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Standardized cognitive training for MS patients

Submission date
11/05/2016

Recruitment status
No longer recruiting

Registration date
25/05/2016

Overall study status
Completed

Last Edited
25/05/2016

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
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of problems including loss of vision, problems with balance and coordination as well as fatigue (extreme tiredness), stress and mental health difficulties such as depression. These symptoms can make life very difficult for sufferers, often causing impaired quality of life, social withdrawal or unemployment. The metacognitive and everyday life relevant training for patients with MS (MaTiMS) program is a new training program designed to help improve the coping abilities of MS patients. The aim of this study is to find out whether the MaTiMS program can reduce cognitive deficits in patients with MS with impaired cognitive function. The study will also look at whether MaTiMS is more effective in combination with BrainStim, a computerized training program.

Who can participate?
Adults with MS who feel they have impaired cognitive function.

What does the study involve?
Participants are allocated into three groups based on the order that they agree to take part in the study (not randomly). Those in the first group continue to receive the standard care provided by the rehab centre that they attend. Those in the second group take part in the MaTiMS program as well as continuing to receive standard care. The MaTiMS consists of six modules which are taught by a trained facilitator in 1.5 hour long sessions twice a week for three weeks (two modules per week). Those in the third group receive the standard care and the MaTiMS in combination with BrainStim, which involves an additional two 45 minute sessions on a computer twice a week for three weeks. At the start of the study and then again after three weeks and three, six and 12 months, participants in all groups complete a number of questionnaires and memory tests in order to find out if their cognitive deficits have been reduced.

What are the possible benefits and risks of participating?
Participants who take part in the MaTiMS training could benefit from improved coping abilities and cognitive function. There are no notable risks involved with participating in the study.

Where is the study run from?
1. Reha Centrum Hamburg GmbH (Germany)
2. Segeberger Kliniken GmbH (Germany)
3. RehaClinic Quellenhof Bad Wildbad (Germany)

When is the study starting and how long is it expected to run for?
January 2016 to June 2018

Who is funding the study?
German Federal Pension Insurance (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
8011-106-31/31.118

Study information

Scientific Title
Metacognitive and functional Training intervention for patients with MS

Acronym

MaTiMS

Study objectives
Study aim:
The aim of the study is to investigate the effectiveness of a metacognitive group intervention approach with MS patients (MaTiMS) in German neurological rehabilitation centres.

Hypothesis:
Perceived neurocognitive deficits will significantly decrease in the intervention group compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hamburg Chamber of Physicians, 30/03/2016, ref: PV5198

Primary study design
Interventional

Study design
Longitudinal non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple Sclerosis (MS)

Interventions
Participants are allocated to one of three groups sequentially (no randomisation).

Intervention group 1: Participants receive standard care as well as metacognitive training (MaTiMS). The MaTiMS sessions take place twice a week for three weeks and last approximately 1.5 hours per group session. MaTiMS combines three fundamental components:
1. Communication of the evidence about cognitive deficits in MS and their treatment based on principles of evidence-based patient information
2. Concrete examples and interactive reflection addressing cognitive biases
3. Information on alternative coping strategies and how to avoid cognitive traps.
The aims are to transfer current research knowledge to patients in order to unveil compromised coping strategies when handling impairments, to collect and present better strategies within the group, and to provide corrective experiences to patients. The ultimate goal is to promote a change in the patient’s metacognition and resulting behavior, thereby facilitating daily life. Our metacognitive approach refers to knowledge about one’s own cognition and addresses metacognitive learning strategies - that is, processes of planning, controlling, and regulating learning. It also includes self-reflection on cognitive processes, experiences of exhaustion, and depression.

Intervention group 2: Participants receive MaTiMS in combination with BrainStim in addition to standard care. The BrainStim training is in the form of 45 minute sessions twice a week for three weeks. The BrainStim training program is a specific working memory training program which

consists of 3 modules:
1. "City Map" targets spatial orientation: In which the user has to find a path using plotted arrows along a virtual city map.
2. "Find Pairs": In which visual object memory and the updating function of working memory are trained. The aim is to remember the location of cards that have been turned over and back again and find pairs of cards with the same image.
3. "Memorize Numbers": In which numbers that are presented for a short time have to be remembered while performing an arithmetic distraction task.

Control group: Participants receive standard care as it usually provided in each of the rehabilitation centres.

Participants are followed up immediately post-intervention (three weeks) and again after three, six and 12 months.

Intervention Type
Mixed

Primary outcome(s)
Perceived cognitive deficits measured using the perceived deficit questionnaire (PDQ) at baseline, 3 weeks, 3, 6 and 12 months.

Key secondary outcome(s)
1. Coping and self-efficacy are measured using the Coping Self Efficacy Scale (CSES) at baseline, 3 weeks, 3, 6 and 12 months
2. Fatigue is measured using the Fatigue Scale for Motor and Cognition (FSMC) at baseline, 3 weeks, 3, 6 and 12 months
3. Working Memory is measured using the Corsi-Block-Test / Digit Span backward (Wechsler Memory Scale revised) at baseline, 3 weeks, 3, 6 and 12 months

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. MS (McDonald-criteria (RRMS, PPMS, SPMS)
2. Expanded Disability Status Scale Score (EDSS) < 6.5)
3. Perceived neuropsychiatric deficits
4. Interest to participate
5. To be in a rehabilitation centre
6. Aged 18-80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Probable MS
2. Neuromyelitis Optica
3.SDMT < -2,5 SD

Date of first enrolment
01/04/2016

Date of final enrolment
30/03/2017

Locations

Countries of recruitment
Germany

Study participating centre
Reha Centrum Hamburg GmbH
Martini Straße 66
Hamburg
Germany
20246

Study participating centre
Segeberger Kliniken GmbH
Am Kurpark 1
Bad Segeberg
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23795

Study participating centre
RehaClinic Quellenhof Bad Wildbad
Kuranlagenallee 2
Bad Wildbad

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75323

Sponsor information

Organisation
German Federal Pension Insurance (Deutsche Rentenversicherung Bund)

ROR
https://ror.org/05am9gt90

Funder(s)

Funder type
Government

Funder Name
German Federal Pension Insurance (Deutsche Rentenversicherung Bund)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request