# The effectiveness of adding a cognitive behavioural therapy aimed at changing lifestyle to an optimal diabetes care system.

No registrations found.

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

## Summary

### ID

NL-OMON24877

**Source**
NTR

**Brief title**
N/A

**Health condition**

Type 2 diabetes mellitus

### Sponsors and support

**Primary sponsor:** EMGO Institute
VU University Medical Center
Van der Boechorststraat 7
1081 BT Amsterdam
The Netherlands
**Source(s) of monetary or material Support:** internal funding EMGo Institute

### Intervention

## Outcome measures

### Primary outcome

1. Differences between intervention and usual care groups in changes in diet, physical activity and smoking behaviour according to the ASE-model, a health behaviour model that assumes that behaviour is determined by attitude (A), social influences (S) and self-efficacy (E);

2. Changes in cardiovascular risk score based on the Oxford Risk Engine (algorithm that includes: age at diagnosis, duration of diabetes, sex, ethnicity, smoking status, systolic blood pressure, HbA1c, total cholesterol, HDL-cholesterol). A risk reduction of 5% is clinical relevant.

### Secondary outcome

1. Quality of life;

2. Patient satisfaction;

3. Changes in medication use, adherence to prescribed medication;

4. Proportion of patients reaching treatment targets according to the guidelines of the Dutch College of General practitioners;

5. Adherence to the 3-monthly visit to the general practitioner.

# Study description

### Background summary

Background:

In patients with type 2 diabetes, the risk for cardiovascular disease is substantial. To achieve a better risk profile, lifestyle changes on diet, physical activity and smoking status are needed. This will involve behaviour changes of the patients, which are often difficult to achieve. A cognitive behavioural therapy that in particular is focused on the self-management of the patient may be effective.

Hypothesis:

The hypothesis that will be tested in the current proposal is that a cognitive behaviour

intervention is more effective in achieving behavioural changes and therefore changes in lifestyle and cardiovascular risk profile than usual care in patients with type 2 diabetes.

Methods:

Patients with type 2 diabetes (n=300) will be selected from general practitioners, who are incorporated in an extended care system. Then, patients will be randomised into an intervention group that will receive the cognitive behaviour therapy (CBT), and a control group that will receive usual care. Patients in the intervention group will be given the CBT, which consists of Motivational Interviewing and Problem Solving Treatment (PST). This CBT consists of 6 individual sessions of 30 minutes to increase the patient's motivation and ability to change their lifestyle. The first session will start with a risk assessment of diabetes complications that will be used to focus the therapy on.
Measurements of weight, waist circumference, blood pressure, fasting capillary glucose, HbA1c, triglycerides, total and HDL-cholesterol will be performed in both groups. Additionally, all patients will receive questionnaires on quality of life, quality of diabetes care, physical activity, eating behaviour, smoking status, depression and behaviour changes.

Expected results:

The cognitive behavioural therapy will enable the diabetes care to have a tool that fits better into the self-management of patients than usual care. This will result in changes in behaviour and that will lead to changes in lifestyle and finally in cardiovascular risk profile. In addition, we also expect that benefits will be achieved in terms of increases in treatment satisfaction, quality of life, and adherence to prescribed diabetes and cardiovascular medication.

## Study objective

A cognitive behaviour intervention is more effective in achieving behavioural changes and therefore changes in lifestyle and cardiovascular risk profile than usual care in patients with type 2 diabetes.

## Study design

N/A

## Intervention

1. Intervention group: a cognitive behavioural therapy (CBT) which consist of a Motivational Interviewing phase and a Problem Solving Treatment phase. The CBT will be performed by dieticians and diabetes nurses and includes 6 individual sessions of 30 minutes. This sessions will be performed within a period of 16 weeks;

2. Usual care group: usual care by general practitioner/practice nurse and an annual check-up Diabetes Research Center as is usual in the optimal care system where the study will be performed.

Both groups will be measured at baseline, at 6 and at 12 months.

Measurements include: demographic patient characteristics, patients' history, diabetes care, clinical patients' characteristics (weight, height, waist circumference, foot inspection, blood pressure, fasting plasma glucose, HbA1c, total cholesterol, HDL-cholesterol) and questionnaires.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients with type 2 diabetes from general practices with the support of a practice nurse;

2. Age 40-70 years;

3. Written informed consent;

4. Capable to fill in questionnaires;

5. Understanding of Dutch language;

6. HbA1c > 7.0 % and/or BMI > 27.0 kg/m2 and/or smoking.

### Exclusion criteria

1. Unstable endocrine disorders, with the exception of diabetes;

2. Malignant disease;

3. Treatment with corticosteroids;

4. Serious mental impairment i.e. preventing to understand the study protocol.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2005 |
| Enrollment: | 300 |
| Type: | Actual |

## Ethics review

Positive opinion

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| Date: | 16-08-2005 |
| 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 | NL68 |
| NTR-old | NTR92 |
| Other | : N/A |
| ISRCTN | ISRCTN12666286 |

# Study results

**Summary results**
N/A