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A cognitive occupation-based programme for people with multiple sclerosis: definitive trial

Submission date
10/02/2026

Recruitment status
Recruiting

Registration date
17/02/2026

Overall study status
Ongoing

Last Edited
13/03/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
We know that 50%-60% of people with multiple sclerosis (MS) have some cognitive problems. These can be difficulties with short-term memory, attention, problem-solving and language. There have been no methods studied which have been proven to be effective at slowing down or reversing the decline in these functions, which have a big effect on quality of life.
The study is exploring a new method of cognitive rehabilitation (COB-MS).

This study will teach people with MS, in a group setting, different techniques to manage the cognitive difficulties they may encounter. Previous research in Ireland has shown the COB-MS programme may have a positive impact. People with MS experienced benefits from the programme, and the results appear promising. Now we are looking to test the COB-MS on a much larger group to see if this early study result works with a larger group of people who have MS. We want to know if the COB-MS can improve daily life for people with MS and if it is cost-effective to run.

Who can participate?
Adult patients with MS.

What does the study involve?
Once enough participants have consented to take part, they will be allocated to one of three groups. One group will be offered the COB-MS in person, one group will be offered the COB-MS online, and one group will continue with their usual care. The allocation to groups is done randomly by a computer programme. The research team do not have control over who is in what group.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
University of Galway, Ireland.

When is the study starting and how long is it expected to run for?
March 2026 to November 2029.

Who is funding the study?
Health Research Board, Ireland

Who is the main contact?
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Contact information

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Principal investigator, Public, Scientific

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Public

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Additional identifiers

Study information

Scientific Title
A Cognitive Occupation-Based programme for people with Multiple Sclerosis: definitive trial (COB-MS)

Acronym
COB-MS

Study objectives
The study aims, through the COB-MS, 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 04/02/2026, University of Galway (Newcastle Road, Galway, H91TK33, Ireland; +353 091524411; ethics@universityofgalway.ie), ref: 2025.08.028

2. Approved 02/10/2025, Galway University Hospitals Clinical Research Ethics Committee (Merlin Park Hospital, Galway, H91, Ireland; +353 091757631; colette.collins@hse.ie), ref: C.A.3491

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

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

Interventions
An occupational therapy intervention aimed at improving daily life functioning for people with multiple sclerosis (MS) who are experiencing cognitive difficulties.

Participants will be allocated to the three arms using an allocation ratio of 1.3 in favour of the intervention arms to allow for clustering of the intervention arm, using randomly permuted blocks.

Participants, with a diagnosis of MS and experiencing cognitive difficulties, will be randomly allocatedto one of three trial arms, using a partially clustered design:
• In-person intervention arm- COB-MS delivered by an occupational therapistin a community setting.
• Online intervention arm- COB-MS delivered by an occupational therapistfully online.
• Control arm- TAU.

Rationale, theory, or goal of the elements essential to the intervention
The COB-MS is a patient-centred, holistic programme which consists of eight sessions- two individual and six group-based. It focuses on managing demands of employment and daily life through education, remediation and adaptation 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 to make strategies meaningful to the participant. The programme aims to help people meet their goals while managing their cognitive challenges. 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.

Steps were 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 home 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.

In the COB-MS, the different mechanisms of action (MoA), the processes through which Behaviour Change Technique (BCT) affects behaviour, relate to various behavioural determinants, highlighting where evidence supports, contradicts, or remains inconclusive about these links. Strongest and most consistent links cluster around goal setting, selfmonitoring, problem solving, social support, and providing information about health consequences, indicating these techniques reliably influence corresponding determinants such as knowledge, skills, behavioural regulation, and motivation. Providing information about health consequences and guidance on how to perform behaviours is also reliably connected with changes in understanding and capability. In contrast, techniques involving restructuring physical or social environments, conserving mental resources, or using prompts and cues show limited or inconsistent evidence of influencing the assessed mechanisms. For several potential mechanisms, such as those relating to environmental restructuring or avoidance strategies, no evaluative evidence is available, indicating that these links remain untested rather than disproven. Overall, behaviour change techniques grounded in selfregulation, goaldirected planning, and the provision of actionable information have the strongest empirical support for influencing identified mechanisms of action.

Materials provided
The occupational therapist is provided with a facilitator handbook, and people with MS are provided with a participant handbook that details the content of the intervention. The handbooks include the essential components of the intervention. Both intervention arms will be provided with a physical copy of the COB-MS handbook (large-print available on request). As the COB-MS is still subject to research and development, the handbook is not yet available publicly, but has received ethical approval.

Procedures, activities, setting and/or processes used in the intervention
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 found 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)]. The focus of COB-MS is on translation to daily life tasks and different areas of cognition in one intervention. Furthermore, occupational therapists will be provided with ongoing supervision.

Intervention provider
COB-MS is designed to be run by a CORU-registered occupational therapist who will be employed by the University of Galway. The occupational therapists will receive training on the COB-MS intervention and protocol, as well as ongoing support to ensure delivery of standardised intervention. By using multiple therapists to carry out the intervention, the feasibility of the COB-MS in practice can be seen, and the potential therapist effect will be addressed.

Modes of delivery
Session one involves an initial meeting (online or in-person) with an occupational therapist who introduces the programme and helps the participant set personal goals. There are then six once-weekly group sessions with a small group (between 5 and 8 people). The group sessions are followed by a final individual session that takes place two weeks after the last group session. Feasibility results found sessions to average 60-70 minutes in length.

Location(s)
The COB-MS will take place in either a community setting or online, depending on allocation. The setting may vary per location but is planned to be a room in an MS Ireland centre. If this is not possible, then the budget allows for a community venue to be hired for the group intervention. Online sessions will use Zoom Workplace- this was found to be feasible and accepted in the feasibility trial. Each occupational therapist will run the COB-MS with approximately eight participants.

When and How Much?
There are eight COB-MS sessions which run over nine weeks. They are once-weekly, with the final session happening two weeks after the penultimate session. 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.

Tailoring
The intervention is planned to be personalised, 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. Participants can also personalise the intervention during one-to-one sessions with the occupational therapist. The intervention dose and content are the same for all participants, and regardless of online or in-person delivery.

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

Fidelity assessment
Key study considerations and actions are detailed in a study-specific checklist. Occupational

therapists will keep a record of the intervention session content, length and other important information such as participant attendance after each session.

Extent of intervention delivered as planned
This data will be captured in the study to allow for complete fidelity testing and future intervention implementation planning.

Usual care
It is expected that the risk of contamination will be low as cognitive rehabilitation is not standard care for patients with MS. As part of the feasibility work completed, a national survey identified what constitutes usual practice in Ireland in cognitive care for MS. We found that only 34% of health care professionals (HCP) screen for cognitive difficulties in practice, 36% provide information on cognition to patients, and 39% of HCPs do not refer elsewhere if difficulties are detected. HCPs placed high importance on cognitive intervention, but there appears to be very little consistency in cognitive assessment and treatment for people with MS. Importantly, findings from the UK and Ireland found that occupational therapists are the HCP mostly likely to assess and treat cognitive difficulties in MS.

Participants (across three arms) may be taking medication that affects cognition–e.g. benzodiazepine antispasmodics, anticholinergic agents. Participants will continue with the pharmacological intervention, but a record of this will be kept at each data point, and changes will be noted. This will be accounted for in the final analysis. All clinical services will be available as usual for the three study arms. Community and hospital-based occupational therapy will be monitored throughout the study, and a sensitivity analysis will be used to monitor the occupational therapy input received (if any) by participants. 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.

Intervention Type
Behavioural

Primary outcome(s)
1. Achievement of personalized patient goals measured using the Patient-Reported Outcome Measure Goal Attainment Scaling (GAS) at 12 weeks

2. The physical and psychological impact of MS on daily life measured using the Patient-Reported Outcome Measure, the Multiple Sclerosis Impact Scale (MSIS-29), at 12 weeks

Key secondary outcome(s)
1. Total number of correct substitutions measured using the Symbol Digit Modality Test at 12 weeks, 6 months and 12 months

2. Recall and Recognition Scores measured using the California Verbal Learning Test II at 12 weeks, 6 months and 12 months

3. Visual attention, processing speed, and executive function measured using Trail Making Test (time in seconds) at 12 weeks, 6 months and 12 months

4. Accuracy of recalling visual shapes in terms of location and identity measured using the Brief Visuospatial Memory Test-Revised at 12 weeks, 6 months and 12 months

5. Memory failures in everyday life measured using the Patient-Reported Outcome Measure the Everyday Memory Questionnaire at 12 weeks, 6 months and 12 months

6. Severity and frequency of the effect of fatigue on functioning measured using the Patient-Reported Outcome Measure the Modified Fatigue Impact Scale-5-item at 12 weeks, 6 months and 12 months

7. Perceived ability to handle challenges measured using the Patient-Reported Outcome Measure, Generalised Self-Efficacy Scale at 12 weeks, 6 months and 12 months

8. The presence and severity of depressive symptoms measured using Patient-Reported Outcome Measure, Patient Health Questionnaire (PHQ-9) at 12 weeks, 6 months and 12 months

9. Measure of health-related quality of life measured using the EQ-5D-5L at 12 weeks, 6 months and 12 months

10. Participants' service use and support needs measured using the Client Service Receipt Inventory (CSRI) at 12 weeks, 6 months and 12 months

Completion date
30/11/2029

Eligibility

Key inclusion criteria
1. Aged 18 years of age or older
2. Have a diagnosis of multiple sclerosis, consistent with the 2024 McDonald Criteria for the Diagnosis of Multiple Sclerosis
3, Have cognitive difficulties
4. Not currently undergoing any other form of cognitive rehabilitation
5. Fluent in written and spoken English,
6. Not experiencing an active relapse- clinically stable for three months
7. Can provide informed consent
8. Are a resident of the Republic of Ireland

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Significant cognitive impairment that would affect reliable participation or capacity to give informed consent
2. Significant diagnosed neurological condition or organic brain damage (unrelated to MS)

Date of first enrolment
31/03/2026

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
Ireland

Sponsor information

Organisation
Ollscoil na Gaillimhe – University of Galway

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type

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

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 5	09/03/2026	13/03/2026	No	No