Participant Information Leaflet

Cognitive Rehabilitation for Attention and Memory in Multiple Sclerosis
CRAMMS

You are invited to take part in our research study

- It is important you understand why the research is being done and what it will involve for you if you decide to take part.
- Please take time to read this information. Talk to others if you wish, and ask if you would like more information.
- You are free to decide whether or not to take part in this study. If you agree to take part, you are free to withdraw at any time without giving a reason. If you choose not to take part, your care will continue in the normal way.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- People with MS and who have attention and memory problems currently only receive advice (usual care).
- We want to find out whether attending a group cognitive rehabilitation programme in addition to usual care is helpful for people with MS to deal with their attention and memory problems.
- If you agree to take part you will receive either the group rehabilitation treatment plus usual care or the usual care only.
- If you are to receive group rehabilitation you will need to be available for 10 group treatment sessions over approximately 10 weeks.
- There will be 4 to 6 people in the each rehabilitation group.
- Everyone taking part will be followed-up for 12 months.
- When you join the study we will ask you to complete short questionnaires and tests. We will repeat some of these during follow-up.
- You have the option to take part in feedback interviews later to tell us about your experience.

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How to contact us

Contact details of your local Assistant Psychologist

[INSERT CONTACT DETAILS HERE]

1. What is the purpose of the study?

Many people with MS experience problems with attention, concentration and memory. They may be offered advice on how to cope with these problems. Cognitive rehabilitation is a structured approach to deal with these problems. The aim of this study is to compare group cognitive rehabilitation programme with usual clinical care. We will assess the usefulness of the rehabilitation in reducing memory and attention problems and what it would cost to deliver this programme in the NHS.

2. Why have I been invited?

You are being invited to take part because you have MS. We are asking people with MS whether they have attention or memory problems in order to find 400 patients willing to take part in the study.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

4. What will happen if I take part?

An assistant psychologist will speak with you by telephone and arrange an appointment. At the first visit the assistant psychologist will explain the study, and ask for your consent to do some initial assessments. These initial assessments are needed to check whether you fulfil all the criteria to take part in the study. This first appointment will take approximately one and a half hours. If you meet the criteria the assistant psychologist will arrange a second appointment. If the results show that you are not suitable for the study, we will let you know by letter and include a brief report of the test results, if you would like one.

Before the second appointment, you will be sent questionnaires to complete at home. The time you require to complete the questionnaires is around 30 minutes. You will need to bring these with you to the second appointment. During this visit you will be given some tasks to complete with the assistant psychologist and also some more questionnaires. This second visit, called the baseline visit, will take approximately one and a half hours.

The assistant psychologist will check when you are available for group cognitive rehabilitation sessions, in case you are allocated to that treatment. The sessions will take place in the hospital or in a community location more local to you.

It may take a little while to have enough people so your assistant psychologist will be in regular contact with you during that time.

When enough participants have been found, each participant will be allocated to receive either group cognitive rehabilitation sessions plus usual care or usual care only. This allocation will be done by a computer and is called randomisation. Neither you nor the assistant psychologist will be able to choose your treatment.

If you are in the usual clinical care group then you will not have to do anything else until your 6 month follow-up appointment. If you are in the cognitive rehabilitation group you will be invited to attend 10 therapy sessions lasting about 1.5 hours which will take place over about 10 weeks and are led by an assistant psychologist.

Some group sessions will be video recorded to check the delivery of the sessions and to understand the effective components of the treatment. If you have an objection to being

seen in the video you can indicate this on the consent form and we will take this into consideration when setting up the camera. However, your voice will still be recorded but we will not use personal information, other than your first name, when talking to you during the sessions. If the treatment is found to be effective we may also use the video as training material for rehabilitation services in the future.

Irrespective of the group you have been allocated to you will have follow-up visits at 6 and 12 months after your randomisation. These last approximately one and a half hours each. A few weeks before each appointment we will send you an appointment reminder. This will also include questionnaires to complete before your appointment. The time you require to complete the questionnaires is around 30 minutes.

At the follow-up appointments you will meet a member of the research team, a research psychologist, who will do the assessments. It is important that this researcher does not know to which group you were randomised, so you will be asked not to discuss your treatment with them.

You will be reimbursed for any reasonable travel expenses you have to make to attend the appointments.

We would also like to hold feedback interviews with some participants from each group. This will give us information about your view of the intervention and current care. The interviews will take place within about three months of the 6 month appointment and will be audio recorded. The interviews will take place in a location convenient you. They will last approximately 1 hour. We may contact you to take part in these interviews, unless you have indicated on the consent form that you prefer that we do not.

With your permission, we will contact your GP to inform them that you are taking part in this study.

5. What are the possible disadvantages and risks of taking part?

There are no particular risks involved in taking part in this study.

6. What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help us to treat people with MS and attention and memory problems better in future.

7. What happens when the research stops?

When the study ends your healthcare will continue as before you took part in the study.

If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal.

8. What if there is a problem?

If you have concerns or questions about any aspect of this study, you should ask to speak to the local researchers. Their contact details are at the front of this sheet.

If any questions remain you can contact the main investigators of this study:

Professor Nadina Lincoln or Dr Roshan das Nair (Nadina.lincoln@nottingham.ac.uk or roshan.nair@nottingham.ac.uk)

The CRAMMS Trial Manager at the Nottingham Clinical Trials Unit, Tel: 0115 88449XX, Email: cramms@nottingham.ac.uk

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via the hospital's Patient Advisory and Liaison Service (PALS) [Local PALS details to be added].

In the event that something does go wrong and you are harmed during the study, there

are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you have grounds for a legal action for compensation but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

9. Will my taking part be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some of the data collected for the study may be looked at by authorised persons from the University of Nottingham who are organising the research They may also be looked at by authorised people to check that the study is carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential,** stored in a secure and locked office, and on a password protected database Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it. Your personal contact details will be sent to the Nottingham Clinical Trials Unit (NCTU) so they can send you questionnaires by post.

You will be asked to consent to your identifiable details being registered with the Health and Social Care Information Centre (HSCIC)). These may be used to help us keep in touch with you and follow up your health status. We will have confidentiality and security agreements in place to ensure your details are dealt with in the strictest confidence.

Your personal data (address, telephone number) will be kept after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

10. What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

11. What will happen to the results of the research study?

We plan to publish the results of this study in a scientific journal. However, you will not be identified in any publication. If you wish, we can send you a summary of the study results.

12. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by NRES Committee West Midlands – South Birmingham Research Ethics Committee.

Thank you for reading this leaflet