ISRCTN21390608 https://doi.org/10.1186/ISRCTN21390608

Self-monitoring of blood glucose (SMBG): comparison of no SMBG, SMBG alone and SMBG with telecare

Submission date
16/04/2014

Recruitment status
No longer recruiting

Registration date
15/05/2014

Overall study status
Completed

Last Edited
07/10/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For people with diabetes monitoring the level of glucose in the blood is an important part of managing their condition. Self-monitoring of blood glucose (SMBG) involves a person with diabetes monitoring their own blood glucose levels using a blood glucose meter. SMBG has been widely accepted as essential for people with type 1 and type 2 diabetes who have insulin injections for their diabetes, as the information gained from the monitoring can help decide the insulin dose required and prevent blood glucose levels from going too low. It can also help the person with diabetes adjust their diet and exercise to better control their blood glucose levels. However, for people with diabetes who do not take insulin and manage their diabetes by taking tablets or through diet and exercise alone, there is a continuing debate regarding the benefit of SMBG. People with type 2 diabetes have their blood glucose level measured at least annually by their GP. It is measured in terms of their Haemoglobin A1c level (or HbA1c). If HbA1c levels are too high, various anti-diabetic medications may be prescribed. Previous studies have not shown consistently that there is an improvement in patients HbA1c levels when they have used SMBG compared to those who haven't. However, it has not always been clear how the patients were monitoring, what action they took as a result of their blood glucose readings and what action their health care professional (GP, diabetes doctor, nurse) took. Without either the patient or health care professional taking any action, it has been shown that SMBG alone will not make a difference. This study will therefore look at whether there is a difference in HbA1c levels after 12 months in patients with type 2 diabetes who use SMBG compared to those who do not, when diabetes education and SMBG training is given to patients. Health care professionals will also be encouraged to take action to adjust medication based on the regular blood glucose readings as opposed to the HbA1c results. The study will also look at how much support needs to be given to patients using SMBG by providing some patients with additional monthly advice and support from a study nurse.

What does the study involve?
People aged between 18 and 80 with type 2 diabetes who are not currently treated with insulin will be invited to take part in the study.

What does the study involve?
Those who take part in the study will be asked to visit their nearest research clinic (this will be their GP practice or local hospital) every 3 months over a 12-month period. They will be randomly allocated to one of three groups. Group 1 will not monitor their blood glucose. Group 2 will monitor their blood glucose (SMBG group). Group 3 will monitor their blood glucose and will also discuss their readings with the study nurse by phone each month and action will be taken where needed (SMBG with telecare group). Participants allocated to the SMBG groups will be asked to attend training so that they can be taught how to use the blood glucose meters. In total, patients in all groups may be asked to attend the clinic up to seven times over the course of the year with each visit lasting between 20 minutes to 1 hour. They will see their GP and other health care professional as normal and will also attend the research clinic every 3 months for some basic clinical measurements to be taken such as HbA1c and cholesterol levels. At the research centre visits they will complete some questionnaires asking about their general well-being and their diabetes.

What are the possible benefits and risks of participating?
Those who take part in the study may benefit from better control of their blood glucose and more appropriate treatment for their diabetes. There are no risks to taking part in the study as patients will be receiving standard care as they should be receiving now. The only difference being that treatment may be more targeted or intensified in patients allocated to the SMBG groups, but this remains to be seen.

Where is the study run from?
15 sites in the UK (see below).

When is the study starting and how long is it expected to run for?
The study started in December 2012 and is expected to run until June 2016.

Who is funding the study?
European Foundation for the Study of Diabetes (EFSD) (Germany).

Who is the main contact?
Sharon Parsons
S.N.Parsons@swansea.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Sharon Parsons

Contact details
Singleton Park
Swansea
United Kingdom
SA2 8PP

Additional identifiers

Protocol serial number
12038

Study information

Scientific Title
Self-monitoring of blood glucose (SMBG): a randomised controlled trial comparing no SMBG, SMBG alone and SMBG with telecare

Acronym
SMBG

Study objectives
To determine whether HbA1c is significantly altered at 12 months in patients who receive SMBG compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales REC panel C, 07/02/2011, 10/WSE03/50

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes; Subtopic: Type 2; Disease: Diabetic Control

Interventions
Participants will be randomised into one of the following three groups:

Group 1: no self monitoring of blood glucose (SMBG), usual diabetes care, general diabetes education via booklet, research clinic visits every 3 months for 12 months

Group 2: SMBG with self adjustment, usual diabetes care, general diabetes education via booklet, SMBG training using Accu-Chek 360° and pattern recognition, use of patient algorithm for self-management adjustment, agreed goal setting/care plan using SMBG readings* at research clinic visits every 3 months for 12 months, refresher training on SMBG at each research clinic visit

Group 3: SMBG with telecare, usual diabetes care, general diabetes education via booklet, SMBG training using Accu-Chek 360° and pattern recognition, use of patient algorithm for self-

management adjustment, agreed goal setting/care plan using SMBG readings* at monthly intervals over the phone and research clinic visits every 3 months for 12 months, refresher training on SMBG at each research clinic visit

*4-point blood glucose profile to be taken 2 days every week (1 day during the week, 1 day during the weekend). 7-point profile to be taken for 3 days the week before the research clinic visit. Results uploaded to study nurse for review as part of care plan.

Patient follow-up is for 12 months in all patient groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
HbA1c result; Timepoint(s): at 12 months

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus patients with a duration of diabetes > 1 year
2. Age 18-80 years
3. HbA1c levels between ≥7.5% and ≤13%
4. Willing and able to provide informed consent
5. Access to a telephone
6. Able to make blood glucose measurements
Target Gender: Male & Female; Upper Age Limit 80 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
446

Key exclusion criteria
1. Diabetes other than type 2 diabetes mellitus (e.g., GAD positive) or treated with insulin
2. Pregnancy
3. Gestational diabetes mellitus
4. Severe chronic hepatic disease
5. Need to use SMBG as part of clinical care
6. Participation in any investigational drug trial within 1 month prior to Visit 1
7. Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study
8. End-stage renal disease (existing or planned dialysis or transplantation) or creatinine >150 umol/L
9. Blindness or severe loss of visual acuity in both eyes

Date of first enrolment
04/12/2012

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Joint Clinical Research Facility
ILS2
Swansea University
Swansea
United Kingdom
SA2 8PP

Study participating centre
Wrexham Maelor Hospital
Wrexham
United Kingdom
-

Study participating centre
St Thomas & West Cross Surgeries
Swansea
United Kingdom
-

Study participating centre
Diabetes Centre
Glangwili Hospital
Carmarthen
United Kingdom
-

Study participating centre
Bellevue Practice
Newport
United Kingdom
-

Study participating centre
Clinical Research Centre
Prince Philip Hospital
Llanelli
United Kingdom
-

Study participating centre
Sketty & Killay Surgeries
Swansea
United Kingdom
-

Study participating centre
Withybush Hospital
Haverfordwest
United Kingdom
-

Study participating centre
Castle Surgery
Neath
United Kingdom
-

Study participating centre
Clarence Medical Centre
Rhyl
United Kingdom
-

Study participating centre
The Practice of Health
Barry
United Kingdom
-

Study participating centre
Llandaff North Medical Centre
Cardiff
United Kingdom
-

Study participating centre
Countess of Chester Hospital
Chester
United Kingdom
-

Study participating centre
Oakenhurst Medical Centre
Blackburn
United Kingdom
-

Study participating centre
Ystradgynlais Group Practice
Ystradgynlais

United Kingdom
-

Sponsor information

Organisation
Abertawe Bro Morgannwg University Health Board (UK)

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Research organisation

Funder Name
European Foundation for the Study of Diabetes (Germany)

Alternative Name(s)
The European Association for the Study of Diabetes, European Association for the Study of Diabetes (EASD), EFSD

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Funder Name
Roche Diagnostics GmbH (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Dr Sharon Parsons (S.N.Parsons@Swansea.ac.uk) once all analyses and publications have been completed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2019	28/09/2020	Yes	No
Protocol article	protocol	26/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes