

# Diabetes Lifestyle Intervention Study Slotervaarthospital

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22216

### Source

NTR

### Brief title

DIALISS

### Health condition

physical activity  
insulin dependent type 2 diabetes  
behavior change

## Sponsors and support

### Primary sponsor: Diabetespoliclinic

Department of internal medicine

Slotervaarthospital

Louwesweg 6

1006 BK Amsterdam

The Netherlands

Tel: +3120-5129333

Web: [www.slz.nl](http://www.slz.nl)

### Source(s) of monetary or material Support: Novo Nordisk Farma B.V.

Flemingweg 18

2408 AV Alphen a/d Rijn

The Netherlands

Tel: +31172-449494

## Intervention

## Outcome measures

### Primary outcome

Primary outcome measure was:

- the change in physical activity measured by the Tecumseh/Minnesota scale.

### Secondary outcome

Secondary outcome measures were:

- differences in quality of life (W-BQ12 scale)
- medication use
- body composition
- tension
- laboratory markers of diabetes
- macro and microvascular complications.

## Study description

### Background summary

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.

### Study objective

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.

## **Study design**

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.

## **Intervention**

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.

## Contacts

### Public

Slotervaarthospital <br>  
Department of internal medicine <br>  
Diabetespoliclinic

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3120-5129333

### Scientific

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Diabetespoliclinic

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## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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 I-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.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2005

Enrollment: 74  
Type: Actual

## Ethics review

Positive opinion  
Date: 21-10-2008  
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	NL1440
NTR-old	NTR1501
Other	Number MECC Slotervaarthospital : 0436
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A