THE UNIVERSITY OF SYDNEY

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Prof. Michael Valenzuela
Leader, Regenerative Neuroscience Group

Computerised Cognitive Training for Mild Cognitive Impairment with Sleep Disturbance

PARTICIPANT INFORMATION SHEET

What is the study about?
You are invited to participate in a study exploring how thinking and memory skills change in response to brain training. This *Participant Information Sheet* contains information about the study and all the procedures involved. Please read this carefully before you decide whether or not to take part. If you agree to take part, you will be asked to sign the *Consent Forms* where you indicate that you understand the information and give your consent to participate in the study. Please feel free to ask questions about any information in this document. You may also wish to discuss this study with a relative or friend, or your doctor.

Why is the research being done?
Research suggests that brain training (also known as computerised cognitive training) improves older people's memory and thinking skills. There has also been research to suggest that brain training helps to improve sleep for those with insomnia, or sleep disturbance. Despite this, there has been little research using brain training to improve memory and thinking skills for those who have both a decline in memory and sleep disturbance. Therefore, we hope to determine whether brain training can improve memory and thinking in people who are at-risk for dementia because they are already showing some signs of decline in their thinking, memory and reasoning abilities.

What is 'brain training'?
Brain training involves exercises of different mental skills such as memory, attention, and reasoning. These exercises challenge the brain and can lead to better mental performance, through the formation of new connections in the brain. With time, the exercises gradually become more difficult in order to keep the brain challenged. These exercises look like simple computer games. No previous computer experience is required to participate in the brain training program.

Who can take part in the study?
The study aims to include people who meet all the following criteria:

- Aged 50 years or older

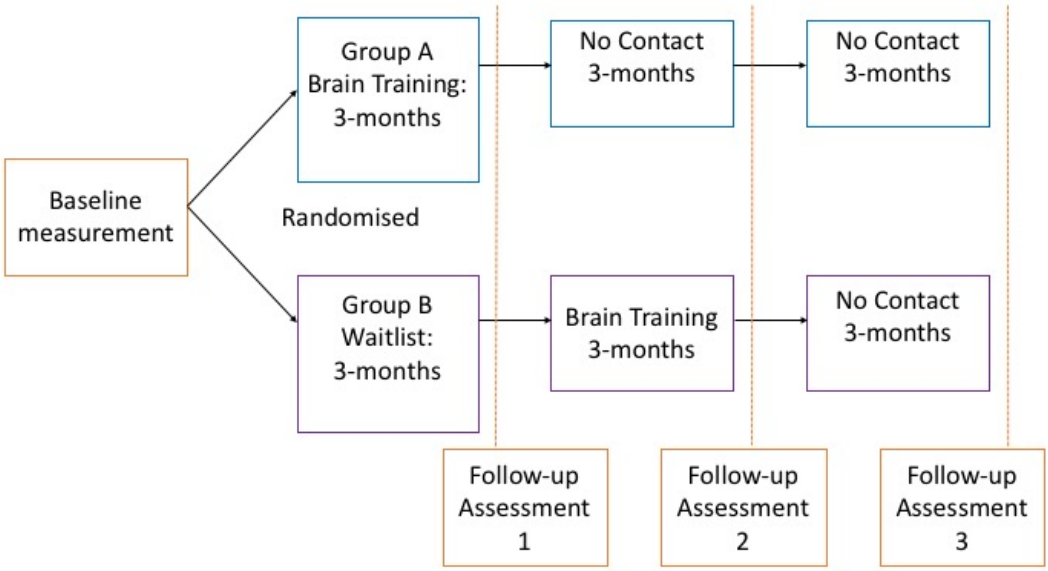
- Has undergone cognitive assessments at the Healthy Brain Ageing Clinic (Brain and Mind Centre, Camperdown) or the Prince of Wales Hospital, Randwick
- Can read, write and speak in English
- Physically able to use a computer (prior experience is not required)
- Able to attend training sessions at the Brain and Mind Centre (94 Mallett st, Camperdown) two times a week for 3 months, and one follow-up appointment every 3 months following the commencement of the trial.

Who is conducting the research?

The study is led by Prof. Michael Valenzuela. He is the leader of the Regenerative Neuroscience Group at the Brain and Mind Centre, University of Sydney. Prof. Valenzuela is an expert in brain training. He has led many studies investigating brain training in older adults. Prof Sharon Naismith is the head of the Healthy Brain Ageing Clinic at the Brain and Mind Centre, University of Sydney. She has helped design the study along with Prof. Valenzuela.

What will I need to do if I participate in the study?

1. **Written consent.** If you agree to participate, we will invite you to come to the Brain and Mind Centre, Mallet Street to discuss the study further and provide written consent.
2. **Baseline assessment.** We need have an idea of your thinking, memory and reasoning performance to see if you are eligible to participate. Some of this information we can obtain from your memory clinic. However, some of this we might have to assess in person. If necessary, this part will take approximately 30 minutes.
3. **Brain Training.** Once we have confirmed that you are able to participate, we will 'randomise' you into one of two groups. This is like tossing a coin; you will have a 1-in-2 chance of being allocated to one of our two brain training schedules. Both groups will receive the same amount of brain training, however at differing time-points. You have 50% chance of starting brain training immediately (as opposed to in 3 months time. The brain-training will be done at the Brain and Mind Centre, twice a week, one hour each time, for 12-weeks.



4. **Follow-up assessments.** Throughout this study, you will be asked to come along to three follow-up assessment assessments at the Brain and Mind Centre. The sessions will be similar to the baseline assessment and other tests you have participated in at your memory clinic. It will help us determine how your thinking and memory skills have changed throughout the course of the study. These will occur at 3, 6 and 9 months after beginning the study.
5. **Genetic test**. This study involves collection of saliva for genetic testing. This sample will be collected during baseline measurements to examine if there are any genetic factors that influence brain training efficacy. Before training will begin, we will ask you to provide a saliva sample. This is done by depositing salavia into a tube. The tube will then be sent to a laboratory where they will analyse your genetic code. This information wll help us explore whether there is a relationship between any of your genes and the effects of brain training. Participation in this part of the study is voluntary-if you do not wish to provide a saliva sample, you are still welcome to participate in all other parts of the study. Your laboratory results will be kept strictly confidential and will not be shared with anyone else. **Importantly, we will not be providing feedback to you about your personal genetic test results**. Your sample will only be used for the purpose of this research study. The saliva sample you provide during the study will be destroyed at the completion of the study, although some samples may be kept if required under the laboratory's accreditation standards.
6. **Sleep assessment.** Around the same time as the baseline and follow-up assessments, we will ask you to undergo an assessment of your sleep quality. This will involve wearing a small electronic bracelet called an "actigraph" for 1-week. The actigraph will record your movement. In addition, we will ask you to fill out a simple sleep diary. Participation in sleep measurement is voluntary-if you do not wish to participate in the sleep portion of the study, you can still participate in all other parts of the study.

Overall, the study involves a time commitment of approximately 9 months. During your involvement with this study, we ask that you do not participate in any other form of brain training for these 9 months.

What are the possible discomforts and risks of the study?

Taking part in this study involves minimal risk. However, there is a very small possibility that during the course of the study we detect that your thinking and mental capacities have declined to the extent as to suggest dementia. Because this is a sensitive issue, we ask that you let us know what level of feedback you would like. You can tell us whether you would like to be informed of a possible dementia diagnosis. In addition, if this is found, you can let us know whether you agree for us to share the results with you next-of-kin or carer. You can state your preferences in the Consent Form at the end of this document. In all such cases, you will be provided with support, counselling and advice from your referring clinic by clinic staff, along with recommendations for further help and assistance.

At any stage of the study, or after the study has ended, you will be able to discuss the implications of your results with Prof. Michael Valenzuela. If you wish to do so, please

let us know by contacting the research staff or Prof. Valenzuela directly. His contact details are provided in the first page of this Participation Information Sheet.

Additionally, it is worth noting that assessments involving thinking and memory processes can sometimes cause people some mild anxiety. However, this usually lessens when testing begins, and the researchers are trained to help provide support and information in this circumstance.

The saliva sample used for the study is taken from spitting into a tube so there are no additional risks of genetic testing. Your sample will only be used for the purpose of this research study. The blood or tissue sample/s you provide during the study will be destroyed at the completion of the study, although some samples may be kept if required under the laboratory's accreditation standards.

What are the anticipated benefits of this study?

This study offers thinking and memory assessments, which some individual may find interesting and beneficial on their own. Brain training has also been shown to produce some improvements in thinking, memory and reasoning, however, this is not certain. Whilst we hope to see your performance improve, we cannot guarantee or promise that your results will change as a result of volunteering in this study.

Will my identity be protected as a participant in this study?

Your personal details will be held in a safe and secure location. Only the researchers involved in this study will have access to your personal information. Any identifable information that is linked with your involvement in the study will remain confidential and will be released only with your permission. You will not be named in any reports or scientific publications resulting from the study. Any publications based on the study will include results pooled across all our participants, so you will remain anonymous and your details will not be singled out. The information you give will be held in a secure location for 20 years after publication. After this time, your personal information will be destroyed. Your genetic sample will not be linked to your name or any personal detail.

Voluntary participation

Participation in this research is voluntary. You may leave the study at any time. Your decision to participate will not affect your relationship with your referring clinic.

Will I be compensated for my participation?

To thank you for participation, we will offer you three $25 Coles and Myer gift cards. One card will be offered after each of the three follow-up assessments.

Will I be told of the findings of the study?

A copy of the study's findings will be sent once the project is completed.

About our Trial Supporters

This study was conceived by Prof. Valenzuela and Prof. Naismith. It is funded by the National Health and Medical Research Council of Australia (NHMRC). No member of the research team has any financial or commercial link with any company related to this research. Results will be publicly available soon after the study is complete through scientific articles and

public communications. However, the research team might use the results of this study to explore partnerships with software or technology companies for future projects.

Who should I ask if I have any questions about the study?
If you have any questions or concerns during the course of the study, do not hesitate to contact: Prof. Michael Valenzuela (tel: 02 9114 4135; email: michael.valenzuela@sydney.edu.au) or the study co-ordinator, Dr Polly Barr, (tel: +61478677239; email: polly.barr@sydney.edu.au).

Any person with concerns or complaints about the conduct of a research study can contact the Manager, Human Ethics Administration, University of Sydney on (Tel) +61 2 8627 8176; (Fascimile) +61 2 8627 8177 or (Email) ro.humanethics@sydney.edu.au quoting 2018/669 or the South Eastern Sydney Local Health District Human Research Ethics Committee Research Support Office on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote *18-245*.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

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CONSENT FORM

I, ……..[PRINT NAME) have read the information sheet provided and give consent to my participation in this study.
By signing this form, I give my consent to:

- Undergo four neuropsychological assessments (i.e. memory and thinking functions);
- Complete self-report questionnaires about my mood and thinking skills;
- Provide a saliva sample for genetic assessment;
- Undergo sleep quality assessments, including wearing an actigraphy and filling out a sleep diary for seven days, four times during the study.
- Undergo cognitive training.
- Allow my referral memory clinic and the Regenerative Neuroscience Group to share only data with each other
- Allow audio recording of certain tasks

I acknowledge that:

1. I understand the general purposes, methods, demands, potential benefits, and possible risks, of the study as outlined in the 'Participation Information Sheet' that has been given to me;
2. I have been given the opportunity to ask questions related to any possible harm I might suffer as a result of my participation and have received satisfactory answers;
3. My participation in the research study is voluntary, and I am free to withdraw at any time without penalty or prejudice;
4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified;
5. I understand that the confidentiality of my medical history will be safeguarded;

6. I understand that my non-identifiable data may be made available to third parties for data sharing purposes in order to improve health, care, services or to conduct further research.
7. If I have concerns about the scientific aspects of the study, I can contact Prof. Michael Valenzuela (Tel: 02 9114 4135; Email: michael.valenzuela@sydney.edu.au), who will be happy to address my concerns.

If signs of possible dementia are found:

1. I DO / DO NOT wish to be told.
2. I DO / DO NOT wish for my next-of-kin or carer to be notified.

Print Name: ……

Signed: ……Witness: ……

Date: …… Witness Signature: ……