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

Gepubliceerd: 19-10-2006 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27291

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Diabetes Mellitus type 2

Ondersteuning

Primaire sponsor: VU University Medical Center, EMGO-Institute
Overige ondersteuning: European Foundation for the study of Diabetes (EFSD)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU Medisch Centrum Amsterdam
EMGO-Instituut
Afdeling Huisartsgeneeskunde
U.L. Malanda
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 20 444 8395

Wetenschappelijk

VU Medisch Centrum Amsterdam
EMGO-Instituut
Afdeling Huisartsgeneeskunde
U.L. Malanda
Van der Boechorststraat 7
Amsterdam 1081 BT
The Netherlands
+31 20 444 8395

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2007
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A