Hybrid cycle exercise training after spinal cord injury.

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Many individuals with a chronic spinal cord injury show a serious inactive lifestyle, associated with secondary complications (e.g. pressure sores, osteoporosis and metabolic syndrome) and a decreased physical capacity. The purpose of this study is...

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

Samenvatting

ID

NL-OMON26274

Bron
NTR

Verkorte titel
ALLRISC- Hybrid cycle exercise training

Aandoening

- spinal cord injury (dwarslaesie)
- paraplegia (paraplegie)
- tetraplegia (tetraplegie)
- decubitus (decubitus)
- osteoporosis (osteoporose)
- metabolic syndrome (metabool syndroom)

Ondersteuning

Primaire sponsor: O.J. Jukema
Faculty of Human Movement Sciences
VU University Amsterdam
Van der Boechorststraat 9
1081 BT Amsterdam
Overige ondersteuning: ZonMw, fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Physical capacity.

Toelichting onderzoek

Achtergrond van het onderzoek

Participants will be recruited from the databases of two Dutch rehabilitation centres.

Doel van het onderzoek

Many individuals with a chronic spinal cord injury show a serious inactive lifestyle, associated with secondary complications (e.g. pressure sores, osteoporosis and metabolic syndrome) and a decreased physical capacity. The purpose of this study is to evaluate and compare the effects of a hybrid cycle exercise training program versus a hand cycle exercise training program and a non-training group on secondary complications, physical capacity and active lifestyle. It is hypothesized that both training interventions will lead to an increased physical capacity and active lifestyle, as well as to a reduced risk of secondary complications, such as metabolic syndrome. Furthermore it is hypothesized that, due to the lower-body exercise, hybrid cycle training will improve vascular function, skin tissue viability, bone mineral density and interface pressure profile of the lower extremity, while arm exercise alone will not lead to these improvements.

Onderzoeksopzet

Timepoints:

1. Pre-test (just before the training intervention);

2. Mid-test (8 weeks);

3. Post-test (end of the training intervention: after 16 weeks);

4. Rollow-up (26 weeks after the end of the intervention).

Methods:

1. Physical capacity: Will be expressed as the peak power output, measured by a graded exercise test in a wheelchair. Additionally, the hybrid cycle training group and the hand cycle training group will perform a graded exercise test in the hybrid cycle and the hand cycle, respectively. Timepoints: 1-4.

2. Metabolic syndrome: Fasting blood samples will be taken to determine the lipoprotein profile, insulin and glucose. Waist circumference will be measured using a tape measure, and blood pressure will be taken on the right arm. Timepoints: 1,3,4;

3. Bone mineral density of the distal femur and proximal tibia: dual energy X-ray absorptiometry (DXA). Timepoints: 1,3,4;

4. Vascular function: Echo Doppler (diameter, flow, thickness and compliance of the a. carotis and a. femoralis).Timepoints: 1,3,4;

5. Interface pressure profile: Interface pressure mat. Timepoints: 1-4;

6. Skin tissue viability: Near Infrared Spectroscopy (NIRS). Timepoints: 1-4;

7. Active lifestyle: PASIPD (questionnaire), odometer. Timepoints: 1-4.

Onderzoeksproduct en/of interventie

1. Hybrid cycle training group: 16 weeks of training in a hybrid cylce; 2x30 min/week; 70% Heart Rate Reserve (HHR);

2. Hand cylce training group: 16 weeks of training in a hand cycle; 2x30 min; 70% HRR;

3. Non-training control group: No training.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Spinal cord injury (paraplegia/tetraplegia);

2. Male/female;

3. Age: 28-65 yrs;

4. Time since injury (TSI): At least 10 yrs;

5. Physically inactive: PASIPD score lower than the 50th percentile of a Dutch SCI cohort study population;

6. Dependent on a handrim propelled wheelchair.

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;

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

3. Progressive disease or secondary complications that could interfere with the study;

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

5. Plans to become more physically active in the months that the experiment is going on.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

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

Ethische beoordeling

Positief advies

Datum:	15-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2717
NTR-old	NTR2855
Ander register	ZonMw, Fonds NutsOhra / MEC VUmc : 60-61300-98-027 / 2011/090;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A