Participan Information Sheet and Consent Form

Full Project Title: Investigating factors that influence the efficacy of cognitive remediation therapy in people with mental illness.

Short Title: Predictors of CRT Efficacy in Schizophrenia

Protocol No. 373/14

Principal Researcher: Professor Susan Rossell

Associate Researchers: Dr Neil Thomas, Dr Wei Lin Toh, Dr Caroline Gurvich

Student Researcher: Ms Maree Reser

1. Introduction

Cognitive Remediation Therapy is a treatment that has shown to be effective improving cognitive skills such as memory, attention and thinking speed. In this context, you are invited to take part in this research project, which aims to further our existing understanding of Cognitive Remediation as a crucial therapy to enhance everyday functioning in people with severe mental illnesses who live in Australia.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;
- consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research project?

As is true with many medicines and forms of therapy, some people seem to benefit from their use more than others. The reasons for this vary. Some people might not have a problem in the area the therapy targets. Because of that, nothing changes. Others may not improve much because the therapy does not meet their particular needs. For others, it is not clear why they do not benefit. The purpose of this study is to investigate what factors might influence how effective Cognitive Remediation Therapy is for clients with severe mental illness. We hope that this study will help us understand more about who is likely to benefit
from Cognitive Remediation Therapy so that we can better match a person and their specific needs with the most appropriate form of help.

A total of 100 individuals will take part in this study. All participants involved in the study will receive Cognitive Remediation Therapy. The research is being conducted by Swinburne University of Technology in collaboration with the Monash Alfred Psychiatry Research Centre (MAPrc). The results of this research will be used by the Student Researcher Maree Reser to obtain a Swinburne Doctorate of Psychology (Clinical).

3. What does participation in this research project involve?

If you fit the eligibility criteria and decide to participate, you will be required to provide consent before attending the first of four testing sessions. The first one, at the beginning of the study (Baseline), will take around 6 hours and will be broken into two 3-hour sessions. The next session, halfway through the study, will take around 1 hour to complete. At the end of the study will be a 3-hour testing session, followed in two months by a final 1-hour session.

As this study will also investigate genetic factors that might influence Cognitive Remediation Therapy outcomes, unless previously provided, you will be asked in the first testing session to provide a blood sample. You will also be required to participate in the Cognitive Remediation Therapy (computer-based cognitive training), attending at least 24 sessions.

Program:

<table>
<thead>
<tr>
<th>Session Description</th>
<th>Duration</th>
<th>Frequency</th>
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<tbody>
<tr>
<td><strong>Test Session 1 (Baseline):</strong> Introduction and interview session. Following your signing of this informed consent form, a number of assessments will be carried out. This will start with an interview. First we will ask you for your basic demographic information such as your date of birth, age and educational background. We will then ask you about your past and current medical and psychiatric history and your experiences (if any) of schizophrenia and depression. You will then be required to respond to a general assessment that will measure cognitive or thinking processes that include, amongst others, memory, attention and problem solving. You will then be asked to give a blood sample.</td>
<td>6 hours, broken into two 3 hour sessions</td>
<td>Once, at beginning of study</td>
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<tr>
<td><strong>Cognitive Remediation Therapy (CRT):</strong> After the initial assessment you will participate in the computer-based training, which targets basic auditory (hearing) and visual (seeing) processes. This will require the use of headphones. In each training session you will work on a range of training tasks. Tasks will vary across training sessions.</td>
<td>1 hour training sessions</td>
<td>1 to 3 times per week, attending a minimum of 24 sessions</td>
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<td><strong>Test Session 2:</strong> Halfway through the CRT (so after two months) will be a brief assessment of select cognitive processes, such as processing speed and verbal learning and memory.</td>
<td>1 hour</td>
<td>Once, after 8 weeks of CRT</td>
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<td><strong>Test Session 3:</strong> Soon after you have finished the CRT we will repeat some parts of the initial assessment. This will not include the demographic questionnaire and you will not need to give blood again.</td>
<td>3 hours</td>
<td>Once, at the end of CRT</td>
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<tr>
<td><strong>Test Session 4:</strong> Eight weeks after you complete the CRT, we will complete the final assessment. As with Session 2, this will be a brief assessment of select cognitive processes, such as processing speed and verbal learning and memory.</td>
<td>1 hour</td>
<td>Once, 8 weeks after completing CRT</td>
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You will have the opportunity to take rest breaks during the assessment sessions. A follow-up telephone call will be made between visits to monitor your interest.

You will not be paid for your participation in the Cognitive Remediation Therapy, but you will be reimbursed for your testing time to the amount of $40 per 3-hour session (testing sessions 1 and 3) and $15 per 1-hour session (testing sessions 2 and 4).

It is important to mention that different members of the research team will conduct the assessment sessions, whereas the Doctoral student (Ms Maree Reser) will conduct the CRT sessions. For the cognitive training you will be using a computer (that we will provide), however previous computer experience and/or skills are not required.

4. **Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision about whether to take part or not, or to take part and then withdraw, will not affect your routine treatment or your relationship with those treating you.

5. **What are the possible benefits?**

We cannot guarantee or promise that you will receive any benefits from this research; however, Cognitive Remediation Therapy might provide benefits improving your cognitive abilities such as memory, attention, thinking speed and planning skills. In addition, the findings gained from this research may contribute toward better diagnostic and therapeutic methods in the future.

6. **What are the possible risks?**

**Clinical assessment**
The clinical assessment will involve the discussion of personal experiences. As such, there is the possibility that you may find the topic of these discussions distressing. The likelihood of distress is low however, as these questionnaires have been designed for research purposes. Furthermore, the investigators are trained and experienced with asking clinical questions in a careful and considerate manner so as to avoid causing psychological distress.

**Cognitive assessment**
These are standard assessments that have been designed for research purposes. There are low risks associated with them. People can become tired, so adequate breaks and rest periods will be provided.

**Blood sampling**
Having blood taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.
7. Can I have other treatments during this research project?

While you are participating in this research project, you should continue with the same medications or treatments that you have been taking. It would be helpful if you advised the CRT specialist, Maree Reser, about any changes in your medications during your participation in the research project.

It is also desirable that your local doctor be advised of your decision to participate in this research project. If you do have a local doctor, we strongly recommend that you inform them of your involvement in this research project.

8. What if new information arises during this research project?

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

9. What if I withdraw from this research project?

If you decide to withdraw, please notify a member of the research team before you withdraw. To facilitate the accuracy of later analyses, please note that a copy of your data collected to that point will be kept on file. If you choose to withdraw that data, please let a member of staff know at the time of withdrawal from the study.

10. How will I be informed of the results of this research project?

A summary of the general findings of this research will be made available to you via either post or email, if you have consented to receive such further communication. These results will potentially be published in appropriate scientific journals and presented at academic conferences. All data in this report will be presented as group data, thereby maintaining your confidentiality.

11. What will happen to information about me?

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

The data that is collected from you will be coded, that is, reference to your identity will be replaced with a code. Data will be stored securely in a locked facility (e.g., locked filing cabinet) or under password protection (if electronic) and will only be accessible by the research team. All data will be stored for 7 years at the Monash Alfred Psychiatry research centre. Data derived from the present study may also be compared with that from previous research conducted by the same investigators.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. All participants will remain anonymous, with results presented as pooled group data only.
12. What will happen to my blood sample?

- The donated blood sample will be coded (labelled with your unique study ID number), frozen and stored securely at the Baker IDI Genomics and Systems Laboratory. This process will be overseen by Dr Kiymet Bozaoglu.

- You will be given the option of donating the blood sample for this research only OR donating the blood sample to a research bio-databank “Cognitive and genetic explanations of mental illnesses (CAGEMIS)” for this research as well as future research projects. There is more information about this in section 13: Optional storage of data in a databank

- If you donate the blood sample for this research project ONLY, the blood sample will be stored for up to seven years after the completion of this research project and then destroyed.

- The blood sample will be used to analyse particular genes that have been shown to be related to cognitive functioning.

- In any publication or presentation arising from results gained from your genetic analysis, information will be provided in such a way that you cannot be identified, except with your permission. As a participant, you will remain anonymous, with results presented as group data only. A summary of the general findings of this research will be made available to you via either post or email, if you have consented to receive such further communication.

13. Optional storage of data in a databank

If you agree, data from this current study will also be included in the CAGEMIS bio-databank that will facilitate research into symptoms, cognitive explanations and genetic factors involved in schizophrenia. Information will be coded in this databank, and stored as outlined above, in line with standard Alfred policy. You will be given an additional information sheet and consent form describing this databank. Agreeing to your data being entered into the CAGEMIS bio-databank is entirely optional. If you later decide to withdraw your data from the CAGEMIS bio-databank, your data will be removed from it.

14. How can I access my information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact the principal researcher if you would like to access your information.

15. What happens if I am injured as a result of participating in this research project?

If you suffer an injury as a result of your participation in this research project, please contact the research staff. Hospital care and treatment will be provided by the public health care system (Medicare) at no cost to you if you are eligible for Medicare benefits and elect to be treated as a public patient.
16. **Who is organising and funding the research?**

This research project is being conducted by Professor Susan Rossell, Drs Neil Thomas, Caroline Gurvich and Wei Lin Toh, and Ms Maree Reser (student researcher). It is funded using funds allocated to Prof. Rossell.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their standard wages).

17. **Is this research project approved?**

The ethical aspects of this research project have been approved by the Human Research Ethics Committees of the Alfred Hospital and Swinburne University of Technology.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

18. **Who can I contact?**

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

**For further information or appointments:**

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher Professor Susan Rossell on 03 9076 6850 or the student researcher Maree Reser at 9214 3604 or on 0451 169 656.

**For complaints:**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: Ms Emily Bingle  
Position: Research Governance Officer, Research & Ethics Unit, Alfred Health.  
Telephone: 03 9076 3619

You will need to tell Ms Bingle the following Alfred Health project number: 373/14.
Consent

Site: The Monash-Alfred Psychiatry Research Centre, The Alfred Hospital

Full Project Title: “Investigating factors that influence the efficacy of cognitive remediation therapy in people with mental illness.”

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for my doctors, other health professionals or hospitals to release information to Monash Alfred Psychiatry Research Centre concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

☐ I freely agree to participate in this research project as described.

☐ I understand that participation will involve providing a blood sample that will be used for genetic testing.

I understand that I will be given a signed copy of this document to keep.

Participant’s name (printed) ……………………………………………………………………………………………………………………………

Signature Date

Name of witness to participant’s signature (printed) ……………………………………………………………………………………………

Signature Date

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks, and I believe that the participant has understood that explanation.

Researcher’s name (printed) …………………………………………………………………………………………………………………………………

Signature Date

☐ I am interested in receiving information about the CAGEMIS bio-databank

☐ I would like to receive information regarding the outcomes of this study.
Withdrawal of Consent

Site: The Monash-Alfred Psychiatry Research Centre, The Alfred Hospital

Full Project Title: “Investigating factors that influence the efficacy of cognitive remediation therapy in people with mental illness.”

Principal Researcher: Professor Susan Rossell
Monash Alfred Psychiatry research centre
Level 4, 607 St Kilda Rd
Melbourne, Victoria, 3004

Telephone: 03 9076 6850
Fax: 03 9207 1545
Email: Susan.Rossell@monash.edu

*To withdraw from this project, please mail or fax this form to the principal researcher at the contact details above. You will receive confirmation on our receipt.

I hereby wish to WITHDRAW my consent to participate in the research project detailed above.

You MAY / MAY NOT (please circle) use information already collected about me during my involvement in this research project, as detailed below:

- [ ] Genetic data from blood sample
- [ ] Demographic and other background information collected during the initial assessment
- [ ] Results from the cognitive tests I completed
- [ ] Information about my progress on the Cognitive Remediation Training tasks

I understand that my withdrawal from participating in the Cognitive Remediation Training WILL NOT affect my participation in other current or future research projects at MAPrc or the Alfred Hospital.

I understand that my withdrawal WILL NOT affect my treatment or any relationship with MAPrc and the Alfred Hospital.

Participant’s Name (printed):

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Signature Date