# Arm support treatment in the early phase after stroke.

No registrations found.

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

## Summary

### ID

NL-OMON26063

**Source**
Nationaal Trial Register

**Brief title**
EarlyArmSupport

**Health condition**

stroke, cerebrovascular accident
beroerte, cerebrovasculair accident

### Sponsors and support

**Primary sponsor:** Roessingh Research and Development
**Source(s) of monetary or material Support:** Innovatiegelden van Revalidatie Nederland

### Intervention

### 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

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.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.Multicenter, randomized intervention study with evaluation measurements before and after 6 weeks of reach training. 70 stroke patients in the sub-acute phase (between 1 and 12 weeks post-stroke) from 7 Dutch rehabilitation centers (10 patients per center): Revalidatiecentrum Het Roessingh (Enschede), Sint Maartenskliniek (Nijmegen), De Hoogstraat (Utrecht), Beatrixoord (Haren), Groot Klimmendaal (Arnhem), Rijndam (Rotterdam) en Revalidatie Centrum Amsterdam. Participants are able to lift the arm (partially) and to perform reach-like movements.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.Before and after training changes in overall arm function (Fugl-Meyer assessment, Stroke Upper Limb Capacity Scale) and work area are quantified.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 objective

Patients who are treated with the ArmeoBoom will have similar or improved arm function in comparison with the patients who receive conventional arm therapy. In case the improvement is similar, the therapy must be more efficient for a therapist (possibility to train two patients on the same time) to make the study succesfull.

### Study design

At baseline and within a week after the training period of 6 weeks.

**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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Start of participation between 1 and 12 weeks post first-ever stroke;

2. Hemiparetic arm, with ability of some elbow extension (MRC score 2 or 3 out of 5);

3. Ability to understand and follow instructions;

4. 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

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| 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): | 01-12-2010 |
| Enrollment: | 70 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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| Date: | 29-09-2010 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 34496
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL2430 |
| NTR-old | NTR2539 |
| CCMO | NL33365.044.10 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON34496 |

# Study results

**Summary results**
Prange, GB. Rehabilitation Robotics - Stimulating restoration of arm function after stroke (dissertation). Enschede, University of Twente, 2009. ISBN 978-90-365-2901-3.