

The effects of a self-efficacy based exercise intervention on physical activity, cardiovascular risk factors and health status in inactive people with type 2 Diabetes Mellitus

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To investigate whether an exercise-program that takes the patient's level of exercise-self-efficacy into account, added to regular care, is more effective compared to regular care in increase the patients level of physical activity, improve...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34032

Source

ToetsingOnline

Brief title

Diafyzob: Exercise intervention for people with type 2 Diabetes Mellitus

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

type 2 Diabetes Mellitus; non insulin-dependent diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: ziektekosten verzekeraar CZ

Intervention

Keyword: Diabetes Mellitus, Physical activity, Primary Health Care, Self-efficacy, Type 2

Outcome measures

Primary outcome

Physical activity, cardiovascular risk factors and health status.

Secondary outcome

Patient satisfaction, diabetes self-efficacy, depressive symptoms and quality of sleep.

Study description

Background summary

Sufficient exercise is important for people with Type 2 Diabetes Mellitus, as it can help to prevent or delay future health problems. Although the knowledge about the effects of physical activity and the number of diabetes-exercise programs is increasing, still a substantial number of people with type 2 Diabetes Mellitus do not exercise enough. Therefore, we have developed a new diabetes-exercise program that takes into account the patients* level of exercise self-efficacy (the confidence that the patients has regarding his/her ability to independently increase their level of physical activity).

Study objective

To investigate whether an exercise-program that takes the patient*s level of exercise-self-efficacy into account, added to regular care, is more effective compared to regular care in increase the patients level of physical activity, improve cardiovascular risk factors and the health status of inactive people with type 2 Diabetes Mellitus

Study design

Non-randomised controlled trial. Participants of the intervention are allocated to the intervention- or control group based on their exercise self-efficacy score. Participants with a high score are allocated to an advice program, participants with a low score to an intensive program. The duration of the intervention is 36 weeks. Participants of the control group receive regular care.

Intervention

The intervention consists of an intensive program and an advice program. Patients with a low self-reported level of exercise self-efficacy are allocated to the intensive program. The intensive program consists of an intake, 24 physiotherapist guided group trainings (1 hour each) and four individual advise-consults with the physiotherapist. Patients with a high exercise-self-efficacy score are allocated to the advice program. The advice program consists of an intake and four individual advise-consults with the physiotherapist. Both programs last 36 weeks, and aim to increase the exercise-level of the participants to at least 3 hours a week.

Study burden and risks

All patients receive regular diabetes care. People in the intervention are participating in a 36 weeks exercise program with the aim to exercise at least 3 hours a week. They are stimulated to keep exercising after the program has ended. Patients in the intervention receive 5 sets of questionnaires; patients in the control group receive 3 questionnaire-sets (20-30 minutes/questionnaire). There are no additional invasive measurements as they are part of regular diabetes care. The risks of the exercise program are limited as a result of an easy accessible program that is guided by professionals. An increase of physical activity can have positive effects on health such as a better physical fitness and improvement of several psychological factors.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- The patient is diagnosed with type 2 Diabetes Mellitus
- The patient exercises less than advised in the Dutch Guidelines for Physical Activity (i.e. at least 30 minutes/day, 5 days/week).
- The patient's BMI is over 25kg/m²
- The patient is born between 1930 and 1992.

Exclusion criteria

- The patient is suffering from a serious complication of type 2 Diabetes Mellitus or other disabling co-morbidity: e.g. unstable angina pectoris, heart failure, very high blood pressure, cerebrovascular accident, serious neuropathy, kidney failure, diabetic foot ulcer(s), proliferative retinopathy, a serious form of cancer, orthopaedic constraints, serious exertion hypertension, unstable coronary ischemia.
- The patient recently participated in an exercise program on an indication other than Type 2 Diabetes Mellitus
- Results of the cycle ergometry debar participation

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	944
Type:	Actual

Medical products/devices used

Registration:	No
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Ethics review

Approved WMO	
Date:	10-11-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24343

Source: Nationaal Trial Register

Title:

5 - The effects of a self-efficacy based exercise intervention on physical activity, ... 15-06-2025

In other registers

Register	ID
CCMO	NL33834.008.10
OMON	NL-OMON24343