**Participant Information Sheet (PIS)**

***ANOMIA IN PEOPLE WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (MS)***

***(Phase I)***

This information sheet provides details about the project *“Investigating anomia in people with Relapsing-Remitting Multiple Sclerosis (MS)”*. This study is part of a doctoral degree being undertaken by Erika P. Cordova Luna at the School of Biological Sciences, University of Manchester.

We would like to invite you to participate in this project. It is important for you to understand this information where you will find about what the study is and what it involves before you decide to participate in the research.

Please read the following information about the study carefully and take the time to decide whether or not you wish to take part in the research. Ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

The study is carried out as an educational project. It is designed to help us understand the nature and extent of anomia (difficulties retrieving words) experienced by many people with MS. We are also interested in knowing how the symptoms of anomia affect MS patients’ everyday functioning, and if a simple language therapy can affect the accuracy and efficiency of word retrieval. Understanding these issues is important if we are to develop more effective communication treatments.

**Why have I been invited to take part in this study?**

You have been invited to join our project because you have Multiple Sclerosis. We will need 50 people to take part in this project.

To take part in the study, we are looking for people who are:

- Adults (>18 years old)

- Diagnosis of Relapsing-Remitting Multiple Sclerosis

- Native English speakers

- Have access to a laptop/tablet/PC to take part in treatment and homework exercises

- Do not have any metal implant in your body

**Do I have to take part?**

No, you do not have to take part in the study if you do not want to. Taking part in the research is voluntary; this means it is completely up to you to decide whether or not to join the study. Your decision to participate in this study will not be connected to the care you are receiving now or in the future. If you decide to take part and sign the consent form but change your mind later, you are free to withdraw at any point during the study without giving a reason and without any consequence to your current or future treatment.

**What will participation involve?**

If you are interested in taking part in this study you will first have an interview at the out-patient clinic after your appointment or at any time/date convenient for you with the researcher Erika Cordova Luna. There she will ask you to provide some information about you, such as age, education, handedness and your medical history (time of diagnosis). The research team will also access some sections of your medical history to confirm relevant information for the study. Then we will carry out some pen and paper tasks involving thinking skills. We will test your memory, attention and will ask you to generate a list of words, follow verbal instructions and write sentences. There will also be a picture naming task using a laptop in which you will name objects which appear on the screen. The testing will last up for 90 minutes. Although if you get tired we can take 10 minutes breaks or divide the tasks into two assessment sessions at a date/time convenient for you. The researcher Erika Cordova Luna will write down your responses and also take an audio recording of what you say, for later analysis.

The initial testing you complete will also provide us with some information regarding if you meet our criteria to take further part in the Phase II of the study. We will then contact you and ask you to participate in the follow-up study, we will need 25 participants. Please note that after completion of the first assessments, you are under no obligation to take further part in the study if you do not wish to do so.

The follow up study consists on a various cognitive assessments (more pen and paper thinking tasks) at your home which will take up to 4 hours and can be divided into 2 or 3 different sessions with 10 minutes breaks to avoid you feeling tired. Also we will invite you to the Manchester Royal Infirmary to take a magnetic scan of your brain taking up to 70 min. Finally, we will give you a computer based language therapy consisting of 4 weekly pre-therapy testing, 10 weekly therapy sessions, with a 6 weeks gap and 2 weekly post-therapy testing sessions. Each therapy session will last an hour. Therapy sessions can be at your home at a date/time convenient for you.

The therapy is aimed to improve your word retrieval skills. However we are unsure of whether or not this system can do this. Please refer to the Participant Information Sheet (Phase II) for further information.

**What are the possible disadvantages and risks of taking part?**

The study involves testing many different thinking skills. Some people might find some of these tasks boring, uncomfortable or become frustrated when trying to solve them, but that feeling will go away once the task stops and will have no long term impact. You will be free to stop at any point if you wish to do so.

**What are the possible benefits of taking part?**

Some people may find taking part in the research interesting, satisfactory and enjoyable.

The research probably will not have direct benefits for you personally, but the information we get might help us understand anomia in MS more fully leading to a better treatment in the future. Finally, we are happy to provide full information about the results of the study in which you took part, so that you can be informed of any methods that proved especially helpful. If you would like a copy of the research findings, please let the researcher know, and we will arrange for a copy of the final written report to be sent to you as soon as it is available.

**Will my taking part in the study be kept confidential?**

Yes. Information which is collected about you during the course of the research, including audio recordings, your answers to questionnaires and computer based tasks, will be kept strictly confidential. The information you provide will be anonymised. This means, your data will be given a unique ID so no one can identify you. These data will be stored securely at the University of Manchester in either a locked filing cabinet or storage facility if in paper format, or on a password protected computer if in electronic format, all in anonymised form. Records will be destroyed at the end of the study. Direct quotes may be used in the write-up of the study, but will be used in such a way so as not to reveal the identity of individuals. Data from the study will be kept for up to 10 years after the date of any publication which is based upon it, to follow recommended good practice guidelines for research.

This information will only be seen by members of the research team. Although, individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data, but all individuals involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

**What will happen if I do not want to carry on with the study?**

You can withdraw from the study completely at any time without giving a reason and without any consequence to your current or future treatment. No further data will be collected from the moment you withdraw. Also, in the unlikely event of a loss of capacity in the duration of the study no further clinical interventions or procedures would be carried out. No new personal data would be collected. However, data already collected may be retained and used for the purposes for which consent has already been given. That information would already be anonymised.

**What if there is a problem?**

It is unlikely that anything will go wrong. However, if you have a concern about any aspect of this study, you should ask to speak to the Chief Investigator:

Dr Paul Conroy, School of Biological Sciences, Zochonis Building, University of Manchester, Oxford Road, Manchester. M13 9PL, by emailing: [**paul.conroy@manchester.ac.uk**](mailto:paul.conroy@manchester.ac.uk) or by telephoning **0161 2752693.** Dr Conroy will do his best to answer your questions.

If we are unable to resolve your concern or you wish to make a formal complaint regarding the study, please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [**research.complaints@manchester.ac.uk**](mailto:research.complaints@manchester.ac.uk)  or by telephoning **0161 275 2674 or 275 2046.**

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**What will happen to the results of the research study?**

The findings will be published as part of a doctoral degree; they may also be published in peer-reviewed journals or presented in conferences. All the participants’ information will be anonymised and there will be no participant details. Also a copy of your consent form will be kept in your medical record. You will not get individual results of the assessments. The assessments are being carried out for research purposes and have limited clinical implications. We will retain your contact details until the end of the study, to send you a lay summary of the study results.

**Who has reviewed the study?**

All research which involves NHS patients has to be reviewed by the National Health Service Research Ethics Committee (REC). This study has been reviewed and approved by the North East - Newcastle & North Tyneside 2 Research Ethics Committee (Ref: 17/NE/0242). The study has also been reviewed by the School of Biological Sciences. This study is sponsored by The University of Manchester.

**Who can I contact for further information?**

If you have any questions or require any additional information, please do not hesitate to contact the Chief Investigator: **Dr Paul Conroy**, School of Biological Sciences, Zochonis Building, University of Manchester, Oxford Road, Manchester. M13 9PL, by emailing: [**paul.conroy@manchester.ac.uk**](mailto:paul.conroy@manchester.ac.uk) or by telephoning **0161 2752693.**

**Participant Information Sheet (PIS)**

***ANOMIA IN PEOPLE WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (MS)***

***(Phase II)***

This information sheet provides details about the project *“Investigating anomia in people with Relapsing-Remitting Multiple Sclerosis (MS)”*. This study is part of a doctoral degree being undertaken by Erika P. Cordova Luna at the School of Biological Sciences, University of Manchester.

We would like to invite you to participate in this project. It is important for you to understand this information where you will find about what the study is and what it involves before you decide to participate in the research.

Please read the following information about the study carefully and take the time to decide whether or not you wish to take part in the research. Ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

The study is carried out as an educational project. It aims is to investigate the nature and extent of anomia (difficulties retrieving words) experienced by many people with MS. We are also interested in knowing how the symptoms of anomia affect MS patients’ everyday functioning, and if a simple therapy can affect the accuracy and efficiency of word retrieval.

**Why have I been invited to take part in this study?**

You have been invited for a follow-up of our project because you met our criteria of participation based on the results of the phase I. We will need 25 people to take part in this project.

**Do I have to take part?**

No, you do not have to take part in the study if you do not want to. Taking part in the research is voluntary; this means it is completely up to you to decide whether or not to join the study. Your decision to participate in this study will not be connected to the care you are receiving now or in the future. If you decide to take part and sign the consent form but change your mind later, you are free to withdraw at any point during the study without giving a reason and without any consequence to your current or future treatment.

**What will participation involve?**

The study will involve different pen and paper tasks. These tasks will measure cognitive functions such as attention, memory, reasoning and language. The assessment takes 2-4 hours divided in different sessions. In each session we can take as many breaks (up to 10 minutes each break) as you want if you get tired. The sessions can be at your home and the researcher Erika Cordova will be visiting you on the day and time that better suit you.

Later, we will invite you to come to the Manchester Royal Infirmary to take a scan of your brain. You will be asked some questions before the scan to make sure it is safe for you. However, if you have any metal in your body or you think you might be pregnant, you will not be able to participate. This is a painless and, as far as it is known at present, an extremely safe procedure and does not involve the use of x-rays procedure. It will take up to 70 minutes. The researcher Erika Cordova will be briefing you before the scan and the radiographer will be performing the examination. All your travel expenses will be refunded.

Finally, you will be asked to take 4 weekly pre-therapy testing, 10 weekly therapy sessions, 2 weekly post-therapy testing with a 6 weeks gap and 2 weekly post-therapy follow-up sessions. Overall, testing and training in this phase will occur over 24 weeks. The training will consist of using a computer programme which we will provide in any technological device you own (such as computer, tablet or laptop). The programme will generate specific target words that we hope will improve naming accuracy. However we are unsure of whether or not this system can do this. Therapy will take place at your home on the day and time that better suit you. Each therapy session will last an hour and will be directed by the researcher Erika Cordova Luna.

**What are the possible disadvantages and risks of taking part?**

There may be a risk for some people of becoming bored or frustrated by taking part when assessing the cognitive functions or while in therapy, but that feeling will go away once the task stops and will have no long term impact. You will be free to stop at any point if you wish to do so.

You also may find the Magnetic Resonance Imaging (MRI) scan machine very noisy, or feel uncomfortable. Ear protection such as noise cancelling headphones will be provided and pillows to ensure you are as comfortable as you can. If you have any metal inside your body or you think you are pregnant you will not be able to participate.

**What are the possible benefits of taking part?**

Some people may find taking part in the research interesting, satisfactory and enjoyable.

We cannot promise the research will help you personally, but the information we get might help us understand anomia in MS more fully leading a better treatment in the future.

**Will my taking part in the study be kept confidential?**

Yes. Information which is collected about you during the course of the research, including audio recordings, your answers to questionnaires and computer based tasks, will be kept strictly confidential. The information you provide will be anonymised. This means, your data will be given a unique ID so no one can identify you. These data will be stored securely at the University of Manchester in either a locked filing cabinet or storage facility if in paper format, or on a password protected computer if in electronic format, all in anonymised form. Records will be destroyed at the end of the study. Direct quotes may be used in the write-up of the study, but will be used in such a way so as not to reveal the identity of individuals. Data from the study will be kept for up to 10 years after the date of any publication which is based upon it, to follow recommended good practice guidelines for research.

This information will only be seen by members of the research team. Although, individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data, but all individuals involved in auditing and monitoring the study, will have a strict duty of confidentiality to you as a research participant.

**What will happen if I do not want to carry on with the study?**

You can withdraw from the study completely at any time without giving a reason and without any consequence to your current or future treatment. No further data will be collected from the moment you withdraw. Also, in the unlikely event of a loss of capacity in the duration of the study no further clinical interventions or procedures would be carried out. No new personal data would be collected. However, data already collected may be retained and used for the purposes for which consent has already been given. That information would already be anonymised.

**What if there is a problem?**

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**What will happen to the results of the research study?**

The findings will be published as part of a doctoral degree; they may also be published in peer-reviewed journals or presented in conferences. All the participants’ information will be anonymised and there will be no participant details. A copy of your consent form will be kept in your medical record. In the event of an incidental finding on the scan, if you agree, we will contact you and your neurologist to communicate the findings. You will not get individual results of the assessments. The assessments are being carried out for research purposes and have limited clinical implications. We will retain your contact details until the end of the study, to send you a lay summary of the study results.

**Who has reviewed the study?**

All research which involves NHS patients has to be reviewed by the National Health Service Research Ethics Committee (REC). This study has been reviewed and approved by the North East - Newcastle & North Tyneside 2 Research Ethics Committee (Ref: 17/NE/0242). The study has also been reviewed by the School of Biological Sciences. This study is sponsored by The University of Manchester.

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