

Diabetes Prevention Eindhoven.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25847

Source

Nationaal Trial Register

Brief title

APHRODITE (Active Prevention in High Risk individuals Of Diabetes Type 2 in Eindhoven)

Health condition

The program focusses on "pre-diabetic" individuals in the 40-70 year age group. Their diabetes risk is assessed with the help of an 8 item questionnaire, which includes a/o BMI, waist circumference, age, family history.

Sponsors and support

Primary sponsor: ZonMW

University of Tilburg / TRANZO

RIVM

Source(s) of monetary or material Support: ZonMW

CZ Zorgverzekeringen

VGZ Zorgverzekeringen

Intervention

Outcome measures

Primary outcome

Reduction of risk-score for type 2 diabetes;

reduction of incident type 2 diabetes.

Secondary outcome

Quality of life of participants;

success- and failure factors in the primary care environment which carries out the program.

Study description

Background summary

The study will explore the efficacy and efficiency of a lifestyle intervention program to reduce the risk / incidence of type 2 diabetes in high-risk individuals, actively selected by their own primary care physician.

Duration of the intervention is 2.5 years. The intervention is based on frequent interviews/discussions between the participant and his/her physician and the nurse-practitioner, on average 4 times per year. In addition, group sessions with a dietician will be held to educate the participants on food aspects and to provide the opportunity to exchange experiences, ask questions, etc. In total the study will comprise 500 participants in the intervention arm and 500 controls. We will study the various success- and failure factors in the primary care setting, and include the participants' experiences, quality-of-life aspects in the final analysis.

Study objective

Prevention of type 2 diabetes (T2D) in high-risk individuals has been proven to be possible, as demonstrated e.g. by the SLIM-, DPP- and DPS- studies. Intervention to achieve lifestyle adjustments appears to be effective in reducing the risk factors and the incidence of T2D. We will investigate the implementation of such a concept in the primary care field, using an active approach, i.e. individuals will be requested to assess their risk for T2D by their own family physician; if high risk, they will be suggested to participate in a lifestyle improvement program, which is aiming to achieve long-lasting effects. Education, motivation, providing tools and support, and monitoring are the main elements of the program. Motivational interviewing is the basic technique to have the participants obtain "ownership" of their situation and of the ways to make the necessary adjustments.

Study design

October 2007: sending out 16,000 letters to patients aged 40-70 years of 45 primary care physicians.

November/ December 2007: selecting high-risk individuals and performing the intake

interviews to have them participate.

January 2008: start actual intervention.

Intervention

Life-style intervention to increase daily physical exercise, improve quality of diet/food intake, aiming at long-lasting and sustained effect. We strive to implement the changes in a gradual way in the normal daily life, avoiding complex and "artificial" measures such as calorie-counting, crash-diets and exaggerated physical exercise.

Contacts

Public

Rijsven 13, .
Frits Wielaard
Eindhoven 5645 KH
The Netherlands
06-51692242

Scientific

Rijsven 13, .
Frits Wielaard
Eindhoven 5645 KH
The Netherlands
06-51692242

Eligibility criteria

Inclusion criteria

Individuals 40-70 years with increased risk to develop type 2 diabetes.

Exclusion criteria

1. Unwilling to participate;
2. current diabetes;
3. serious (terminal) illness;

- 4. unable to participate mentally or physically;
- 5. pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Control:	Placebo

Recruitment

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

Ethics review

Positive opinion	
Date:	10-10-2007
Application type:	First submission

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	NL1049
NTR-old	NTR1082
Other	TRANZO / University of Tilburg : FW
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A