# Brain plasticity and functional recovery in low-functioning stroke patients trained with a dynamic hand orthosis: a MRI pilot study

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To develop well-described protocols for three tasks, i.e. a grasping task based on movement imagery, a button-press task, and a somatosensory finger mapping task, to be used in a larger ensuing clinical study by stroke patients in the 7T-MRI scanner...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Movement disorders (incl parkinsonism) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON43523

**Source**
ToetsingOnline

**Brief title**
Brain changes and functional recovery in hand orthosis use

### Condition

- Movement disorders (incl parkinsonism)

**Synonym**
hemiparesis, impaired arm-hand function due to a stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Adelante

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

## Intervention

**Keyword:** arm-hand function, dynamic hand orthosis, MRI, stroke

## Outcome measures

### Primary outcome

a) Motor performance level (FM, ARAT, ABILHAND);

b) Hand motor performance and brain activation patterns during task

performance (fMRI);

c) Reaction time / movement time (button-press task);

d) Grip force

e) Somatosensory hand performance (fMRI);

f) T1-weighted anatomical scans and resting state scans (fMRI).

### Secondary outcome

n.a.

# Study description

### Background summary

Most arm-hand rehabilitation approaches for stroke patients have been evaluated in patients with residual motor function. Recently, dynamic hand-extension orthoses have become available that unlock new training regimes for low-functioning stroke patients. We aim to investigate the brain mechanisms underlying the effects of orthosis-supported rehabilitation training to help optimise and fine-tune treatment regimen for low-functioning stroke patients, for whom, until now, treatment options are very limited. However, before em-barking on such large scale clinical study, the necessary test protocols that can also be used in an MRI scanner must first be developed and fine-tuned. This is the aim of this pilot study.

### Study objective

To develop well-described protocols for three tasks, i.e. a grasping task based on movement imagery, a button-press task, and a somatosensory finger mapping task, to be used in a larger ensuing clinical study by stroke patients in the 7T-MRI scanner at Scannexus / Maastricht university in Maastricht. Initial brain imaging data associated with hand movement in orthosis-assisted and non-orthosis-assisted conditions will be collected in three healthy subjects and two patients with a severe hemiparesis (UAT 0-1) due to a stroke. Furthermore, the two patients will be asked to use the hand orthosis at least * hour per day over a period of six weeks, before and after which MRI data and arm-hand motor performance data will be collected.

**Study design**

This pilot study is an observational study.

**Study burden and risks**

The participants in this pilot study will, themselves, have no direct benefit from their participation. This pilot study will yield a) well-described protocols regarding tasks to be performed in a 7T-MRI scanner, and b) initial brain imaging data associated with hand movement in orthosis-assisted and non-orthosis-assisted conditions. These data will also be used to estimate group sizes in an ensuing larger clinical study. No risks are associated with participation in this study. In this study, no medical product is used. The SaeboGlove hand orthosis, a non-investigational product, poses no harm to the subjects. The 7T-MRI measurements pose no harm to the participants.

# 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 patients:
• Chronic unilateral supratentorial stroke;
• Post-stroke time > 12 months;
• Age >= 18 years;
• Severely impaired arm-hand function (AHF): Utrechtse Arm-hand Test (UAT) score 0-1;
• Ability to comprehend the test and measurement instructions (in Dutch).;Healthy persons:
- age >=18 years
- no history of stroke
- no impaired arm-hand function
- able to comprehend the test and measurement instructions in Dutch.

## Exclusion criteria

CVA patienten:
• Severe cognitive impairments;
• Spasticity in the affected arm-hand: Modified Ashworth Scale (MAS) score >=2;
• Severe additional orthopaedic, rheumatoid, neurologic impairments of the body that may *further impede arm-hand task execution;
• No informed consent. ;• MRI contra-indications: epilepsy, claustrophobia, medication, metal parts in the body (metal plates or screws, clips on blood vessels, braces, metal wire behind teeth, prostheses, piercings, tattoos (including permanent makeup), artificial cardiac valve, anticonception spiral, metal splinters, pacemaker, insulin pump, other electronic devices)

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-06-2016 |
| Enrollment: | 5 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | dynamic hand orthosis |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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| Date: | 07-03-2016 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

# 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 | NL55631.015.15 |

# Study results

Date completed: 22-12-2016

Actual enrolment: 5

**Summary results**
Trial is onging in other countries