast, blood monitoring provided a more visible reminder, both of having diabetes and of the effects of activities on blood glucose, which may have raised the level of threat perceived, echoing previous research where blood monitoring led to anxiety and self-blame in participants whose glucose readings were high [28].

We conclude that in the context of the present trial, which reflects current practice in the UK, urine monitoring, as part of structured self-management education, is as effective as blood monitoring over the first 18 months after diagnosis. Many participants found urine monitoring useful and acceptable and, if this method of self-monitoring was made available as the method of choice at diagnosis, then it might lead to substantial cost savings without impairing outcomes. Nevertheless, the significant number who chose to switch to blood monitoring suggests that many found this method more useful. For these individuals, self-monitoring of blood glucose should be a legitimate option, but the present results suggest they might be more likely to benefit if they received ongoing advice and support for this approach from their primary care team.

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#### Competing interests

M.J.D. has acted as consultant, advisory board member and speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim and Roche, and received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Pfizer, Merck Sharp & Dohme and GlaxoSmithKline. K.K. has acted as consultant and advisory board member for Novo Nordisk, Eli Lilly, Merck Sharp & Dohme, Bristol Myers Squibb and Roche, and received payment for lectures from Novo Nordisk, Eli Lilly, Sanofi-Aventis, Novartis, Merck Sharp & Dohme, Janssen, Astra Zeneca and Boehringer Ingelheim Ltd. J.S. has received consultancy fees from Roche Diagnostics Australia, and grants and consultancy fees from Sanofi Diabetes. S.H. reports personal fees from Lifescan. The remaining authors have no competing interests to declare.

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## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Table S1.** Sensitivity and per protocol analyses showing changes from baseline for biomedical outcomes.
**Table S2.** Sensitivity and per protocol analyses showing changes from baseline for psychosocial outcomes.