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Research: Care Delivery

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 [$\text{HbA}_{1c} \geq 58$ to ≤ 119 mmol/mol ($\geq 7.5\%$ to $\leq 13\%$)]. 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 ($n = 148$). The primary outcome was HbA_{1c} 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 HbA_{1c} 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 -0.52 to -0.07; $P = 0.01$) in the control group, 11.4 mmol/mol (95% CI -14.11 to -8.76) or 1.1% (-1.29 to -0.81; $P < 0.0001$) in the group using self-monitoring of blood glucose alone and 12.8 mmol/mol (95% CI -15.34 to -10.31) or 1.2% (95% CI -1.40 to -0.94; $P < 0.0001$) in the group using self-monitoring of blood glucose plus TeleCare. This represents a reduction in HbA_{1c} of 8.9 mmol/mol (95% CI -11.97 to -5.84) or 0.8% (95% CI -1.10 to -0.54; $P \leq 0.0001$) with structured self-monitoring of blood glucose compared to the control group. Participants with lower baseline HbA_{1c} , shorter duration of diabetes and higher educational achievement were more likely to achieve $\text{HbA}_{1c} \leq 53$ 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.

(Clinical trial registration no.: ISRCTN21390608)

Diabet. Med. 00: 1–13 (2019)

Introduction

It is recognized that self-monitoring of blood glucose (SMBG) helps to improve glycaemic control and identify hypoglycaemia in people with Type 1 and Type 2 diabetes

treated with insulin, whilst there is ongoing debate regarding the clinical benefits of using SMBG in those with Type 2 diabetes who are not on insulin therapy [1]. Many studies and meta-analyses have been conducted since the first evaluation of SMBG in 1983 [2], with little consensus on the benefit, in part because of the variation in intervention regimens and study populations [3–18]. In 2009, the International Diabetes Federation guidelines on SMBG use in non-insulin-treated Type 2 diabetes presented evidence supporting structured blood glucose (BG) monitoring

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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.

combined with appropriate action [19]. This emphasized the need for both healthcare professionals and people with Type 2 diabetes to be suitably informed and willing to conduct and incorporate paired (pre- and postprandial) BG profiles into diabetes care plans. Despite additional evidence in support of structured SMBG [8], SMBG is still being introduced into clinical trials and practice in an unstructured way, with little benefit [20]. Currently, regulatory authorities recommend limiting the use of SMBG in people with Type 2 diabetes not on insulin therapy to testing for hypoglycaemia, limiting SMBG to a safety role instead of it being an integral part of self-management [21,22].

The concept of telemedicine, that is using telecommunications to deliver health services, has become increasingly popular, and many studies have incorporated features of telemedicine into studies on diabetes management showing improvement in glycaemic control when compared to usual care [23]. The form of communication used and level of interactivity are thought to have an impact on the effectiveness of the telemedicine intervention, with methods allowing two-way communication between the healthcare provider/person with diabetes proving more successful.

We conducted a randomized controlled trial (RCT) to determine if the use of structured SMBG in a large population of people with Type 2 diabetes not on insulin therapy would improve HbA_{1c} over 12 months, compared to a control group receiving usual care as per NICE guidelines, and also whether the addition of a monthly telephone consultation with a trained study nurse (TeleCare) provided additional glycaemic benefit.

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 SMBG alone or a group performing 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. HbA_{1c} at baseline was 58 to 119 mmol/mol (7.5–13%) and 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 HbA_{1c} 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 HbA_{1c} 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

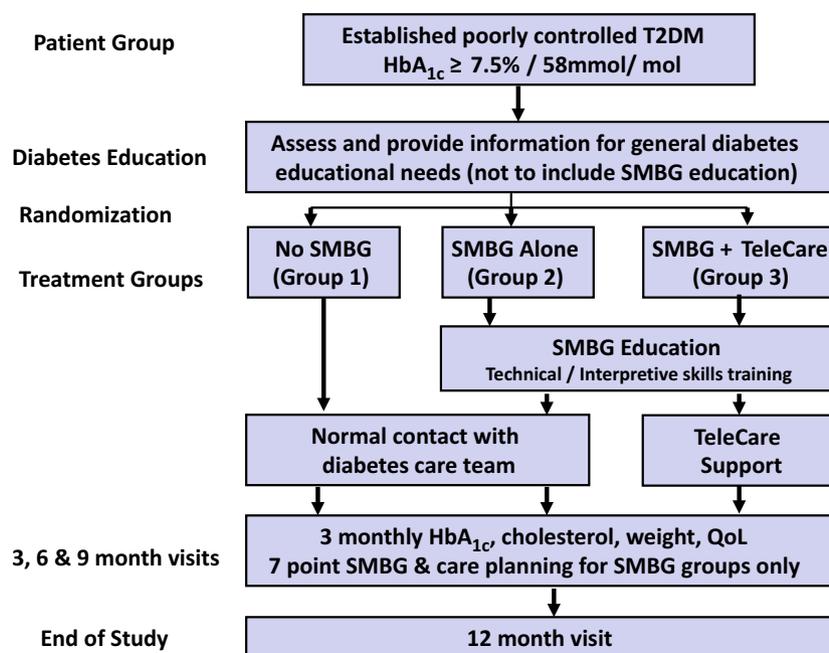


FIGURE 1 Study design flow chart. QoL, quality of life; SMBG, self-monitoring of blood glucose; T2DM, type 2 diabetes.

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

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 HbA_{1c} 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 HbA_{1c} results remained blinded to all participants, their study team and diabetes team throughout the study. Final HbA_{1c} results were reported after participation in the study was completed.

Secondary comparative outcomes included: HbA_{1c} at 3, 6 and 9 months; percentage of people achieving the HbA_{1c} 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, HbA_{1c} 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, HbA_{1c} 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

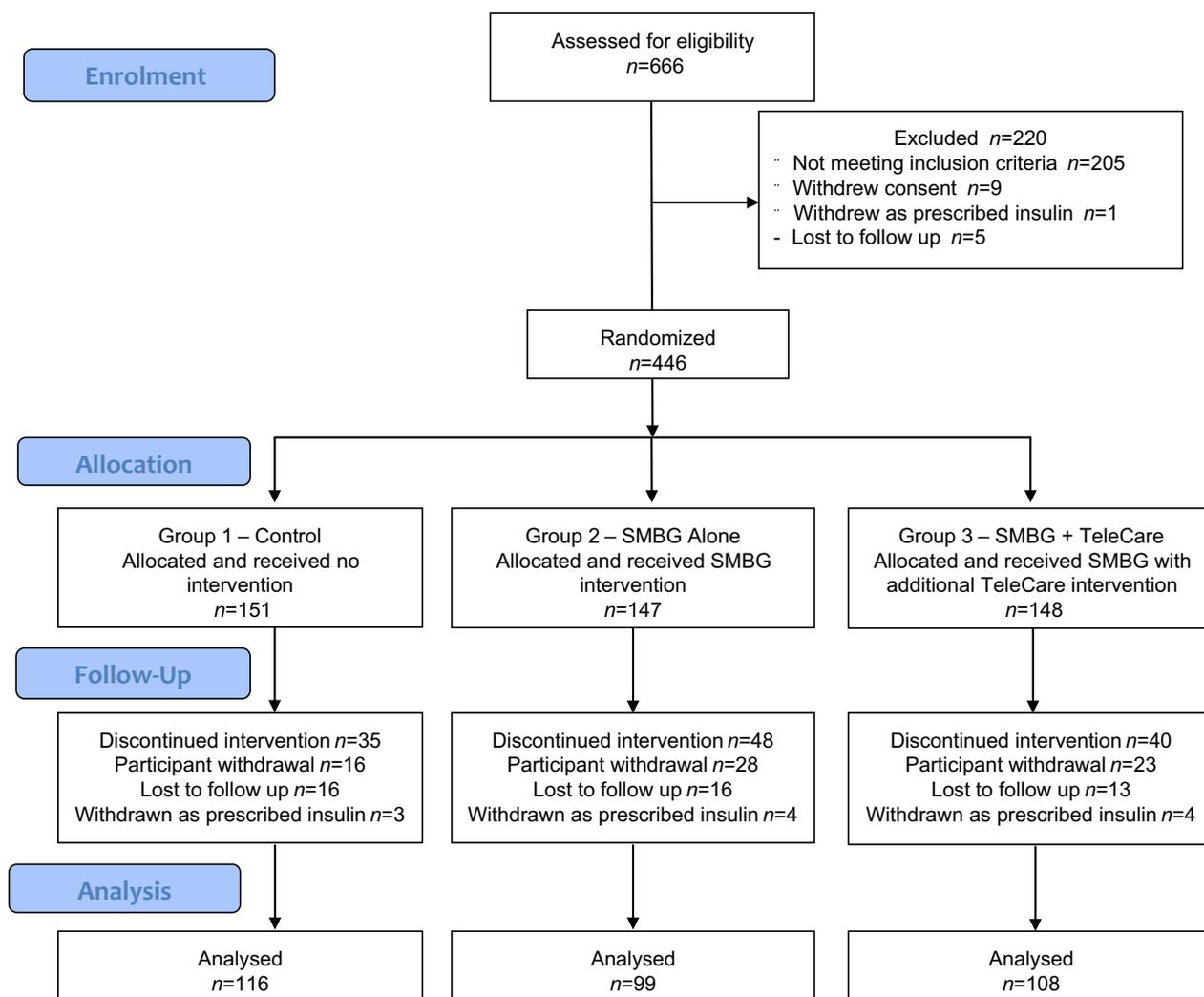


FIGURE 2 Consort diagram. SMBG, self-monitoring of blood glucose.

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

HbA_{1c} 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 HbA_{1c} 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 HbA_{1c} 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. HbA_{1c} analysis are presented in Table 2 and Table S2.

Secondary outcomes

Of the 446 participants, 113 (25.3%) reached the target HbA_{1c} of ≤ 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 HbA_{1c} concentration [hazard ratio (HR)

Table 1 Baseline characteristics of the three groups at randomization

	Control (no SMBG) (<i>n</i> =151)	SMBG alone (<i>n</i> =147)	SMBG+ TeleCare (<i>n</i> =148)
Age, years	60.7 (10.98)	62.9 (9.34)	61.6 (9.82)
Men, <i>n</i> (%)	88 (58)	82 (56)	88 (60)
Ethnicity: white ¹ , <i>n</i> (%)	135 (95)	137 (99)	133 (95)
Weight ² , kg	95.3 (19.42)	95.0 (17.82)	95.8 (20.84)
BMI ³ , kg/m ²	33.4 (6.03)	33.5 (6.72)	33.4 (6.66)
Waist circumference ⁴ , cm	110.4 (14.09)	109.5 (12.89)	109.9 (13.77)
HbA _{1c} , mmol/mol	71.0 (11.74)	69.8 (11.83)	70.8 (12.53)
HbA _{1c} , %	8.7 (1.07)	8.5 (1.08)	8.6 (1.15)
Total cholesterol ⁵ , mmol/l	4.7 (1.42)	4.8 (1.31)	4.5 (1.32)
Education ⁶ , <i>n</i> (%)			
None	37 (25)	24 (16)	29 (20)
O' level stage	37 (25)	51 (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 ⁷ , <i>n</i> (%)			
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 ⁸ , <i>n</i> (%)			
Yes	16 (11)	23 (16)	19 (13)
No	79 (52)	72 (49)	71 (48)
Previously	56 (37)	51 (35)	58 (39)
Duration of diabetes, <i>n</i> (%)			
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, <i>n</i> % yes	103 (68)	104 (71)	103 (70)
Diabetic complications: yes ⁹ , <i>n</i> (%)	24 (16)	35 (25)	28 (19)
Diabetes medications ¹⁰ , <i>n</i> (%)			
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 (SD), 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.

1.58, 95% CI 1.28 to 1.97; *P*<0.0001], duration of diabetes of < 5 years (HR 1.54, 95% CI 1.06 to 2.23; *P*=0.024) and higher education status (HR 1.57, 95% CI 1.07 to 2.30; *P*=0.02) were more likely to achieve the target HbA_{1c} of ≤53 mmol/mol (≤7%) at 12 months.

After adjusting for baseline HbA_{1c} concentration, duration of diabetes and attainment of higher education, the probability (HR) of participants achieving HbA_{1c} ≤53 mmol/mol (≤7%) within 12 months was 3.23 (95% CI 1.99 to 5.24; *P*<0.0001) times higher in the combined SMBG group compared to the control group (Fig. S6). There was no significant difference between the SMBG alone and the SMBG plus TeleCare group [HR 0.93, 95% CI 0.62 to 1.40; *P*=0.72 (Fig 4)].

Analyses of secondary outcomes are summarized in Table 3. There was a statistically significant but not clinically relevant reduction in total cholesterol levels at 3 months (–

0.28 mmol/l, 95% CI –0.50 to –0.05; *P*=0.017) and 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

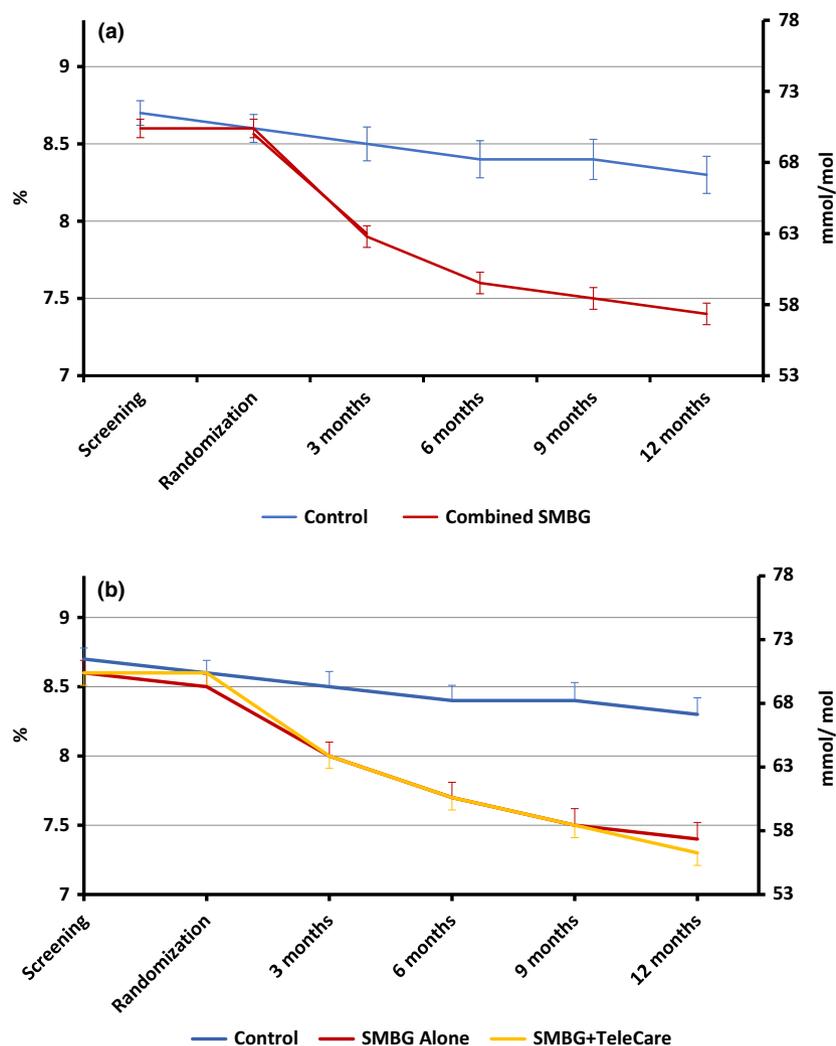


FIGURE 3 Comparison of mean (SEM) HbA_{1c} between (a) the control and combined SMBG groups and (b) the three groups over the 12-month study period.

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 $\geq 80\%$ 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

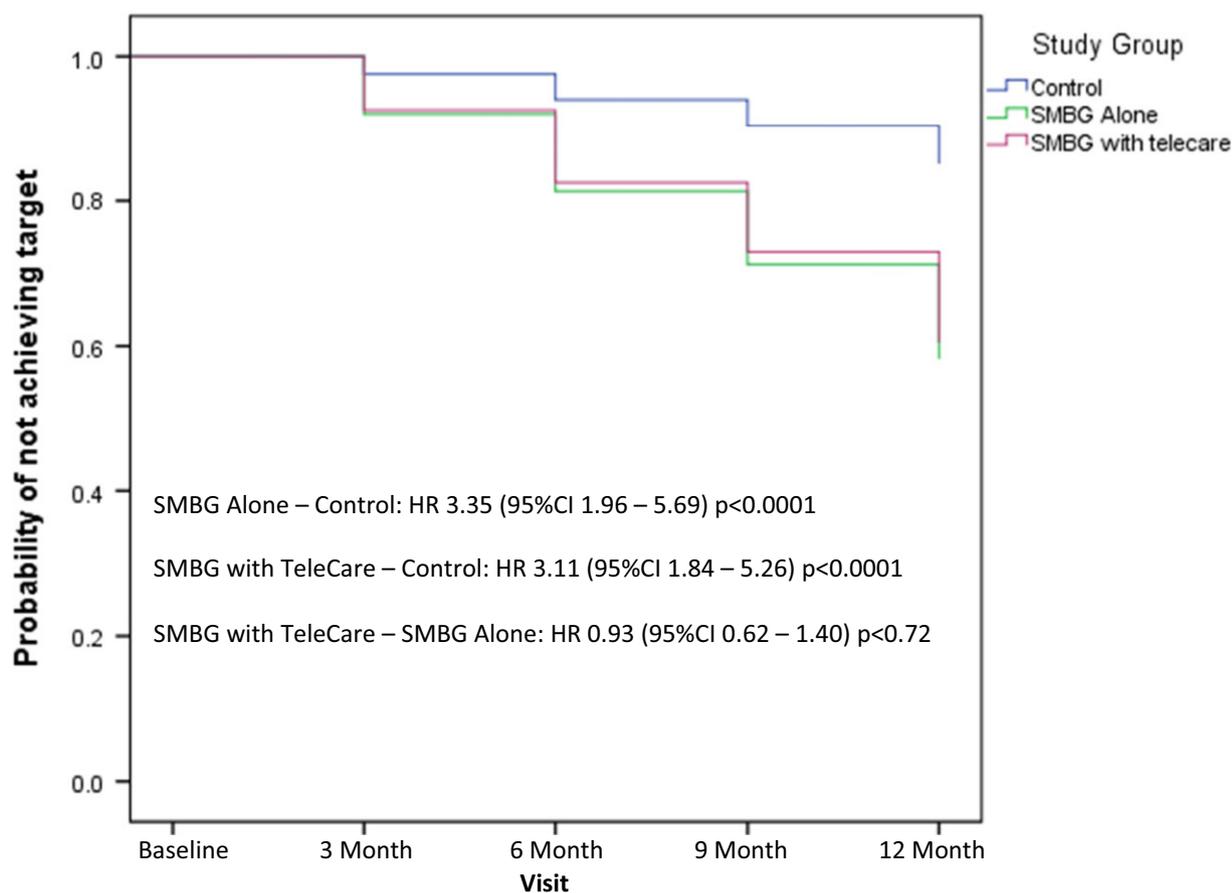
either of the SMBG groups (92.8%, 270/291) considered SMBG a useful way of managing their diabetes at randomization. This increased to 96.5% (193/200) of those performing SMBG at study completion (after 12 months). The number of participants who said they would prefer not to self-monitor reduced over 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)	Control (No SMBG)		SMBG Alone		SMBG + TeleCare		Estimated treatment difference (95% CI)		P value	SMBG + TeleCare – SMBG Alone	P value
	SMBG Alone	Control	SMBG Alone	Control	SMBG + TeleCare	Control	SMBG + TeleCare – Control				
At 3 months mmol/mol	-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)	-5.17 (-7.49 to -2.85)	-1.63 (-4.03 to 0.78)	<0.0001	0.184			
At 3 months %	-0.17 (-0.32 to -0.03)	-0.49 (-0.65 to -0.34)	-0.64 (-0.80 to -0.49)	-0.32 (-0.53 to -0.10)	0.004 (-0.68 to -0.25)	-0.15 (-0.37 to 0.07)	<0.0001	0.188			
At 6 months mmol/mol	-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)	-7.89 (-10.82 to -4.97)	-1.91 (-4.95 to 1.12)	<0.0001	0.217			
At 6 months %	-0.22 (-0.40 to -0.03)	-0.76 (-0.96 to -0.56)	-0.93 (-1.12 to -0.74)	-0.54 (-0.81 to -0.26)	0.0001 (-0.98 to -0.44)	-0.17 (-0.45 to 0.10)	<0.0001	0.217			
At 9 months mmol/mol	-1.70 (-3.99 to 0.59)	-10.19 (-12.62 to -7.77)	-10.97 (-13.33 to -8.61)	-8.50 (-11.83 to -5.17)	-9.27 (-12.56 to -5.98)	-0.78 (-4.16 to 2.61)	<0.0001	0.653			
At 9 months %	-0.16 (-0.37 to 0.05)	-0.93 (-1.15 to -0.71)	-1.01 (-1.22 to -0.79)	-0.77 (-1.07 to -0.47)	<0.0001 (-1.15 to -0.55)	-0.08 (-0.39 to 0.23)	<0.0001	0.608			
At 12 months mmol/mol	-3.25 (-5.71 to -0.78)	-11.44 (-14.11 to -8.76)	-12.82 (-15.34 to -10.31)	-8.19 (-11.82 to -4.56)	-9.58 (-13.10 to -6.06)	-1.39 (-5.06 to 2.28)	<0.0001	0.458			
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 (-1.08 to -0.42)	<0.0001 (-1.19 to -0.55)	-0.12 (-0.45 to 0.21)	<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.



Number at Risk

	Baseline	3 Month	6 Month	9 Month	12 Month
Control	151	131	127	115	116
*SMBG alone	146	118	93	78	65
SMBG+TeleCare	148	126	105	87	74

FIGURE 4 Achieving a target $HbA_{1c} \leq 7\%$. The graph shows time interval to event (achieving $HbA_{1c} \leq 7\%$ without relapse).

Significant covariates were HbA_{1c} concentrations at baseline, duration with diabetes and attainment of higher education. *One missing value with one of the significant covariates: education. HR, hazard ratio; SMBG, self-monitoring of blood glucose.

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 HbA_{1c} 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 HbA_{1c} had deteriorated by $\geq 15\%$ over a 6-month period. Two of these participants were reported on two separate occasions. At no time was the actual HbA_{1c} 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 HbA_{1c} 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	SMBG+ TeleCare - Control	P
Total cholesterol*, mmol/l						
At 3 months	0.12 (-0.06 to 0.30)	-0.31 (-0.50 to -0.12)	-0.01 (-0.20 to 0.18)	-0.43 (-0.69 to -0.17)	-0.12 (-0.39 to 0.14)	0.001
At 6 months	0.01 (-0.19 to 0.21)	-0.25 (-0.46 to -0.03)	-0.02 (-0.23 to 0.18)	-0.26 (-0.52 to 0.04)	-0.03 (-0.32 to 0.26)	0.087
At 9 months	-0.17 (-0.38 to 0.04)	-0.27 (-0.49 to -0.05)	0.01 (-0.20 to 0.22)	-0.10 (-0.41 to 0.20)	0.18 (-0.12 to 0.48)	0.509
At 12 months	-0.08 (-0.29 to 0.13)	-0.35 (-0.57 to -0.12)	0.03 (-0.18 to 0.25)	-0.26 (-0.57 to 0.04)	0.11 (-0.19 to 0.41)	0.088
Mean weight (kg) [†]						
At 3 months	-0.68 (-1.12 to -0.24)	-1.28 (-1.76 to -0.80)	-0.96 (-1.42 to -0.49)	-0.60 (-1.25 to 0.05)	-0.28 (-0.92 to 0.36)	0.071
At 6 months	-1.07 (-1.62 to -0.52)	-1.66 (-2.26 to -1.06)	-1.09 (-1.66 to -0.51)	-0.59 (-1.40 to 0.23)	-0.02 (-0.81 to 0.78)	0.157
At 9 months	-1.46 (-2.07 to -0.86)	-1.53 (-2.19 to -0.87)	-1.15 (-1.78 to -0.52)	-0.06 (-0.96 to 0.83)	0.31 (-0.56 to 1.19)	0.888
At 12 months	-1.55 (-2.19 to -0.92)	-2.13 (-2.83 to -1.43)	-1.47 (-2.13 to -0.81)	-0.58 (-1.52 to 0.36)	0.09 (-0.83 to 1.00)	0.227
Mean BMI (kg/m ²) [†]						
At 3 months	-0.19 (-0.37 to -0.01)	-0.46 (-0.65 to -0.26)	-0.25 (-0.44 to -0.06)	-0.27 (-0.53 to -0.00)	-0.05 (-0.31 to 0.21)	0.050
At 6 months	-0.36 (-0.57 to -0.15)	-0.61 (-0.84 to -0.37)	-0.38 (-0.60 to -0.16)	-0.24 (-0.56 to 0.07)	-0.02 (-0.32 to 0.29)	0.127
At 9 months	-0.46 (-0.69 to -0.24)	-0.48 (-0.73 to -0.23)	-0.42 (-0.65 to -0.18)	-0.01 (-0.35 to 0.32)	0.05 (-0.28 to 0.37)	0.935
At 12 months	-0.49 (-0.73 to -0.25)	-0.77 (-1.04 to -0.51)	-0.39 (-0.64 to -0.15)	-0.28 (-0.64 to 0.07)	0.09 (-0.24 to 0.43)	0.114
Mean waist circumference (cm) [§]						
At 3 months	0.33 (-0.43 to 1.09)	0.60 (-0.23 to 1.43)	-0.42 (-1.22 to 0.38)	0.26 (-0.86 to 1.39)	-0.76 (-1.86 to 0.35)	0.179
At 6 months	0.49 (-0.33 to 1.31)	0.12 (-0.78 to 1.02)	-0.59 (-1.44 to 0.26)	-0.37 (-1.59 to 0.85)	-1.08 (-2.26 to 0.11)	0.074
At 9 months	0.11 (-0.74 to 0.96)	0.11 (-1.70 to 1.13)	-0.76 (-1.63 to 0.11)	-0.89 (-2.14 to 0.35)	-0.88 (-2.09 to 0.34)	0.157
At 12 months	-0.30 (-1.18 to 0.57)	-1.32 (-2.28 to -0.36)	-1.59 (-2.48 to -0.70)	-1.02 (-2.32 to 0.28)	-1.29 (-2.53 to -0.04)	0.043
						0.689

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.

Table 4 Number of people with medication changes during the study

Completers only	All participants <i>n</i> =323	Control <i>n</i> =116	SMBG alone <i>n</i> =99	SMBG + TeleCare <i>n</i> =108
Participants whose total number of diabetes medications remained the same, <i>n</i> (%)	188 (58.2)	84 (72.4)	50 (50.5)	54 (50)
Participants whose total number of diabetes medications increased, <i>n</i> (%)	131 (40.6)	32 (27.6)	45 (45.5)	54 (50)
Participants whose total number of diabetes medications decreased, <i>n</i> (%)	4 (1.2)	0	4 (4)	0

Table 5 Engagement with the SMBG regimen

Completers only	Combined SMBG <i>n</i> =207	SMBG alone <i>n</i> =99	SMBG +TeleCare <i>n</i> =108
No BG meter readings (missing data), <i>n</i> (%)	4 (1.9)	2 (2.0)	2 (1.9)
Adherence \geq 80% total readings*, <i>n</i> (%)	148 (71.5)	68 (68.7)	80 (74.1)
Adherence paired testing [†] \geq 80%, <i>n</i> (%)	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.

structured SMBG group were three times more likely to reach the HbA_{1c} target of \leq 53 mmol/mol (\leq 7%) than those receiving standard care. Those participants with a lower baseline HbA_{1c} 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 HbA_{1c} of just over 12 mmol/mol (1%) when structured SMBG is used, which is comparable to the reduction in HbA_{1c} after the addition of an oral antidiabetic agent [28]. This is a larger change than the majority of previous studies included in several meta-analyses which showed only a moderate improvement in HbA_{1c}, with a difference of $<$ 0.5% between SMBG and usual care [14]. A closer critique identified considerable heterogeneity among the former studies, particularly in terms of the populations studied and interventions used [29]; however, other studies that have used structured SMBG have also shown benefit with regard to glycaemic control and quality of life, and a reduction in depression and distress [7,8,30]. The increase in antidiabetic medication prescribed to the SMBG cohort over the course of the present study illustrates the potential of obtaining and using BG profiles to facilitate a

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 (HbA_{1c} reduction of \sim 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 HbA_{1c} compared to those undertaking structured SMBG alone; however, there was a significant difference in HbA_{1c} 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 HbA_{1c} 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.

Figure S2. Algorithm for Participants.

Figure S3. Clinical Algorithm 1.

Figure S4. Clinical Algorithm 2.

Figure S5. Participant retention throughout the study.

Figure S6: Achieving a target HbA1c ≤ 53 mmol/mol (7%) in the Control and Combined SMBG groups.

Table S1. Reason for study withdrawal.

Table S2. Primary outcome by treatment group.

Table S3. Secondary outcomes by treatment group.

Table S4. Oral medication prescribed at baseline and 12 months for those who completed the study.

Table S5. Episodes of hypoglycaemia.