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A cognitive, occupation-based programme for people with multiple sclerosis (COB-MS)

Submission date
03/09/2019

Recruitment status
No longer recruiting

Registration date
04/09/2019

Overall study status
Completed

Last Edited
01/10/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
The aim of this research is to test the feasibility of running a large-scale trial of an occupational therapy intervention called a Cognitive Occupation-Based programme for people with Multiple Sclerosis (COB-MS), as well as its preliminary effectiveness. That is, the aim of the research is to assess whether or not it is possible to properly test this programme and whether or not it is likely to work. The study will focus on how acceptable the intervention is and how well the trial runs. Ten occupational therapists will run the COB-MS with 100 people with MS. This project has the potential to directly influence clinical practice and benefit the lives of people with MS, by enabling them to manage their disease symptoms in a positive way that allows them to live well with MS.
Cognitive impairments are common in multiple sclerosis and affect daily life in many ways. We propose a new way in which people living with MS can empower themselves to live active and fulfilling lives - a novel intervention that enables people with MS who are experiencing difficulties with their cognition to live positively. Here we propose an intervention that tackles cognitive difficulties early, allows patients to manage their own symptoms and is transferable to real-world situations.

Who can participate?
People with MS and occupational therapists who work with people with MS.

What does the study involve?
Participants will randomly be assigned to receive the COB-MS programme or treatment as usual. The COB-MS programme takes place over nine weeks in eight sessions lasting 60-90 minutes. Participants will be asked to fill in questionnaires before and after the treatment period. At the end of the period, the participants in the control group will be offered the COB-MS treatment. Occupational therapists taking part will be asked to provide their feedback on the treatment programme.

Added 23/09/2020: Due to the impact of COVID-19 this trial is now been conducted online: data collection and delivery of the intervention.

What are the possible benefits and risks of participating?
Potential benefits of participation include: access to a free cognitive occupation-based programme, designed specifically for people living with MS; informational benefits relating to the management of MS; and a greater understanding of the individual's role in their MS management. When this research project is concluded, all participants will receive a summary of the main findings. Of note, it could take in excess of 6 months before final results are published. Though there is no foreseen risk of participating, there is the potential that a person or persons may become upset when discussing cognitive or other difficulties, in which case, our research staff has the skills necessary to deal with such occurrences.

Where is the study run from?
National University of Ireland Galway

When is the study starting and how long is it expected to run for?
October 2019 to July 2022

Who is funding the study?
Health Research Board, Ireland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Version 1

Study information

Scientific Title
A Cognitive Occupation-Based programme for people with Multiple Sclerosis (COB-MS): a randomised pilot trial to improve cognition and daily functioning for people with multiple sclerosis

Acronym
COB-MS

Study objectives
Given that the current study is a feasibility trial, hypotheses are not appropriate at this stage of research, However, the following are objectives of this feasibility trial:
Objective 1: To field test the outcome measures and procedures used in the trial.
Objective 2: To determine the preliminary efficacy of COB-MS in comparison with treatment as usual wait-list controls in improving everyday life challenges associated with cognitive difficulty and secondary outcomes related to cognition, mood, fatigue, quality of life and pain.
Objective 3: To determine the acceptability and feasibility of the COB-MS and to investigate the barriers and facilitators to using COB-MS through:
• Interviews with people who decline to take part;
• Interviews with PwMS who participated in the COB-MS; and
Focus groups with OTs who ran the COB-MS.
Objective 4: To examine the effects of a patient-designed-and-informed participant information sheet with a standard, researcher-designed information sheet on recruitment to the trial (i.e. as a study-within-a-trial [SWAT]); rate of consent and relationship with participant retention; and understanding and preference regarding the two different participant information sheets.
Objective 5: To determine the appropriateness of progression to a definitive trial through gathering and assessing key trial information, such as:
• Retention of participants during intervention and follow-up;
• Feasibility of chosen outcomes to measure efficacy of the interventions within a definitive trial;
• Feasibility of randomisation methods, including allocation;
• Rate of unblinding; and
• Estimating intracluster correlation and sample size for definitive cluster RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/08/2019, Galway University Hospitals Clinical Research Ethics Committee (Research Office, Room 212, Research and Innovation Centre, NUI Galway, Ireland; +353 91 495312; ethics@nuigalway.ie), ref: C.A. 2231

Study design
Single-blind cluster-randomized control pilot trial

Primary study design

Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
This is a single-blind randomised control pilot trial. This study will use a treatment as usual, wait-list control group (TAU) comparison examined over four time points, as part of both preliminary clinical efficacy and feasibility outcomes: prior to and following the intervention, at 12 weeks follow-up and six-month follow-up. Follow-up data will be collected to gauge maintenance of the intervention gains, if evident.

There will be two arms- COB-MS and TAU control. Occupational therapists (OT) will be used as stratification factors. After the participants have been assigned to their corresponding OT, they will be randomly allocated in a 1:1 rate to one of the arms through a web-based randomisation service. Therefore, each therapist will deliver both interventions, COB-MS and TAU, and will have the same number of participants in each group. To further feasibility testing of COB-MS implementation, OTs will recruit participants with MS (PwMS) where possible.

The study will be single-blinded as the research assistant collecting the data will be blind to participant allocation. Participants with MS will know what arm of the study they have been allocated to. Structures will be in place that will increase the likelihood of blinding.

The COB-MS research will follow the Medical Research Council's (MRC) Framework for development and evaluation of RCTs for complex interventions to improve health that describes four phases: development; feasibility / piloting; evaluation and implementation. Here we are focused on the feasibility/piloting phase.

Cognitive Occupation-Based Programme for People with MS:
The Template for Intervention Description and Replication (TIDieR) checklist will be used here to describe the intervention.

1. Phrase that describes the intervention:
An occupational therapy intervention aimed at improving daily life functioning for people with multiple sclerosis who are experiencing cognitive difficulties.

2. Rationale, theory, or goal of the elements essential to the intervention:
The COB-MS is a patient-centred holistic programme which consist of eight sessions- two individual and six group-based. It focuses on managing demands of employment and daily life through education, remediation and adaption using compensatory strategies, routines and learning new techniques that can be integrated into daily contexts. It recognises the impact of emotion, motivation and other non-cognitive functions.
The COB-MS looks at the context/environment within which the person lives in order to make strategies meaningful to the participant. The programme aims to help people meet their goals while managing their cognitive challenges. Table below shows brief content of each COB-MS session. The group sessions focus on aspects of cognition and cognitive rehabilitation. There is an emphasis on group discussion and peer learning. Participants have a chance to practice strategies in the group and at home.

The aim of COB-MS is to equip people with MS with strategies to manage their own symptoms. Self-management interventions are relatively new in health research but have been found to be highly effective in the management of long-term conditions such as diabetes and arthritis. A number of steps have been taken in designing the COB-MS which addressed the maintenance of gains and continuation of strategies developed through the intervention – these include incorporating behaviour change principles into the COB-MS, integrating homework activities into weekly routines, providing people with MS with handbooks which detail each COB-MS session, setting regular goals and having a definitive list of strategies that work for that person at the end of the last COB-MS session.

3. Materials provided:
The occupational therapist is provided with a facilitator handbook and PwMS provided with a participant handbook that details the content of the intervention. The handbooks that are provided to occupational therapists and PwMS are the essential components of the intervention. The handbooks are approximately 125 pages in length- each session is summarised as well as space for in-group and homework activities. Participants can keep the handbooks at the end of the intervention period and are encouraged to review them regularly. As the COB-MS is still in development and testing the handbooks is not yet available publicly.

4. Describe each of the procedures, activities, setting and/or processes used in the intervention:
The COB-MS will take place in a community setting. The setting may vary per site but is likely to be in a room in which the occupational therapist is based in. If this is not possible then the budget allows for a community venue to be hired for the six weeks of the group intervention. The individual sessions will be in participants own homes, local community healthcare setting or equivalent. The COB-MS group receive two hours of one-to-one occupational therapy as well as six-hours of group-based occupational therapy focused on cognitive rehabilitation. Each group session has a mixture of theory/background discussion on aspects of cognition (10 mins) and strategies (15 mins). This is followed by opportunities to practice strategies (15 mins) and discuss usefulness, application to own life and goals (20 mins). The strategies that are included in the handbook are evidence-based- they have either been proven effective with an MS population [e.g. Story memory technique (Chiaravalloti et al., 2005)] or with a population with brain injury [e.g. Goal Management Training (Levine et al., 2000)]. In the COB-MS the focus is on translation to daily life tasks and different areas of cognition in one intervention.
Occupational therapists will be provided with ongoing supervision by phone, email or in person at their workplace, if requested (session-specific supervision).

5. Who is the intervention provider?
The COB-MS is designed to be run by a qualified occupational therapists who has experience and expertise in managing everyday life challenges. The occupational therapists receives training in the COB-MS, as well as ongoing support if required. The lead applicant (author of handbook) will be responsible for training the occupational therapists and along with postdoc will be available throughout for supervision and guidance. By using multiple therapists to carry out the intervention, feasibility of the COB-MS in practice can be seen.

6. Describe the modes of delivery:
Session one involves an initial visit with an occupational therapist who introduces the programme and helps the participant set some personal goals. There are then six once-weekly group sessions with a small group (between 5-9 people). The group sessions are then be followed by a final individual session that takes place two weeks after the last group session. Each COB-MS session is set to last between 60-90 minutes. Clinical judgement will be required to assess the group/individual in terms of tolerance and fatigue.

7. Location(s) where the intervention occurs:
The first and last sessions take place in a location that is convenient to the PwMS. This is often the person's home but it may also be in the occupational therapist's workplace. The group sessions take place in a private room that is available for the occupational therapist to use in their own workplace. Each occupational therapist will run the COB-MS with 9-10 participants.

8. When and How Much:
There are eight COB-MS Session which run over nine weeks. They are once-weekly with the final session happening two weeks after the penultimate session. The COB-MS sessions last between 60-90 minutes. The recommended duration spent on homework is 30 minutes per day 5 days /week but this is likely to vary and will be monitored through the study. Each participant will receive the intervention once.

9. Tailoring:
The intervention is planned to be personalised. This happens through the setting of individual goals in the first session. Participants are encouraged to apply what they are learning in the group sessions to their own lives and goals. PwMS can also personalise the intervention when they have one-to-one sessions with the occupational therapist. The intervention dose and content is the same for all participants.

10. Modifications:
The intervention should not be modified during the course of the study. Fidelity measures will be in place to address this.

11. Planned fidelity assessment:
Occupational therapists will keep a record of the intervention session content, length and other important information after each session. A sample (two per COB-MS group) of COB-MS sessions per occupational therapist will be audio/video-recorded and compared for intervention fidelity, with permission from occupational therapist and group members.

12. The extent to which the intervention was delivered as planned:
This data will be captured in the study to allow for complete feasibility data to be collected and future trial planning. Participants will be asked to rate the occupational therapists at the end of the COB-MS sessions on a number of areas relevant to the delivery of the intervention. This will be anonymous, data will be pooled and occupational therapists will be aware of this in advance.
Occupational Therapist Rating- Answered via six-point Likert scale, ranging from strongly disagree (1) to strongly agree (6).
1. My OT expertly knew about the COB-MS programme.
2. The OT was empathetic to the group.
3. I was confident in my OT.
4. The OT communicated well.
5. My OT was well prepared.
6. The OT was effective at delivering the intervention.

Engagement with the intervention:
Engagement with the intervention will be used as a proxy for compliance with weekly home-based activities. Engagement will be recorded by participants in their handbook. This will include self-monitoring of completion of home-based activities and rating on a weekly basis taking account of effort, intention, time spent and actual completion. This will be collected at the end of the final COB-MS session. Occupational therapists will discuss home-based activities as a

“Review” activity at the beginning of each group session. Here participants will have the opportunity to reflect on home-based activities and discuss what worked well and what did not work. It may also act as an incentive to complete activities in advance of group sessions.

Control Condition:
Participants randomised to the control arm of the study will receive the COB-MS at the end of the data collection period. This is particularly important given that OTs will be involved in recruiting and we do not wish impact on clinical relationships. Control participants will be assessed at the same time points as the intervention arm. Control data (following COB-MS) will not be analysed.
Participants will also be asked to fill in a form indicating any services/ interventions they have had during the intervention period- occupational therapy being the most important to record here. This will allow for the estimation of what treatment as usual consists of for the control participants.

It is expected that the risk of contamination will be low as cognitive rehabilitation is not standard input for patients with MS. Occupational therapy treatment is also not regular part of usual care for people living in the community and if it is it would generally be of lower intensity and the focus is not likely to be on cognition. This is will be monitored throughout the study and a sensitivity analysis will be used to monitor the occupational therapy and cognitive rehabilitation contribution in each group. In order to reduce the chance of contamination occupational therapists trained in the COB-MS will be asked not to pass on their knowledge to non-COB-MS trained occupational therapists. Occupational therapists will be asked to sign a declaration as part of the consenting process stating that they will not share their knowledge or the manual/resources with non-trained occupational therapists and will not use COB-MS methods outside the trial.

Considering patient burden, therapist burden, available resources and the challenge of ensuring that the active comparator is standard per therapist it was decided not to use an active control group for this feasibility study. The higher costs associated with an active control coupled with the risk of a higher drop-out rate for the control condition led to the decision not to use an active control.

Added 23/09/2020:
Due to the impact of COVID-19 this trial is now been conducted online: data collection and delivery of the intervention.

Intervention Type
Other

Primary outcome(s)
Goal Attainment Scaling at the 12-week follow-up

Key secondary outcome(s))
Current secondary outcome measures as of 25/11/2019:
At 12 weeks and 6 months follow-up:
1. Prediction of future cognitive decline measured using the Symbol Digit Modality Test
2. Cognitive function assessed by the California Verbal Learning Test II
3. Visual attention and task switching assessed by the Trail Making Test
4. Visuospatial learning and memory assessed using the Brief Visuospatial Memory Test-Revised
5. Memory assessed by the Everyday Memory Questionnaire Revised and by a relative's report

6. Impact of fatigue on participant's life assessed by the Modified Fatigue Impact Scale
7. Self-efficacy assessed using the Generalised Self-Efficacy Scale (GSES)
8. Quality of life assessed by the Multiple Sclerosis Quality of Life-54 (MSQoL-54)
9. Mental health assessed using the General Health Questionnaire (GHQ-12)

Previous secondary outcome measures:
At 12 weeks and 6 months follow-up:
1. Prediction of future cognitive decline measured using the Symbol Digit Modality Test
2. Cognitive function assessed by the California Verbal Learning Test II
3. Visual attention and task switching assessed by the Trail Making Test
4. Memory assessed by the Everyday Memory Questionnaire
5. Self-report of cognitive difficulties assessed by the Perceived Deficits Questionnaire
6. Trait and state anxiety assessed by the Spielberger Trait Anxiety Inventory
7. Perceived stress assessed by the Perceived Stress Scale
8. Impact of fatigue on participant's life assessed by the Modified Fatigue Impact Scale
9. Quality of life assessed by the Multiple Sclerosis Quality of Life -54 (MSQoL-45)
10. Self-efficacy assessed by the Generalised Self-Efficacy Scale (GSES)
11. Pain assessed by the Brief Pain inventory
12. Depression assessed by the Beck's Depression Inventory II

Completion date
01/07/2022

Eligibility

Key inclusion criteria
People with MS:
1. Aged 18 years of age or older
2. Fluent in written and spoken English
3. Diagnosis of multiple sclerosis
4. Cognitive difficulties, as shown by a score of >22 on the MSNQ
5. Clinically stable (we define "clinically stable" as not having an active relapse)
6. Can provide informed consent
7. No neurologic history other than MS, including evidence of current dementia
8. No history of major depressive disorder, schizophrenia, or bipolar disorder I or II
9. No history of diagnosed substance use or dependence disorder
10. Not currently undergoing any other form of cognitive rehabilitation
11. Living in the community

Occupational Therapists:
1. Currently working in Ireland as an occupational therapist
2. CORU-registered
3. Have experience working with people with MS
4. Can commit to the requirements of the study

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
94

Key exclusion criteria
People with MS:
1. Cognitive impairment that would affect reliable participation or capacity to give informed consent
2. Are incarcerated or institutionalized
3. Significant neurological condition or organic brain damage (unrelated to MS).

Occupational Therapists:
1. Not meeting the inclusion criteria

Date of first enrolment
01/10/2019

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
Ireland

Study participating centre
National University of Ireland Galway
University Rd
Galway
Ireland
H91

Sponsor information

Organisation
NUI Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. The data will be shared publically. The data access procedures are yet to be fully decided. Data will be shared at the following locations:
1. Irish Social Science Data Archive (ISSDA)http://www.ucd.ie/issda/data
2. Irish Qualitative Data Archive (IQDA) at https://www.maynoothuniversity.ie/iqda

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2024	24/09/2024	Yes	No
Protocol article		17/03/2020	19/03/2020	Yes	No
Protocol article	Protocol for a study-within-a-trial	24/01/2020	01/10/2025	Yes	No
	Update to protocol		01/10		

Protocol article		20/01/2023	/2025	Yes	No
Dataset			28/03/2024	No	No
Other publications		26/07/2023	27/07/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			05/12/2022	No	Yes
Preprint results		27/03/2024	28/03/2024	No	No
Statistical Analysis Plan	SAP is within protocol	17/03/2020	28/03/2024	No	No