# Cost-effectiveness of care for patients with type 2 diabetes, an evaluation of an innovative shared diabetes care model.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24530

**Source**
NTR

**Brief title**
N/A

**Health condition**

Diabetes Mellitus type 2

### Sponsors and support

**Primary sponsor:** Institute of Research in Extramural Medicine, VU University Medical Center, Amsterdam
**Source(s) of monetary or material Support:** ZonMw

### Intervention

### Outcome measures

**Primary outcome**

1. The risk of developing coronary heart disease (using the UKPDS risk engine at baseline, 2 yrs before and year 1 and 2 after baseline);

2. All direct and indirect costs (cost diary); 3. Costs per lifeyear gained.

**Secondary outcome**

1. Absolute levels of fasting glucose;
2. HbA1c level;
3. Blood pressure;
4. Cholesterol;
5. Percentages adequately controlled patients (in accordance with the 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; Percentage of patients that received all 3-monthly check-ups, a complete annual check-up, were hospitalized;
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. QALY's 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.

# Study description

**Background summary**

BACKGROUND: Type 2 diabetes is a highly prevalent chronic disease, which leads to considerable morbidity and premature mortality. Strict control of the disease can lead to a much better prognosis. Multifaceted professional interventions can enhance the performance of health professionals in managing patients with diabetes. However, a complete evaluation of the effects and costs of such interventions has not yet been performed. OBJECTIVE: To evaluate the effectiveness and cost-effectiveness of an innovative shared diabetes care model both in the short and in the long term use of health care, costs of health care, morbidity, mortality and quality of life. STUDY DESIGN AND POPULATION: a quasi-experimental pre-test-post-test control group design among general practice patients with type 2 diabetes mellitus, aged 40 – 75 years. INTERVENTION: 1) In Amsterdam we will implement an innovative shared diabetes care model. The implemented diabetes care consists of structured care achieved by the use of a central database, a coordinating role for the diabetes nurse and an active recall system. An annual diabetes check is offered to patients in combination with patient education by a diabetes nurse and a consultation with a dietician. A diabetes nurse will support diabetes care in general practice. 2) We will investigate the structured diabetes care as it is implemented in West-Friesland. In West-Friesland, patients receive care by the diabetes care system (DCS) in addition to the care delivered by their own GP. The DCS coordinates regional diabetes care using a centrally

organized database that is available to all involved caregivers. Diabetes nurses and dieticians perform an annual follow-up examination of individual patients and coordinate the care among different healthcare providers. The diabetes nurses visit the GPs every 6 months to compare and discuss mean risk factor levels of the patients in that GP's practice with mean levels from all GPs. Patient empowerment in the DCS consists of 3 elements in order to improve patient self-management: providing education; supplying information; and promoting self-monitoring of blood glucose.

**Study objective**

The intervention will primarily effect 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.

**Intervention**

Intervention I:
A shared care model will be implemented in Amstelland in cooperation with the organisations involved with local diabetes care: VUmc, Amsterdam Homecare Organisation, Amsterdam doctors laboratory (ATAL) and local general practitioners as part of the CBO. The implemented diabetes care consists of structured care achieved by the use of a central database, a coordinating role for the diabetes nurse and an active recall system. An annual diabetes check is offered to patients in combination with patient education by a diabetes nurse and a consultation with a dietician. A diabetes nurse will support diabetes care in general practice.
Intervention II:
In addition to the evaluation of the implementation of the structured diabetes care in Amstelland, we will investigate the structured diabetes care as it is successfully implemented in West-Friesland. In West-Friesland, patients receive care by the diabetes care system (DCS) in addition to the care delivered by their own GP. The DCS coordinates regional diabetes care using a centrally organized database that is available to all involved caregivers. Diabetes nurses and dieticians perform an annual follow-up examination of individual patients to assess glucose control, cardiovascular disease risk profile, and the presence of complications, and coordinate the care among different healthcare providers, including GPs, specialists, and podotherapists. The diabetes nurses visit the GPs every 6 months to compare mean risk factor levels of the patients in that GP's practice with mean levels from all GPs, and to discuss results for individual patients. The diabetes nurses also provide specific therapeutic advice for the GPs to implement. Patient empowerment in the DCS consists of 3 elements in order to improve patient self-management: providing education; supplying information; and promoting self-monitoring of blood glucose.
Controlgroup:
The control group consists of patients of GP's who are affiliated to the NIVEL's "CMR-Peilstations", and patients of GP’s, located in West-Friesland, who do not receive care by the Diabetes Care system. Diabetes patients in the control group will receive the current usual diabetes care.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients with type 2 diabetes;
2. Age 40-75 years;
3. Written informed consent;
4. Capable to fill in questionnaires;
5. Understanding of Dutch language.

## 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 GP.

# Study design

## Design

Study type: Interventional

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| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-03-2007 |
| Enrollment: | 1200 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 08-12-2006 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL820 |
| NTR-old | NTR833 |
| Other | : N/A |
| ISRCTN | ISRCTN66124817 |

# Study results

**Summary results**
N/A