INFORMATION SHEET

Title
Randomized Controlled trial of Social Cognition Interaction Training

Coordinating Principal Investigator
Dr Frances Dark

Principal Investigator
A/Professor James Scott

Location

Protocol
CADENCE-SCIT

This Participant Information and Consent Form is 8 pages long. Please make sure that you have all of the pages.

Introduction
You are invited to take part in a multisite clinical trial of interventions aimed at improving skills needed socially. These skills can be affected by your illness. The aim of this clinical trial is to compare two therapies on their ability to improve thinking skills that help in social interaction for those who have experienced psychosis.

Before you decide if you wish to consent to your participation we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take time to read the following information carefully and if appropriate discuss it with friends, family and your doctor. One of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. It is desirable that your doctor be advised of your decision to participate in this study. If you have a doctor we strongly recommend that you inform them of your participation in this study. Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the clinical trial. You will be given a copy of the Participant Information and Consent Form to keep as a record.
What is the purpose of this study?

Psychotic disorders include groups of illnesses that may affect a person’s thoughts, perceptions, emotions, social skills or communication. This study will look at which of the two therapies works best in improving thinking skills that help in social interactions. The two therapies are Social Cognition Interaction Training (SCIT) and Befriending Therapy (BT). Social Cognition Interaction Training (SCIT) is a group based training that aims to improve social thinking and functioning for people who have experienced psychosis. It involves education about emotions and social interaction using games and technology such as watching DVD’s. Befriending means being a friend or companion. Befriending Therapy (BT) is a talking therapy which involves discussing hobbies, interests, or things you enjoy in life. It may also involve activities like going for a walk or playing games. It is different from Social Cognition Interaction Training (SCIT) because it won’t focus on social interactions or the difficulties you have in social situations. Both groups are equally as effective in providing social support.

Your participation in this trial will help us to determine if Social Cognition Interaction Training (SCIT) or Befriending therapy are worthwhile programs to offer as part of standard treatment to people who suffer from psychosis.

This research has been initiated by the Coordinating Principal Investigator, Dr Frances Dark who is employed at Metro South Hospital and Health Service.

Do I have to take part in the study?

No, you do not have to take part in this clinical trial. It is voluntary. If you decide to take part you will be given this Participant Information Sheet and asked to sign the attached Consent Form. You will be given a copy to keep for your records. If you decide to participate you can change your mind at any stage without this affecting your routine treatment or future health care.

What does participation in the study involve?

You are invited to take part in the clinical trial.

You will be participating in a randomised controlled trial. The term randomised indicates that you will be selected into either the Social Cognition Interaction Training (SCIT) or Befriending Therapy (BT) group completely by chance (flip of a coin). This clinical trial will randomise participants in a 1:1 design, which means there is an equal chance of being in either the Social Cognition Interaction Training (SCIT) or Befriending Therapy (BT) group.
Step 1 Screening Process
At first contact with a member of the research team, you will be asked to take part in an initial interview (screening interview) which will take approximately 1 hour. If this screening process confirms that you can take part in the study, you will be provided with the opportunity to enter the next phase of the study.

Step 2 Contact
Both programs involve participating in group sessions.
You will be asked to attend group sessions once per week for 12 weeks. Each session will last approximately 2 hours. Additionally, you will also be asked to attend three sessions as an individual – one at the beginning of the trial, one at the end of the trial and one at follow up 3 months later.

At each individual session a clinical trial research assistant will conduct a series of clinical assessments which will take approximately 2 hours to complete. This will involve asking questions about your thinking and problem solving skills, how you think in social situations and your skills in recognising emotions from images of people.

The research assistant conducting the clinical assessments will be unaware (blind) of which group you are in. By keeping the research assistant unaware of which group you are in, and then comparing Social Cognition Interaction Training (SCIT) versus Befriending Therapy (BT), we will be able to learn if Social Cognition Interaction Training (SCIT) improves thinking skills that helps in social interactions for people who suffer from psychosis. This type of evidence can help all patients to receive better treatments in the future.

Will participating in the study cost me anything?
There are no additional costs associated with participating in this clinical trial. To compensate you for your time and any inconvenience you will receive a total of $150 worth of Coles/Myer gift vouchers. We will provide a $50 voucher on completion of the baseline assessment, end of study assessment and follow up assessment 3 months later.
What are the possible benefits of taking part?
We cannot guarantee or promise that you will receive any benefits from this clinical trial; however your participation will help us better understand if Social Cognition Interaction Training (SCIT) and Befriending Therapy (BF) are effective in improving thinking skills that help in social interactions for those people who experience psychosis.

What are the possible risks and disadvantages of taking part?
There are some possible adverse effects or risks related to participation in this clinical trial which include:
(a) Very occasionally, talking about mental illness can be upsetting. If by chance any of the group sessions or individual sessions causes you discomfort, you will not be expected to continue unless you wish to do so. If you do not want to continue or feel distressed or uncomfortable, a member of the clinical trial team will provide support to ensure your well-being. If you indicate a potential for self-harm or other serious risk to self or others, a member of the clinical trial team will report these responses immediately to the treating clinician.
(b) Clinical Assessments. The main inconvenience is the time spent completing these tasks. If you find the testing tiring, you can have as many breaks as required or complete the assessments over two sessions.
(c) Group sessions. The main inconvenience is the time spent participating in the activities. If you find the activities tiring, let your therapist know.

Can I have other treatments during this study?
You will be able to remain on all of your current treatments whilst participating in the trial. We ask that during the study you do not participate in any group sessions related to Social Cognition Interaction Training (SCIT) or Befriending Therapy (BF). But, you are able to continue your treatment as usual (medications and psychosocial treatments).

What do I do if I wish to withdraw from the study?
Your participation in this clinical trial is voluntary. You may choose not to participate, or you may decide to withdraw your consent and discontinue your participation from this trial at any time without affecting current or future care. If you wish to withdraw from this study please advise the clinical trial team. As part of consenting to this clinical trial, you agree that the data, including audio transcripts, you provide will be used for the clinical trial if you decide to withdraw.
What happens when the study ends?

Once the study is completed, the results will be grouped together and comparisons will be made between the Social Cognition Interaction Training (SCIT) and Befriending Therapy (BT) groups. These results will be published in a scientific journal and presented at scientific and community forums. You will be provided a summary of these results.

What will happen to information about me?

Any information obtained in connection with this clinical trial that can identify you will remain confidential and will only be used for the purpose of this clinical trial and it will only be disclosed with your permission, except as required by law.

The information collected is classified as re-identifiable. This means that details that identify you have been removed from the information (by replacing this information with a code), but that is possible to link the code back to you if necessary. The code will be stored separately from the data. The information collected from you in this clinical trial will be entered into a database, using the code rather than your personal identifiable details. However, the clinical trial team, regulatory authorities, and Metro South Human Research Ethics Committee (HREC) and site Governance, will be able to inspect and have access to confidential data that identifies you by name. Any analysis, interpretation and publication of the study results will not identify you.

As part of the study requirements all sessions of both groups will be audio recorded as part of checking the accuracy and reliability of sessions. The audio tape will only be used by Dr Frances Dark (Coordinating Principal Investigator) and will be destroyed after completing the accuracy and reliability ratings.

The paper files from your interviews and audio tapes from the group’s sessions will be stored in locked filing cabinets in a dedicated research office. Computer files will be kept on a password-protected computer at a designated site (which has high level security). Only approved clinical trial staff, Metro South Human Research Ethics Committee and site Governance may access your data. Records relating to the results of the trial will be kept for 7 years. After the 7 year period your paper records will be shredded and destroyed and computer files deleted.

How can I access my information?

In accordance with relevant Australian and/or Queensland privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named in the question section of this document if you would like access to your information.
Who is organising the study?

This clinical trial is being overseen by the Coordinating Principal Investigator Dr Frances Dark and Principal Investigator A/Professor James Scott.

Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This clinical trial has been reviewed and given approval by Metro South Human Research Ethics Committee and site Governance.

How do I get more information?

You should ask for any information you want. If you would like more information about the study or if there is any matter about it that concerns you, either now or in the future, do not hesitate to ask one of the members of the clinical trial team or your doctor. Before deciding whether or not to take part you may wish to discuss the matter with a relative or friend or with your doctor. You should feel free to do this.

If you have any questions about the study at any time, feel free to contact the researchers

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Ethical Guidelines and Independent Contact

This study has been approved by Metro South Human Research Ethics Committee and local site Governance, which is an appropriately constituted HREC under the National Health and Medical Research Council of Australia.

If you have any complaints about any aspect of the clinical trial, the way it is being conducted or any questions you can contact the HREC Coordinator, Metro South Human Research Ethics Committee on 3443 8047 (phone); or EthicsResearch.PAH@health.qld.gov.au (email). All complaints will be treated in confidence, investigated fully and you will be informed of the outcome.
Participant Consent Form

Study Title: Randomized Controlled trial of Social Cognition Interaction Training (SCIT)

- I have read (or had read to me), the Information Sheet and I understand the purpose of the clinical trial, what is involved, what data is being collected, any possible risks, inconveniences or discomforts involved, and what will be done with the data upon completion of the clinical trial.

- I have been given the time and opportunity to ask questions about the clinical trial and any questions I have asked have been answered clearly and to my satisfaction. I have also been given the opportunity to discuss this clinical trial with a person not connected to the clinical trial.

- I understand that all information provided by me is treated as strictly confidential and will only be shared with the clinical trial team and not be released by the clinical trial team unless required to do so by law.

- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Metro South Hospital and Health Service concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

- I understand that research data gathered for the clinical trial will be published but will not be individually identifiable in any of these publications.

- I know that I may withdraw from the trial at any time without having to give any reason or affecting my current or future medical treatment.

- I understand I will receive a copy of the participant information and signed consent form to keep.

- I understand and consent to those regulatory authorities and other organisations referred to in the participant information having access to my confidential information.

- I agree to participate in this research and give my consent voluntarily.

In addition (optional): (initial next to your response)

- I give permission for a member of the clinical trial team to recontact me within 5 years of signing this consent, regarding possible participation in further mental health research.
  
  Yes  
  No

- I give permission for a member of the clinical trial team to notify the participant’s treating Psychiatrist of their participation in the study.
  
  Yes  
  No

- I give consent for the research team to review my health outcomes via my medical records (paper and electronic) and Health Research Databases during the course of the current study.
  
  Yes  
  No