ISRCTN59358434 https://doi.org/10.1186/ISRCTN59358434

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

Submission date	Recruitment status	[X] Prospectively registered
26/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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?
Results article	results	04/04/2013		Yes	No
Results article	results	19/04/2013		Yes	No