

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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26716

Source

NTR

Brief title

Dialert

Health condition

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

Sponsors and support

Primary sponsor: EMGO Institute, VU University Medical Center

Source(s) of monetary or material Support: Dutch Diabetes Research Foundation

Intervention

Outcome measures

Primary outcome

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

intervention.

Secondary outcome

Is there a significant difference in metabolic outcomes (weight, BMI, weight circumference, lipids, blood pressure, insulin resistance and HbA1c) psychological and behavioural outcomes (perceived risk and seriousness of diabetes, self-efficacy beliefs (diet, exercise, smoking), outcome expectancies, distress, motivation to change and self-reported health behaviours (diet, exercise, smoking, alcohol)) and psychological distress (anxiety and depression) from baseline to 3 months between intervention and controls and at 6 and 9 months following the intervention between and within both ethnic groups?

Do baseline patient characteristics predict weight loss at 6 and 9 months follow-up, within and across both ethnic groups.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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 or read in Dutch or Turkish.

Study design

Design

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

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-01-2010
Enrollment:	268
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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 NL1919

NTR-old NTR2036

Other Scientific Committee of the EMGO Institute for Health and Care Research :
WC2008-101

ISRCTN ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A