

## 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.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor).

Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part, it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

### **Why is this study being done?**

We know that 50%-60% of people with multiple sclerosis 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 your quality of life.

The study is exploring a new method of cognitive rehabilitation. Early small studies have shown the COB-MS technique looks promising and may help people with MS combat one symptom/aspect of their illness.

### **Why am I being asked to take part?**

You have been asked to take part in this study because you have Multiple Sclerosis. You can take part if you are:

- 1) aged 18 years of age or older,
- 2) fluent in written and spoken English,
- 3) have a diagnosis of multiple sclerosis.,
- 4) have cognitive difficulties.
- 5) are clinically stable, (We define "clinically stable" as not having an active relapse)
- 6) not currently undergoing any other form of cognitive rehabilitation,

Unfortunately, you cannot take part in this study if you have:

- 1) Significant neurological condition or organic brain damage (unrelated to MS).-

## What can I expect if I agree to take part?

Once all the participants have applied, 50% will be allocated to a waiting list, and the other 50% will progress into the main study. Once the study is complete the people on the wait list will also get to participate in the therapy. For more information on this processes, please watch this video: <https://youtu.be/xnmr1hz2L-c>

The therapy will have 5 phases.

Phase 1: A researcher will conduct various tests and interviews which will give the study information on what stage your illness is at and also the cognitive issues you feel as a result of Multiple Sclerosis. These tests will take approx. 90 mins and will take place in a location convenient for you.

Phase 2: You will be allocated an Occupational Therapist who will have an initial one on one meeting with you to discuss the goals you hope to achieve as a result of the study. This meeting will take about one hour and may be held in your home, or an office.

Phase 3: This stage consists of 6 group sessions with other participants in the study and your allocated OT. These sessions will last about one hour and will be in a central location. You will be learning new techniques at each session and the aim is for you to practice what you have learned at home and work.

Phase 4: You will have a wrap up meeting with the OT to discuss what you have learned in the study, and to find out if you have any benefit. This will take one hour and will be either in your home, or at the OT's office.

Phase 5: The researcher who tested you at the start will test your two more times, at 12 & 36 weeks after completion of the training, to see if there has been any measurable change in your cognition as a result of the methods you have been taught. These tests will take approx. 90 minutes and will take place in a location convenient for you.

Once the study is complete, we will give you the results. This will happen approximately 12 months after the final Phase 5 assessment.

If you are on the wait-list, this is what will happen:

Phase 1: A researcher will conduct various tests and interviews which will give the study information on what stage your illness is at and also the cognitive issues you feel as a result of Multiple Sclerosis.

Phase 2: The researcher who tested you at the start will test your two more times, at 12 & 36 weeks after the test in Phase 1, to see if there has been any measurable change in your cognition over time. These tests will take 90 mins-two hours and will take place in a location convenient for you.

**Phase 3:** You will be allocated an Occupational Therapist who will have an initial one on one meeting with you to discuss the goals you hope to achieve as a result of the study. This meeting will take one hour and may be held in your home, or an office.

**Phase 4:** This stage consists of 6 group sessions with other participants in the study and your allocated OT. These sessions will last about one hour and will be in a central location. You will be learning new techniques at each session and the aim is for you to practice what you have learned at home and work.

**Phase 5:** You will have a wrap up meeting with the OT to discuss what you have learned in the study, and to find out if you have any benefit. This will take one hour and will be either in your home, or at the OT's office.

### **What if I do not want to take part?**

You are free to decline to take part in this study. You are free to start the study and then withdraw at any time.

In the event you do decide to withdraw, it would be helpful for us to know why you have stopped participating.

### **What are the benefits for me in taking part?**

1. You will be contributing to new research in the area of cognitive therapy for PwMS.
2. The therapy might benefit you at work and at home.
3. You will be contributing to a greater understanding of effective therapies for cognition for PwMS.
4. You will be helping other PwMS.

### **What are the risks?**

There are several potential risks in taking part in this study. They are:

- **Lost time:** If the therapy doesn't help you, or you are on the wait list, then the time spent on the study could be of no benefit to you.
- **Energy cost:** Fatigue is a common symptom of MS and participating in the study will use energy you could use for some other purpose.
- **No benefit:** The therapy doesn't work for you
- **Financial cost:** The location of the sessions could be some distance from where you live and the cost of getting to the sessions will not be reimbursed by the study.
- **Confidentiality:** See next page on "confidentiality".

### **Where can I get further information?**

If you are interested in taking part or would like further information on this research, please contact us via email at [cobms@nuigalway.ie](mailto:cobms@nuigalway.ie) or telephone 0874491154.