The effects of hybrid cycle exercise training in inactive people with a chronic spinal cord injury.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON35731

Source
ToetsingOnline

Brief title
Hybrid cycle exercise training after spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
paralysis, spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw;Fonds Nuts Ohra

Intervention

Keyword: hybrid cycle exercise, physical capacity, spinal cord injury

Outcome measures

Primary outcome

The main study parameter is the physical capacity, expressed by the peak power output, assessed during a peak exercise test in a wheelchair on a motor-driven treadmill.

Secondary outcome

The secondary outcome measures are: metabolic syndrome, bone mineral density of the disal femur and proximal tibia, tissue viability of the sitting area and interface pressure profile, vascular function, immune function, bowel function, active lifestyle, participation and quality of life.

Study description

Background summary

People with a chronic spinal cord injury are often physically inactive and suffer from different secondary complications (e.g. cardio-vascular diseases, osteoporosis and pressure sores), resulting in a decreased mobility, participation and quality of life. Avoiding this downward spiral is therefore crucial. Physical exercise can have benificial effects on different secondary complications, activity level, quality of life and participation.
Therapeutic exercise for individuals with spinal cord injury (SCI) has traditionally involved upper-body activities due to their lower-limb paralysis. However, systematic disuse of the lower body leads to secondary complications such as lower-limb muscle atrophy, osteoporosis and pressure sores. Reactivating the inactive lower body by functional electrical stimulation (FES) has the potential to alleviate these problems. A major advantage of electrical stimulated (ES)-induced exercise of the paralyzed legs over voluntary arm exercise is that it can utilize a large muscle mass that otherwise would be dormant. Recent technological developments have introduced a hybrid tricycle (Berkelbike) where ES-induced lower-body exercise can be combined with

voluntary upper-body exercise. This study evaluates the effects of a 16-week hybrid cycle training program by comparing this program with a 16-week hand cycle training program and a non-training group.

Study objective

The primary objective is to evaluate the short- and long-term effectiveness of a hybrid cycle training program on physical capacity, active lifestyle, participation, and quality of life among a group of inactive individuals with a chronic SCI. Furthermore, the effects on *disuse and inactivity*-related measures such as skin, muscular, bone and vascular characteristics among these people are studied.

Study design

Multicentre randomized controlled trial

Intervention

A 16-week training intervention on a hybrid cycle or hand cycle. Both experimental groups will train 2x/week, 30 min. on 70%HRR. The control group will not receive any training.

Study burden and risks

Subjects will participate in a 10-month (including a 6-month follow-up period) research project, where the experimental groups execute a 16-week training program on a hybrid cycle or on a hand cycle (2x30 min/wk, 70%HRR). Measurements will be performed before the start of the training (pre-test), after 8 weeks of training (mid-test), directly after the training (post-test), and 26 weeks after the post-test (follow-up test). Measurements will include (sub)maximal exercise testing, cardiovascular and neuromuscular function tests, as well as daily functioning and quality of life and participation. Since both hand cycling and hybrid cycling involve a large muscle mass and balanced loading, it is not expected to cause overload injuries when training at 70%HRR. The graded exercise tests in the wheelchair and in the specific set-up (either a hybrid cycle or a hand cycle) might lead to local discomfort of the upper extremity during the test and/or muscle soreness after the test. However, comparable research with hybrid cycle and hand cycle training in people with SCI showed no serious musculoskeletal complaints during training and testing. Furthermore, the risks during training and testing sessions are relatively low because of thorough screening prior to participation and safety precautions throughout training and testing. The expected beneficial training effects in combination with the limited risks would justify execution of the proposed study.

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

- Spinal cord injury
- Physically inactive
- Age: 28-65 yrs.
- Time since injury (TSI): at least 10 yrs.
- Dependent on a handrim propelled wheelchair.

Exclusion criteria

- Cardiovascular contra-indications for testing according to the American College of Sports Medicine (ACSM) guidelines.
- Severe musculoskeletal complaints of the upper extremities neck or back.

- Progressive disease or psychiatric problem that could interfere with the study.
- Not having enough knowledge of the Dutch language to understand the purpose of the study and the testing methods.
- Plans to start another lifestyle (e.g. become more physically active, diet changes) in the months that the experiment is going on.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-08-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35928.029.11