Improving mobility in diabetic patients through resistance training

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

Summary

ID

NL-OMON34079

Source
ToetsingOnline

Brief title
n.v.t.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Muscle disorders
- Peripheral neuropathies

Synonym
polyneuropathy; multiple affection of the nerves

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: activities of daily living, diabetic polyneuropathy, muscle weakness, quality of life

Outcome measures

Primary outcome

Muscle strength in the leg: the strength of the plantar- and dorsalfelxors and

for the knee and hip extensors and flexors will be determined.

Fysical activity: during one week, the daily activity will be determined using

an accelerometer.

Mobility: this will be determined using a questionnaire and a 6 minutes walking

test.

Gait analysis: walking patterns will be analysed using video analysis and the

force plait.

Secondary outcome

Quality of life wil be measured using a questionnaire.

Difficulty in Activities of daily living Tasks (DAT) will be determined using

EMG during a 6 minutes walking test.

Study description

Background summary

Impaired mobility is a major health problem affecting many subjects with diabetes mellitus. It is associated with loss of quality of life and it is a strong predictor for poor health outcomes. Reduced lower extremity muscle function, as a consequence of diabetic polyneuropathy, is a major cause of impaired mobility. We hypothesize that a programme of resistance training will counterbalance the effects of polyneuropathy on muscle wasting, and will improve mobility and associated quality of life.

Study objective

The objective of this study is to develop a resistance training intervention that improves mobility and quality of life in diabetic patients. It is also our intension to achieve a better understanding of the relation between diabetic neuropathy and muscle weakness, limited mobility and quality of life. Moreover, insight will be gained in optimizing training programmes for neuropathic patients.

Study design

It's a prospective randomized clinical trial.

Intervention

During 24 weeks, the patients of the intervention group will participate in a resistance training program. Two subsequent intervention programmes will be offered. Initially the first 12 week resistance trainings stage will aimed at improving function of lower leg muscles; subsequently a more extended programme affecting total limb musculature (lower- and upper leg) will be provided (also 12 weeks).
During these trainings period, patients will train 3 times a week; once a plenary training session of 1,5 hour provided by a physical therapist. And 2 trainings sessions of half an hour each, by them selves at home.

Study burden and risks

The subjects who will participate in this study will run no more risks then they do in their daily living.

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

diabetic patients with polyneuropathy: valkscore >5; diabetic type 2; age >50 years;, 20diabetic patients without polyneuropathie: diabetic type 2; age >50 years; 20healthy elderly subjects: age >50 years, 20

Exclusion criteria

muscular related diseases
ischemia
amputation (except for toe amputation)

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):	01-07-2006
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-04-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL11910.068.06