Low-intensity wheelchair training in inactive people with a chronic spinal cord injury.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27828

Bron
Nationaal Trial Register

Aandoening

Spinal cord injury
Wheelchair
Training
Physical capacity

Dwarslaesie
Rolstoel
Training
Fysieke capaciteit

Ondersteuning

Primaire sponsor: Prof. dr. C. Visscher
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Center for Rehabilitation
University Medical Center Groningen (UMCG)
University of Groningen

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Overige ondersteuning: VSBFonds Nuts Ohra subsidieronde (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

This study is an evaluation of evaluate the short- and long-term effectiveness of low-intensity handrim wheelchair and regular intensity exercise training on physical capacity, daily (wheelchair)
activities, participation and quality of life, as well as on the risk of secondary complications (upper body overuse and cardiovascular risk factors) in three groups of individuals with a paraplegia (N=30, 3x10) and tetraplegia (N=30, 3x10), TSI>10y, age: 28-65y, dependent on a handrim propelled wheelchair, and without contra-indications.

The experimental groups will receive 16 weeks either low-intensity training (wheelchair: 2x30 min/week on 35% heart rate reserve (HRR) or hand cycle training (2x30 min/week on 70% HRR), while a control group will not receive training.

Doel van het onderzoek

People with a spinal cord injury are often dependent on a (hand rim) wheelchair and have an inactive lifestyle. Therefore, it is important to develop a good protocol for wheelchair training, which prevents overuse of the musculoskeletal system on one hand and improves the physical capacity and prevents the occurrence of secondary complications on the other hand. In the world of sport the training guidelines of the ACMS (ACSM, 1993, 1997) are often used. An intensity of 70-80%HRR, a frequency of 3-5x/week and a duration of 20-30 min. are in general accepted criteria to induce a training effect. However, Haskell (1994) proposed different training guidelines to improve physical fitness and health. According to Haskell, exercise at a lower intensity (30-40%HRR) and with a more divers pattern of light activities of different durations performed every day (like activities of daily living), might be more suitable for (extreme) inactive people. Additionally the risk for overuse injuries will be smaller. In 2006 a research project has been performed to study the effect of a 7-week low-intensity (30%HRR, 3x 70 min/week) wheelchair training in able-bodied subjects. The results showed

that a low-intensity wheelchair training can improve the physical capacity and propulsion technique in healthy young men. The next step is to investigate the effect of this training in inactive people with a chronic spinal cord injury.
The primary objective is to evaluate the effectiveness of low-intensity hand rim wheelchair exercise training on physical capacity, daily (wheelchair) functioning, participation and quality of life in people with a spinal cord injury. Furthermore, the effect on secondary complications such as upper body overuse and cardiovascular risk factors in inactive people with a chronic spinal cord injury will be studied.

Onderzoeksopzet

Screening:

Potential subjects are located through the databases of an interest organisation for persons with SCI and the rehabilitation centers (see 8.2) and are selected based on age (28-65y), TSI (>10y) and activity level (PASIPD score<75th percentile of a Dutch SCI cohort (de Groot et al., 2010)).

Before the first test, participating subjects will be screened by a physician on cardiovascular or musculoskeletal contraindication. Antropometric measurements will be performed and, based on a questionnaire and the subject’s history and medical chart, information on demographics, lifestyle habits and secondary complications will be recorded (Haisma et al., 2007). In addition, a wheelchair check-up will take place, which will include recording of wheelchair specifications and maintenance status.

In each week of testing, blood samples and saliva samples will be taken in the morning, when subjects are in fasting state, to determine the components of the metabolic syndrome.

Exercise testing - wheelchair:

Subjects of all three groups will conduct the handrim wheelchair exercise and skill tests with their own wheelchair. A set of wheels providing biofeedback and other parameters on propulsion technique (Optipush), e.g. force and cadence, will replace that of the subject’s wheelchair.

Maximal isometric strength test. The maximal isometric wheelchair push test will be conducted to determine the subject's maximal force on the handrim. This is a wheelchair-specific strength test in which subjects, while sitting in their wheelchair, push themself forward as hard as possible. The wheelchair remains stationary due to a cable, which is attached to a force transducer and to the wheel axle.

After the isometric strength test there will be a resting period of eight minutes. Then there will be a three minutes warming up period. After warming up there is a three minutes rest

period before starting the 30 s sprint test.

Sprint power test. A 30s sprint test will be performed. Peak forces and peak and mean power output will be recorded. After a 10 minutes resting period the submaximal test starts.

Submaximal performance test. Consists of two times three minutes wheelchair propulsion on two different workloads (power out (PO)) and a constant velocity; workload and velocity both depend on baseline capacity. A 2-min rest period will be between the two blocks. LPD and RPE will be recorded.

The gross mechanical efficiency (ME) will be calculated from the energy expenditure (En) and PO according to: ME = PO (W) • En-1 • 100%.

After a 2-min rest interval, the graded exercise test (GXT) will be performed.

Maximal aerobic capacity test: GXT. consists of 1-min exercise blocks in which the velocity of the treadmill belt is held constant and in which the workload will be increased every step by adding extra resistance (Fadd) through a pulley system (Valent et al., 2007b). The test will be ended when the subject can no longer maintain his or her position on the belt as a consequence of exhaustion, or when the subject indicates that he/she wants to stop. A separate drag test will be performed to determine the drag force (Fdrag) of the wheelchair-user system using the protocol of Van der Woude et al. (1986). Power output will be calculated from Fdrag, added load (Fadd) and the velocity of the belt (v) according to: PO = (Fdrag + Fadd) * v.

Exercise testing – hand cycle:

Hand cycle (sub)maximal performance tests. These tests will only be performed by the hand cycle group and are necessary for eliciting correct exercise intensity during the hand cycle training (see 4.5). The same protocol will be followed as during the (sub)maximal wheelchair performance tests.

Wheelchair skills:

The Wheelchair Circuit (Kilkens et al., 2004, Kilkens et al., 2002) is a test to assess manual wheelchair skill performance. It consists of 8 different standardized tasks that will be performed in a fixed sequence on a floor surface and on a motor-driven treadmill. The tasks

are (1) figure-of-8 shape, (2) crossing a doorstep (height, 0.04m), (3) mounting a platform (height, 0.10m), (4) 15-m sprint, (5) 3% slope, (6) 6% slope, (7) wheelchair propulsion (3 minutes), and (8) transfer. Performance in a stationary and dynamic (10m) wheelie task will give insight in the overall wheelchair skill of the participant (Cowan et al., submitted 2010). All subjects will use their own wheelchair, only for the 15m sprint it will be instrumented with Optipush wheels (see footnote c above). During circuit performance, the ability to perform the test items, performance times of the figure-of-8 shape and 15-m sprint, and peak heart rates during the 3% and 6% slope items on the treadmill will be recorded. Heart rate (in beats/min) will be registered with a Polar sport tester Vantage NVe at a 5-second storage interval.

Lung function:

Flow-volume curves will be made with an Oxycon (Viasys) to assess respiratory function. Three repeated curves will be made and if the resultant curve does not have its characteristic shape, an extra measurement will be made. The FVC (in liters) and FIV1 and FEV1 (in liters) for each subject will be additionally expressed as a percentage of what that subject was expected to score in comparison with an age, sex, and height-matched able-bodied population.

Muscle strength:

To determine the strength of the upper extremities, the shoulder abductors, internal and external rotators, elbow flexors and extensors, and wrist extensors in both arms will be tested with the manual muscle test (MMT). The strength is rated on a scale ranging from 0 to 5 (Haisma et al., 2006). The scores of the 12 muscle groups give a MMT sum score (maximum is 60).

The muscle groups (with exception of the wrist extensors) that scored 3 or greater on the MMT will be tested with handheld dynamometry (HHD) according to a standardized protocol (Haisma et al., 2006). The maximum force (in Newton) of the 10 muscle groups will be summated.

Daily activity monitoring:

In the week preceding each measurement session, a lightweight odometer installed on the subjects' wheelchair will be used to measure the number of wheel revolutions. In addition, subjects are asked to keep a daily activity diary on each of the days that the odometer is installed.

Questionnaires:

Questionnaires will be filled out at home in the week before each designated measurement session(s), in order to determine functional status and independence (FSS, SCIM (filled out by investigator in rehabilitation center), pain and complaints of the upper extremity (WUSPI, questionnaires wrist- and other musculoskeletal complaints), physical activity (PASIPD, EAMQ), life satisfaction (HADS), health-related quality of life (a brief version of WHOQOL), participation (USER-P), illness cognition (ICQ), self-efficacy (ESES, SEWMS), and – only before the pre-test – social support (SSL-12), and wheelchair satisfaction (D-QUEST). This will take approximately 1 hour. After each test and training session a complaints diary will be filled out to monitor the occurrence of musculoskeletal problems.

Onderzoeksproduct en/of interventie

The experimental groups will receive 16-week low-intensity wheelchair exercise training (35%HRR; 2x30min/week) or handcycling training (70%HRR, 2x30 min/week) while the control group will not receive any training.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients, aged > 28 yrs, with a chronic spinal cord injury (>6y), and an inactive lifestyle (lowest 75% of normscore of spinal injury patients on physical activity questionnaire 'PASIPD').

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cardiovascular contra-indications for testing according to the American College of Sports Medicine (ACSM) guidelines, or a resting diastolic blood pressure above 90 mm Hg or a resting systolic blood pressure above 180 mm Hg;

2. Musculoskeletal complaints of the upper extremities, neck or back;

3. Progressive disease;

4. Psychiatric problem;

5. Not having enough knowledge of the Dutch language to understand the purpose of the study and the testing methods;

6. Plans to start another lifestyle (e.g. more physical active, diet) in the months that the experiment is going on.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37191
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2891
NTR-old	NTR3037
CCMO	NL21812.029.08

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37191

Resultaten

Samenvatting resultaten
N/A