Feasibility of technology-assisted task-oriented skill training of the upper extremity in persons with a cervical spinal cord injury: a pilot study

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The aim of this project is to assess the feasibility of the technology assisted training to improve arm hand skilled performance using the Haptic Master in persons with C-SCI.Research questions:Is it feasible to train persons with a C-SCI with a...

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

Summary

ID

NL-OMON34084

Source
ToetsingOnline

Brief title
Technology-assisted task-oriented skill training in C-SCI

Condition

- Spinal cord and nerve root disorders

Synonym
cervical spinal cord injury, damage to the spinal cord at the level of the neck

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arm-hand skill performance, cervical spinal cord injury, technology, training

Outcome measures

Primary outcome

- VLT (SF) (Van Lieshout Test)

- SCIM III (Spinal Cord Independence Measure version III)

Secondary outcome

- International classification for Surgery of the Hand in Tetraplegia (ICSHT)

- Microfet

Study description

Background summary

Arm hand skilled performance plays a major role in the rehabilitation of persons with a cervical spinal cord injury (C-SCI). A small improvement may have major impact on the level of independence and the quality of life. To improve arm hand skilled performance and taking into account the importance of client-centred therapy, a task-oriented client centred training module was developed for C-SCI. Results demonstrate a substantial improvement in arm hand skilled performance. However, patients report that repetitive training may not be challenging enough. Technology assisted training, which is known to improve motivation and to be more challenging for patients might solve this problem. Additionally, technology supported training offers the opportunity to training without the help of therapists.

Last year a pilot study was done training persons with stroke to improve arm hand skilled performance using a Haptic Master. The Haptic Master, enables persons to train daily activities by *themselves*. The Haptic Master consists of :1) a computer screen with information, 2) a individual tailored training program for arm and hand, 3) a robot arm which may help persons to move their arm.
This project will assess the feasibility of the technology assisted training

using the Haptic Master in persons with C-SCI.

Study objective

The aim of this project is to assess the feasibility of the technology assisted training to improve arm hand skilled performance using the Haptic Master in persons with C-SCI.
Research questions:
Is it feasible to train persons with a C-SCI with a technology supported program for 6 weeks, aimed at the improvement of arm hand skilled performance?
What is the order of magnitude as to possible short-term effects of such training on arm hand function and arm hand skilled performance in persons with a C-SCI?
What is the order of magnitude as to possible long-term effects of such training on arm hand function and arm hand skilled performance in persons with a C-SCI?

This feasibility study will be used to set up a randomised clinical trial that will assess the benefits of technology supported training on arm hand skilled performance in persons with C-SCI.

Study design

This is a prospective study in which it is expected that 6 persons with a C-SCI, who have finished their rehabilitation longer than 1 year will participate. The participants will be trained using an Haptic Master aimed at improving their arm hand skilled performance. A baseline measurement will be taken before the start of the training, an intermittent measurement after 4 weeks, a measurement directly after finishing the training and a follow-up measurement at 6 months after finishing the training. The feasibility and the order of magnitude of improvement on arm hand skilled performance will be evaluated on the shorter and longer term.

Data analysis:
To answers the different research questions, data of the different measurement moments will be compared. Data will be analysed descriptively.

Plan of Action:
In the preparatory phase, participants will be recruited and de training program will be finalised. In the second phase, 6 participants will be measured and trained. In the 3th phase, data will be analysed and in the last phase the results will be reported.

Intervention

The intervention consists of an 6 weeks technology supported task oriented

training to improve arm hand skilled performance, in which there will be trained 4x a week; 2x 30* a day with 30* rest in between. The training will be given by an occupational therapist in which the Haptic Master will be used.

Study burden and risks

The training consists of several movements in various directions performed by the participant from a sitting position. The burden is 4 times a week for 1. 5 hour per day for a period of 6 weeks. The risks are equivalent to (or even less than) the risk in normal daily life activities.

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

- (in)complete C-SCI at level C3-T1
- having finished active rehabilitation at least one year ago
- presence of problems with arm-hand skill performance
- age 18 years or older
- ability to sit up for at least 4 hours
- minimal wrist extension of 10 degrees
- minimal finger extension of 30 degrees

Exclusion criteria

- Additional neurologic, orthopedic, or rheumatic illnesses which may interfere with daily activities and arm-hand function
- Severe spasticity (Ashworth score no higher than 4)
- Inability to perform measurement of arm-hand function and arm-hand skill performance

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2011
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	27-12-2010
Application type:	First submission
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	NL34524.068.10