PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide if you would like to participate, it is important that you understand why the study is being carried out and what it will involve. This Participant Information Sheet aims to inform you about the purpose, procedure, as well as any potential risks and benefits of this study. Please read it carefully. If you agree to take part, you will be asked to sign a consent form and it is important that prior to doing so you fully understand and are comfortable with what is being asked of you. If there is anything you are unclear about we are more than happy to explain it to you. Please take your time in making your decision. We would like to thank you in advance for reading through this Information Sheet and for considering being involved in our research.

Study background

Electroconvulsive therapy (ECT) is a medically safe procedure in which small electric charges are passed through the brain triggering a brief seizure. ECT is the most effective treatment available for severe depression; a pervasive and often life-threatening mental illness. However, its use is limited by the cognitive side-effects associated with the treatment, the most significant of which is retrograde autobiographical amnesia. This refers to deficits regarding personal memories about one’s own life acquired in the past. It is not known however, how much of the memory difficulties experienced by patients undergoing ECT can be accounted for by the experience of low mood, nor the habitual passage of time. Without such information it is not possible to know precisely how ECT affects memory, improve the treatment so as to minimise cognitive side effects, nor design interventions to target any persisting deficits.

The purpose of this study

The purpose of this study is to investigate the extent and nature of memory deficits associated with ECT. To achieve this, autobiographical memory function will be compared between healthy participants and two groups of depressed participants; those who are, and those who are not receiving ECT. This will provide valuable information on whether or not the treatment of ECT causes memory deficits beyond those caused by clinical depression and the passage of time. Not only would such information increase our understanding of the mechanisms of memory, depression and ECT, but it could also lead to improvements in the treatment of severe depression. Given the continuous growth of depression worldwide, this is a task of critical urgency.
**Why have I been chosen?**

You have been asked to participate in this study as a healthy volunteer. In this study we are hoping to compare the scores on a series of assessments between those who like yourself, are healthy, with those who are depressed and are receiving ECT and those who are depressed but are treated by other means. The information your scores would provide, should you agree to participate, would enable a better understanding of the mechanisms of memory and how it is affected by time, depression and its treatment. This could help improve the treatment available for depression and ensure that any cognitive difficulties experienced subsequently are not left untreated.

**Do I have to take part?**

It is entirely up to you to decide whether or not to take part in this study. If you do decide to take part, you will be given this Information Sheet to keep as well as a copy of your Consent Form. **Please note that you can withdraw your participation at any point of this study without giving a reason.** You may also request that any data you have supplied be withdrawn or destroyed up until the point of publication. Please be aware that such decisions will be without punishment and will not affect your rights.

**What will happen if I decide to take part?**

If you agree to help us, you will be asked to complete a series of assessments with a trained member of our clinical research team. The assessments will occur at three time points; at the beginning of your inpatient treatment, then at one month and four months following your initial assessment. Therefore, the total duration of your participation in our study from your first to last appointment will be four months.

The assessments will contain tests aimed to measure aspects of your mood, cognitive ability and memory. Completing assessments at set time points will allow us to track changes in function over time and enable comparison of any changes between the tree study groups.

The assessments will take place at St. Patrick’s Mental Health Services. These will be arranged to be at a time that best suits you, and you will receive a reminder of each in advance. Your initial meeting with the team will be the longest, lasting approximately 1 hour and 30 minutes. The two subsequent meetings will last no longer than 1 hour.

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

Although taking part in the study will not benefit you directly, the information you provide will contribute to scientific knowledge on depression. Furthermore, the results of the study are hoped to inform further research with the ultimate aim of improving available treatment and the quality of life of depressed individuals and their families.

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

Although this study carries no physical risks, we appreciate that completing assessments may induce tiredness or distress for some participants. Every attempt will be made to minimize any negative psychological effects experienced during your participation. Details of support services in case of any distress caused will be provided, should you wish to use them. Furthermore, you will be encouraged to take as many breaks as needed when completing the
assessments. The necessity of returning to St Patrick’s for follow up assessments may also cause inconvenience. We will ensure that these are arranged at a time that suits you best and reimbursement for travel costs will be available.

**Will my taking part be confidential?**

Yes. All of the information gathered about you during the course of this study will be kept strictly confidential. Your data will be stored using a unique participant protocol number, and as such, your personal details (i.e. name or address) will not be attached to any information you provide during the course of this study. All of your data will be protected using encrypted software and will be held solely by the research team. The only circumstance in which confidentiality cannot be guaranteed is where evidence exists that there is a serious risk of harm or danger to either you or another individual or where disclosure is required as part of a legal process or Garda investigation. In such instances, information may be disclosed to significant others or appropriate third parties without permission being sought. Where possible, you will be provided with a full explanation regarding necessary procedures and intended actions.

**What happens at the end of the study?**

The results of the study will be presented at conferences and published in scientific journals. The identity of people who have taken part will always be kept strictly confidential. Under the Freedom of Information Act (2014), the data compiled from this study will be stored securely for a period of 10 years, after which, it will be destroyed in accordance with the data protection legislation at the time. As is common research practice, during this period the data gathered may be re-analysed to inform other arising research questions. You may also request access to your own data during this period.

**Permission**

This study is being carried out with the full support of St Patrick’s Mental Health Services and Trinity College Dublin and has been approved by their respective ethical committees. Should you agree to take part, your consultant and GP will also be informed of your participation.

**Further Information**

If you have any questions about the study, please do not hesitate to contact theamberstudy@gmail.com. Additionally, you may contact the principle investigator and supervisor of the study Professor Declan McLoughlin using the contact details listed below.

Address: Department of Psychiatry, Trinity College Dublin, St Patrick’s University Hospital, James’s Street, Dublin 8
Phone: 01 2493385
Email: d.mcloughlin@tcd.ie

Thank you for taking the time to read this Participant Information Sheet

The AMBER-Dep Research Team