

Self-contained training for stroke patients during inpatient rehabilitation

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

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

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

All

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

ROR

<https://ror.org/04bkje958>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Kliniken Schmieder

Results and Publications

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