PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Efficacy of a participation-oriented outpatient neurorehabilitation program in patients with chronic acquired brain injury

Trial Acronym

TEAM

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

This randomized controlled clinical trial is designed to show that a intensive 4-week outpatient rehabilitation program is more effective in chronic patients with acquired brain injury than typical standard care. The so called TEAM intervention focuses on participation in the sense of the WHO ICF. The intervention consists of an interdisciplinary treatment team (occupational therapists, physiotherapists, speech and language therapists, neuropsychologists, rehabilitation physicians, social services, medical and nursing resources specialists) which treats patients over 4 weeks with 4 hours per day (monday to friday). Before the start of the program, patients define patient-specific participation goals, that they want to achieve within the 4 week treatment period. Treatment success is measured in single blinded fashion by means of the Goal Attainment Scale (GAS). Additional outcome domains are independence in the activities of daily living, quality of life, participation measures, as well as caregiver strain. The control group will be treated for the same length of time as the TEAM intervention group according to standard care within the German outpatient setting. After 3 months, there will be a crossover, i.e. patients in the control group will move on to receive the TEAM intervention and vice e versa. Final outcomes will be assessed after 6 and 12 months in the individual living environments (homes, nursing homes) of the patients.

Organizational Data

- DRKS-ID: **DRKS00009602**
- Date of Registration in DRKS: **2015/11/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

DRKS-ID: **DRKS00009602**
Date of Registration in DRKS: **2015/11/19**
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.: **446-12 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **I63 - Cerebral infarction**
- ICD10: **S06 - Intracranial injury**

Interventions/Observational Groups

- Arm 1: **Treatment for 4 weeks with an intensive interdisciplinary outpatient neurorehabilitation program with 4 hours of therapy per day (monday - friday), called TEAM intervention. This intervention is based on the definition of a real life participation goal for each individual patient. All interdisciplinary team members (physiotherapy, occupational therapy, speech and language therapy, neuropsychology, rehabilitation physicians, social services, medical and nursing resource specialists) work towards the achievement of these goals. A further speciality of the program is, that training / tutoring of next of kin and optimizing factors regarding the living environments (homes) of patients are also part of the intervention.**
- Arm 2: **Outpatient treatment according to standard care for this patient population with acquired brain injury within the German health care system (Control group)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

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

Primary Outcome

Achieving an individually defined therapeutic goal, assessed by means of the Goal Attainment Scale (GAS) at the start of the study (t1), after 1 month (t2), after 3 months (t3), after 4 months (t4), after 6 months (t5), and after 12 months (t6; all time points given in relation to the baseline t1 measurement)

Secondary Outcome

Improvement of the independence in the activities of daily living (measured by FIM), improvement of the quality of life (measured by EuroQOL, SF-36), improvement of life participation (measured by WHODAS II), reduction of caregiver strain (measured by mCSI), each at the start of the study (t1), after 1 month (t2), after 3 months (t3), after 4 months (t4), after 6 months (t5), and after 12 months (t6; all time points given in relation to the baseline t1 measurement)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Therapiezentrum Burgau, Burgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/03**
- Target Sample Size: **50**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/12/03**

Target Sample Size: **50**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

**Stroke or traumatic brain injury at least 6 months prior to enrollment,
Discharge from inpatient neurorehabilitation at least 3 months prior to enrollment,
Daily commute to the Burgau treatment site feasible,
Capability to endure at least 6 hours of daily therapy,
Life expectancy of at least 1 year,
Informed consent by patient or legal representative,
Age: 18-85 years**

Exclusion criteria

**Lack of participation impairment,
Insufficient German language skills,
Unwillingness of health care plan to cover the associated treatment costs**

Addresses

- **Primary Sponsor**

Neurologische KlinikKlinikum der Universität München
Mr. Prof. Dr. med. Andreas Bender
Marchioninistr. 15
81377 München
Germany

Telephone: **+4989440075824**
Fax: **+4989440075920**
E-mail: **andreas.bender at med.uni-muenchen.de**
URL: **https://www.klinikum.uni-muenchen.de/**

- **Contact for Scientific Queries**

Contact for Scientific Queries

Neurologische KlinikKlinikum der Universität München
Mr. Prof. Dr. med. Andreas Bender
Marchioninistr. 15
81377 München
Germany

Telephone: **+4989440075824**
Fax: **+4989440075920**
E-mail: **andreas.bender at med.uni-muenchen.de**
URL: **https://www.klinikum.uni-muenchen.de/**

■ **Contact for Public Queries**

Therapiezentrum Burgau
Ms. Luzia Fischer
Kapuzinerstr. 34
89331 Burgau
Germany

Telephone: **+498222404404**
Fax: **+498222404453**
E-mail: **l.fischer at therapiezentrum-burgau.de**
URL: **www.therapiezentrum-burgau.de**

■ **Collaborator, Other Address**

Institut für Medizinische Informatik, Biometrie und Epidemiologie (IBE)Klinikum der Universität München
Mr. Prof. Dr. Ulrich Mansmann
Marchioninistr. 15
81377 München
Germany

Telephone: **+4989440074491**
Fax: **+4989440077491**
E-mail: **mansmann at ibe.med.uni-muenchen.de**
URL: **http://www.ibe.med.uni-muenchen.de**

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.)**

Bundesministerium für Gesundheit (BMG)
Rochusstr. 1
53123 Bonn
Germany

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

Bundesministerium für Gesundheit (BMG)
Rochusstr. 1
53123 Bonn
Germany

Telephone: **+49228994413915**
Fax: **+4922899104413915**
E-mail: **[---]***
URL: **www.bmg.bund.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/09/30**

Trial Publications, Results and other documents

- Paper **Abschlusspublikation im Deutschen Ärzteblatt**

** 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.*