

Implementation of a concept for active primary prevention of type 2 diabetes in a primary care setting.

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Objective is to study the implementation of a proven concept for active primary prevention of type 2 diabetes in a Dutch primary care setting, in order to assess whether such a concept can be applied on a broader scale, and as such contribute to the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30482

Source

ToetsingOnline

Brief title

Active prevention of type 2 diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

metabolic disorder, pre-diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: ZonMW, zorgverzekeraars (VGZ en CZ)

Intervention

Keyword: diabetes, implementation, prevention

Outcome measures

Primary outcome

- The change of the risk score of the participants as compared with the control group
- evolution fasting plasma glucose values as compared with control group.
- the the incidence of type 2 diabetes as compared with the control group.

Secondary outcome

- experience participants, drop-out rates, success and failure factors.
- experience physicians, workload, motivation, practical aspects.

Study description

Background summary

The increase of type 2 diabetes is a serious threat for public health. For individuals with so-called pre-diabetes it has been shown that prevention of type 2 diabetes is possible via an adjustment of their lifestyle (weight, exercise, diet). This concept could be very useful in coping with the epidemic. Currently, knowledge about the various aspects of implementation of such a concept in the primary care is lacking.

Study objective

Objective is to study the implementation of a proven concept for active primary prevention of type 2 diabetes in a Dutch primary care setting, in order to assess whether such a concept can be applied on a broader scale, and as such contribute to the general prevention policy to be developed in the Netherlands.

Study design

Primary care physicians will select individuals with a high risk for type 2 diabetes with the help of a risk-score questionnaire. High risk individuals will

meet with their physician to be informed about their situation and will be offered an intervention program, which should decrease and reduce their risk factors. Participants will be coached intensively by their physician and the physician-assistant. In addition, group based educational sessions will be held.

Intervention

The intervention is based on several factors: education, motivation, providing skills, monitoring and adaptation of the environment (i.c. the partner of the participant). For each participant a program will be discussed and agreed on which takes the personal circumstances into account. Clear and realistic targets will be established for the key objectives weight loss, exercise and diet composition.

Study burden and risks

limited burden; a few times per year interaction/meeting with physician/assistant, and a few times per year participation in a session for health / lifestyle education.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

increased risk for type 2 diabetes as assessed with a risk score form (FINDRISK)

Exclusion criteria

diabetes; serious health conditions precluding participation in an active lifestyle improvement program; e.g. terminal disease, physical disability, mental disability.

Pregnancy, use of medication influencing glucose tolerance

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO
Date: 01-03-2007
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL15878.060.07