

The effect of different types of motor imagery on walking, tiredness, quality of life, motor imagery ability and gait adaption with music beat in people with multiple sclerosis

Submission date 10/12/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/08/2018	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Multiple sclerosis (MS) is a chronic 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. In scientific studies, 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. Motor imagery is such a new physiotherapy treatment for people with multiple sclerosis (MS). Motor imagery means that somebody thinks about moving her or his body in a certain way without actually moving. Therefore, the purpose of this study is to explore different types of motor imagery in terms of their effects on walking, fatigue and quality of life.

Who can participate?

Patients aged 18 and over with mild to moderate MS at the MS Clinics Innsbruck, Austria

What does the study involve?

Participants are randomly allocated to one of three groups. The treatment takes place at participants' homes and lasts 4 weeks. Participants are asked to sit down, close their eyes and imagine that they are walking at various speeds according to a CD. They are asked to do this 6 times a week for 17 minutes. The audio mix on the CDs is changed every week. For group 1 the CD includes motor imagery with music and verbal guiding, For group 2 the CD includes motor imagery with music, For group 3 the CD includes motor imagery alone. All groups also receive weekly phone calls for support and their normal medical treatment. Participants' walking is assessed using two walking tests: a 7.6-metre short walking test to assess walking speed and a 6-minute walk test to measure walking endurance. Adaption of their gait with the music beat is assessed on a short walkway using video recording. Participants are asked to imagine stepping movements while seated. Participants are further be asked to fill in three questionnaires about fatigue, quality of life and motor imagery ability. This procedure lasts about 44-66 minutes plus

time for motor imagery familiarisation, information (25 to 30 minutes, depending on questions you may have) and rest. Assessments take place at the start of the study and after 4 weeks. Refreshments are provided during testing and travelling and parking costs can be refunded. If one of the treatments is found to be more effective than the others, you will immediately receive information and the relevant CD.

What are the possible benefits and risks of participating?

You might benefit from better walking and feeling less fatigued, but this cannot be guaranteed. 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. It is not expected that there will be any side effects caused by 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?

September 2015 to September 2017.

Who is funding the project?

The Austrian MS Research Society has been contacted for funding the material costs of this study. Otherwise the study will be self-funded by the researcher.

Who is the main contact?

Dr Barbara Seebacher

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effect of different types of motor imagery on walking, fatigue, quality of life, motor imagery ability and sensorimotor synchronisation in people with multiple sclerosis

Study objectives

There is no difference between motor imagery with music and verbal cueing, motor imagery with music and motor imagery alone to change walking speed, walking distance, fatigue, quality of life, motor imagery ability and gait synchronisation with music beat in people with multiple sclerosis (MS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. College Research Ethics Committee of the University of Brighton, UK, 17/12/2015
2. Ethics Committee of the Medical University of Innsbruck, Austria, 26/02/2016, ref: AN2014-0052 334/4.14 358/5.13 (3743a)

Study design

Prospective three-group parallel randomised controlled single-centre trial, including a pilot study

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

The intervention will consist of:

Group 1: Motor imagery with instrumental music and verbal cueing emphasising the temporal music pattern

Group 2: Motor imagery with instrumental music

Group 3: Motor imagery

All participants will continue to have their normal treatment, weekly phone calls supporting their motor imagery and asking for their health condition, motor imagery familiarisation, study CD prepared, weekly change of audio mix

Participants in all groups will be asked to practise once a day for 17 minutes, 6 times a week for 4 weeks, while seated on a chair, with eyes closed, using the kinaesthetic mode from a first person perspective. This means that they should 'feel' themselves walking during the imagery.

Intervention Type

Behavioural

Primary outcome measure

All outcome measures will be taken at baseline and at follow-up, after the 4 weeks intervention:

1. Timed 25-Foot Walk
2. 6-Minute Walk Test

Secondary outcome measures

All outcome measures will be taken at baseline and at follow-up, after the 4 weeks intervention:

1. Modified Fatigue Impact Scale
2. Multiple Sclerosis Impact Scale-29
3. German short form of the Kinaesthetic and Visual Imagery questionnaire
4. Time-Dependent Motor Imagery Screening test
5. Sensorimotor synchronisation: Video-assisted quantitative gait analysis (ccc.Utilius-Fairplay5 motion analysis software) during walking to music beat, right/left sides separately: Step length and step time variability, proportion of step duration to the beat duration, synchronicity

Overall study start date

01/09/2015

Completion date

30/09/2017

Eligibility

Key inclusion criteria

1. People with mild to moderate MS (Expanded Disability Status Scale 1.5-4.5)
2. Aged 18 years or over
3. Clinical definite MS according to McDonald's criteria
4. All MS phenotypes
5. Any ethnicity
5. German speaking

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

75

Key exclusion criteria

1. Concomitant diseases which are affecting rhythmic cued motor imagery and walking (e.g. untreated hearing impairment)
2. A relapse of MS within the last three months
3. Known pregnancy
4. Any overt cognitive deficits or depression
5. A relapse during the intervention period will lead to exclusion of the participant

Date of first enrolment

03/03/2016

Date of final enrolment

16/08/2016

Locations**Countries of recruitment**

Austria

Study participating centre

Medical University of Innsbruck

Department of Neurology

Anichstrasse 35

Innsbruck

Austria

6020

Sponsor information**Organisation**

University of Brighton (UK)

Sponsor details

c/o Dr Raija Kuisma
School of Health Sciences
49 Darley Road
Eastbourne
England
United Kingdom
BN20 7UR

Sponsor type

University/education

Website

<https://www.brighton.ac.uk/about-us/contact-us/academic-departments/school-of-health-sciences.aspx>

Organisation

Medical University of Innsbruck (Austria)

Sponsor details

Clinical Department of Neurology
Anichstrasse 35
Innsbruck
Austria
6020

Sponsor type

University/education

Website

<https://www.i-med.ac.at/neurologie/>

Organisation

University of Brighton

Sponsor details

Sponsor type

Not defined

Website

<http://www.brighton.ac.uk/>

ROR

<https://ror.org/04kp2b655>

Funder(s)

Funder type

Research organisation

Funder Name

Austrian MS Research Society

Results and Publications

Publication and dissemination plan

It is proposed to publish the pilot study results after analysis of the pilot study (conference presentation, scientific article). After completion and analysis of the main study, participants will be informed about the study results. Then, the main study will be presented at international and national conferences, followed by a scientific journal article.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	pilot study results	02/03/2018		Yes	No
Results article	results	01/10/2019		Yes	No