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Cost-effectiveness of care for patients with type two diabetes: an evaluation of an innovative shared diabetes care model

Submission date	Recruitment status
26/02/2007	No longer recruiting
Registration date	**Overall study status**
26/02/2007	Completed
Last Edited	**Condition category**
30/06/2014	Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] 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
N/A

Study information

Scientific Title

Study objectives
The intervention will primarily affect the level of patient control with regard to glycemia, lipid levels and blood pressure. We will expect a substantial decline in the occurrence and severity of complications and mortality and an improved quality of life. The innovative shared diabetes care is expected to be more cost-effective than the usual diabetes care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
A quasi-experimental pre-test-post-test control group design

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus type two (DM type II)

Interventions
An innovative shared diabetes care model ('ketenzorgmodel') will be implemented in general practices in Amstelland. The 'ketenzorgmodel' will be implemented with a central organisation of the diabetes care with a central database, a central coordinating role for diabetes nurses (changed professional roles), and an active recall system. The annual diabetes check is offered to patients by the central organisation, in combination with patient education, by a diabetes nurse and a consultation with a dietician. In addition, structured education will be offered to general practitioners and their assistants, and a diabetes nurse will support diabetes care in general practice.

Diabetes patients in the control group will receive the current usual diabetes care. The control group will consist of patients of GP's who are affiliated to the Netherlands Institute for Health Services Research (NIVEL) Continuous Morbidity Registration Centres (CMR sentinel stations

[CMR-Peilstations]). NIVELs 'CMR-Peilstations' consitute a representative group of 60 Dutch GPs in 45 practices throughout the Netherlands.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The risk of developing coronary heart disease (using the United Kingdom Prospective Diabetes Study [UKPDS] risk engine at baseline, two years before and year one and two after baseline)
2. All direct and indirect costs (cost diary)
3. Costs per life year gained

Secondary outcome measures
1. Absolute levels of fasting glucose
2. HbA1c level
3. Blood pressure
4. Cholesterol
5. Percentages adequately controlled patients (in accordance with the Dutch College of Family Physicians [NHG] standards)
6. Diabetes specific and generic quality of life
7. Patient satisfaction
8. Quality of life
9. Quality of care as experienced by the patient:
a. percentage of patients that received all three-monthly check-ups
b. a complete annual check-up
c. were hospitalised
10. Total mortality measured by life expectancy
11. Total morbidity measured by morbidity-free life expectancy and the Net Present Value (NPV) of the number of life years gained
12. Quality Adjusted Life Years (QALYs) gained for the intervention scenario compared to the current practice scenario
13.The NPV of total intervention costs
14. The NPV of total costs of care for diabetes and its complications
15. Incremental costs per QALY gained

Overall study start date
01/03/2007

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Patients with type two diabetes
2. Age 40 to 75 years
3. Written informed consent

4. Capable to fill in questionnaires
5. Understanding of Dutch language

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Patients will be excluded for participation in this study if no beneficial effects can be expected in favour of the patient, according to the opinion of the General Practitioner (GP).

Date of first enrolment
01/03/2007

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Emgo-Instituut
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
VU University Medical Centre (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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?
Results article	results	25/06/2014		Yes	No