

Effect of self-monitoring of glucose in non-insulin treated patients with type two diabetes

Submission date 02/05/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 02/05/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/12/2016	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR807

Study information

Scientific Title

The effect of self monitoring of blood glucose and urine glucose relative to usual care without self monitoring on diabetes related distress and glycaemic control in patients with type 2 diabetes who are not using insulin

Acronym

IN CONTROL

Study objectives

By applying self monitoring of glucose, patients with Diabetes Mellitus type two (DM2) may cope more independently with their disease. Self monitoring can aid in diabetes control by giving the patient the ability to make appropriate day-to-day treatment choices in diet and physical activity as well as in medication. Furthermore, it will improve a patient's recognition of hypoglycaemia or severe hyperglycaemia, and enhance patient empowerment regarding the effects of lifestyle and medication on glycaemic control and thereby provide a better perceived quality of life.

Please note that as of 26/10/2009 this trial was updated. All updates can be found under the relevant field with the above update date. The overall trial end date has been extended from 01/07/2009.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The ethics board of the VU Medical Centre, 22/11/2007

Primary study design

Interventional

Study design

Randomised active-controlled parallel-group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes Mellitus type two (DM2)

Interventions

A stratified, randomised six-arm clinical trial among DM2 patients with an Hb1Ac of 7.0% or above who are not using insulin. Eligible and consenting subjects will be randomly assigned to the intervention groups Self Monitoring of Blood Glucose (SMBG) or Self Monitoring of Urine Glucose (SMUG), or to the control group.

Before randomisation the patients will be stratified according to treatment (i.e. using Sulphonylureas [SU] or not [Non-SU]). The SMBG and SMUG will be an integral part of a wider educational strategy; the intervention groups and the control group will receive a standardised treatment program to change their diet and lifestyle.

In addition, patients in the SMBG group will be educated to use the SMBG-device and patients in the SMUG-group will be educated to use the urine tests. They will learn to know and understand the ranges of test results and what steps to take in response to a high or low, or positive or negative reading.

The intervention groups will perform self-monitoring according to standard testing frequency instructions during one year.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Problem Areas In Diabetes scale (PAID) assessed at baseline and at 6 and 12 months after inclusion
2. Glycaemic control measured by glycated haemoglobin concentration (HbA1c-level) at baseline and at 6 and 12 months after inclusion
3. Cost-effectiveness assessed using cost-diaries and the European Quality of Life (EuroQoL) questionnaire

Key secondary outcome(s)

1. Frequency and severity of hypoglycaemia
2. Change in well-being: 12-item Well Being Questionnaire (WBQ-12)
3. Patient satisfaction: Diabetes Treatment Satisfaction Questionnaire (DTSQ)
4. Changes in lifestyle factors:
 - a. diet behaviour (Dutch Eating Behaviour Questionnaire [DEBQ])
 - b. physical activity (Short Questionnaire to Assess Health enhancing physical activity [SQUASH])
5. Changes in medication use
6. Compliance
7. Medical care utilisation

All secondary outcomes will be assessed at baseline, 6 and 12 months after inclusion.

Completion date

01/11/2010

Eligibility

Key inclusion criteria

1. All patients are participants of the Diabetes Care System West-Friesland
2. Patients with type two diabetes with HbA1c levels of 7.0% or above who are not using insulin
3. Younger than 76 years
4. Known disease duration of over one year
5. Not used self monitoring of glucose in the previous year

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe complications of diabetes
2. Pregnant women
3. Unable to carry out self monitoring of glucose
4. Unable to fill in questionnaires/diaries

Date of first enrolment

01/07/2007

Date of final enrolment

01/11/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

VU Medical Centre Amsterdam

Amsterdam

Netherlands

1081 BT

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Research organisation

Funder Name

European Foundation for the Study of Diabetes (EFSD) (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

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Results article	results	01/04/2016		Yes	No
Protocol article	protocol	27/04/2009		Yes	No