Diabetes Prevention Eindhoven.

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Prevention of type 2 diabetes (T2D) in high-risk individuals has been proven to be possible, as demonstated e.g. by the SLIM-, DPP- and DPS- studies. Intervention to achieve lifestyle adjustments appears to be effective in reducing the risk factors...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25847

Bron
NTR

Verkorte titel
APHRODITE (Active Prevention in High Risk individuals Of DIabetes Type 2 in Eindhoven)

Aandoening

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.

Ondersteuning

Primaire sponsor: ZonMW
University of Tilburg / TRANZO
RIVM
Overige ondersteuning: ZonMW
CZ Zorgverzekeringen
VGZ Zorgverzekeringen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction of risk-score for type 2 diabetes;
reduction of incident type 2 diabetes.

Toelichting onderzoek

Achtergrond van het onderzoek

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, acively 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 comprize 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.

Doel van het onderzoek

Prevention of type 2 diabetes (T2D) in high-risk individuals has been proven to be possible, as demonstated 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.

Onderzoeksopzet

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

November/ December2007: selecting high-risk individuals and peerforming the intake

interviews to have them participate.

January 2008: start actual intervention.

Onderzoeksproduct en/of interventie

Life-style intervention to increase daily physical excercise, 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 excercise.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unwilling to participate;

2. current diabetes;

3. serious (terminal) illness;

4. unable to participate mentally or physically;

5. pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1049
NTR-old	NTR1082
Ander register	TRANZO / University of Tilburg : FW
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A