



***PPI in the COB-
MS Trial***

AN EMBEDDED PATIENT RESEARCHERS
EXPERIENCE

The Foundation



- Setup to Succeed
 - MS Society of Ireland
 - PPI Ignite
 - HRB
- Building Blocks
 - Trial Steering Committee
 - Trial Management Group
 - PPI Advisory Panel
 - Embedded Patient Researcher

Patient impact on the Study



- Scripting and recording videos for both participants and occupational therapists delivering the program.
- ★ Developing a Participant Information Sheet that will be used as part of a sub-study (SWAT) to assess whether a patient-designed information sheet works better than a researcher-designed one.
- Reducing and selecting outcome measures used in the trial.
- Helping train occupational therapists and research assistants on the needs of the patient.
- Developing a “Top tips” for occupational therapists who are delivering groups with people with MS.
- Presenting 5 Positive Outcomes of PPI at Public Health and Health Services Research Alliance Meeting.
- Advising on best locations to recruit participants and how to access some more difficult to recruit areas.
- ★ Being actively involved in the recruitment of participants with MS, including interviews with national and local print media and radio.

Patient impact on the Study



- ★ • Supporting development of the COB-MS participant manual.
- Contacting participants regarding delivery method change to online from face-to-face, in light of COVID-19.
- Developing a bi-monthly COB-MS Newsletter for program participants.
- Providing support with respect to interpreting qualitative data from program participants.
- Developing non-traditional means of dissemination to lay communities.
- Interviewing participants who completed the program with respect to its feasibility and acceptability, as well as their experience of the program.
- Writing Open Letter to HRB Open about reflections of PPI to promote PPI to researchers and encourage others to get involved in PPI.

Patient Information Sheet



COB-MS Information Leaflet



COB-MS

Supported By



We are conducting a study aiming to change these common situations:

From this:	The possible result:
"I am thinking of quitting my job, it has become overwhelming!"	"I have a SMART way of working now, I will stay in my job."
"Often, I will arrive in the kitchen and forget why I came."	"It (forgetting why I went somewhere) happens less frequently once I learned these new skills."
"The pub is too frantic for me, I cannot socialise anymore."	"I have found new ways to meet friends and chat. I don't miss out on the fun."

These are common situations faced by people with multiple sclerosis. They **may** signal that you have some cognitive problems, which has an impact on more than 50% of people with MS. The symptoms can have a direct impact on your work, social and home life.

This study will teach people, in a group setting, different techniques to manage the cognitive difficulties you encounter. Early, small scale studies in Ireland have shown the COB-MS programme may have a positive impact. Now we are looking to test the COB-MS on a larger group, approx 100 people with MS, to see if this early study result works with a larger group of people who have MS. If it is successful a much larger study will be conducted, perhaps internationally, to find out if this programme should be part of the treatment of cognitive difficulties for MS patients.

You are being invited to take part in a research study to be carried out in various locations throughout Ireland by Occupational Therapists.



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.

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

- 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.

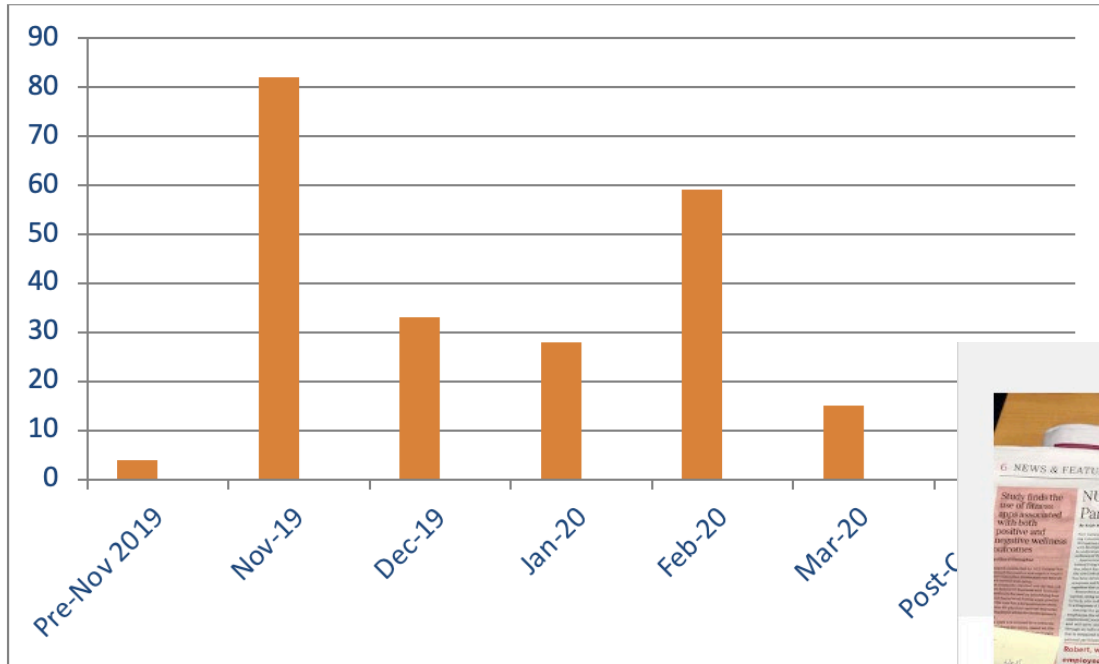
Patient Information Sheet



	Post-doc PIL	PPI PIL
Flesch Reading Ease	37 ('Difficult')	62 ('Plain English')
Reading Age (years) (11-12 is recommended)	18.4	14.5
Mean Sentence Length (15-20 words is recommended)	24	18.7
% Passive verbs (10% or at the most 20% is recommended)	32.5	21
Clear Communication Index (>90 is recommended)	46.7	71.4
Suitability Assessment of Materials	69%	80%



Recruitment



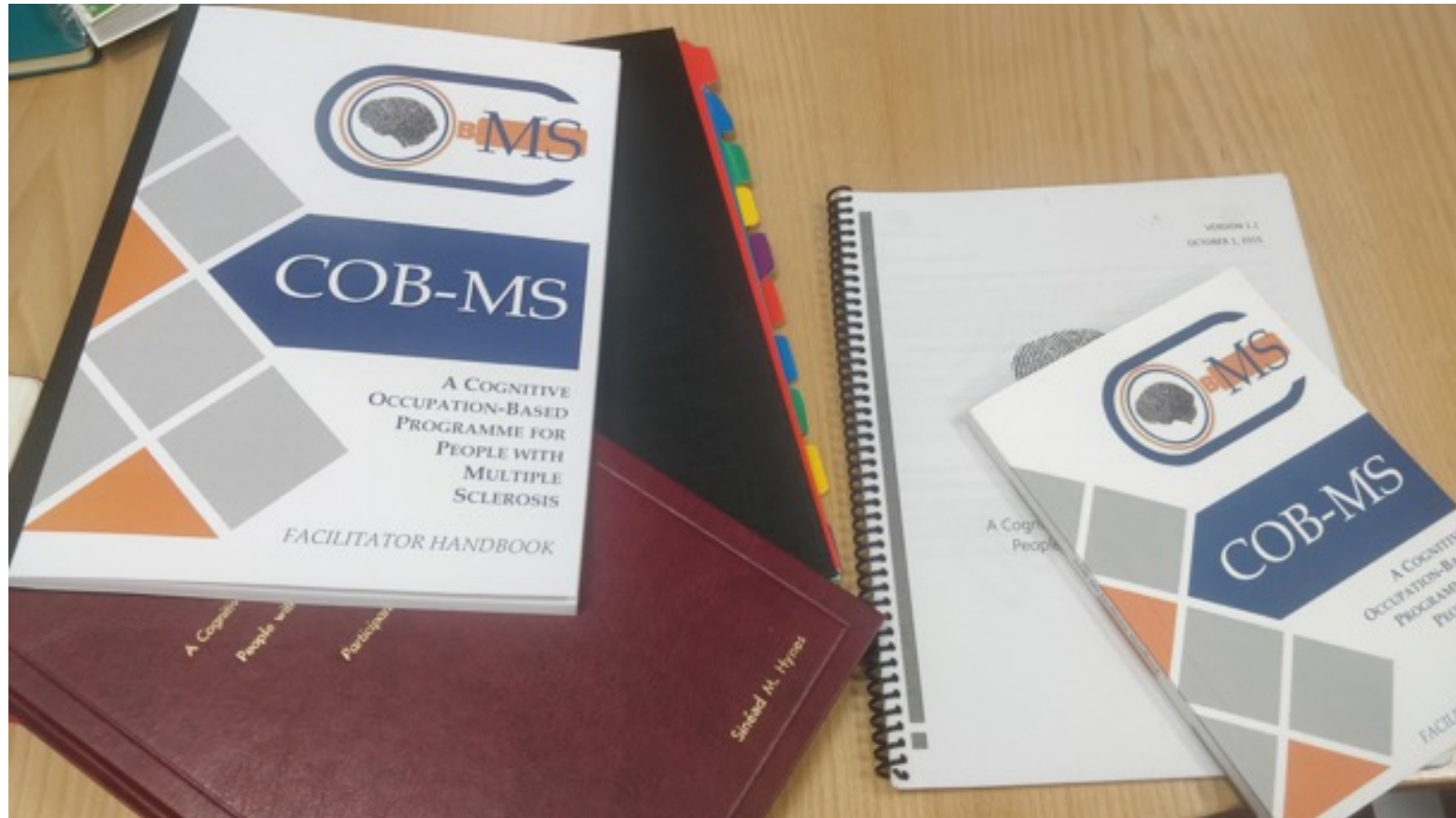
5 needed for MS trial
 "Donegal has the highest prevalence of MS compared with anywhere else in the country"
 BY CATHERINE COOK
 DONEGAL people living with Multiple Sclerosis (MS) are being sought to take part in a landmark study launched recently to help patients deal with cognitive difficulties and transform their lifestyles through the ability to remain in employment and manage their own care.
 The special NUI Galway study aims to tackle the problem with the research programme focusing the direct involvement of MS patients in its development.
 Speaking to the Donegal News, Researcher, Mr Robert Joyce who has



Farmer's Journal
 SIN (NUIG)
 Donegal News

- Useful approach for recruiting "underserved"(NIHR,2020) groups and increasing diversity of participants recruited to trials?

Participant Manual



Study Impact on the Patient



- Using a negative to create a positive
- Courage
- Optimism



The Team

