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# Occupational orientation in medical neurorehabilitation (Berufliche Orientierung in der Medizinischen Neurorehabilitation [BOMeN])

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 29/08/2007 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 03/10/2007 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 03/10/2007 | Nervous System Diseases | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

GfR 06/006

# Study information

## Scientific Title

## Acronym
BOMeN

## Study objectives
The trial studies survivors of stroke or brain injury with a special occupational difficulty concerning the reintegration to work. For these patients return-to-work is accompanied by explicit strains because of the coincidence of physical and cognitive impairments. Furthermore patients with acquired brain injury often focus only on the physical deficits and do not show adequate awareness for cognitive constraints.

Hypotheses:
1. Until 15 months after rehabilitation the ratio of (re-)employed persons in the intervention group is significantly higher than the ratio of (re-)employed persons in the control group
2. Until 15 months after rehabilitation the ratio of (re-)employable persons in the intervention group is significantly higher than the ratio of (re-)employable persons in the control group
3. Patients of the intervention group can be re-integrated significantly quicker than patients of the control group
4. Re-integrated patients who participated in the intervention group show significantly less days of incapacity for work than re-integrated patients who participated in the control group
5. Patients who participated in the intervention group show a significantly higher satisfaction with life and health than patients who participated in the control group
6. Patients who participated in the intervention group show a significantly higher motivation for rehabilitation than patients who participated in the control group
7. The intervention treatment will gain a higher valuation than the control treatment by the parties involved (patients and rehabilitation workers)

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics Committee of the Arztekammer Westfalen-Lippe and the Medical Faculty of the Westfalischen Wilhelms Unitersigy of Munster. Approved on 24th May 2007 (ref: 2007-235-f-S)

## Study design
Randomised controlled trial.

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Neurorehabilitation for survivors of stroke and brain injury

## Interventions
Intervention group: Patients of the intervention group take part in a newly developed rehabilitation concept called Occupational Orientation in Medical Neurorehabilitation (BOMeN) which consists of nine sessions of 3 hours during a 4-week rehabilitation. In this therapy the patients get to know relevant information about stress, perspectives, motivation and the relevance of attention, memory, planning functions and motor skills for everyday working life. The contents are mediated by patient education, experiments of perception and ergotherapeutic exercises. Furthermore the neuropsychological, socialmedical and ergotherapeutical assessments are more related to work and therapy is integrated in a fixed schedule. Finally different disciplines show a higher degree of interworking.

Control group: Medical Neurorehabilitation (MeN) patients of the control group take part in the conventional rehabilitation concept (MeN) which contains shorter units of assessment and therapy without an explicit relation to work. The average duration of treatment in both groups is controlled.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
The following variables are measured by standardized or self-developed questionnaires:
1. Re-employment (patients) 15 months after rehabilitation
2. (Re-)employability (patients) 15 months after rehabilitation
3. Days of incapacity to work (patients), measured using the Indicators of the Status of Rehabilitation questionnaire (Indikatoren des Reha-Status [IRES]) 15 months after rehabilitation
4. Expectations concerning the rehabilitation (patients), measured using the Questionnaire on Expectations and Motivation Concerning Rehabilitation (Fragebogen zu Reha-Erwartungen und Reha-Motivation [FREM]) at the start and end of rehabilitation
5. Motivation for rehabilitation (patients), measured using the Diagnostic Investigation of Motivation Concerning Work questionnaire (Diagnostik von Arbeitsmotivation [DIAMO]) at the start and end of rehabilitation, 6, 12 and 15 months after rehabilitation
6. Satisfaction with life and health (patients) (the 36-item Short Form health survey [SF-36]/the World Health Organization Quality of Life Questionnaire [WHO-QoL-BREF]) at the start and end of rehabilitation, 6, 12 and 15 months after rehabilitation
7. Satisfaction with rehabilitation procedure and contents (patients and rehabilitation workers). Timepoints for patients: at the start and end of rehabilitation, 6, 12 and 15 months after rehabilitation. Timepoints for workers: once in Summer 2008.

### Secondary outcome measures
1. Cognitive functional status at the start and end of rehabilitation, 6, 12 and 15 months after rehabilitation
2. Motivation for work at the start and end of rehabilitation, 6, 12 and 15 months after rehabilitation

### Overall study start date
01/07/2007

### Completion date
30/06/2010

## Eligibility

### Key inclusion criteria
All participants must meet all of the following conditions:
1. Positive prognostic estimation of occupational ability
2. Stroke or craniocerebral trauma
3. Estimated Functional Independence Measure (FIM) greater than or equal to 90

Also, all participants must meet at least one of the following conditions:
1. Advice for medical rehabilitation based on paragraph 51.1 of the Social Security Statutes, Book No. 5 (SGB V)
2. Inability to work for 3 months during the last 12 months
3. Ability to work is less than 6 hours
4. Not in paid work before start of rehabilitation
5. Necessary occupational reorientation
6. Application for a pension
7. Risk of early retirement

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
306

### Key exclusion criteria
1. Older than 60 years
2. Acute psychiatric disorder
3. Acute addiction
4. Restrictive aphasic disorder
5. Insufficient knowledge of German language
6. Estimated FIM <90
7. Neurological diseases other than stroke or craniocerebral trauma

**Date of first enrolment**
01/07/2007

**Date of final enrolment**
30/06/2010

# Locations

**Countries of recruitment**
Germany

**Study participating centre**
**Johanniterstrasse 7**
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# Sponsor information

**Organisation**
Association for Rehabilitation Sciences Nordrhein-Westfalen e.V. (Germany)

**Sponsor details**
Königsallee 71
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**Sponsor type**
Not defined

**Website**
http://www.rehaforschung-nrw.de

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Association for Rehabilitation Sciences Nordrhein-Westfalen e.V. (Gesellschaft für Rehabilitationswissenschaften Nordrhein-Westfalen e.V.) (ref: GfR 06006 / 623-06)

### Funder Name
Houses of Holy Order of Johanniter Rehabilitation Centre (Johanniter-Ordenshäuser Bad Oeynhausen gemGmbH) (ref: BOMeN 98410)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration