**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

Western Sydney Local Health District

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| **Title** | Is there a synergistic effect of adding social cognition remediation to cognitive remediation therapy in young people? A randomised controlled trial |
| **Short Title** | Advantage Trial |
| **Coordinating Site Investigator** | Professor Anthony Harris |
| **Investigator(s)** | Ms Carlie Dodds, Ms Beverly Moss, Dr Daniel Pellen, Dr Roger Gurr & Dr Julia Lappin |
| **Location** | Western Sydney Local Health District, Nepean Blue Mountains Local Health District, North Sydney Local Health District and South Eastern Sydney Local Health District. |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project as someone who could benefit from cognitive therapies. The research project is testing a new combination of treatments for cognitive problems. The treatments involved are called Cognitive Remediation Therapy and Social Cognition and Interaction Therapy (SCIT).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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 don’t 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 your local doctor.

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

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 have the tests and treatments 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?**

Cognitive Remediation Therapy (CRT) and SCIT are both beneficial treatments that are recommended in Australia to treat different issues in mental illness. However, we don’t know how best to combine these treatments. This research looks at two ways of combining the treatments and will find out which one works best.

This research has been funded by the Western Sydney Local Health District Research and Education Network.

**3 What does participation in this research involve?**

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance, like flipping a coin. In this way we will be able to interpret the results in a fair and appropriate way and avoid jumping to conclusions about how best to combine the treatments.

Everyone who comes into the study will receive Cognitive Remediation Therapy. After this people will be put into two different groups – one group will receive SCIT the other will be invited to attend any other Group Therapy activity run at their Recovery centre for an equivalent period of time. This could be an exercise group, an art group or something else. The team will tell you what is available. Your experience of treatment will be much the same no matter which of the groups you are allocated to as you will be working with your treatment team in two groups for about the same period of time each week.

After you have signed the consent from, you will sit down with a psychologist who will test your thinking skills using a number of psychological tests. These tests check your attention and concentration, your memory, planning skills, ability to recognise emotions, understand what other people might be thinking and feeling and how you view the world. We will also ask you a series of questions about your diagnosis, your treatment history and your symptoms of mental illness including about any hallucinations or delusions, your mood and level of anxiety. If there are details that you cannot remember we will ask your permission to contact your treating doctor. All of this will take about 4 hours of your time but will give your treating team valuable information to help treat you. With your permission we would give that information to your treating team. We will repeat these tests after you have finished the study and once more after a further 3 months.

There are no additional costs associated with participating in this research project, nor will you be paid for taking part. You will continue on your usual medication and be treated by your usual psychiatrist or doctor. The extra psychological tests required as part of the research project will be provided to you free of charge.

**4 What do I have to do?**

Everyone who takes part in the study will continue to see their usual treating doctor and treating team. In addition, you will be asked to do some extra groups. These groups will either be for CRT + SCIT or CRT + another Group Therapy.

We have been using CRT for about 15 years. In this treatment we ask people to use computer games to help train their thinking skills. We will do that for about an hour with a small number of other people twice a week for 10 weeks.

We have been using social cognitive therapy for about 5 years. These therapies help you recognise people’s emotions and train you to think about how other people think and feel. They also help you examine your own biases in how you think. This treatment will be run twice a week for 10 weeks.

**5 Other relevant information about the research project**

We plan to have 42 people take part in the research over the next 12-18 months. The research will run at a number of places in Western Sydney Local Health District, Nepean Blue Mountains Local Health District, North Sydney Local Health District and South Eastern Sydney Local Health District.

**6 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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

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

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment with your clinical care team. Other options are available; these include medication and other psychosocial groups that your treating team will be running*.* Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include improved cognitive functioning, such as improved attention, concentration, and planning, and depending on your treatment group allocation, you may improve either your social skills, or your level fitness.

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

The groups that we would be asking you to take part in ask you to push your thinking skills using computer games. Sometimes people can get headaches from using a computer screen but this is unusual. If you get a headache when looking at computer screens please tell us. Although CRT/SCIT usually has a small positive effect on the symptoms of psychosis a small number of people report an increase in these symptoms (around 5 in 100). Finally, some people are upset if they don’t think they have benefited from the treatment, but this can happen with any treatment.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to refer you back to your treating team for appropriate support. This counselling will be provided as part of your usual care free of charge.

If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you. Any side effect will be managed free of charge by your treating medical team.

**10 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

**11 Can I have other treatments during this research project?**

Whilst you are participating in this research project, we will ask you not to take part in other psychosocial treatments that are specifically targeting cognitive processes or specific social cognitive skills. What medication you are on is up to your treating doctor, but we would ask you to tell us if there are any changes.

**12 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. There are no known risks to your health for withdrawing from the trial.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• The treatment being shown not to be effective

• The treatment being shown to work and not need further testing

**14 What happens when the research project ends?**

After the end of the project you may be able to take part in the treatment that you were not randomised to. This will depend upon the resources of your treating team. All the treatments are known to have beneficial effects.

The results of the study will be reported back to your treating team and they will be able to give you this information. We will provide them with a brochure reporting the final results.

**Part 2 How is the research project being conducted?**

**15 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The paper records of the study will be kept in a locked cabinet in the Department of Psychiatry at Westmead Hospital. The computer files will be stored on a password protected computer. The computer file will not have your name, only an identifying code. The information will only be available to the research team except when you have given us permission to tell your own doctors and treating team the results of some of your tests. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Occasionally researchers are asked to bring together the results of a large number of similar research projects. This is called a meta-analysis and is very valuable. If we were asked to take part in such a project we would only provide deidentified information that would not be individually recognisable.

Information about you may be obtained from your health records and treating team if you are unsure of the information. This might be for example the name and dose of your medication if you didn’t remember it. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records by your treating team.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

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 as required by law.

**16 Complaints and compensation**

If you wish to make a complaint about the study in the first instance you should contact Professor Harris who is the chief investigator on the trial. He will respond to your issue and report the complaint to the Western Sydney Human Research Ethics Committee. If you do not think your issue has been resolved you should make a complaint to Ms Clare Lorenzen, the Executive Director of the Western Sydney Local Health District Mental Health Service. All contact details are at the end of this consent form.

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**17 Who is organising and funding the research?**

This research project is being conducted by Professor Anthony Harris. It is being funded by a grant from the Western Sydney Local Health District Research and Education Network. Neither Professor Harris or the Local Health District will benefit financially from the results of this research. There are no financial benefits that will come to you from your involvement in the research project.

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

**18 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Western Sydney Local Health District.

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

**19 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

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 study doctor on 8890 6688 or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

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:

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| Reviewing HREC name | Western Sydney Local Health District |
| HREC Executive Officer | Kellie Hansen |
| Telephone | 8890 9007 |
| Email | Wslhd-researchoffice@health.nsw.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Research Governance Officer)**

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| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

**Consent Form -** *Adult providing own consent*

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| --- | --- |
| **Title** | Is there a synergistic effect of adding social cognition remediation to cognitive remediation therapy in young people? A randomised controlled trial |
| **Short Title** | Advantage Trial |
| **Coordinating Site Investigator** | Professor Anthony Harris |
| **Investigator(s)** | Ms Carlie Dodds, Ms Beverly Moss, Dr Daniel Pellen, Dr Roger Gurr & Dr Julia Lappin |
| **Location** | Western Sydney Local Health District, Nepean Blue Mountains Local Health District, North Sydney Local Health District and South Eastern Sydney Local Health District. |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Associate Professor Anthony Harris concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I acknowledge that any regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

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 and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

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|  | Name of Participant (please print) | |  |  |  |  |
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|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor**

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

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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| --- | --- |
| **Title** | Is there a synergistic effect of adding social cognition remediation to cognitive remediation therapy in young people? A randomised controlled trial |
| **Short Title** | Advantage Trial |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Associate Professor Anthony Harris |
| **Associate Investigator(s)** | Ms Carlie Dodds, Ms Beverly Moss, Dr Daniel Pellen, Dr Roger Gurr & Dr Julia Lappin |
| **Location** | Western Sydney Local Health District, Nepean Blue Mountains Local Health District, North Sydney Local Health District and South Eastern Sydney Local Health District. |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Western Sydney Local Health District.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.