Trial Description

Title

Participation-related attainment through therapies and assistive devices in patients with mobility-restricting paralytic syndromes

Trial Acronym

NeuroMoves

URL of the trial

[---]*

Brief Summary in Lay Language

NeuroMoves is intended to investigate the current care situation of people with mobility impairments after a stroke or paraplegia after the patient has been discharge from stationary primary treatment. Over a period of 8 months we want to record the quality of care with a view to physiotherapeutic measures and mobility aids such as the wheelchair or walking aids. Therefor we will ask participants and, if possible, also their physiotherapists about the therapy goals and how they are achieved. For this purpose, we provide participants with a tablet for the duration of the study, which asks a few questions daily at a selectable time. In addition, we would like to objectively measure the distance walked in everyday life or covered with the wheelchair using a motion sensor.

We hope to use this data to gain insights into how ambulatory care can be made more targeted with regard to individual therapy goals, so that there is no deterioration in mobility following initial inpatient treatment.
The study is being carried out in several hospitals in Germany. A total of 500 people are supposed to participate. The study is coordinated by the Department of Paraplegiology at the University Hospital of Heidelberg. It is financed by the Innovation Fund of the Federal Joint Committee (G-BA).

Brief Summary in Scientific Language

A central goal of rehabilitation is to restore independent mobility as a pedestrian or wheelchair user. However, mobility in patients with paralysis syndromes after a stroke or paraplegia after inpatient medical rehabilitation is continuously decreasing despite the provision of remedies and aids. The aim of the study is to identify factors in the existing outpatient care structure using physiotherapy as an example, which lead to a decrease in mobility.
Patients with newly occurring mobility-restricting paralysis syndromes are recruited at the end of inpatient-rehabilitation treatment and are followed up for 8 months in an outpatient setting. Walking ability and wheelchair mobility are systematically recorded by means of activity tracking and functional scores. The mobility level is correlated with the participation-related achievement of objectives, the type and extent of the provision of therapeutic appliances and aids and the analysis of the extent of cooperation between outpatient service providers.

The study findings should lead to a new form of care in which outpatient-oriented, needs-oriented and coordinated outpatient therapeutic appliances and aids are provided, which lead to a stabilisation or increase in mobility in patients with stroke and paraplegia with mobility-restricting paralysis syndromes in the home environment.

Three planned study visits (baseline, interim and final visits) will take place at intervals of approximately 4 months each. The first study visit (baseline visit) is carried out at the end of inpatient rehabilitation. The study participants come to the study center for the interim (after 4 months) and final visits (after 8 months). Personal data, medical examinations, functional examinations on mobility and everyday limitations are collected at the 3 study points. Questionnaires on mobility, the use of aids and quality of life will also be answered. It will take about 3 hours to complete all examinations and answer the questionnaires at the respective visits.

At the baseline visit the study participants will receive an activity tracker (sensor for recording mobility at home) and a tablet which is intended for daily use over the entire period of 8 months. The Activity Tracker will record the distance travelled and the number of steps over the course of the day. The sensor is attached to the shoe or frame of the wheelchair (no position tracking!). In addition, the study participants will receive a tablet to answer daily questions about their daily condition and physiotherapy (approx. 2 min.). The treating physiotherapist should also answer questions on the tablet about therapy goals, goal achievement and therapy measures for a prescription period.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

After completion of the evaluation and upon request to the study director in Heidelberg, desired data can be passed on anonymously.

Organizational Data

- DRKS-ID: **DRKS00020487**
- Date of Registration in DRKS: **2020/02/18**
- 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.: **S-858/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1246-3301**

Health condition or Problem studied

- Free text: **Paraplegia, Hemiplegia**

Interventions/Observational Groups

- Arm 1: **Assessments are conducted at three visit points (baseline, interim and final visits) within the 8-month observation period. The baseline visit takes place in the clinic at the end of the initial inpatient treatment. For the interim and final visits, participants must come to the respective study center. Identifying data, main diagnoses and relevant secondary diagnoses are collected exclusively during the baseline visit. The coding of the main diagnosis (stroke or paraplegia) or secondary diagnoses is based on the ICD-10 version 2019.**
  STUDIES ON NEUROLOGICAL-FUNCTIONAL IMPAIRMENT
  In order to be able to classify the neurological-functional impairment of the participants, NIHSS and mRS are collected for baseline and final visits in participants with stroke. The ISNCSCI and SCIM are determined for participants with paraplegia.

  a. 10MWT, TUG
  The 10MWT is a mobility test that measures the time taken to cover a short distance of 10 meters. This time is then used to determine the self-selected walking speed. The TUG (Timed Up and Go Test) is used to assess the risk of falling and the balance from sitting to standing and walking.
  The use of aids is permitted for both tests and is documented. For patients who are not able to walk, these tests are unsuitable and are not performed.
  b. FIM
  The Functional Independence measure is an 18 items measurement tool that evaluates motoric, cognitive and social functions. A clinician assesses these items. In consideration of the overall cohort this measurement was selected because it has been validated for stroke and paraplegia patients. Not like the SCIM which is used only in patients with paraplegia.
  c. mRMI
  The modified Rivermead Index is an 8-item measurement tool that evaluates the mobility.
  d. WST-Q
  The wheelchair skill test questionnaire evaluates objectively the skills and safety of patients using either a manual or electrically driven wheelchair. It will be used only for subjects who are wheelchair users.
  e. Wheelchair questionnaire
  This questionnaire has been developed by the team of this study. The WST-Q asks about the type of wheelchair and its accessories as well as satisfaction with them.
  f. Barthel Index
  The Barthel Index is an evaluation procedure of the daily skills of a patient and helps to systematically record the independence or respectively the need of care of a patient.

  Surveys in respect to quality of life and depression
  a. DASS questionnaire
  The DASS is a screening procedure to assess depression, anxiety and stress in the past week.
  b. WOQOL-BREF-DIS
  This instrument records the subjective quality of life of a subject. It covers

**physical and mental wellbeing, social relations and environment.
The Modul DIS deals with questions regarding the physical impairments of a subject.**

**Questionnaire regarding the individual health network of patients
At the last visit, participants receive a questionnaire to answer questions on their supply/health network. There are two separate questionnaires for stroke and paraplegia participants.**

**Activity tracking
At the baseline visit, participants receive a sensor and a tablet computer for activity tracking. While the tablet is only needed to transfer the sensor data, the sensor must be attached on the shoe or wheelchair during the day. The measurement of walking or wheelchair mobility is the primary outcome parameter of the activity tracker. The distance per day and the number of steps per day are measured by means of an inertial sensor (IUM) with a triaxial accelerometer, a gyroscope and a magnetometer. There is no GPS module within the sensor and a position tracking is therefore not possible.
For the case that the mobility parameters of the activity tracker differ extremely to the baseline visit or if no data have been transmitted to the data base the study team will contact the subject by phone or email to clarify the cause and offer support.
At the baseline visit, each participant is equipped with one sensor. For the data evaluation and the optimal attachment (e.g. shoe or wheelchair) of the sensor, the main mobility category must be estimated.
• Pedestrian: Mainly and safe pedestrian who don't need a wheelchair or use it only rarely. These are stroke patients with very slight hemiplegia. The sensor will be attached by means of a clip device to the laces/Velcro of the footwear of the unimpaired or motorically better leg.
• Wheelchair user: Mainly wheelchair users who cannot walk at all or only in a therapeutic setting. These are, for example, patients with complete paraplegia or complete hemiplegia after a stroke. The sensor will be attached to the frame of the wheelchair using a clip device.
• Waking and Wheelchair user: Participants who move both walking and in a wheelchair. These are patients with, for example, incomplete paraplegia or moderate hemiplegia. The Activity Tracker will be either attached to the footwear of the unimpaired or motorically better leg and to the wheelchair.**

Every day, the participants must recharge the sensor and the tablet. The sensor data is transmitted to the tablet via a Bluetooth connection. A wireless internet connection is required to upload the sensor data from the tablet to the study database. Usually, this upload takes place once a day, but can also be delayed up to a week. The participants will be instructed accordingly during baseline visit.

**Recording of and evaluation of therapy goals by patient
Every day, the participant is asked to answer questions about his or her daily condition with the tablet. If there is a new physiotherapy prescription of if an old prescription ends, questions about therapy goals (at the beginning) or therapy evaluation (at the end) should be answered. In addition, the participants are reminded to take the tablet with them to their next physiotherapy session.
Treatment measures, recording of therapy goals and evaluation of therapists
The treating physiotherapist answers also questionnaires on the patients tablet. While at the beginning of a prescription, the individual therapy goals are asked about, at the end of the prescription the therapy evaluation and**

therapy methods are asked about.

Recruitment and informed consent
Suitable participants will be identified, screened and recruited in one of nine study centres at the end of their initial inpatient rehabilitation.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1) Structural recording of the quality of therapy and wheelchair supply and care results depending on patient factors, especially with regard to participation orientation
2) Objective measurement of mobility parameters (walking distance and/ or wheelchair distance) in daily life by using activity tracking.

Secondary Outcome

1) Recording of mobility-related therapies and assistive devices
2) The individual supply network of patients with a focus on the ambulatory physiotherapy
3) Identification of effective therapy and assistive devices
4) Identification of the need for coordination of measures

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Paraplegiologie, Heidelberg**
- Medical Center **Segeberger Kliniken GmbH, Neurologisches Zentrum, Bad Segeberg**
- Medical Center **August Bier Klinik, Bad Malente-Gremsmühlen**
- Medical Center **BG Klinikum, Hamburg**
- Medical Center **Klinikum Bad Bramstedt GmbH, Bad Bramstedt**
- Medical Center **Heinrich-Sommer-Klinik, Bad Wildbad**
- Medical Center **Rochus Klinik, Bad Schönborn**
- Medical Center **Kliniken Schmieder, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/05/12**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

1) Patients with paraplegia or stroke at the end of inpatient rehabilitation
2) Age between 18-85
3) Limitation of walking ability/mobility (Score ≤ 4 at item 8 of mRMI)
4) At least mobile, at study start, with wheelchair (also an electric wheelchair)
5) Able to understand and follow the study procedures (use of tablet, WLAN access at least once a week guaranteed)
6) Patient is able to consent
7) Signed informed consent form

Exclusion criteria

1) Severe psychiatric diseases (e.g. Schizophrenia, ongoing suicidal tendencies)
2) Depending on a respirator
3) For repeated stroke pre-existing limitation of the ability to walk/mobility
4) No capability to move independently at study start (bedridden: mRS = 5)
5) All physical and mental limitations which prevent the implementation of the study procedure significantly
6) Severe cognitive deficits (where applicable: minimental state examination ≤ 23, e.g. 3x lack of orientation)

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **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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  Germany

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  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

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.*