Effect of structured self-monitoring of blood glucose, with and without additional TeleCare support, on overall glycaemic control in non-insulin treated Type 2 diabetes: the SMBG Study, a 12-month randomized controlled trial

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Abstract

Aim To examine the impact of structured self-monitoring of blood glucose, with or without TeleCare support, on glycaemic control in people with sub-optimally controlled Type 2 diabetes.

Methods We conducted a 12-month, multicentre, randomized controlled trial in people with established (>1 year) Type 2 diabetes not on insulin therapy, with sub-optimal glycaemic control [HbA₁c ≥58 to ≤119 mmol/mol (≥7.5% to ≤13%)]. A total of 446 participants were randomized to a control group (n=151) receiving usual diabetes care, a group using structured self-monitoring of blood glucose alone (n=147) or a group using structured self-monitoring of blood glucose with additional monthly ‘TeleCare’ support (n=275). The primary outcome was HbA₁c at 12 months.

Results A total of 323 participants (72%) completed the study; 116 (77%) in the control group, 99 (67%) in the self-monitoring of blood glucose alone group and 108 (73%) in the self-monitoring of blood glucose plus TeleCare group. Compared to baseline, the mean HbA₁c was lower in all groups at 12 months, with reductions of 3.3 mmol/mol (95% CI –5.71 to –0.78) or 0.3% (95% CI –1.29 to –0.81; P<0.001) in the group using self-monitoring of blood glucose plus TeleCare group. This represents a reduction in HbA₁c of 8.9 mmol/mol (95% CI –11.97 to –5.84) or 0.8% (95% CI –1.10 to –0.54; P<0.0001) with structured self-monitoring of blood glucose compared to the control group. Participants with lower baseline HbA₁c, shorter duration of diabetes and higher educational achievement were more likely to achieve HbA₁c ≤53 mmol/mol (7.0%).

Conclusions Structured self-monitoring of blood glucose provides clinical and statistical improvements in glycaemic control in Type 2 diabetes. No additional benefit, over and above the use of structured self-monitoring of blood glucose, was observed in glycaemic control with the addition of once-monthly TeleCare support.

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Additional glycaemic benefit. Consultation with a trained study nurse (TeleCare) provided patient adherence to treatment of people with Type 2 diabetes not on insulin therapy. Results showed that this standardized, structured SMBG intervention, with or without additional TeleCare, provided statistically and clinically significant improvements in glycaemic control.

Structured SMBG should be offered as part of the self-management process for all people with sub-optimally controlled Type 2 diabetes, even when not treated with insulin. Unstructured SMBG (other than for safety purposes) should be regarded as a waste of valuable time and resources.

What’s new?

- This 12-month randomized controlled trial examined the impact of structured self-monitoring of blood glucose (SMBG), with and without TeleCare support, on glycaemic control in people with sub-optimally controlled Type 2 diabetes.
- Results showed that this standardized, structured SMBG intervention, with or without additional TeleCare, provided statistically and clinically significant improvements in glycaemic control.
- Structured SMBG should be offered as part of the self-management process for all people with sub-optimally controlled Type 2 diabetes, even when not treated with insulin. Unstructured SMBG (other than for safety purposes) should be regarded as a waste of valuable time and resources.

Participants and methods

Full details of the study protocol have been published previously [24]. In brief, the SMBG Study was an open, multicentre RCT. Participants had sub-optimally controlled Type 2 diabetes, were not receiving insulin therapy and were involved in the study for 12 months after randomization to one of three groups: a control group, a group performing structured SMBG alone or a group performing structured SMBG and receiving TeleCare (Fig. 1). The study was conducted across 16 sites, nine of which were general practices and seven of which were based within hospitals across Wales and England. All participants remained under the care of their general practitioner (GP) throughout the course of the study, and medication changes were prescribed by the GP when recommended by the local study team.

The South East Wales Research Ethics Committee (Panel C) gave ethical approval for the study (Ref. 10/WSE03/50).

Participants

Participants were aged between 18 and 80 years, having been diagnosed with Type 2 diabetes for at least 1 year. HbA1c at baseline was 58 to 119 mmol/mol (7.5–13%). Participants were not receiving insulin therapy. Those who, in the opinion of their GP, needed to monitor their BG for clinical reasons were excluded from the study, but those using SMBG for safety reasons, in line with UK Driver and Vehicle Licensing Agency guidance, were eligible to be enrolled.

Procedures

The study procedures are shown in Fig. 1. Written informed consent was provided by all participants prior to any study activities taking place, following a full written and oral explanation of the study. Randomization was performed remotely by Swansea Trials Unit via email using a central database. Study site and previous experience of using SMBG (Yes/No) were used as stratifying factors for randomization. The allocation sequence was generated dynamically to maintain an approximate balance of 1:1:1 across the three groups overall. The participants randomized to the control group (Group 1) received their usual care and had contact with their diabetes team, GP or hospital clinic, as normal. Routine HbA1c results were used to facilitate glycaemic management by their GP as per usual care. All participants attended the 3-monthly study visits, which involved collecting clinical data, taking a blood sample to measure HbA1c and total cholesterol levels, the completion of participant-reported outcome measures (not reported in the present paper) and review of the participant diary in which significant events, medication changes and contact with healthcare professionals were recorded. General diabetes education was provided by a study nurse during the baseline visit after all questionnaires had been completed and prior to randomization. The study nurses used the ‘Your Guide to Type 2 Diabetes’ education booklet produced by Diabetes UK for people living with diabetes to ensure consistency of information [25]. The booklet provided an explanation of Type 2
diabetes and an overview of how the various diabetes medications work and how they should be taken. It also provided information on BG control, food, weight management, living well with diabetes and complications. Study nurses went through the booklet with each participant, highlighting information relevant to the individual and answering any questions. The education session was tailored to the needs of each participant and took an average of 1 hour, in conjunction with the baseline visit. All participants were given a copy of the Diabetes UK booklet to keep for their personal reference and use throughout the study. Diabetes-related questions that arose throughout the study were discussed with reference to the booklet.

Participants in the two SMBG groups (groups 2 and 3) attended an additional study visit (visit 2a) compared to those in the control group in order to undertake structured SMBG training (Fig. S1). Instruction was given on the correct method for taking and measuring BG. Thereafter, the participants were asked to measure their BG levels after fasting, 2 h after breakfast, and before and 2 h after their main meal on 2 days each week. During the week prior to the 3-monthly study visits, participants were asked to perform a seven-point BG profile (before and 2 h after three main meals, and at bedtime) on 3 days. At each study visit BG meters were downloaded and a calibration check carried out. All participants in the SMBG groups were offered the Accu-Chek 360° Diabetes Management System software (as used by the study nurses) to use at home if they wished.

Participants in the SMBG groups were asked to record their BG readings on the Accu-Chek 360° View Tool, a paper tool used to produce daily profiles of BG readings. They were shown how to interpret their SMBG results, how to identify patterns of glycaemic abnormalities and how to deal with abnormal glycaemic patterns. A stepped approach was taken, taking action to first correct any patterns of hypoglycaemia, then fasting hyperglycaemia and then post-meal hyperglycaemia. Standardized algorithms were provided to the participants (Fig. S2) and the study nurses and physicians to guide decisions around lifestyle and/or medication adjustment (Figs S3 and S4). All actions taken in response to the BG monitoring were recorded. At each study visit, for those in the SMBG groups, glycaemic management was based on SMBG results alone, with a care plan developed for the coming month(s) in partnership between the participant and study nurse, based on the adopted algorithms.

In addition to the education and support provided to group 2 (SMBG alone) participants, those in group 3 (SMBG plus TeleCare) were contacted by telephone at an agreed time each month by their study nurse to review the previous months’ BG readings and related events. Those who chose to use the Accu-Chek 360° software were able to download their meter to their own computer and securely email the BG results to the study nurse in advance of their TeleCare consultation. Those who chose not to use the software reported their readings verbally over the phone, which were then verified at the next study visit. At each consultation, patterns of glycaemic abnormalities were identified and explored jointly by the participant and study nurse, and a care plan was then co-produced for the coming month which was documented by the participant in their diary.

All study nurses attended a standardized training programme delivered by the research team in addition to

![Study Design Flow Chart](https://example.com/study_flowchart.png)

**FIGURE 1** Study design flow chart. QoL, quality of life; SMBG, self-monitoring of blood glucose; T2DM, type 2 diabetes.
successfully completing an online treatment management programme (Virtual College Healthcare e-Academy, Safe Use of Non-Insulin Therapies). Refresher training was provided to the study staff approximately every 4 months at study update meetings.

Outcomes
The primary outcome for the study was HbA1c at 12 months in those who undertook SMBG and the control group. All blood samples were sent to a central Good Clinical Laboratory Practice accredited laboratory for analysis. All study HbA1c results remained blinded to all participants, their study team and diabetes team throughout the study. Final HbA1c results were reported after participation in the study was completed.

Secondary comparative outcomes included: HbA1c at 3, 6 and 9 months; percentage of people achieving the HbA1c target of ≤53 mmol/mol (7%) at 12 months; and total serum cholesterol, weight, BMI and waist circumference at 3, 6, 9 and 12 months. Whenever insulin therapy was required, those participants were withdrawn from further participation in the study. Outcome measures specific to the SMBG groups included confirmed episodes of BG < 4.5 mmol/l and acceptability of SMBG. In those in the SMBG groups, attitudes towards SMBG were ascertained using locally derived questionnaires at randomization (SMBG 8) and at each subsequent study visit (SMBG 14). These questionnaires contained eight and 14 items, respectively, and included questions on attitudes towards SMBG, action taken as a result of the BG readings and confidence in their ability to take action. The questionnaires were self-completed and the responses were recorded to each item as yes/no/don’t know.

Sample size
The sample size calculation has been published previously [24]. Assuming an effect size of 0.333, attrition of 20% with 0.05 significance and 0.8 power, a sample size of 398 would be required to achieve the study primary aim. A conservative and pragmatic sample size of 450 (n=150 per treatment group) was adopted, which allowed an attrition rate of ~30%.

Statistical analysis
Participants who completed the study were analysed according to their allocated group. To answer the primary objective, data from the two SMBG groups were pooled for comparison with the control group, as prespecified in the statistical analysis plan. As a result of the inclusion criteria, HbA1c data were positively skewed, confirmed by residuals from a linear mixed model for repeated measures; the robustness of findings was therefore assessed using two data transformations (square root, natural log). Analyses of the transformed data led to the same conclusion regarding the intervention effect; for ease of interpretation, only the analysis of the untransformed data is reported. The primary outcome, HbA1c and all continuous secondary outcomes (total cholesterol, mean weight, BMI, mean waist circumference) were analysed using mixed models for repeated measurements with a random effect to account for variation at baseline, and correlation between repeated measures within individual participants was modelled by a first-order autoregressive process. We considered the following potential covariates and factors: age; gender; ethnicity; education level; employment status; smoking status; duration of diabetes; presence of diabetic complications; previous use of SMBG; cholesterol level; height; weight; BMI; and waist circumference. Covariates with significant main effect and key interaction were included in the models. Multiple imputation (using iterative Markov chain Monte Carlo methods) assessed the effect of missing data on the primary comparison between the combined SMBG groups and the control group. Twenty datasets with imputed values were created post-randomization (convergence at 400 iterations, psr<1.05). The primary comparison was undertaken in each imputed dataset separately, with estimates pooled using Rubin’s rules for comparison with analysis of the original data.

All randomized participants were included in the primary, secondary and safety analyses. The primary analysis of all outcomes followed the intention-to-treat (ITT) principle. All statistical analyses were performed with SPSS version 22 and were verified by a second independent statistician.

Results
Between December 2012 and June 2015, 446 participants met all eligibility criteria and were randomly assigned to a control, an SMBG alone or an SMBG plus TeleCare treatment group (Fig. 2). A total of 67 participants withdrew from the study after randomization and 45 were lost to follow-up. An additional 11 participants were withdrawn as they were prescribed insulin therapy during the study (Table S1). The numbers of participants prescribed insulin were similar across the three groups (three, four and four participants in groups 1, 2 and 3, respectively). There was no significant difference in the proportions of people who left the study between the control group (23.2%, 35/151) and the combined SMBG group (29.8%, 88/295); chi-squared =2.21, df=1, P=0.137). Neither was there a significant difference in the percentage of people leaving the study between the SMBG alone (32.7%, 48/147) and SMBG plus TeleCare group (27.0%, 40/148; chi-squared =1.12, df=1, P=0.35). Over half of those who left the study (58%, 65/112) did so between the randomization and 3-month visit (Fig. S5). A total of 323 participants (72%) completed the study.

Baseline characteristics for those randomized according to treatment group are included in Table 1. At the start of the
study a small number of participants (6%, 25/446) were managing their diabetes through diet and exercise alone, 39% (174/446) were on monotherapy, and 55% (247/446) were taking two or more oral antidiabetic medications.

**Primary outcome measure**

HbA1c levels decreased throughout the study in all three groups; it decreased from 71 mmol/mol (8.7%) to 67 mmol/mol (8.3%) in the control group and from 70 mmol/mol (8.6%) to 57 mmol/mol (7.4%) in the combined SMBG group. At 12 months, there was a greater reduction in mean HbA1c in the combined SMBG group of 12.2 mmol/mol (1.1%) compared to 3.3 mmol/mol (0.3%) in the control group, with the difference being significant, after adjusting for age at screening, gender, total cholesterol, BMI and duration of diabetes ($P<0.0001$; Fig 3a). The estimated treatment difference between the combined SMBG group and the control group was 8.9 mmol/mol (95% CI $-11.97$ to $-5.84$) or 0.8% (95% CI $-1.10$ to $-0.54$; $P<0.0001$). There was no significant difference, however, in HbA1c reduction at 12 months between the two SMBG groups ($P=0.458$; Table 2 and Fig 3b). The pooled estimate from the 20 imputed datasets showed similar findings. HbA1c analysis are presented in Table 2 and Table S2.

**Secondary outcomes**

Of the 446 participants, 113 (25.3%) reached the target HbA1c of $\leq 53$ mmol/mol ($\leq 7$%) at 12 months, with significantly more participants in the combined SMBG group than in the control group reaching the target (control group = 20/151, 13.2%; combined SMBG = 93/295, 31.5%; chi-squared =17.64, df=1, $P<0.0001$); however, the percentage of people achieving the target was similar for the SMBG alone (46/147, 31.3%) and the SMBG plus TeleCare groups (47/148, 31.8%; chi-squared =0.007, df=1, $P=0.93$). Participants with a lower baseline HbA1c concentration [hazard ratio (HR)
relevant reduction in total cholesterol levels at 3 months (Table 3). There was a statistically significant but not clinically significant difference in waist circumference at 12 months (–1.16 cm; 95% CI –2.25 to –0.07; \( P=0.037 \)) between the control group and the combined SMBG group (Table S3).

For those who completed the study, the overall number of diabetes medications prescribed increased over the study period in 131 participants (40.6%), with 188 (58.2%) remaining on the same total number of medications. A few participants (4, 1.2%) in the SMBG alone group completed the study taking fewer diabetes medications than at baseline (Table 4). The SMBG participants were more likely to have the number of medications increased during the study (chi-squared =12.63, \( df=1, P<0.0001 \)) in contrast to those in the control group who were more likely to remain on the same total number of diabetes medications (chi-squared =15.02, \( df=1, P<0.001 \)). The total number of diabetes medications prescribed increased in the control group.

### Table 1: Baseline characteristics of the three groups at randomization

|                      | Control (no SMBG) (n=151) | SMBG alone (n=147) | SMBG+ TeleCare (n=148) |
|----------------------|---------------------------|---------------------|------------------------|
| Age, years           | 60.7 (10.98)              | 62.9 (9.34)         | 61.6 (9.82)            |
| Men, n (%)           | 88 (58)                   | 82 (56)             | 88 (60)                |
| Ethnicity: white, n (%) | 135 (95)               | 137 (99)            | 133 (95)               |
| Weight, kg           | 95.3 (19.42)              | 95.0 (17.82)        | 95.8 (20.84)           |
| BMI, kg/m²           | 33.4 (6.03)               | 33.5 (6.72)         | 33.4 (6.66)            |
| Waist circumference, cm | 110.4 (14.09)         | 109.5 (12.89)       | 109.9 (13.77)          |
| HbA1c, mmol/mol      | 71.0 (11.74)              | 69.8 (11.83)        | 70.8 (12.53)           |
| Total cholesterol, mmol/l | 8.7 (1.07)              | 8.5 (1.08)          | 8.6 (1.15)             |
| Education, n (%)     |                           |                     |                        |
| None                 | 37 (25)                   | 24 (16)             | 29 (20)                |
| O’ level stage       | 37 (25)                   | 31 (35)             | 41 (28)                |
| Further education    | 23 (15)                   | 27 (19)             | 25 (17)                |
| Higher education     | 50 (33)                   | 37 (25)             | 47 (32)                |
| Other                | 4 (3)                     | 7 (5)               | 6 (4)                  |
| Employment, n (%)    |                           |                     |                        |
| Employed             | 57 (38)                   | 36 (25)             | 43 (29)                |
| Self-employed        | 17 (11)                   | 7 (5)               | 9 (6)                  |
| Unemployed           | 9 (6)                     | 14 (10)             | 12 (8)                 |
| Retired              | 68 (45)                   | 90 (61)             | 83 (57)                |
| Smoker, n (%)        |                           |                     |                        |
| Yes                  | 16 (11)                   | 23 (16)             | 19 (13)                |
| No                   | 79 (52)                   | 72 (49)             | 71 (48)                |
| Previously           | 56 (37)                   | 51 (35)             | 58 (39)                |
| Duration of diabetes, n (%) |                       |                     |                        |
| 1 to 3 years         | 30 (20)                   | 20 (14)             | 28 (19)                |
| 3 to 5 years         | 29 (19)                   | 32 (22)             | 23 (16)                |
| 5 to 10 years        | 53 (35)                   | 47 (32)             | 55 (37)                |
| >10 years            | 39 (26)                   | 48 (33)             | 42 (28)                |
| Ever used SMBG, n (%) | 103 (68)                  | 104 (71)            | 103 (70)               |
| Diabetic complications, yes, n (%) | 24 (16) | 35 (25) | 28 (19) |
| Diabetes medications, n (%) |                       |                     |                        |
| Monotherapy          | 63 (42)                   | 54 (37)             | 57 (39)                |
| Dual therapy         | 56 (37)                   | 50 (34)             | 55 (37)                |
| Triple therapy       | 25 (17)                   | 29 (20)             | 28 (19)                |
| 4+ medications       | 2 (1)                     | 0                   | 2 (1)                  |
| No diabetes medications (diet only) | 5 (3) | 14 (9) | 6 (4) |
| Diabetes knowledge   |                          |                     |                        |
| Percent with correct answers to ADKnowl Q | 64.7 (25.2) | 66.2 (25.2) | 65.5 (25.3) |

ADKnowl Q, Audit of Diabetes Knowledge questionnaire. Data are mean (so), unless otherwise indicated. Missing data: ethnicity, n = 25; weight, n = 18; BMI, n = 13; waist circumference, n = 22; total cholesterol, n = 3; education, n = 1; employment, n = 1; smoking, n = 1; complication, n = 11; and medication, n = 2.
prescribed increased by 146, with the largest proportion being dipeptidyl peptidase-4 inhibitors (17.0%) and sodium-glucose co-transporter-2 inhibitors (13.3%; Table S4). The mean (SD) number of medications increased in all three groups, from 1.7 at baseline to 2.0 (0.89) in the control group, 2.1 (0.96) in the SMBG alone group and 2.4 (0.73) in the SMBG plus TeleCare group by the end of the study period.

Engagement with the SMBG regimen

Adherence to the SMBG regimen, defined as having ≥80% of expected total SMBG readings, was seen in 71% of the participants who completed the study, and 80% of those who completed also undertook paired testing, defined as two or more readings in one day (Table 5). Those who completed the study took part in an average of six TeleCare consultations over 12 months, with each TeleCare meeting lasting a mean of 30 min. A large percentage of those assigned to either of the SMBG groups (92.8%, 270/291) considered SMBG a useful way of managing their diabetes at randomization. This increased to 96.5% (193/200) of those performing SMBG at study completion (after 12 months). The number of participants who said they would prefer not to self-monitor reduced over time from 37 (12.7%) at randomization to 14 (7.0%) at 12 months. The number of participants who found monitoring made them anxious decreased over time from eight (3.4%) at 3 months to three (1.5%) at 12 months, although there was an increase from eight (3.4%) at 3 months to 10 (5.0%) at 12 months in those who found the act of monitoring painful. By study completion, 88% of those using SMBG said they felt confident to make lifestyle changes, with 83% saying they had made lifestyle changes as a result of monitoring their BG profiles.

Within the SMBG groups 1032 episodes of BG levels <4.5 mmol/l were recorded by 130 participants (44%); the mean number of episodes was 3, and the median (range) was 0 (0–
Table 2 Primary outcomes by treatment group

|                        | Changes from baseline (95% CI) | Estimated treatment difference (95% CI) | P value |       |       |       |
|------------------------|---------------------------------|----------------------------------------|---------|-------|-------|-------|
|                        | Control (No SMBG)               | SMBG Alone                              | SMBG + TeleCare | SMBG Alone – Control | SMBG + TeleCare – Control | SMBG + TeleCare – SMBG Alone | P value |
| Primary outcomes by treatment group | At 3 months | -1.88 (-3.48 to -0.28) | -5.42 (-7.14 to -3.70) | -7.05 (-8.73 to -5.36) | -3.54 (-5.89 to -1.19) | -0.32 (-0.68 to -0.25) | <0.0001 | <0.0001 | <0.0001 | 0.184 |
|                        | At 6 months | -2.37 (-4.40 to -0.34) | -8.35 (-10.54 to -6.16) | -10.26 (-12.37 to -8.16) | -5.98 (<8.96 to -3.00) | -0.54 (-0.81 to -0.26) | <0.0001 | <0.0001 | <0.0001 | 0.217 |
|                        | At 9 months | -1.70 (-0.40 to -0.03) | -10.19 (-12.62 to -7.77) | -10.97 (-13.33 to -8.61) | -8.50 (-11.83 to -5.17) | -0.91 (-12.56 to -5.98) | <0.0001 | <0.0001 | <0.0001 | 0.653 |
|                        | At 12 months | -3.25 (-0.37 to 0.05) | -11.44 (-1.15 to -0.71) | -12.82 (-1.22 to -0.79) | -1.07 (-1.07 to -0.47) | -0.77 (-1.26 to -0.58) | <0.0001 | <0.0001 | <0.0001 | 0.608 |
|                        | At 12 months | -0.30 (-0.52 to 0.07) | -1.05 (-1.29 to -0.81) | -1.17 (-1.40 to -0.94) | -0.75 (-1.18 to -0.55) | -0.87 (<1.08 to -0.42) | <0.0001 | <0.0001 | <0.0001 | 0.477 |

Data are mean (95% CI), treatment difference (95% CI). HbA1c levels were analysed using a mixed model for repeated measurements. Significant covariates were age, gender, cholesterol, BMI and duration of diabetes.
61) episodes (Table S5). Using the current clinical definition of hypoglycaemia of <4.0 mmol/l [26], 328 episodes were reported by 86 participants (29%); the mean number of episodes was 1, and the median (range) was 0 (0 – 27) episodes, while 13 episodes of clinically significant hypoglycaemia (BG < 3.0 mmol/l) were recorded by 10 participants (3%); the mean number of episodes was 0.04, and the median (range) was 0 (0–2) episodes. There were no recorded episodes of severe hypoglycaemia requiring third-party assistance.

**Adverse events**

No related and unexpected serious adverse events were reported within the study period. A total of 18 serious adverse events were reported from 10 sites; these were considered to be unrelated to the study. The HbA1c results from the control group were monitored for deterioration by the Data Monitoring Committee and as a result, 18 participants in the control group were notified to their GP via their local study team as their HbA1c had deteriorated by ≥15% over a 6-month period. Two of these participants were reported on two separate occasions. At no time was the actual HbA1c result reported, only that there was deterioration. Fifteen of the 18 participants in the control group whose GP was notified continued and completed the study. The remaining three were lost to follow-up.

**Discussion**

The present RCT showed that structured SMBG reduced HbA1c at 12 months by a statistically and clinically significant degree compared to a control group receiving usual care not involving SMBG. Importantly, participants in the
Table 3 Secondary outcomes by treatment group

| Changes from baseline (95% CI) | Estimated treatment difference (95% CI) |
|--------------------------------|----------------------------------------|
|                                | Control (no SMBG) | SMBG alone | SMBG+ TeleCare | SMBG alone - control | P | SMBG+ TeleCare - Control | P | SMBG+ TeleCare - SMBG alone | P |
| Total cholesterol*, mmol/l     |                          |            |                |                      |   |                          |   |                          |   |
| At 3 months                    | 0.12                     | 0.31       | 0.01           | -0.06 to 0.30       |   | -0.12                     | 0.352 | 0.31                     | 0.026 |
| At 6 months                    | 0.01                     | -0.25      | -0.02          | -0.20 to 0.18       |   | -0.26                     | 0.087 | -0.03                     | 0.139 |
| At 9 months                    | -0.17                    | -0.02      | 0.01           | -0.23 to 0.18       |   | -0.10                     | 0.509 | 0.18                      | 0.29  |
| At 12 months                   | -0.08                    | -0.26      | 0.03           | -0.20 to 0.22       |   | -0.26                     | 0.088 | 0.11                      | 0.463 |
| Mean weight (kg)†              |                          | -0.29      | -0.20          | -0.18 to 0.25       |   | -0.26                     | 0.058 | 0.13                      | 0.474 |
| At 3 months                    | -0.68                    | -0.18      | 0.06           | -1.12 to -0.04      |   | -0.60                     | 0.071 | -0.28                     | 0.397 |
| At 12 months                   | -1.07                    | -1.15      | -1.15          | -1.10 to -0.10      |   | -0.60                     | 0.157 | -0.02                     | 0.969 |
| At 9 months                    | -1.36                    | -1.53      | -0.58          | -1.78 to -0.52      |   | -0.66                     | 0.888 | 0.18                      | 0.483 |
| At 12 months                   | -1.55                    | -1.47      | -0.58          | -1.52 to -0.36      |   | -0.66                     | 0.227 | 0.09                      | 0.853 |
| Mean BMI (kg/m²)‡              |                          | -0.21      | -0.42          | -2.83 to -1.43      |   | -0.60                     | 0.050 | 0.05                      | 0.683 |
| At 3 months                    | -0.19                    | -0.46      | -0.25          | -1.04 to -0.81      |   | -0.53                     | 0.050 | 0.05                      | 0.683 |
| At 6 months                    | -0.36                    | -0.61      | -0.38          | -0.65 to -0.30      |   | -0.53                     | 0.127 | -0.02                     | 0.913 |
| At 9 months                    | -0.57                    | -0.48      | -0.42          | -0.84 to -0.37      |   | -0.64                     | 0.935 | 0.05                      | 0.781 |
| At 12 months                   | -0.69                    | -0.77      | -0.39          | -0.73 to -0.23      |   | -0.64                     | 0.114 | 0.09                      | 0.586 |
| Mean waist circumference (cm)§ |                          | -0.70      | -0.65          | -1.04 to -0.51      |   | -0.64                     | 0.114 | 0.09                      | 0.586 |
| At 3 months                    | 0.33                     | 0.60       | -0.42          | -1.22 to -0.38      |   | 0.26                      | 0.644 | -0.76                     | 0.179 |
| At 6 months                    | 0.49                     | 0.12       | -0.59          | -0.35 to 1.09       |   | -0.86                     | 0.551 | -1.08                     | 0.074 |
| At 9 months                    | 0.11                     | -0.78      | -0.76          | -1.07 to -0.10      |   | -1.39                     | 0.159 | -0.88                     | 0.157 |
| At 12 months                   | -0.30                    | -1.52      | -1.15          | -2.28 to -0.36      |   | -2.14                     | 0.123 | -1.29                     | 0.043 |

Data are mean (95% CI), treatment difference (95% CI). Total cholesterol, weight, BMI and waist circumference were analysed using mixed models for repeated measurements. Significant covariates included in the models were: *total cholesterol: age, gender and current smoker; †weight: age, gender, height, waist and duration of diabetes; ‡BMI: gender, duration of diabetes and waist; † waist circumference: gender, BMI and non-smoker.
structured SMBG group were three times more likely to reach the HbA1c target of ≤53 mmol/mol (≤7%) than those receiving standard care. Those participants with a lower baseline HbA1c and shorter duration of diabetes were more likely to achieve the target. Providing additional monthly TeleCare support, as described, did not achieve any additional significant improvement in glycaemic control over and above that seen in the structured SMBG-only group, but there was a significant difference when compared to the control group.

The findings from this RCT are in line with those studies in people with Type 2 diabetes with sub-optimal control whilst not on insulin therapy that have also employed structured SMBG, having defined the timing and frequency of SMBG and utilisation of results for adjustment of management [27]. The present study showed a reduction in HbA1c of just over 588

Table 4 Number of people with medication changes during the study

| Completion status | All participants (n=323) | Control (n=116) | SMBG alone (n=99) | SMBG + TeleCare (n=108) |
|------------------|--------------------------|----------------|------------------|-----------------------|
| Participants who increased their diabetes medication, n (%) | 131 (40.6) | 32 (27.6) | 45 (45.5) | 54 (50) |
| Participants who decreased their diabetes medication, n (%) | 4 (1.2) | 0 | 4 (4) | 0 |

Table 5 Engagement with the SMBG regimen

| Completion status | Combined SMBG (n=207) | SMBG alone (n=99) | SMBG + TeleCare (n=108) |
|------------------|------------------------|------------------|------------------------|
| No BG meter readings (missing data), n (%) | 4 (1.9) | 2 (2.0) | 2 (1.9) |
| Adherence ≥80% total readings*, n (%) | 148 (71.5) | 68 (68.7) | 80 (74.1) |
| Adherence paired testing† ≥80%, n (%) | 166 (80.2) | 76 (76.7) | 90 (83.3) |

BG, blood glucose.
*Total number of BG readings taken if testing regimen followed for 12-month period.
†Two or more BG readings per day.

more targeted approach to prescribing and to overcome the issue of clinical inertia in the treatment of hyperglycaemia in Type 2 diabetes [31]. The relatively early improvement in glycaemic control (HbA1c reduction of ~0.5% compared to the control group) during the initial 3-month period suggests that lifestyle changes (diet, physical fitness) must have been a major contributor. Structured SMBG, in the form of paired BG testing, allowed the participants to become quickly aware of the impact of different dietary intake on their BG profiles. They were therefore better able to adjust their food and drink intake, along with adjusting physical activity, as part of a ‘self-learning’ process, thereby increasing their self-confidence and providing the basis of a more meaningful consultation with their healthcare professionals.

The SMBG schedule employed was designed to be a reasonable balance between not being too onerous whilst providing sufficient BG profiles to enable meaningful management decisions to be made. Despite this intention, 24% of all study withdrawals in the SMBG groups were attributable to difficulty adhering to the prescribed testing regimen. The minimum testing frequency required to maintain engagement whilst producing relevant information on which to base self-management decisions needs to be determined on an individual basis. The additional TeleCare support provided to those undertaking structured SMBG did not achieve a further improvement in HbA1c compared to those undertaking structured SMBG alone; however, there was a significant difference in HbA1c compared to the control group, which is consistent with other studies in a recent meta-analysis comparing the use of TeleCare to usual care in the management of glycaemic control [23]. That review concluded that
telemedicine had the greatest effect when introduced to those with higher HbA1c levels and when used to facilitate medication adjustment, as we observed using structured SMBG. The TeleCare support provided in the present study was monthly consultation via telephone contact, which helped to maintain engagement with the study and with the testing regime, although the glycaemic differences achieved between the groups were not statistically significant.

In conclusion, structured SMBG, i.e. using paired BG readings to generate BG profiles to identify patterns of glycaemic abnormalities and taking appropriate action when needed, should be available as part of the self-management process for people with sub-optimally controlled Type 2 diabetes, including those not on insulin therapy. People living with Type 2 diabetes should not be denied the option of structured SMBG. They should receive the equipment and training necessary to help them to record their BG results accurately and in a meaningful way and should be provided with the knowledge to interpret the results and take appropriate action, such as making lifestyle changes or seeking further advice. Those not able to engage fully with the procedure will be identified through regular review within the first few months and should either be offered additional support or structured SMBG can be discontinued. The present study supports the use of structured SMBG in primary care. Unstructured SMBG, other than as advised in the NICE guidance, should be regarded as a waste of valuable time and resources and can no longer be justified. Healthcare policies in relation to people with sub-optimally controlled type 2 diabetes not on insulin therapy should reflect these observations.

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Competing interests
None declared.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Structured SMBG Intervention.
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Figure S3. Clinical Algorithm 1.
Figure S4. Clinical Algorithm 2.
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Table S1. Reason for study withdrawal.
Table S2. Primary outcome by treatment group.
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