Effect of self-monitoring of glucose in non-insulin treated patients with type 2 diabetes.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27291

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Diabetes Mellitus type 2

Sponsors and support

Primary sponsor: VU University Medical Center, EMGO-Institute
Source(s) of monetary or material Support: European Foundation for the study of Diabetes (EFSD)

Intervention

Outcome measures

Primary outcome

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 after inclusion;
3. cost-effectiveness assessed using cost-diaries and the EuroQol.

Secondary outcome

1. Frequency and severity of hypoglycaemia;
2. Change in well-being: Well being questionnaire (W-BQ12);
3. Patient satisfaction: Diabetes Treatment Satisfaction Questionnaire (DTSQ);
4. Changes in lifestyle factors: diet behaviour (Dutch Eating Behaviour Questionnaire (DEBQ)); physical activity (Short Questionnaire to Assess Health Enhancing Physical Activity (SQUASH));
5. Changes in medication use;
6.Compliance;
7. Medical care utilization.

Study description

Background summary

OBJECTIVE: to assess the effects of self monitoring of blood glucose (SMBG) and urine glucose (SMUG) relative to usual care without self monitoring on diabetes related distress and on glycaemic control in patients with type 2 diabetes who are not using insulin.
STUDY DESIGN AND POPULATION: The study design is a randomized intervention study among 600 patients with type 2 diabetes with a glycated haemoglobin (HbA1c) concentration ¡Ý 7,0% who are not using insulin. Before randomization the patients will be stratified according to treatment (i.e. patients on sulphonylurea therapy or not). All patients are participants of the Diabetes Care System West-Friesland. INTERVENTION: 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 education program to change their diet and lifestyle. During 1 year, the intervention groups will perform SMBG or SMUG according to standard testing frequency instructions . The test results are used to modify diet, exercise and/or medications in consultation with the diabetes nurse who will give tailored made advice. PRIMARY OUTCOME MEASURES are distress (quality of life): problem areas in diabetes scale (PAID), Glycaemic control measured by HbA1c concentration, and cost effectiveness.

Study objective

By applying self monitoring of glucose, patients with diabetes type 2 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.

Intervention

A stratified, randomized 6-arm clinical trial among DM2 patients with a 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 randomization 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 1 year.

Contacts

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Eligibility criteria

Inclusion criteria

1. All patients are participants of the Diabetes Care System West-Friesland;
2. Patients with type 2 diabetes with HbA1c levels of 7,0% or above who are not using insulin;
3. Younger than 76 year;
4. Known disease duration of over 1 year; 5. Not used self monitoring of glucose in the previous year.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL794
NTR-old	NTR807
Other	: N/A
ISRCTN	ISRCTN84568563

Study results

Summary results
N/A