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**INFORMATION SHEET**

**Title** Randomised control trial of stand-alone resistance training in people with Chronic Psychotic Disorders

## **Coordinating Principal Investigator** Dr Nicole Korman

**Principal Investigator** Dr Nicole Korman

**Location**

**Protocol** SART

*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 clinical trial of interventions aimed at understanding how people experiencing mental illness respond mentally and physically to exercise that they engage in. This is important as it helps to understand in more detail how exercise may assist in people’s future recovery from their mental illness.

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. 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?**

People with chronic psychotic disorders can experience significant burden from active symptoms of their mental illness, and difficulties with their physical fitness and health leading contributing to difficulties with functioning in every day life. There is an urgent need to develop effective treatments that may improve functioning and recovery rates for people with chronic psychotic disorders.

Your participation in this trial will help us to compare two types of exercise therapy to see if they are acceptable and achievable interventions for people who experience chronic psychotic disorders.

This research has been initiated by the Coordinating Principal Investigator, Dr Nicole Korman 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 at the Community Care Unit.

**What does participation in the study involve?**

You will be participating in a randomised controlled trial. The term randomised indicates that you will be selected into either Group 1 (resistance training) or Group 2 (moderate intensity aerobic interval training) 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 Group 1 or Group 2. Neither the research team nor the mental health staff at your Community Care Unit (CCU) will have any involvement in deciding which group you are allocated to.

**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 30 minutes. 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 Physical and Mental Health Assessments (Prior to group allocation)**

You will be asked to complete a number of assessments before the program begins, (of which some will be repeated at the end of the program, i.e. at 8 weeks).

This will involve a number of questionnaires about your mental health and daily functioning (which will take approximately 45 minutes) and also several physical health assessments that will be conducted at baseline and end point visit.

*Physical activity* – measured by using a wrist-worn activity monitor (similar to a wrist watch) for 5 days before the program begins. You will be asked several questions about how much physical activity you normally engage in.

*Physical capacity* – there will be several brief tests of your physical capacity, such as walking as far as you can on a flat surface for 6 minutes, standing up and sitting down as often as you can in 30 seconds, checking your grip strength and how many push ups you can do in a minute. These assessments are brief and will be repeated before and after the 8 week program.

*Physical Health* - blood pressure, weight, waist circumference. These will be repeated before and after the program.

**Step 3 Contact (Allocation of groups)**

**Group 1** will be asked to engage in a resistance training exercise program involving instruction by the exercise physiologist at the Community Care Unit you are residing in, using gym equipment (hand weights, mat, and resistance bands).

**Group 2** will be asked to engage in an aerobic training program involving instruction by the exercise physiologist at the Community Care Unit you are residing in, and you will be able to use equipment such as a seated bike, step up or treadmill available at the Community Care Unit.

Both programs will be developed together with you and individualised, so that you only engage in exercise that you feel you can manage.

Both groups will be offered three days per week for eight weeks and occur individually.

Both groups will be offered a fortnightly 20 minute health coaching session with a research team member to help you with motivation to attend your sessions.

Once you are allocated to either Group 1 or Group 2 you will not be able to change out of the group you are allocated to. You will be asked not to engage in exercise outside of supervised study sessions unless it is the type of exercise you have been shown in the study, for the duration of the eight week program. However, you can withdraw from the study at any time and continue accessing the gym and exercise physiologist if you wish to.

**Physical and Mental Health Measures**

You will be asked to repeat a number of clinical and physical measures at the end of the exercise program (i.e. at 8 weeks), that were taken at the beginning of the study.

This will involve asking questions about your mental health and daily functioning, physical capacity and physical health measures as documented above. These assessments will take approximately 45 minutes to complete.

There will be several questionnaires about how you found an individual exercise session in both week 3 and week 8 of the program.

You will also be asked about how you found the whole 8 week exercise program after the study is completed.

**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 either a total of $80 worth of Coles/Myer gift vouchers ($40 voucher on completion of the baseline assessment and $40 at end of study assessment) or a Garmin Vivofit wearable device (worth $80) at the end of the study assessment, the choice will be yours. Participants who agree to the optional small group discussion at the end will also be offered a $20 gift card to compensate them for their time.

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

Exercise of different types has been shown to have the capacity to improve the mental and physical health of people with mental illness, and to protect against the onset of depression.

You may enjoy the exercise you are offered during study sessions and may feel satisfaction that you are contributing to advancing knowledge about how exercise can impact physical and mental health.

**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:

1. 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.
2. 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.
3. Musculoskeletal injuries. You may feel discomfort when exercising, if this occurs the exercise physiologist will adjust the exercise intervention. To participate in this research, you will need to first be assessed as being safe to participate in exercise by your exercise physiologist at the Community Care Unit as per their usual exercise guidelines.

**Can I have other treatments during this study?**

For the period of this study, you will be asked not to engage in a different exercise program outside of the supervised study sessions you have been randomised to. (i.e. if you are randomised to a resistance training program you cannot engage in an aerobic training program).

**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 at the Community Care Unit. 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 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 resistance training group and aerobic training group. 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 excel spreadsheet, using the code rather than your personal identifiable details. However, the clinical trial team 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.

The paper files from your interviews will be stored in locked filing cabinets at The Coorparoo Community care Unit. Computer files will be kept on a password-protected Queensland Health computer at Coorparoo Community Care Unit. 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 15 years. After the 15 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 Nicole Korman.

**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

Dr Nicole Korman 3727 7200

Email: Nicole.Korman@health.qld.gov.au

#### 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 MSH-Ethics@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** Randomised control trial of stand-alone

 resistance training in people with Schizophrenia

**Protocol** SART

**Coordinating Principal Investigator** Dr Nicole Korman

**Principal Investigator** Dr Nicole Korman

**Location**

**Declaration by Participant**

* 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 to release information to the research team about my suitability to participate in this program. I understand that such information will remain confidential.
* I acknowledge that participation in this study involves completing assessments of physical activity, including wearing a physical activity monitor for the duration of the study. I also acknowledge that I can remove the monitor at any time if it becomes too uncomfortable.
* 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 at the Community Care Unit.
* I understand I will receive a copy of the participant information and signed consent form to keep.
* I understand and consent to those 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)**

* At completion of the intervention, I give consent to participate in a small group discussion about my attitude and feelings regarding the intervention I participated in

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Printed Name of Participant Initial

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Signature of Participant Date (participant to date)

**Declaration by Study Doctor/Senior 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.

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Printed Name of Study Doctor/Senior Researcher Initial

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Signature of Study Doctor/Senior Researcher Date