The influence of a robot-mediated functional arm training protocol on arm function of chronic stroke patients

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The objective of this study is to determine whether arm function changes after active-movement stimulating (ACTS) training and if so, which mechanisms (neurophysiologic, biomechanic and/or functional domains) are influenced by ACTS training.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON31273

Source
ToetsingOnline

Brief title
Robotic functional arm training for chronic stroke patients

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: subsidie door SenterNovem

Intervention

Keyword: robotics, stroke, training, upper extremity

Outcome measures

Primary outcome

Primary study parameters are intra-subject changes in muscle activity and biomechanics of arm movements (at the impairment level).

Secondary outcome

The Fugl-Meyer assessment, the Motricity Index (both are clinical scores of the motor status of the arm) and the Action Research Arm Test (for functional abilities of the arm) are included to examine changes at the functional level.

Study description

Background summary

Active generation, and initiation, of movement is a very important aspect of post-stroke arm training, since active movements produce more brain activation and better motor learning than passive movements, in which the arm is guided. To enable active use of the arm, supporting the weight of the arm using 3D gravity compensation during reach and retrieval movements is beneficial. In addition, providing feedback by emphasising movement error may be helpful by stimulating patients to generate more appropriate movement patterns. Integration of these aspects into a new training protocol, using a robotic device to provide feedback about undesired movements, may provide a rehabilitation application to enhance restoration of arm function after stroke.

Study objective

The objective of this study is to determine whether arm function changes after active-movement stimulating (ACTS) training and if so, which mechanisms (neurophysiologic, biomechanic and/or functional domains) are influenced by ACTS training.

Study design

A multiple baseline design is used to examine whether individual changes in arm function occur after ACTS training, by pre- and post-training measurements of neurophysiologic, biomechanic and functional aspects of upper extremity movement.

Intervention

The intervention consists of a training program of 6 weeks of upper extremity training of reaching and grasping exercises, supplemented to (potential) regular stroke rehabilitation. Training sessions take place 3 times per week for 60 minutes. Unwanted (abnormal) movements are opposed by robotic device to provide additional feedback.

Study burden and risks

The burden and the risks for participants are limited to a minimal extent, since the movement tasks consist of functional and familiar arm movements, performed only within the abilities and reach of the participants. Furthermore, the robotic device used to provide feedback about unwanted movements is designed in such a way that movements can not be performed outside the participants* abilities, since the device can only resist movements that the participants generate themselves and can not move the arm of participants by itself.
Participation of patients in this experiment may have a direct benefit for them, in that they receive an additional amount of therapy besides their (potential) regular rehabilitation programme, which has been reported to be beneficial for post-stroke rehabilitation. However, since the study purpose is to investigate whether this type of training induces changes in arm function, this improvement in arm function can not be guaranteed.

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

Stroke at least 6 months prior to admittance to experiment
Right upper extremity affected (experimental set-up only suitable for right arm)
Receiving/having received treatment at the Roessingh Centre of Rehabilitation
Ability to lift arm (partly) against gravity

Exclusion criteria

Shoulder pain, either in rest or in movement
Additional neurologic, orthopaedic or rheumatologic disease of right upper extremity, which is likely to interfere with mobility and/or strenght of the arm
Inability to understand and follow instructions

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):	24-04-2008
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL16576.080.07