Evaluating the feasibility and preliminary efficacy of a Cognitive Occupation-Based programme for people with Multiple Sclerosis (COB-MS): an update to the protocol for a feasibility cluster-randomised controlled trial.

Christopher P Dwyer  
National University of Ireland Galway: University of Galway

Alberto Alvarez-Iglesias  
Health Research Board Clinical Research Facility Galway: HRB Clinical Research Facility

Robert Joyce  
National University of Ireland Galway: University of Galway

Timothy J Counihan  
Galway University Hospitals

Dympna Casey  
National University of Ireland Galway School of Nursing and Midwifery

Sinéad M Hynes (✉ sinead.hynes@nuigalway.ie)  
National University of Ireland Galway  
https://orcid.org/0000-0002-3199-7355

Research Article

Keywords: multiple sclerosis, occupational therapy, cognitive occupation-based programme, cognitive rehabilitation, feasibility, protocol

Posted Date: December 14th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-2332061/v1

License: © This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License
Abstract

Background

Cognitive difficulties experienced by people with MS impact on quality of life and daily functioning, from childcare and work, to social and self-care activities. The COB-MS was developed as a holistic, individualised cognitive rehabilitation intervention to address the wide-ranging symptoms and functional difficulties that present in MS, including the ability to maintain employment, social activities, home management and self-care. The aim of the research is to evaluate the feasibility and preliminary efficacy of COB-MS for people with MS.

Methods

One hundred and twenty people with MS will be assigned to participate in either the COB-MS programme or a treatment as usual, wait-list control group as part of this single-blind, cluster-randomised controlled feasibility and preliminary efficacy trial of the COB-MS programme. The COB-MS group will participate in an eight session occupational-based cognitive rehabilitation programme over nine weeks. The primary outcome measure is the Goal Attainment Scaling at 12 weeks. Participants will be assessed pre-intervention, post-intervention, 12 weeks post-intervention and six months post-intervention. Qualitative evaluations of participants’ perspectives will also be examined as part of the feasibility study. Due to the impacts of COVID-19, all of the above trial activities were completed remotely. Data was collected online or by post and the COB-MS intervention was delivered online by occupational therapists to small groups of people with MS.

Discussion

Results will provide recommendations for a future definitive trial of COB-MS, with respect to both feasibility and preliminary, clinical efficacy.


Update

This update describes the amendments to the study that were made (and approved by Research Ethics Committee) due to the impact of COVID-19 pandemic. This update should be read in conjunction with the original published protocol [1].

The trial was halted for approximately six months from March 2020 to September 2020. Baseline data collection began in December 2019 and was stopped at the beginning of March 2020. Occupational
therapists were trained in person prior to the trial being halted. The COB-MS intervention delivery was planned to begin March 2020 but was halted. No participants had received the COB-MS intervention.

The research team worked with Public and Patient Involvement (PPI) Advisory Group and Trial Steering Committee to adapt the trial. The changes that took place are detailed below. The changes involved a full change from in-person to remote data collection and intervention delivery. All changes made to the protocol were approved by Galway University Hospitals on 04.09.2020 and University of Galway Research Ethics Committees 16.09.2020.

Method

Design

The original study design - single-blind, cluster randomised feasibility trial of the COB-MS programme - remained. Because of the change to online delivery of the COB-MS, the cluster design was no longer essential. The randomisation was, however, completed prior to the COVID-19 pandemic and the feasibility of this design was also being assessed through the trial and therefore no changes were made as a result of the pandemic.

Participants

Setting

The original study was setting's were participant's own homes and accessible community venues. There locations were to be used as locations to run the intervention and collect data. Following the arrival of COVID-19 in Ireland, no further in-person contact took place.

The research remains community-based and will be delivered online due to impact of COVID-19. Participants will link with the research team and occupational therapists from their own homes, but the COB-MS will be delivered online. Platform used will comply with Health Service Executive policy and standards and will be GDPR compliant and be in keeping with NUI Galway data protection policies – e.g Microsoft Teams, Attend Anywhere and “Zoom for Healthcare”.

Data will be collected in Ireland (online), and remotely via postal response booklets.

Recruitment

A number of the occupational therapists originally recruited to deliver the COB-MS intervention were redeployed because of the COVID-19 pandemic – for example occupational therapists had moved to positions in COVID-19 testing centres, or from community to hospital-based care. Other occupational therapists had significantly increased caseloads because they were covering larger caseloads due to redeployments and those who were unwell. These issues led to a withdrawal of some occupational therapists from the trial.
This meant that recruitment was re-opened for occupational therapists. Recruitment took place in the same way as originally planned and eligibility criteria remained the same with the exception of the requirement to deliver the COB-MS intervention online rather than i-person.

No further recruitment of participants with MS was necessary. The research team did, however, contact each participant enrolled into the trial to ensure that they wanted to continue participation following resumption and that they were able to participate online.

**Measures**

No changes were made to the outcomes collected or the associated timings. Baseline data that was collected in-person from participants prior to March 2020 will not be included in the final analysis given the timeframe that elapsed before intervention delivery (or control equivalent). All participants will be re-assessed remotely, as described below.

All data will be collected remotely. Self-report questionnaires will be completed by participants either on paper (and posted back using a self-addressed and stamped envelope) or online through Microsoft Forms. Other outcomes will be completed online or over the phone with participants.

Data collection sessions - Participants will be posted the response sheet booklets in advance of data collection session and complete the outcomes via video call in conjunction with the research assistant. The response sheet will be in a separate envelope not opened until instructed by the research assistant. Barcellos et al. [2] reported remote testing of SDMT and CVLT II to be equivalent and reliable for people with MS. We further tested this with other cognitive measures [3] and found this method of data collection to be equivalent.

**Interventions**

**COB-MS (Experimental) Condition**

The COB-MS was initially planned to take place in a community setting but this has moved online due to impact of COVID-19. Both individual and group session will take place online. All sessions (individual and group) will take place online. Both the participant and the occupational therapist will ensure that they have privacy for the session. This is especially important for the participants during the group sessions. Each occupational therapist will run the COB-MS with 5–6 participants. The group size has reduced to allow for online delivery (5–6 people per group) as suggested by the COB-MS PPI group.

Any occupational therapist who took part in an in-person COB-MS training day will have a refresher training online. All newly recruited occupational therapists will be trained online. All of the occupational therapists delivering the COB-MS will have access to training videos and material, as well as resources that can be used in the delivery of the online COB-MS sessions.

Participants with MS in the experimental group will receive a physical copy of the COB-MS handbook in the post.
Control Condition

No change was made to the control condition. All participants, regardless of their allocation, were contacted to reconfirm consent once the changes to delivery were explained. The control condition will be offered the intervention following the completion of data collection.

Statistical analysis

The statistical analysis plan remains unchanged from the initial protocol.

current status of the study

This adapted protocol was approved and implemented in September 2020. Data collection was completed November 2021. Trial result reporting is underway.

Abbreviations

COB-MS A Cognitive Occupation-Based programme for people with Multiple Sclerosis

MS Multiple sclerosis

PPI Public Patient Involvement

Declarations

Ethics approval and consent to participate

Ethical approval was provided by Galway University Hospitals on 04.09.2020 and University of Galway Research Ethics Committees 16.09.2020. All participants will take part in this study based on informed consent.

Consent for publication

All participants will take part in this study based on informed consent, in which they know their non-personalised data will be reported in published dissemination.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed for this protocol. Data and materials will be made available from the trial once completed and reported on.

Competing interests

The authors declare that they have no conflict of or competing interests to report.
**Funding**

The current study is funded by the Health Research Board (Ireland), under a Definitive Interventions and Feasibility Award (DIFA-FA-2018-027). Higher Education Authority Support for COVID-19 Related Research Costed Extensions supported RJ part-time for six-months.

**Authors’ contributions**

CPD was involved in the development of the study and the writing of the protocol. AAI was involved in the statistical aspects of the trial development and editing of the manuscript. RJ was involved in the PPI aspects of the trial development and editing of the manuscript. TC and DC were involved in trial development and editing of the manuscript. SMH developed the COB-MS, designed the study and wrote the extended study protocol and the update following the COVID-19 pandemic.

**Acknowledgements**

The authors would like to acknowledge the COB-MS PPI Advisory Group for their help in preparing the adaptation of this trial during the COVID-19 pandemic lock-down.

**References**

