Hybrid cycle exercise training after spinal cord injury.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26274

Source
NTR

Brief title
ALLRISC- Hybrid cycle exercise training

Health condition

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

Sponsors and support

Primary sponsor: O.J. Jukema
Faculty of Human Movement Sciences
VU University Amsterdam
Van der Boechorststraat 9
1081 BT Amsterdam
Source(s) of monetary or material Support: ZonMw, fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Physical capacity.

Secondary outcome

1. Metabolic syndrome;

2. Bone mineral density (BMD) of the distal femur and proximal tibia;

3. Vascular function;

4. Interface pressure profile;

5. Skin tissue viability of the sitting area;

6. Active lifestyle.

Study description

Background summary

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

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Faculty of Human Movement Sciences
VU University Amsterdam
Van der Boechorststraat 9
A.J.T. Bakkum
Amsterdam 1081 BT
The Netherlands
+31 (0)20 5982628
Scientific
Faculty of Human Movement Sciences
VU University Amsterdam
Van der Boechorststraat 9
A.J.T. Bakkum
Amsterdam 1081 BT
The Netherlands
+31 (0)20 5982628

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-04-2011
Application type:	First submission

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

Study results

Summary results
N/A