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# Self-contained training for stroke patients during inpatient rehabilitation

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 23/07/2017 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/08/2017 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 25/11/2020 | Nervous System Diseases | |

## Plain English summary of protocol

Background and study aims
A stroke occurs when the blood supply is cut off to the brain. A majority of stroke patients are affected by an impaired function of the upper extremity (upper body and arms). Numerous studies have indicated that there is a relationship between intensity and amount of training on the one hand and improvement of functions on the other hand. Usually, patients with a severe paresis (muscle weakness) of the upper extremity are treated with the ArmeoSpring exoskeleton during their inpatient rehabilitation. An exoskeleton is a frame that is put on the arm to help support the arm weight and help improve function. The aim of this study is to examine what happens when treatment time with this device is increased without investing additional personnel.

Who can participate?
Stroke patients aged 18 to 85

What does the study involve?
Participants receive 24 training sessions with the exoskeleton over four weeks. This is connected to a computer that offers virtual reality. The degree in which they can move their arm while in the exoskeleton is recorded.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in motor function. The device is safe and has a certificate allowing to use it for patient treatment. There are no known risks.

Where is the study run from?
Kliniken Schmieder (Germany)

When is the study starting and how long is it expected to run for?
February 2016 to February 2017

Who is funding the study?
Kliniken Schmieder (Germany)

Who is the main contact?
Prof. Dr. Joachim Liepert
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# Contact information

### Type(s)
Public

### Contact name
Prof Joachim Liepert

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
1-2016

# Study information

### Scientific Title
Using an upper extremity exoskeleton for semi-autonomous exercise during inpatient neurological rehabilitation- a pilot study

### Study objectives
A self-contained robot-assisted training in addition to conventional inpatient rehabilitation is feasible.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
University of Constance, 21/04/2016

### Study design

An interventional study with the ArmeoSpring exoskeleton used as a device for additional self-contained training in evenings and on weekends. The study explores feasibility and acceptance. It is single-centre because it is a pilot study

## Primary study design
Interventional

## Secondary study design
Non randomised study

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet. Contact: j.liepert@kliniken-schmieder.de

## Health condition(s) or problem(s) studied
Stroke patients

## Interventions
Participants receive self-contained training with the Armeo Spring exoskeleton over a period of four weeks with up to 24 treatment sessions.

The exoskeleton is connected to a computer that offers a variety of games in a virtual reality environment. For example, patients can paint a room, can grasp objects in a supermarket, can catch balls and so on. The degree to which the patients can move the arm while it is positioned in the exoskeleton is determined. Movements visible on the screen are adjusted to this individual level of performance.

There is no follow up.

## Intervention Type
Device

## Primary outcome measure
Feasibility (recording of side effects or adverse events) is measured using a structured interview once a week during the 4 weeks. Patients and supervisors are interviewed after the first, second, third and fourth week.

## Secondary outcome measures
Acceptance is measured using the visual analogue scale at the end of the treatment period (after 4 weeks)
Motor function is measured using Wolf Motor Function Test at baseline and after 4 weeks of additional therapy.

## Overall study start date
02/02/2016

### Completion date
08/02/2017

## Eligibility

### Key inclusion criteria
1. Treatment in a neurological rehabilitation hospital for > 4 weeks
2. Stroke patients
3. Severe upper limb paresis
4. Ability to understand instructions and make own decisions
5. Aged 18-85 years old

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
85 Years

### Sex
Both

### Target number of participants
10

### Total final enrolment
10

### Key exclusion criteria
1. Unwillingness to participate
2. Inability to understand the instructions

### Date of first enrolment
02/05/2016

### Date of final enrolment
06/01/2017

## Locations

### Countries of recruitment
Germany

**Study participating centre**
**Kliniken Schmieder**
Zum Tafelholz 8
Allensbach
Germany
78476

# Sponsor information

**Organisation**
Kliniken Schmieder

**Sponsor details**
Zum Tafelholz 8
Allensbach
Germany
78476

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/04bkje958

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Kliniken Schmieder

# Results and Publications

**Publication and dissemination plan**
We plan to publish data on feasibility, acceptance and changes of motor functions.

**Intention to publish date**
12/08/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Joachim Liepert; email: j.liepert@kliniken-schmieder.de

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 02/08/2018 | 25/11/2020 | Yes | No |