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

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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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON33639

Source
ToetsingOnline

Brief title
[not applicable]

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Synonym
arteriosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cognitive behavioural therapy, diabetes mellitus, lifestyle, Prevention

Outcome measures

Primary outcome

Effects in terms of changes in cardiovascular risk profile and changes in risk

of developing diabetes

Secondary outcome

- Changes in dietary, physical activity, and smoking behavior.

- Economic evaluation from the societal perspective and from the perspective of

the health insurer

Study description

Background summary

Title of the study
Primary prevention of diabetes mellitus type 2 and cardiovascular diseases using a cognitive behavior program aimed at lifestyle changes in people with abdominal obesity

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.

Study 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.

Study design

A multicenter randomized controlled trial

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 burden and risks

Participation involves time investment (altogether about 5 hours for participants in the intervention group and 2 hours for the control group). There are no risks associated with trial participation.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
1081 BT Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
1081 BT Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 30-50 years, living in West-Friesland, at moderate or high risk of cardiovascular diseases and/of high risk of developing diabetes mellitus, able to perform physical exercise.

Exclusion criteria

diabetes or cardiovascular diseases (in the past or during recruition), pregnancy, mobility problems.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-09-2007
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO Date:	03-08-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-08-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ISRCTN	ISRCTN59358434
CCMO	NL16579.029.07