A Cognitive Occupation-based Programme for People with Multiple Sclerosis: A Cluster Randomised Pilot Trial to Improve Cognition and Daily Functioning for People with Multiple Sclerosis

Participant Information

Thank you for taking the time to read this. You are invited to take part in a research study that will investigate the effects of the newly developed Cognitive Occupation-Based programme for people with multiple sclerosis (COB-MS), on both cognitive and daily functioning. Before you decide whether you would like to be part of this research study, it is important that you understand why we are conducting this research and what it will involve.

Background information

Approximately 50-60% of the 9,000 people in Ireland living with MS have difficulties with cognition, which impacts on their quality of life and daily functioning in wide-ranging occupations, from childcare and work, to social and self-care activities. Despite the high prevalence of cognitive difficulties for people living with MS, there is a lack of research on programmes developed to decrease these difficulties and their effects, while also supporting patients by helping them to function well in everyday life. COB-MS was developed with a focus on rehabilitation, through an individualised cognitive intervention, to address the wide-ranging symptoms and functional difficulties that present in MS, including the ability to maintain: employment, social activities, managing the home and self-care. The aim of this research is to evaluate both the feasibility and the preliminary effects of the programme on cognitive and daily functioning for people with MS. Thus, we are currently recruiting participants for this specially designed COB-MS research programme.

<u>You are eligible to take part in the COB-MS study if all the following are true:</u>

- You are aged 18 years or over;
- You are fluent in written and spoken English;
- You have a diagnosis of multiple sclerosis;
- You have cognitive difficulties;
- You have no neurologic history other than MS (e.g. dementia);
- You have no history of major depressive disorder, schizophrenia, or bipolar disorder I or II;
- You have no history of diagnosed substance use or dependence disorder;
- You are not currently undergoing any other form of cognitive rehabilitation;
- You are not currently experiencing an active relapse;
- You can provide informed consent;
- You are a resident of the Republic of Ireland;
- You are not living with cognitive impairment that would affect reliable participation or capacity to give informed consent;
- You are not incarcerated or institutionalized; and
- You are not living with significant neurological condition or organic brain damage (unrelated to MS).

The current research is funded by the Health Research Board, supported by MS Ireland and is conducted at the National University of Ireland, Galway. It received Ethical Approval by the HSE on xx/xx/xx.

What will happen if I volunteer to take part?

If you decide that you would like to take part in this study, first, you will be asked to provide informed consent, in light of the information being provided to you here. If you consent to take part, you will be contacted for a meeting at a venue that suits you (e.g. your home) and asked to complete a questionnaire about your health and how it affects you, as well as a short series of cognitive tasks. In the days following, you will be randomly allocated to one of two groups. One group will be invited to attend the COB-MS programme over a nine-week period, while the other group will not be invited to attend at that time. However, this second group will have access at a later stage, after the research aspect of the programme has been completed. The assignment of participants to the two groups will be processed automatically and completely at random. Regardless of group assignment, all participants will be asked to complete another questionnaire and set of cognitive tasks at the end of the 9 week programme, again, 12 weeks later and a fourth and final time, 6 months after the programme's end. The data collected will be compared between groups, across times, in order to maximise our ability to assess the feasibility and potential benefits of the programme. For more information on the randomisation and data comparison processes, please watch this video: xxx

The programme consists of eight 60-90 minute sessions, over a nine week period, with a qualified occupational therapist, focusing on: (1) 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; (2) recognising the impact of emotion, motivation and other non-cognitive functions; and (3) helping people meet their goals while managing their cognitive challenges. Specifically, two individual sessions will take place in your home or at a venue that suits you and will focus on goal-setting and personalising important aspects of the programme; and six group sessions will take place at a convenient location in the community (e.g. occupational therapist's office), focusing on cognition and its rehabilitation (e.g. memory, attention and decision-making), with emphasis on group discussion and learning. Participants will have opportunities to practice strategies during the sessions and at home.

A random selection of participants who took part in the programme will also be called for an interview regarding their experience of the programme and its acceptability. All collected data will be processed for the purpose of informing the preliminary effects of this programme and the feasibility of conducting this project on a larger scale. Specifically, data will be imputed to an electronic file and stored on an encrypted hard drive, where it will be analysed consistent with the objectives of this study. All hard copies of data will be kept and stored at NUIG in two separate locked cabinets. With respect to interview data, audio files will be transcribed into a written script and immediately destroyed thereafter. Consistent with NUI Galway and best practice guidelines, remaining research data are to be retained (consistent with the method described above) for 5 years before being destroyed. The data collected will only be used for this study. **All of the information with which you provide us will be kept anonymous, confidential and secure.**

Are there any risks or benefits of participating?

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.

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.

If you are interested in taking part or would like further information on this research, please contact us via email at cobms@nuigalway.ie or telephone 087 449 1154.

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