The effects of self-monitoring of glucose in non-insulin treated patients with type 2 diabetes

Published: 27-11-2007
Last updated: 09-05-2024

To assess the effects and the cost effectiveness of self monitoring of glucose in DM2 patients who are not using insulin on diabetes related distress, glycaemic control and changes in behavioural determinants.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON31259

Source
ToetsingOnline

Brief title
In Control

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes type 2

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: European Foundation for the Study of

Diabetes,LifeScan

Intervention

Keyword: Self-monitoring, Type 2 diabetes

Outcome measures

Primary outcome

Baseline measurements and follow-up measurements (after 6 and 12 months) are used to explore short-term and long-term effects. Primary outcome measurements will be assessed in terms of change in diabetes related distress and in glycaemic control (HbA1c).

Secondary outcome

Secundary outcome measurements will be assessed in terms of change in behavioural determinants, change in patient satisfaction and in changes in lifestyle factors (dietary behaviour and physical activity). An economic evaluation will be performed after 12 months from the societal perspective and from the perspective of the health insurer.

Study description

Background summary

The percentage of patients with diabetes mellitus type 2 (DM2) is growing rapidly. This is partly due to the ageing population, changes in lifestyle and the resulting epidemic of obesity. DM2 imposes a significant burden on patients* quality of life, and number of healthy life years due to both microvascular and macrovascular complications. By sustaining a good glucose control the onset of these complications can be delayed and its progression reduced. Self monitoring of glucose can aid in diabetes control by giving the patient the ability to make appropriate day-to-day treatment choices in diet and physical activity. It is hypothesized that self-monitoring of glucose will motivate DM2 patients to become active participants in their own care leading

to a reduce in diabetes related distress and an increased glucose control.

Study objective

To assess the effects and the cost effectiveness of self monitoring of glucose in DM2 patients who are not using insulin on diabetes related distress, glycaemic control and changes in behavioural determinants.

Study design

This 3-armed randomized clinical trial will be implemented in the structured Diabetes Management System West Friesland (DMS). Six-hundred patients with DM2 will be recruited and randomised into respectively 3 groups (n=200 per group); Self Monitoring of Blood Glucose (SMBG), Self Monitoring of Urine Glucose (SMUG) and usual care.

Intervention

All 3 groups will receive standardized usual diabetes care conform the DMS. The intervention groups will receive additional instructions on how to use and interpret respectively SMBG or SMUG.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-DM2 patients treated with diet and/or oral hypoglycaemic agents
-Not requiring insulin at inclusion
-HbA1c><= 7.0%
-Known disease duration of over 1 Year
-Not used self monitoring of blood glucose or urine glucose in the previous year
-Age between 45 and 75 years

Exclusion criteria

-Severe complications of diabetes
-Unable to carry out SMBG or SMUG
-Unable to fill in questionnaires/diaries
-Unable to understand the Dutch language
-Circumstances likely to interfere with all measurements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2008
Enrollment:	600
Type:	Actual

Medical products/devices used

Generic name:	Blood glucose monitoring system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ISRCTN	ISRCTN84568563
CCMO	NL19594.029.07