New training modules aimed at improving upper extremity skilled performance in persons with a cervical spinal cord injury

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

Summary

ID

NL-OMON31338

Source
ToetsingOnline

Brief title
TRUE-SPeCS

Condition

- Spinal cord and nerve root disorders

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

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Revalidatie Limburg

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

Intervention

Keyword: arm-hand function, cervical spinal cord injury, skilled performance, training

Outcome measures

Primary outcome

MMT (manual muscle testing)

GAS (Goal Attainment Scale)

VLT-SF (Van Lieshout Test)

FIM (Functional Independence Measure)

QIF (Quadriplegia Index of Function)

COPM (Canadian Occupational Performance Measure)

SF-36 (Mental Health en Vitality scales of the SF-36)

LSQ (Life satisfaction questionnaire)

Rosenberg Self-Esteem scale

Self efficacy scale

Secondary outcome

HADS (Hospital Anxiety Scale)

ROM (range of motion)

Spasm (5-point scale)

Modified ashworth scale

Pain (4-point scale)

Study description

Background summary

In persons with a cervical spinal cord injury (C-SCI) arm and hand impairments play a major role in the rehabilitation. The current rehabilitation program for persons with C-SCI is a comprehensive package in which persons are trained on function and activity level according to lesion level and lesion completion. However, the program is not explicitly focused on the client*s individual needs. Donnelly (2004) describes that patients tend to be more pro-active if they are involved in the rehabilitation process and that results of therapy are better if the rehabilitation was client-centred (Wressle 2002). Theories about motor learning emphasise the importance of training tasks at the level of activities and training the actual skill. (Shumway-Cook 2001). The NVDG considers modifying the rehabilitation program in order to reduce the length of the inpatients stay, to offer a program that focuses on the personal needs of each patient and to offer therapy modules.

In this project a specific client-centred task-oriented training module to improve upper extremity skilled performance in persons with C-SCI will be developed and evaluated.

Study objective

The aim of the study is to develop and evaluate a specific client centred task-oriented training module for upper extremity skilled performance in persons with C-SCI.

The research questions are:
1. Does an 8-weeks client-centred task-oriented training module for upper extremity skilled performance improve the specific tasks?
2. Does an 8-weeks client-centred task-oriented training module for upper extremity skilled performance improve general arm hand skilled performance?
3. Does an 8-weeks client-centred task-oriented training module for upper extremity skilled performance improve the quality of life?

Study design

Methodology

This is a longitudinal intervention study in which 2 groups of persons i.e. persons with a C-SCI during their active rehabilitation program and persons with a C-SCI who have finished their active rehabilitation program, will participate. The amount of progress on arm-hand skilled performance (AHSP) after the specific training will be assessed. Firstly, results of measurements on AHSP of the proposed study will be compared with data of earlier research in which persons received the therapy as usual. Furthermore, data collected before the start of the patient-dedicated AHSP training program will be

compared to those collected after cessation of this therapy module and at a follow-up measurement.

Data-analyses

To answer the different research questions data of the 3 measurements moments will be compared using a Friedman-test. Furthermore, data of the training group will be compared to data of the reference group using a Mann-Withney-U test.

Plan of action

In phase 1 (march 2007-march 2008) patients will be recruited. In phase 2 (March 2007-april 2008) participants will be trained. In phase 3 (May 2008-June 2008) data will be analysed. In phase 4 (July 2008-september 2009) results will be reported.

Intervention

Intervention consists of an 8 weeks client-centred task-oriented training module for arm hand skilled performance. Three self-chosen tasks according to upper extremity performance will be trained.
Progress on specific tasks, on general arm-hand-skilled performance and on quality of life will be evaluated.

Study burden and risks

The risks during the project do not exceed the risk associated with normal daily activities.

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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

- incomplete cervical spinal cord injury
- age between 18 and 70 years
- presence of problems with specific arm-hand skills performance

Exclusion criteria

- Additional neurologic, orthopaedic or rheumatologic diseases which strongly interfere with ADL functioning and arm hand skills performance (AHSP)
- Inability to perform AHSP measurements

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC SRL/iRv: St Revalidatie Limburg/iRv Kenniscentrum voor Revalidatie en Handicap (Hoensbroek)

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	NL16418.022.07