Trial Description

Title

Effects of Robot PARO on People after Stroke

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In most cases the right hemisphere stroke leads to hemiplegia on the left side of the body. Besides of their constrained movement, affected persons often face difficulties in spatial perception. That means objects on the paralyzed side cannot be seen.
This study uses the robotic technology PARO to improve the reduced perception. This technology comes in the shape of a young seal with white fur. PARO replies with sounds or moves the fins when spoken to or touched.
The main object of this study is to examine if the spatial perception on the paralyzed side improves when the robotic technology PARO is used.
Promotion: Hessisches Ministerium für Wissenschaft und Kunst and Fachhochochschule Frankfurt am Main (01.10.2012 - 30.09.2014)

Brief Summary in Scientific Language

Neglect is an impaired spatial perception, which often occurs after a stroke in the right hemisphere. The most distinctive characteristic of the neglect is that the contralesional body or space is neglected. In most cases, the affected persons can no longer recognize visual, optical and tactile stimuli on their left side anymore.
In the early phase, the therapies to improve the spatial perception of the patient are based on a multisensory stimulation. By presenting as many stimuli as possible, the neglected side of the body and of the spatial perception is stimulated to active exploration.
Concepts to improve the perception are essential parts of therapeutic care during early neurological rehabilitation. Unfortunately, nursing interventions to reduce the deficits in spatial perception are currently neither in effect nor subject of systematic nursing examinations. Thus, this project is initiated.
In this study, the robotic technology PARO is used as a therapeutic medium for multisensory stimulation. PARO is developed in Japan based on the model of a young seal specifically for therapeutically treatments. First results indicate that the use of this robotic technology evoke enhanced activity, increased interaction and wellbeing of the patient.
The principal aim of this study is to develop a theory based intervention to improve the rehabilitation. The intervention will be tested in a pilot study in a special clinic for neurological early rehabilitation.

Organizational Data

- DRKS-ID: **DRKS00005427**
- Date of Registration in DRKS: **2014/02/12**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2013-90 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **R29.5 - [generalization R29: Other symptoms and signs involving the nervous and musculoskeletal systems]**

Interventions/Observational Groups

- Arm 1: **Study participants will receive in addition their therapy 6 single treatment over a period of 2 weeks on Mon - Wed - Fri**
  During a therapy unit (up to 30 minutes) the PARO robot technology is employed.
- Arm 2: **Study participants will receive in addition their therapy 6 single treatment over a period of 2 weeks on Mon - Wed - Fri. During a therapy unit (up to 30 minutes) they receive a non-specific treatment as reading aloud.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
-

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Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

-Unilateral Neglect

- Cancellation test (Cats-Test) (Haid et al. 2010), Line bisection

Pre-and post-measure (before and after single units)

Pre-, post-and follow-up measurement (before treatment, after treatment (2 weeks) and another 2 weeks later)

- Beobachtungsbogen für räumliche Störungen (BRS) (Neumann et al.2007)

Pre-, post-and follow-up measurement (before treatment, after treatment (2 weeks) and another 2 weeks later)

Secondary Outcome

Activies of daily living (ADL)
Pre-, Postmessung und Follow-up (Vor Behandlung, nach Behandlung (2 Wochen) und weitere 2 Wochen später)
-Early Functional Ability (EFA) (Heck et al. 2000-6; 3:125-133)
- Selbständigkeits-Index für die Neurologische und Geriatrische Rehabilitation (SINGER) (Gerdes et al., 2012)
- Barthel Index (BI) (AGAST, 1997: 21-29)

Body Functions
- National Institute of Health Stroke Scale (NIH-SS) (Schädler et al 2006)

Human-Robot-Interaction
- Emotional display (Libin, Alexander & Libin, Elena (2002): Human-Robot Interaction Scale. By courtesy of Libin, Alexander, June 2013.)

Acceptance and attitude to technology
- Open questions

Pre-and post-measure (before and after single units)
Physiological Parameters (Blood Pressure, Pulse, O2-Saturation)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Asklepios Neurologische Klinik Falkenstein, Königstein i. Taunus**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/14**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **60 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

patients with neglect left/ right brain damage
after a first stroke; Setting: neurological early rehabilitation.

Exclusion criteria

Persons with increased intracranial pressure, which can not take head of bed elevation; Persons with pathogens such as
MRSA

Addresses

- **Primary Sponsor**

  Fachhochochschule Frankfurt am Main
  Mr. Dr. Ing. Detlev Buchholz

Primary Sponsor

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/07/25**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*