# Primary prevention of diabetes mellitus type 2 and cardiovascular diseases using a cognitive behaviour programme aimed at lifestyle changes in people with abdominal obesity.

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28000

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

Prevention, lifestyle, Cognitive behavior treatment, diabetes mellitus type 2, cardiovascular disease.

Preventie, leefstijl, cognitief gedragsprogramma, diabetes mellitus type 2, hart- en vaatziekten

### Sponsors and support

**Primary sponsor:** G.Nijpels
**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

1. Changes in cardiovascular risk score (risk function developed by the SCORE-project);
2. Changes in diabetes risk calculation (risk function from data of the ARIC Study);

### Secondary outcome

1. Changes in lifestyle factors:
a. dietary behaviour;
b. physical activity;
c. smoking behaviour;
2. Changes in perceived health;
3. Changes in medical care utilization;
4. Changes in waist circumference.
5. Cost effectiveness and cost-utility (costdiary and Euroqol).

# Study description

### Background summary

Background:
Partly because of the ageing population, and partly due to changes in lifestyle and the resulting epidemic of obesity, the percentage of people with cardiovascular diseases (CVD) and diabetes mellitus type 2 (DM2) is growing rapidly. CVD and DM2 are to a large extent caused by lifestyle dependent risk factors, such as overweight, reduced physical activity, and an unhealthy diet. Changing these risk factors has the potential to postpone or prevent the development of CVD or DM2.

Objective:
The objective of the study is to assess the effects and cost-effectiveness of a cognitive behavior intervention in people at risk for CVD or DM2.

Design:
A multicenter randomized controlled trial.

Study population:
Twelve thousand inhabitants aged 30-50 living in several municipalities in the semi-rural region of West-Friesland will be invited in a two-step screening procedure. In the first step people will receive an invitation to measure their own waist circumference with a tape

measure. People with abdominal obesity (based on the waist circumference) are invited for the second step of the screening, including blood pressure, taking a blood sample and anthropometric measurements. With these measurements persons with a moderate or high risk of CVD or a high risk of DM2 can be identified. These person will be randomly assigned to an intervention group (n=300) and a control group (n=300).

Intervention:
The intervention group will receive a cognitive behavior program (CBP) given by specially trained nurse practitioners at general practices. The CBP consists of up to six individual sessions of 30 minutes and aims to increase the participants' motivation and ability to change their lifestyle. The CBP will be followed by 3-monthly booster sessions by phone or e-mail. The participants in the control group will receive written information about their risk of CVD and/or DM2, and existing brochures on health guidelines regarding physical activity and diet, and on smoking cessation. The intervention will be coordinated throughout the Diabetic Research Center Hoorn, in which the measurements also will take place. After baseline there will be three follow up measurements (after 6, 12 and 24 months). An economic evaluation will take place after 24 months.

### Study objective

It is hypothized that a cognitive behavioral program that in particular is focused on motivation and self-management in persons at high risk for CVD and/or DM2 will change their behavior, which reduces the risk on developing DM2 and the risk on CVD.

### Intervention

The intervention group will receive a cognitive behavior program (CBP) consisting of Motivational Interviewing and Problem Solving Treatment, a program that in particular is focused on motivation and the self-management of the participants. Up to six individual CBP sessions of 30 minutes will be given, followed by 3-monthly booster sessions by phone or e-mail. Participants in the control group will receive written information and existing brochures about their risk of CVD and/or DM2.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Persons aged 30-50;
2. With a moderate or high risk of CVD (as calculated according to the SCORE-project);
3. Or a high risk of DM2 (as calculated according to the risk function of the ARIC Study").

## Exclusion criteria

1. Having diabetes
2. Previous CVD;
3. Pregnancy;
4. Current malignant disease;
5. (Severe) Mobility problems.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2007 |
| Enrollment: | 600 |
| Type: | Anticipated |

## Ethics review

Not applicable

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|---|---|
| Application type: | Not applicable |

## 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 | NL879 |
| NTR-old | NTR893 |
| Other | : N/A |
| ISRCTN | ISRCTN59358434 |

## Study results

**Summary results**

N/A