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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/07/2007

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

Age group
Adult

Sex
Both

Target number of participants
600

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)

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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

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, EFSD

Funding Body Type
Private sector organisation

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

Location
Germany

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

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