

Impact of a walking program on lifetime risk for cardiovascular disease in type 1 and type 2 diabetes mellitus*

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To examine the impact of walking training on the lifetime risk for cardiovascular disease in DMT2 and DMT1 patients and to assess whether these effects are preserved 3 months after the Nijmegen 4-Day marches. Results will be compared with a control...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON37496

Source

ToetsingOnline

Brief title

Walking training and diabetes mellitus type 1 and 2

Condition

- Cardiac disorders, signs and symptoms NEC
- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Diabetesfonds

Intervention

Keyword: cardiovascular disease, diabetes mellitus, walking exercise

Outcome measures

Primary outcome

Lifetime risk score for cardiovascular disease

Secondary outcome

not applicable

Study description

Background summary

Diabetes mellitus type 1 (DMT1) and type 2 (DMT2) represent a major health problem in the Western society. Physical inactivity plays a detrimental role in the development of DMT2, whilst physical inactivity also contributes to the increased risk for future cardiovascular events and vascular complications in DMT1 and DMT2. To support this notion, exercise training has various beneficial effects, including decreasing the cardiovascular risk in DMT1 and DMT2. Nonetheless, exercise training in a gym-based setting is associated with low motivation to continue an active life style. Walking exercise represents an attractive type of exercise that can be performed everywhere. Moreover, performing exercise training in preparation for an event (such as the Nijmegen 4-Day Marches) is associated with a clear goal and may therefore enhance motivation to adopt an active life style and to remain physically active. These changes in life style are believed to contribute to a lower risk for future cardiovascular risk in those patients. The purpose of this study is to examine the impact of walking exercise training in DMT1 and DMT2 on the lifetime risk for cardiovascular disease, but also whether subjects remain physically active after finishing the Nijmegen 4-Day marches.

Study objective

To examine the impact of walking training on the lifetime risk for cardiovascular disease in DMT2 and DMT1 patients and to assess whether these effects are preserved 3 months after the Nijmegen 4-Day marches. Results will

be compared with a control group of non-exercising DMT2 and DMT1 patients

Study design

Subjects will undergo 3-months of walking exercise and take part in walking training program.

Intervention

Walking exercise (ViaVierDaagse)

Study burden and risks

To calculate the lifetime risk score, subjects undergo a number of measurements for body characteristics (10 minutes; e.g. height, weight, blood pressure), fill in a questionnaire (5 minutes) and subjects will undergo blood withdrawal (5 minutes; cholesterol, glucose, insulin). Finally, to calculate the lifetime risk score subjects also undergo a submaximal cycling test (*strand test) to estimate the maximal oxygen consumption (30 minutes). This set of experiments (50min in total) will be performed before, immediately after, and at 3 months after the walking training (3 times 50min).

Subjects will perform walking exercise training. This type of exercise training is safe, and not associated with any health risk. Although walking training will be performed under home-based conditions, regular feedback will be provided and clear instructions will be provided (written and orally) about potential risks of walking exercise (injuries, but also the risk for hypoglycaemia). Feedback and information will be provided by Prof. Dr Cees Tack from the Department of Internal Medicine from the UMC St Radboud. The Department of Physiology has a long and strong history of performing exercise training studies in healthy volunteers (children, adolescents, middle-aged and older subjects) as well as various patient groups (including DMT1 and DMT2).

Taken together, our study involves minimally and non-invasive measures, whilst our intervention is believed to have a strong and potent health benefit for DMT1 and DMT2 patients and will gain important and novel information about the impact of exercise training in DMT1 and DMT2 patients.

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

- Diagnosed with type 2 diabetes mellitus (type 2 diabetes patients only)
- Diagnosed with type 1 diabetes mellitus (type 1 diabetes patients only)
- Mentally and physically capable to perform exercise training (type 1 and 2 diabetes)
- Age >18 year

Exclusion criteria

- Subjects with vascular complications due to type 1 and 2 diabetes mellitus (e.g. diabetic foot ulcer, foot ulcers as a consequence of polyneuropathology or foot ulcers of any other cause)
- Presence of an absolute contra-indication for the performance of exercise (SOP inspanningstest, department of physiology)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	46
Type:	Anticipated

Ethics review

Approved WMO	
Date:	14-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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

CCMO

ID

NL40101.091.12