

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

<b>Submission date</b> 26/02/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/02/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## Study information

Scientific Title

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

### **Study objectives**

It is hypothesised that a cognitive behavioural program that in particular is focused on motivation and self-management in persons at high risk for Cardiovascular Disease (CVD) and/or Diabetes Mellitus type two (DM2) will change their behaviour, which reduces the risk on developing DM2 and the risk on CVD.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

VU University Medical Center on 06/2007 (Ref: 2007/107)

### **Study design**

Randomised, active controlled, parallel group, multicentre trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Diabetes Mellitus type two (DM2), cognitive behaviour treatment, lifestyle, prevention, cardiovascular disease

### **Interventions**

The intervention group will receive a Cognitive Behaviour 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 three-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.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

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)

### **Key secondary outcome(s)**

1. Changes in lifestyle factors:
  - 1.1. Dietary behaviour
  - 1.2. Physical activity

- 1.3. Smoking behaviour
2. Changes in perceived health
3. Changes in medical care utilisation
4. Changes in waist circumference
5. Cost effectiveness and cost-utility (cost diary and Euroqol questionnaire)

**Completion date**

01/08/2010

## Eligibility

**Key inclusion criteria**

1. Persons aged 30 to 50 years
2. With a moderate or high risk of CVD (as calculated according to the Systematic COronary Risk Evaluation [SCORE]-project)
3. Or a high risk of DM2 (as calculated according to the risk function of the Atherosclerosis Risk In Communities [ARIC] Study)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Not Specified

**Key exclusion criteria**

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

**Date of first enrolment**

01/08/2007

**Date of final enrolment**

01/08/2010

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**  
VU University Medical Centre  
Amsterdam  
Netherlands  
1081 BT

## Sponsor information

**Organisation**  
VU University Medical Centre (VUMC) (The Netherlands)

**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

### 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?
<a href="#">Results article</a>	results	04/04/2013		Yes	No
<a href="#">Results article</a>	results	19/04/2013		Yes	No