Towards a more cost-effective diabetes control in primary care: six-monthly monitoring compared with three-monthly monitoring in type 2 diabetes mellitus. The EFFIMODI (EFFIcient MOnitoring of DIabetes) trial.

Published: 17-03-2009
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To determine whether the generally recommended three-monthly follow up in the usual diabetes care in general practice can be reduced to six-monthly follow up for some of the patients.

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

Summary

ID

NL-OMON33609

Source
ToetsingOnline

Brief title
EFFIMODI

Condition

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

Synonym
type 2 diabetes mellitus; non insulin dependent diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW - Doelmatigheidsonderzoek

Intervention

Keyword: Frequency of monitoring, Primary care, Randomised controlled trial, Type 2 diabetes mellitus

Outcome measures

Primary outcome

Glycemic control, expressed as HbA1c%.

Secondary outcome

Blood pressure, body mass index, cholesterol, patients* quality of life and

distress, satisfaction with care, costs.

Study description

Background summary

Scientific evidence for the frequency of monitoring of type 2 diabetes mellitus (DM2) patients is lacking. If the standard three-monthly control in general practice can be reduced to six-monthly control, this would on the one hand reduce the use of medical services, and thus reduce costs, and on the other hand alleviate the burden of people with DM2.

Study objective

To determine whether the generally recommended three-monthly follow up in the usual diabetes care in general practice can be reduced to six-monthly follow up for some of the patients.

Study design

Randomised, controlled equivalence trial; patient preference trial.

Participants are asked if they have a strong preference for continuing the current care. If not, they will be randomised into a group that receives three-monthly follow up and a group that receives six-monthly follow up. If they prefer continuing the current care, they will be included in the preference arm and thus receive three-monthly follow up.
Repeated measures analysis will be used to be able to optimally use all data available. For outcomes that have only baseline and final measurements, ANCOVA will be used. Furthermore, a cost-minimisation analysis or a cost-effectiveness analysis will be carried out, depending on the results of the intervention trial.

Intervention

Six-monthly follow up in DM2 care by the same team (GP, practice nurse/diabetes nurse, practice assistant) and with the same targets according to Dutch guidelines instead of standard three-monthly monitoring.

Study burden and risks

The patients will fill out a questionnaire twice, with a total duration of 90 minutes. There is no risk associated with participation in the trial.

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

- People with type 2 diabetes mellitus;
- Aged 40-80 years;
- Treated by their general practitioner.

Exclusion criteria

Contra-indications for less frequent than three-monthly monitoring:
- Duration of type 2 diabetes mellitus for less than one year;
- Insulin treatment;
- HbA1c >7.5%;
- Systolic blood pressure >145 mmHg;
- Total cholesterol >5.2 mmol/L.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2009

Enrollment:	2250
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-06-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL25787.041.08