ISRCTN43768812 https://doi.org/10.1186/ISRCTN43768812

Effect of a new rehabilitation program in patients with neurological diseases

Submission date
20/03/2012

Recruitment status
No longer recruiting

Registration date
08/05/2012

Overall study status
Completed

Last Edited
19/09/2014

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
For most people the ability to go back to work after severe illness is very important. But for persons with acquired brain damage this is an enormous challenge, even for those who are less impaired in their functional abilities and whose restrictions initially appear less relevant. These patients often leave the rehab hospital expecting that they will be directly able to carry on like before. However, they too usually meet difficulties in everyday life. Studies have identified two relevant approaches in rehabilitation: the program should be as close to reality as possible and it should include patient education. Therefore, a new and potentially more effective rehabilitation program has been developed in order to prepare people for return to everyday life and work. This program includes work simulation: and psycho-educational lessons. The work simulation is similar to the patients usual individual working conditions. This way, patients can test their work-related abilities and deficits. In the psycho-educational lessons the patients are given the chance to talk about their experiences during the work simulation and their difficulties, and they can learn how to cope with everyday work life. The aims of this study are to investigate if the new rehabilitation program (BoReM-N) is more effective than the usual programs. The question is whether it helps patients to return to work and to everyday life.

Who can participate?
Study participants have neurological diseases, are younger than 61 years, and have the capability to go back to work.

What does the study involve?
Participants are randomly assigned either to the new program (BoReM-N) or to usual care. Contrary to current programs, the new rehabilitation program is orientated towards the everyday working world. It contains work simulations and work-related psycho-educational lessons. The patients receive handouts with key information from the lessons. At the beginning and at the end of the rehabilitation stay and 6,12 and 15 months thereafter, participants have to complete questionnaires. In these questionnaires participants are able to give feedback about the return to everyday life and to work.

What are the possible benefits and risks of participating?
The potential benefit for participants is a better preparation for return to work and everyday life. There are no known risks of participating.

Where is the study run from?
The study takes place at this two neurological rehabilitation centers in western Germany: Johanniter-Ordenshäuser Bad Oeynhausen gemGmbH, Neurologisches Rehabilitationszentrum Godeshöhe - Bonn Bad Godesberg.

When is the study starting and how long is it expected to run for?
Patients are enrolled in the study between January 2011 and May 2012. Follow-up examinations will continue until September 2013.

Who is funding the study?
Gesellschaft für Rehabilitationswissenschaften Nordrhein-Westfalen (GfR-NRW e.V.) .

Who is the main contact?
Dr Anke Menzel-Begemann
anke.menzel-begemann@uni-bielefeld.de

Study website
http://www.uni-bielefeld.de/gesundhw/ag6/projekte/berufliches%20reha-modul.html

Contact information

Type(s)
Scientific

Contact name
Dr Anke Menzel-Begemann

Contact details
University of Bielefeld
School of Public Health
Department of Public Health Nursing & Health Sciences Research
Universitätsstr. 25
Bielefeld
Germany
33615
+49 521 106 4818
anke.menzel-begemann@uni-bielefeld.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GfR09003 / 623 - 10

Study information

Scientific Title
Effect of work simulation modules compared to usual care on return to work in medical rehabilitation for patients with neurological diseases

Acronym
BoReM-N

Study objectives
To evaluate return to work and patient-related outcomes of the new rehabilitation program (BoReM-N) compared to the current traditional rehabilitation programs.

The trial studies survivors of neurological diseases 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, cognitive and language impairments. Furthermore, patients with acquired brain injury often focus only on the physical deficits and don't show adequate awareness for cognitive and language constraints - especially might ones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Association of Westfalen-Lippe and the Medical Faculty of the Westfälische Wilhelms University of Muenster, 28/09/2010, ref: 2010-345-f-S
[Ethik-Kommission der Ärztekammer Westfalen-Lippe und der Medizinischen Fakultät der Westfälischen Wilhelms-Universität Münster]

Study design
Randomised controlled clinical interventional multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neurological diseases

Interventions
1. Intervention group = BoReM-N
Patients of the intervention group take part in a new developed reha-concept called BoReM-N (work simulation modules in the context of occupational orientation in medical neurorehabilitation), which consists of six psychoeducational sessions of 2 hours during a 3-week rehabilitation and three work simulation sessions of 3 hours. In the first run of the work simulation the patients are to be observed while trying to do work-related jobs. The second and third time the work simulation runs under therapeutic perspective. In this therapy - added by the educational sessions - the patients get to know relevant information about stress, perspectives, realistic aims and the relevance of cognitive, language and motor skills for everyday working life. Furthermore, the neuropsychological, socialmedical and ergotherapeutical single assessments are more related to work and assessment and therapy is integrated in a semi-fixed schedule. Finally the different disciplines show an higher degree of interworking.

2. Control group = MeN
Patients of the control group take part in the conventional reha-concept which contains shorter units of assessment and therapy without an explicit relation to work.

The average number of minutes of treatment in both groups is controlled.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The following variables are measured by standardized or self-developed questionnaires:
1. Re-employment
2. (Re-)employability
3. Days of incapacity to work (IRES)

Secondary outcome measures
The following variables are measured by standardized or self-developed questionnaires:
1. Expectations concerning the rehabilitation (FREM)
2. Satisfaction with life and health (SF-36/WHO-QoL-BREF)
3. Satisfaction with rehabilitation procedure and contents

Overall study start date
10/01/2011

Completion date
28/09/2013

Eligibility

Key inclusion criteria

1. Necessary condition:
1.1. Neurological disease
1.2. Positive prognostic estimation of occupational ability
1.3. Estimated FIM =/> 90
2. Sufficient condition:
2.1. Advice for medical rehabilitation based on §51.1 SGB V
2.2. Inability to work for 3 months during the last 12 months
2.3. Ability to work is less than 6 hours
2.4. Inoccupation before start of rehabilitation
2.5. Necessary occupational reorientation
2.6. Application for a pension
2.7. Risk of early retirement

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
304

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

Date of first enrolment
10/01/2011

Date of final enrolment
28/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
University of Bielefeld
Bielefeld
Germany
33615

Sponsor information

Organisation
Rehabilitation Research of North Rhine-Westphalia (Germany)

Sponsor details
[Gesellschaft für Rehabilitationswissenschaften Nordrhein-Westfalen e.V.]
Garstenstraße 194
Münster
Germany
48147
+49 521 238 2631
info@rehaforschungs-nrw.de

Sponsor type
Hospital/treatment centre

Website
http://www.rehaforschung-nrw.de/rehawissen_start/index.php

ROR
https://ror.org/049btft62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Gesellschaft für Rehabilitationswissenschaften Nordrhein-Westfalen [GfR] (Germany), ref: GfR09003 / 623 - 10

Funder Name
Johanniter-Ordenshäuser Bad Oeynhausen gemGmbH (Germany)

Funder Name
Universität Bielefeld (Germany), ref: PSP - D - 3510 - 0006 - 0013 - 5000

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