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The effect of rhythmic cued motor imagery on walking, fatigue and quality of life in people with multiple sclerosis

Submission date
24/03/2014

Recruitment status
No longer recruiting

Registration date
04/04/2014

Overall study status
Completed

Last Edited
11/04/2016

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a long-term and disabling illness of the brain and spinal cord. Patients with MS often have problems with walking and an overwhelming tiredness. Therefore, activities of daily life are challenging and quality of life is poor. Physiotherapy has been found to be useful to improve walking, fatigue and quality of life in patients with MS. This is even more true for physiotherapy settings that are tailored to the individual patient's needs. In recent years, new physiotherapy strategies have been developed. Two of them are motor imagery and rhythmic auditory stimulation. Motor imagery means that somebody thinks about moving her or his body in a certain way. Motor imagery of walking has been shown in studies to improve walking. Motor imagery can be practised with verbal guiding and/or audible information. It has been found in studies that it is easier to concentrate on the motor imagery with this additional information. Further, motor imagery works best when patients 'feel' the movement they imagine. Rhythmic auditory stimulation means that while moving a person hears the rhythm made by music or a metronome, and that this person´s movement is influenced by the rhythm. Rhythmic auditory stimulation also has been shown to improve walking in patients with neurologic diseases. Only two studies were found to test the effects of rhythmic auditory stimulation in people with MS. These were only small studies showing that balance and fatigue got better. Several researchers compared the effect of music and metronome signals on walking. This was mostly done in patients with stroke and Parkinson´s disease. The studies' results showed a walking improvement, and motor imagery was more lively and precise with any audible signals. Therefore, it will be interesting if either music or metronome signals can support motor imagery in patients with MS. In this study, a combination of motor imagery and music or metronome signals will be used. This study seeks to find out the effect of rhythmic-cued motor imagery on walking (speed and distance), tiredness and quality of life in people with multiple sclerosis.

Who can participate?
Adult, German-speaking, MS patients at the participating clinic can take part.

What does the study involve?
You will be randomly allocated to one of three groups: A, B or C. Group A receives motor

imagery with music and verbal guiding, plus weekly phone calls for support; group B receives motor imagery with metronome signals and verbal guiding, plus weekly phone calls for support; and group C receives usual treatment plus weekly phone calls asking about well-being. If you are in the treatment groups you will be informed beforehand. The treatment will take place at your home and it will last 4 weeks. You will be asked to sit down, close your eyes and imagine that you are walking at various speeds, according to the CD. You are asked to do this six times a week for 17 minutes. The Audio Mix on the CDs will be changed every week. Walking will be assessed using two walking tests. You will be asked to fill in five questionnaires about walking, fatigue and quality of life. Assessments will be taken at the start and after 4 weeks. Refreshments will be provided during testing.

What are the possible benefits and risks of participating?
You will not be at risk of falling or exhaustion during the home-based motor imagery, therefore the treatment is considered to be safe. The walking tests will be done in a hallway close to the wall and you will be safeguarded by the researcher. You will be allowed to rest during the assessments if you wish to. You might benefit from the intervention if you are in the treatment group with better walking and feeling less fatigued; however, this cannot be guaranteed. No side effects are expected as result of this treatment.

Where is the study run from?
MS Clinics, Innsbruck Medical University, Department of Neurology, Austria.

When is the study starting and how long is it expected to run for?
The study starts in March 2014. Participants will be enrolled on the study for a period of two and a half years (September 2016); however, the study will extend beyond this if necessary, up to 42 months (September 2017).

Who is funding the study?
Multiple Sclerosis Society of Austria (Austria)

Who is the main contact?
Mrs Barbara Seebacher
b.seebacher@aon.at

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Berger

Contact details
Innsbruck Medical University
Department of Neurology
Anichstrasse 35
Innsbruck
Austria
6020
+43 (0)512 504 26277
thomas.berger@i-med.ac.at

Type(s)
Scientific

Contact name
Mrs Barbara Seebacher

Contact details
Physiotherapie Bürgerhof
Schwarzseestraße 14/20
Kitzbühel
Austria
AT-6370
-
b.seebacher@aon.at

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of rhythmic cued motor imagery on walking, fatigue and quality of life in people with multiple sclerosis: a randomised controlled single-centre trial

Study objectives
H01: A rhythmic cued motor imagery will not change walking distance and walking speed in people with multiple sclerosis (MS)
H02: A rhythmic cued motor imagery will not change fatigue in people with MS
H03: A rhythmic cued motor imagery will not change (health-related) quality of life in people with MS

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Brighton, Faculty of Health and Social Science, Faculty Research Ethics Governance Committee, 09/01/2014, ref: 13 053.
2. Ethics Committee of Innsbruck Medical University, 02/04/2014, ref: AN2014-0052 334/4.14

Study design
Randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Multiple sclerosis

Interventions
Pilot study: participants will be randomly allocated to one of three groups (below)
Main study: there will be a specific allocation to groups (stratified block randomisation)

Group A: guided motor imagery plus rhythm from music, weekly phone calls for support. Sitting position, eyes closed, first-person perspective, 6 times a week, 17 minutes, 4 weeks; weekly change of Audio-Mix provided by a CD designed for this study. Detailed instructions.

Group B: guided motor imagery plus metronome cues, weekly phone calls for support. Same procedure.

Group C: controls. Normal treatment, weekly phone calls, asking about well-being.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in walking measured by the Timed 25-Foot Walk (T25FW) and 6-Minute Walk Test (6MWT). Assessments will be taken at the start and after 4 weeks.

Secondary outcome measures
Change of:
1. Walking (MS Walking Scale-12, MSWS-12)
2. Fatigue (Modified Fatigue Impact Scale, MFIS)
3. Quality of life (MS Impact Scale-29, MSIS-29)
4. Health-related quality of life (Short-Form Health Survey-36, SF-36, EQ-5D-3L)
Assessments will be taken at the start and after 4 weeks.

Overall study start date

31/03/2014

Completion date
19/02/2016

Eligibility

Key inclusion criteria
1. People with mild MS (Expanded Disability Status Scale, EDSS 1.5 to 4.5)
2. Aged 18 years or over
3. Clinical MS according to McDonald's criteria as diagnosed by Innsbruck MS Clinics
4. All MS phenotypes
5. Any ethnicity
6. German speaking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Concomitant other diseases which are affecting rhythmic cued motor imagery and walking (e. g., hearing impairment)
2. A relapse of MS within the last 3 months
3. Known pregnancy
4. Any cognitive deficits or depression, diagnosed and documented by the MS Clinics in Innsbruck
5. A relapse during the intervention period will lead to exclusion of the participant

Date of first enrolment
09/04/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
Austria

Study participating centre
Innsbruck Medical University
Innsbruck
Austria
6020

Sponsor information

Organisation
Innsbruck Medical University (Austria)

Sponsor details
c/o Professor Thomas Berger
Clinical Department for Neurology
Anichstrasse 35
Innsbruck
Austria
6370
+43 (0)512 504 26277
thomas.berger@i-med.ac.at

Sponsor type
University/education

Website
https://www.i-med.ac.at/mypoint/

ROR
https://ror.org/03pt86f80

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society of Austria (Austria)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No
Results article	results	01/02/2017		Yes	No