Diabetes Lifestyle Intervention Study Slotervaarthospital

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In patients with non-insulin dependent type 2 diabetes, intensive, short term physical activity is associated with decreased blood glucose levels and number of cardiovascular complications. In patients who are insulin dependent however, the effects...

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

Samenvatting

ID

NL-OMON22216

Bron
Nationaal Trial Register

Verkorte titel
DIALISS

Aandoening

physical activity
insulin dependent type 2 diabetes
behavior change

Ondersteuning

Primaire sponsor: Diabetespoliclinic
Department of internal medicine
Slotervaarthospital
Louwesweg 6
1006 BK Amsterdam
The Netherlands
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Web: www.slz.nl
Overige ondersteuning: Novo Nordisk Farma B.V.
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Tel: +31172-449494
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure was:
- the change in physical activity measured by the Tecumseh/Minnesota scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: In patients with non-insulin dependent diabetes type 2, intensive, short term physical activity is associated with decreased blood glucose levels and number of cardiovascular complications. In patients who are insulin dependent however, the effects of physical activity are less clear. Moreover, short-term, intensive lifestyle interventions often fail to significantly improve physical activity in the long term. The aim of this study was to determine the sustainability and effects upon physical activity and effects on HbA1c levels and other clinical parameters of diabetes of a 2-year behavior intervention program in insulin dependent patients with diabetes type 2.

Doel van het onderzoek

In patients with non-insulin dependent type 2 diabetes, intensive, short term physical activity is associated with decreased blood glucose levels and number of cardiovascular complications. In patients who are insulin dependent however, the effects of physical activity are less clear since few studies are conducted with only insulin dependent type 2 diabetes patients included. Moreover, short-term, intensive lifestyle interventions often fail to significantly improve physical activity in the long term because of high drop out rates. The aim of this study was to determine the sustainability and effects upon physical activity, HbA1c levels and other clinical parameters of type 2 diabetes of a 2-year, behavior intervention program in insulin dependent type 2 diabetes patients.

Onderzoeksopzet

The inclusion period was 1 year, from juli 2005 until juli 2006.

Measurements of every individual were performed at baseline and after 1 and 2 years.

The study was finished in august 2008.

Onderzoeksproduct en/of interventie

The intervention program was based on the PACE (Physician-based Assessment and Counseling for Exercise) program; to stimulate exercise in participants on low profile by written information, short personal advise and telephone follow-up.

The program consisted of 4 visits per year at the physiotherapist and a 15-minute telephone call 6 weeks after each visit.

In the first consult, the physiotherapist and the subjects made a personal exercise program together based on the persons¡¯ baseline exercise pattern, medical condition, exercise tolerance and personal preferences.

The goal was for the participants to exercise at a medium intensive level, 160-180 minutes per week and spread over at least three times per week, based on the Diabetes Prevention Program.

During the following contacts, the subjects were instructed and encouraged to achieve or maintain the intended goal.

Participants in the control group received no individual advice, no programs were provided and no additional appointments were scheduled, apart from the visits for the annual measurements.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A clinical trial involving patients at the Dutch Slotervaart Hospital, who had type 2 diabetes and were using insulin.

Subjects aged until 70 years and exercising less than 180 minutes per week, spread over at least three times per week, were included to the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Eligible persons were excluded if they met one of the following conditions:

1. Poor knowledge of the Dutch language

2. Life-expectancy of less than 5 years

3. Clinical manifest cardiovascular disease (hospitalization as a result of heart disease until 6 months before inclusion

4. Angina pectoris class ¡Ý II (NYHA)

5. Left heart-block or aorta-stenosis)

6. Pregnant women

7. Repeated hospitalization because of recurrent hypoglycaemia

8. Pre-terminal kidney-failure

9. Proliferative retinopathy

10. Usage of an insulin pump

11. Revalidation therapy

12. Psychiatric diseases

13. Chronic alcohol and/or drugs abuse

14. Decreased physical tolerance because of unrelated diabetic co-morbidity, like COPD or immune diseases.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2005
Aantal proefpersonen:	74
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2008

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	NL1440
NTR-old	NTR1501
Ander register	Number MECC Slotervaarthospital : 0436
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A