Arm support treatment in the early phase after stroke

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The purpose of this study is to compare the effect of arm support therapy with conventional therapy, directed at arm function in stroke patients in the sub-acute phase, with regard to both motor aspects and user experiences.

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

Summary

ID

NL-OMON34496

Source
ToetsingOnline

Brief title
Arm support early after stroke

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: Innovatiegelden van Revalidatie Nederland

Intervention

Keyword: Arm function, Arm support, Robotics, Stroke

Outcome measures

Primary outcome

Before and after training changes in overall arm function (Fugl-Meyer assessment, Stroke Upper Limb Capacity Scale) and work area are quantified.

Secondary outcome

Also, user experience of therapist and patient (semi-structured interviews) are identified after training. Both before and after training a Visual Analog Scale for pain is filled in by patients.

Study description

Background summary

After a stroke, many patients suffer from an impaired motor task performance of the upper extremity. Optimal restoration of arm and hand function is important for stroke patients to independently perform activities of daily living. To stimulate restoration of arm function after stroke, intensive and task-specific training is essential. To implement this, the application of robotic devices in rehabilitation is promising. Especially, active movements may be facilitated by the application of arm support. One of the biggest advantages of arm support using a robotic device is currently the possibility to 'automate' treatment (a therapist can treat multiple patients simultaneously) so that the productivity of health care can be increased and the costs can be reduced. Contemporary research on this has focused on patients in the chronic phase after stroke. However, it is likely that especially patients in the sub-acute phase after stroke benefit from this application, since recovery processes can be stimulated directly.

Study objective

The purpose of this study is to compare the effect of arm support therapy with conventional therapy, directed at arm function in stroke patients in the

sub-acute phase, with regard to both motor aspects and user experiences.

Study design

Multicenter, randomized intervention study with evaluation measurements before and after 6 weeks of reach training.

Intervention

The participants receive reach training for the affected arm during 6 weeks, 3 times 30 minutes per week. The intervention group (35 persons) will train using the ArmeoBoom system for arm support and the control group (35 persons) will perform standardized reaching exercises, with similar training intensity.

Study burden and risks

The risks for the participants are limited to a minimum, since the movement tasks consist of functional and familiar arm movements, all executed within the ability of the person. Furthermore, the measurements in this study are relatively simple (no special equipment required) and non-invasive and pose no risk or inconvenience for the participants.
Participation in this study may present an immediate benefit for the participant, in the sense that additional training of reaching of the affected arm is received.

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

- Start of participation between 1 and 12 weeks post first-ever stroke
- Hemiparetic arm, with ability of some elbow extension (MRC score 2 or 3 out of 5)
- Ability to understand and follow instructions
- Ability to endure training and evaluation sessions

Exclusion criteria

- Co-morbidity of other diseases (incl. pain) that limit use of the arm

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2011

Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2010
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

ID: 26063
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL33365.044.10
Other	TC 2539
OMON	NL-OMON26063