Diabetes mellitus and the Nijmegen 4-day marches: the sweet effects of walking exercise

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Ethical review	Not approved
Status	Will not start
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON35321

Source
ToetsingOnline

Brief title
Diabetes and walking exercise

Condition

- Diabetic complications

Synonym
diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Diabetes Fonds

Intervention

Keyword: cardiovascular risk, diabetes mellitus type 2, exercise training, insulin resistance

Outcome measures

Primary outcome

1) Insulin resistance (objective 1)

2) Cardiovascular risk (objective 1)

3) Vascular function and structure (objective 1)

4) Glucose homeostasis (objective 2)

5) Fluid and electrolyte balance (objective 2)

Secondary outcome

N/A

Study description

Background summary

Type 2 diabetes mellitus (T2DM) represents a major health problem in the Western society. Physical inactivity plays a detrimental role in the development of T2DM, but also contributes to the increased cardiovascular risk. To support this notion, exercise training has various beneficial effects, including improvement in insulin sensitivity and cardiovascular risk factors. Walking exercise represents an attractive type of exercise that can be performed everywhere. Moreover, participating in a training program in preparation for a walking event (i.e. Nijmegen 4-Day marches) may enhance motivation to perform exercise and remain physically active after cessation of the training program. Since relatively little is known about the effect of walking exercise training on insulin resistance and cardiovascular risk factors, the current study will be conducted.
When walking exercise is performed for prolonged periods, such as during the Nijmegen 4-Day marches, subjects may develop fluid- and electrolyte imbalance. We found that such problems occur more often in men, older subjects and overweight/obesity. Whether patients with T2DM are prone to develop such problems during prolonged walking is not known. Moreover, relatively little is known about the impact of prolonged walking exercise on glucose levels, which

may be importantly influenced by prolonged walking exercise.

Study objective

The first objective is to examine the impact of 4-month walking training on physical fitness, insulin resistance and cardiovascular risks in T2DM and their controls and to assess whether these effects are preserved 3 months after cessation of the training program. The second aim is to assess the impact of prolonged walking on fluid- and electrolyte balance and glucose homeostasis in patients with T2DM and a matched group of healthy control subjects during the Nijmegen Four Day Marches

Study design

Longitudinal study

Study burden and risks

For objective 1, subjects will undergo blood withdrawal (for measures of metabolic control and cardiovascular risk) and non-invasive measurements of vascular function and structure before and after the exercise training. The Department of Physiology has a long track-record using the proposed techniques to examine the vasculature and metabolic control in healthy subjects as well as in patient groups (e.g. spinal cord injury, older subjects, type 1 and 2 diabetes mellitus). These tests involve the repeated inflation of blood pressure cuffs and application of the non-invasive echo-Doppler technique. We have never had problems regarding these non-invasive tests nor complaints from our test subjects. 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 diabetes mellitus type 1 and 2). Subjects will perform walking exercise training. This type of exercise training is safe, and not associated with any health risk.
During the 4-day marches, we will take daily venous blood samples and perform non-invasive measurements to gain better insight into the hydration status of subjects (such as body weight changes after exercise). Also, continuous glucose monitoring will be applied to measure glucose homeostasis. All measures, therefore, are minimally invasive and not associated with an important health risk for these patients. Taken together, our study involves minimally and non-invasive measures, whilst our intervention is believed to have a strong and potent health benefit for type 2 diabetes patients and will gain important and novel information about the impact of exercise training in type 2 diabetes 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 at least 2 years ago (for the group of type 2 diabetes patients only)

Exclusion criteria

- Smoking
- Subjects with vascular complications due to type 2 diabetes mellitus (e.g. diabetic foot ulcer)
- Body weight lower than 36,5 kg
- Presence of an obstructive disease of the gastro-intestinal tract, including (but not only) diverticolosis and inflammatory intestinal disease.

- History of surgery of the intentines, excluding cholecystectomia and appendectomy
- Magnetic Resonance Imaging (MRI) planned during the period in which subjects have ingested the CorTempTM sensor or planned 48 h after the 4-Day Marches.
- pacemaker or presence of another electromedical apparatus

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	96
Type:	Anticipated

Ethics review

Not approved

Date:	20-02-2012
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	ID
CCMO	NL39109.091.11