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Towards a more cost-effective diabetes control in primary care: the EFFIMODI (EFFIcient MOnitoring of DIabetes) trial

Submission date 02/06/2009	**Recruitment status** No longer recruiting
Registration date 14/07/2009	**Overall study status** Completed
Last Edited 25/04/2014	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

80-82310-98-09058

Study information

Scientific Title
Six-monthly monitoring compared with three-monthly monitoring in type 2 diabetes mellitus: a randomised, controlled, patient-preference equivalence trial in primary care

Acronym
EFFIMODI

Study objectives
As of 30/03/2010 this record has been updated; all changes can be found in the relevant field with the above update date.

Current primary objective as of 30/03/2010:
Does six-monthly monitoring of well controlled people with type 2 diabetes mellitus (DM2) in primary care lead to equivalent cardiometabolic control as three-monthly monitoring?

Initial primary objective at time of registration:
Does six-monthly monitoring of well controlled people with type 2 diabetes mellitus (DM2) in primary care lead to equivalent glycaemic control as three-monthly monitoring?

Secondary objectives:
1. What are the costs of six-monthly follow up of DM2 patients compared with three-monthly follow up?
2. In case the three-monthly follow up is more effective than the six-monthly follow up: what is the incremental cost-effectiveness of three-monthly versus six-monthly follow up of DM2 patients in general practice?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee (MREC) Utrecht approved on the 17th March 2009 (ref: 08-453, CCMO number: NL25787 041 08)

Study design
Single centre randomised controlled patient-preference equivalence trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)

Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Control: three-monthly diabetes monitoring by general practitioner and practice nurse
Intervention: six-monthly diabetes monitoring by general practitioner and practice nurse
The intervention will last one and a half year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current information as of 30/03/2010:
Percentage of people that remains under good cardiometabolic control, defined as having HbA1c less than or equal to 7.5% and systolic blood pressure less than or equal to 145 mmHg and total cholesterol less than or equal to 5.2 mmol/l. HbA1c, systolic blood pressure and total cholesterol will be collected from the general practitioners' Information System.

Initial information at time of registration:
Change in glycaemic control, expressed as the mean change in HbA1c percentage between baseline and follow-up. HbA1c will be collected from the general practitioners' Information System.

Secondary outcome measures
Differences in:
1. Blood pressure, collected from the general practitioners Information System
2. Body mass index, collected from the general practitioners Information System
3. Cholesterol, collected from the general practitioners Information System
4. Fasting blood glucose, collected from the general practitioners Information System
5. Lifestyle factors (smoking behaviour, physical activity), measured using the SQUASH questionnaire before and after the intervention period
6. Patients' quality of life, measured using the 36-item Short Form Health Survey (SF-36) and EuroQoL questionnaire (EQ5D) before and after the intervention period
7. Diabetes-specific distress, measured using the Problem Areas In Diabetes (PAID) questionnaire before and after the intervention period
8. Satisfaction with care, measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) before and after the intervention period
9. Adherence with medications, collected from the general practitioners Information System

Added as of 30/03/2010:
10. HbA1c, collected from the general practitioners' Information System

Overall study start date
16/04/2009

Completion date
01/06/2011

Eligibility

Key inclusion criteria
1. People with DM2
2. Aged 40 - 80 years, either sex
3. Treated by their general practitioner

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2250 participants (1125 in preference arm, 1125 in randomised arm)

Key exclusion criteria
Contraindications for less frequent than three-monthly monitoring:
1. Duration of DM2 for less than one year
2. Insulin treatment
3. HbA1c greater than 7.5%
4. Systolic blood pressure greater than 145 mmHg
5. Total cholesterol greater than 5.2 mmol/L

Date of first enrolment
16/04/2009

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.juliuscentrum.nl

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)
(ref: 80-82310-98-09058)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/05/2010		Yes	No
Results article	satisfaction results	30/07/2013		Yes	No
Results article	results	01/09/2014		Yes	No