Dialert, effects of a lifestyle intervention in Dutch and Turkish 1st degree relatives of persons with type 2 diabetes, a randomised controlled trial.

Gepubliceerd: 29-09-2009 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26716

Bron
NTR

Verkorte titel
Dialert

Aandoening

Diabetes Mellitus type 2, life style, prevention, intervention, overweight

Ondersteuning

Primaire sponsor: EMGO Institute, VU University Medical Center
Overige ondersteuning: Dutch Diabetes Research Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main endpoint is to achieve significant reduce of body weight at 3 months following the intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Prevention trials (e.g. Diabetes Prevention Program) in overweight persons with IGT have convincingly demonstrated that the risk of developing type 2 diabetes (T2DM) can significantly be reduced by modest weight reduction by means of lifestyle changes (diet, exercise). Family history (FHi) is a known risk factor for T2DM, and more so in the presence of overweight. Targeting preventive actions towards this group therefore is advocated and indeed prioritized in the National Action program for Diabetes but not yet practiced. Ethnic minorities warrant specific attention in this context. To date, no studies have tested the effects of offering lifestyle counselling specifically targeted at people with a FHi of diabetes from ethnic minorities. Persons from Turkish origin are known to be at increased risk for type 2 diabetes and cardiovascular disease but so far received little attention. This study is the first to compare the effects of group based lifestyle-counselling in Dutch and Turkish-Dutch 1st degree overweight relatives of patients with diabetes. Eligible participants will be recruited via their General Practitioner or outpatient clinic. The study is conducted in close collaboration with community health services in the Amsterdam region (GGD). Basic content and learning principles of the program are derived from existing behaviour change interventions in the field. Unique features of the program are the review of own family history of T2DM, a diabetes risk assessment and promoting family communication on diabetes prevention.

Objective:
The main objective of this study is to test and compare the effectiveness of a lifestyle-oriented intervention in Dutch and Turkish-Dutch 1st degree relatives of type 2 diabetes patients with overweight.

Study population:
First-degree relatives of type 2 diabetes patients, between age 29 and 55, and overweight.
Intervention: The intervention comprises 2 interactive group sessions and one booster session, supplemented with a patient manual and newsletters. The follow-up program aims to sustain achieved behaviour changes. The wait-list control group receives the intervention 3 months after baseline. A culturally appropriate Turkish version of the program will be made

available.

Main study endpoints:
The main endpoint is to achieve significant body weight loss at 3 months following the intervention. Secondary outcomes include anthropometric, medical, behavioural and psychological indices, along with process indicators.

Doel van het onderzoek

We hypothesize that the intervention will prove to be more effective than the control condition in achieving significant body weight loss at 3 months;

We expect to observe significant changes in metabolic, psychological and behavioural parameters at 3, 6 and 9 months following the intervention in both ethnic groups, resulting in reduced risk of developing type 2 diabetes and cardiovascular disease.

Onderzoeksopzet

Baseline, 3, 6, 9 months (+ 12 months in the control group).

Onderzoeksproduct en/of interventie

The intervention comprises 2 interactive group sessions, supplemented with a patient manual. To sustain achieved behaviour changes the follow-up program includes a booster session and 4 newsletters.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible are first-degree relatives of type 2 diabetes patients (father, mother, brother or sister, son or daughter), between 25 and 65 years of age, and overweight (Body Mass Index of ≥ 25 or waist circumference > 88 cm for females and > 102 cm for males). In the Turkish group, both first and second generation Turkish immigrants are eligible.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:

1. Diagnosed with type 1 or 2 diabetes;

2. Currently under medical treatment for ischemic heart disease;

2. Cancer;

3. Renal failure;

4. Diagnosed with a psychiatric disorder;

5. Pregnancy or physically/mentally too impaired to participate in the study (e.g. unable to come to the location of the assessments and interventions);

6. Not able to write of read in Dutch or Turkish.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2010
Aantal proefpersonen:	268
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1919
NTR-old	NTR2036
Ander register	Scientific Committee of the EMGO Institute for Health and Care Research : WC2008-101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A