WESTERN SYDNEY UNIVERSITY

Participant Information Sheet (General)

Project Title: Investigating the neural substrates of the cognitive deficits in Mild Cognitive Impairment

Who is carrying out the study?

Dr Genevieve Steiner, Ph: (02) 4620 3708, Email: G.Steiner@westernsydney.edu.au
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You are invited to participate in this study being conducted by Dr Genevieve Steiner, Research Officer, National Institute of Complementary Medicine, Western Sydney University, Campbelltown Campus.

What is the study about?

This project aims to increase our knowledge of the brain activity that relates to the problems with memory and thinking that occur in Mild Cognitive Impairment (MCI). This is important for understanding the disease and how it works (basic science), as well as for the development of targeted treatments (translational research). This project will compare the brain activity of 32 people with MCI and 32 age-matched healthy people.

What does the study involve?

If you decide to participate in this project, you will be asked to attend a screening session which involves completing a Participation Consent Form, a questionnaire on your general health, a brief cognitive test, and a brief test on depression. If you have MCI, then we also need a close family member or friend (e.g., spouse, sibling, child over 18 years old) to confirm that you have been experiencing problems with cognition either during the screening session or beforehand on the telephone or via email.

The screening session will be followed by 2 separate testing sessions that take approximately 2-3 hours each. One testing session will require you to complete a battery of pen-and-paper cognitive tests administered by the researcher. These tests are designed to assess your attention/processing speed, memory, language, visuospatial skills, and executive function.

The other testing session will take place on a separate day, approximately 1 week later, and involves the completion of a series of computerised cognitive tests whilst having your brain activity (electroencephalograph, EEG) recorded. You will be fitted with an electrode cap that will be used to record your brain activity from your scalp. Four electrodes will also be fitted to your face, to monitor eye movements, one on your nose, and one on each ear for reference points. A small amount (10 mls) of gel is used to fill the electrodes, the gel is harmless, and brushes out of the hair as soon as it is dry. Tissues and baby wipes are available to clean around the eyes. You will be seated in an air-conditioned testing booth. The experiment involves the recording of ongoing brain waves during a series of tasks in which you will hear a series of sounds, see a series of picture, letters, or numbers, and asked to respond by pressing a button. The tasks are similar to the pen-and-paper cognitive tests and also designed to test

your attention/processing speed, memory, language, visuospatial skills, and executive function. Because of their brevity, test results will not be an accurate index of cognitive abilities, and will therefore not be communicated to you. The entire procedure is expected to take approximately 6 hours over the two testing sessions.

How much time will the study take?

The study will take approximately 1 week to complete, consisting of a screening interview, followed by two testing sessions on separate days approximately 2-3 hours in duration, and 1 week apart.

Will the study benefit me?

Although you will not receive any direct personal benefits for participating in the study, this research project has the potential to increase our understanding of the changes in the brain that occur with Mild Cognitive Impairment (MCI). This work may lead to new knowledge which could assist in the development of targeted treatments for people with MCI. You will not be out of pocket for your involvement in this research as you will be reimbursed $30 for your travel expenses to-and-from the testing site at the Western Sydney University, Campbelltown Campus.

Will the study involve any discomfort for me?

EEG is non-invasive research, so there is very minimal discomfort involved. It is possible that there may be a very small amount of discomfort when the electrode cap is fitted on your head. The researcher will do everything possible to ensure that this experience is as comfortable for you as possible. This will be done by ensuring that your cap is the correct size, and the researcher will check with you throughout the experiment to ensure that the cap remains comfortable.

How is this study being paid for?

The study is being sponsored by the National Institute of Complementary Medicine at the Western Sydney University.

Will anyone else know the results? How will the results be disseminated?

All aspects of the study, including results, will be confidential and only the researchers will have access to information on participants. The data collected from you and other participants will be stored with a participant code and there will be no identifiable information recorded, apart from age and sex, to ensure your confidentiality is maintained. A range of analyses will be conducted on the de-identified data, and the results of these examinations may be published in *academic journals* and/or discussed/ displayed in *conference presentations*. In any case, only group information and trends will be presented. No reference will ever be made to individual results, or individual participants.

Can I withdraw from the study?

Participation is entirely voluntary: you are not obliged to be involved and - if you do participate - you can withdraw at any time without giving any reason and without any consequences. If you decide to withdraw from the study, your data will be destroyed and not used for any purpose.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them with the chief investigator's contact details. They can contact the chief investigator to discuss their participation in the research project and obtain an information sheet.

What if I require further information?

When you have read this information, Dr Steiner will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, or you require further support upon completion of the study, please feel free to contact Dr Steiner via email: or telephone: (02) 4620 3708.

What if I have a complaint?

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H11152.

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through the Office of Research Services on Tel 02-4736 0883 Fax 02-4736 0013 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form.