

The view of diabetic patients about self monitoring of blood glucose and the influence on glycemic control and quality of life.

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The objective of the study is to:- explore views of patients with type 1 or type 2 diabetes about SMBG- investigate the associations between demographic aspects, biological aspects, quality of life, adherence to SMBG and views of patients about SMBG...

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

Summary

ID

NL-OMON32931

Source

ToetsingOnline

Brief title

the view about self monitoring of blood glucose

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: gelden van het Medisch Research Fonds en Stichting Langerhans; subsidieaanvraag is gedaan bij het Diabetes Fonds: uitslag juli 09., Sanofi-aventis

Intervention

Keyword: glycemic control, quality of life, self monitoring of blood glucose, self-management

Outcome measures

Primary outcome

Qualitative research: to develop a concept or 'new theory' which describes the diabetic patient's view about SMBG.

Quantitative research: A description of associations between patients' characteristics, quality of life and patient's view about SMBG. The 'new theory' will further be tested.

Secondary outcome

not applicable

Study description

Background summary

Self monitoring of blood glucose (SMBG) is an important factor in achieving optimal glycemic control. Blood glucose monitoring results provide guidelines for meal planning, exercise and medication use. Adherence to glucose monitoring, investigated in several international studies, is suboptimal. In The Netherlands there is attention to the performance of SMBG (technical aspects). There is little attention to and limited information about patient's views of the profits and the burden of SMBG. This study investigates the experience with SMBG from the patient's view.

Study objective

The objective of the study is to:

- explore views of patients with type 1 or type 2 diabetes about SMBG

- investigate the associations between demographic aspects, biological aspects, quality of life, adherence to SMBG and views of patients about SMBG

Study design

The study design consists of a qualitative and a quantitative study.

Qualitative research: the chosen method is Grounded Theory approach. We will start with 2 focus groups. Followed by in-depth interviews with 20 type 1 diabetic patients and 20 type 2 diabetic patients. On the basis of the results of this research a questionnaire will be developed about the patient's view concerning SMBG.

Quantitative research: 100 subjects with type 1 diabetes and 100 subjects with type 2 diabetes are asked to complete several validated questionnaires about quality of life and self efficacy and the new questionnaire about the patient's view concerning SMBG. Demographic information and information about the health status are collected from the medical report.

Study burden and risks

Talking or thinking about one's view about SMBG may cause psychological burden.

Knowledge of the view of patients about SMBG can help to design effective disease management programs and to develop further clinical guidelines and quality standards about SMBG.

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

patients with type 1 or type 2 diabetes and treatment with insulin

age > 18 years

experience with injecting insulin and self monitoring of blood glucose for at least one year

Exclusion criteria

Poor command of the Dutch language

Patients with severe co-morbidity (physically and mentally)

pregnancy

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-09-2009

Enrollment: 260

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 26-08-2009

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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

CCMO

ID

NL27433.075.09