***Physically active one way or another***

**Researchers**: Professor Michael Breakspear1,2, Dr Justin Chapman1,3, A/Prof Sue Patterson2, Dr Shuichi Suetani3, Natalie Avery2,Caroline Tully, Jacqui Byrne1

*1QIMR Berghofer Medical Research Institute, 2Metro North Mental Health Service, 3Metro South Addiction Mental Health Service.*

**Introduction**

Thank you for your interest in taking part in this research study. This Participant Information Sheet/Consent Form tells you about the study. Please read this information carefully, and ask questions about anything you want to know more about. You will be given a copy of this information sheet to keep. Your participation is voluntary; this means you can choose whether or not to participate. Your decision about participation will have no impact on the care provided by mental health services.

You may be eligible to take part in this study if you are receiving mental health services from the Metro South Addiction and Mental Health Services and over 18 years of age. You will not be able to take part if you are currently physically active. Before beginning, you will be asked to complete a medical screening questionnaire about your physical suitability to exercise, and we may need to contact your doctor for further information. If your doctor advises that this study is not suitable given your current physical conditions, you will not be able to participate. The study is not suitable for people with an eating disorder because of the specific care required for exercise programs for people with these symptoms.

**Why is this study being conducted?**

The aim of this study is to understand how to assist people recovering from mental illness to become more physically active. This is important for the future development and promotion of appropriate physical activity programs.

**This is a *randomised* study**, which means that if you choose to participate, you will be randomlyallocated (like flipping a coin) to *Group 1* or *Group 2*. It is important to note that neither the researchers nor the staff involved in your care will have a say in which group you are allocated to.

**What does participation involve?**

*Group 1* is a motivational program, and *Group 2* is a gym exercise program. *Group 1* will track their physical activity using a wrist-worn *fitness tracker* (pictured left), and participate in group motivational discussions about becoming physically active. G*roup 2* will receive a *gym membership*, and participate in an exercise program designed to increase gym confidence and exercise knowledge.

**Both programs involve one (1) group session per week over eight (8) weeks.** Groups will be with up to 10 people, at a local PCYC community gym (Police-Citizens Youth Club). To assess the longer-term impact, we’ll ask that you continue using the fitness tracker or gym membership (depending on your group) for a further 8 weeks (**16 weeks total**) without group sessions.

**All participants will be asked to complete a number of assessments** before the program begins, and at the end of the program (after 8 weeks). The assessments will include: a) physical assessments; and b) mental health and wellbeing questionnaires. After the additional follow-up period (16 weeks), we’ll ask you to participate in a focus group discussion about your experiences with the program, and things that you liked or didn’t like.

The physical assessments will include: 

* + - * *Physical activity* will be measured using a wrist-worn activity monitor (pictured right) that you will be asked to wear for baseline and the 8-week program. The activity monitor *measures movement only* and does not tell us anything about the kind of activity you do or where you go. You can take the monitor off at any time if it becomes too uncomfortable.
* *Physical capacity* will be measured using a walk test, which involves walking as far as you can, back and forth along a flat surface in six minutes.
* *Physical health:* Weight, height, blood pressure and waist circumference will be measured.

You will receive Coles & Myer gift cards at each assessment point to recompense you for your time: $20 at the beginning, $30 after eight weeks, and $40 after 16 weeks. There are no costs associated with participating. Although we cannot reimburse transport costs, free parking is provided at the PCYC.

**How will my identity and information be kept confidential?**

All the information we use will be looked after as required by the National Statement on Ethical Conduct in Human Research and legislation. Your information will be stored securely on a password protected drive at RBWH and QIMR Berghofer Medical Research Institute, and not shared with anyone outside the research team. We will ensure your privacy and confidentiality are protected by allocating you a code, and then using that code to label information that you provide.

**What will happen to the information I provide?**

Feedback that participants provide about the program will be assessed to determine if these programs are acceptable to people recovering from mental illness. Information gathered from the assessments will be used to see how people respond to different exercise programs. We will look for a change in assessment scores between the start and finish of the program, and we will compare the results from both groups. The results of this project will be published and/or presented in a variety of forums, and will be represented in a way that no-one in the study can be identified. We will not share any information which could lead to you being identified. **Everything recorded in this study is confidential.**

At conclusion of the study, the information about you will be deidentified using a code, and stored electronically on secure drives at QIMR Berghofer for future reference. In accordance with Australian and Queensland privacy 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 researcher named at the end of this document for this purpose.

**Risks and Benefits**

Exercise has been shown to be beneficial for our health and wellbeing, and you may experience benefits from becoming more physically active. Physical activity also has an inherent risk of injury, and some people feel discomfort during exercise. You will be asked to complete a medical screening questionnaire, and we will contact your doctor as required before participation. Any exercises will be tailored to your ability and preference. You may enjoy the group programs, and feel satisfaction in knowing that you are contributing to the development of information which could improve exercise opportunities for people recovering from mental illness.

Wearing the activity monitors may cause some discomfort, but you can take them off at any time if they become too uncomfortable. They do not need to be recharged, and they are water resistant so you won’t need to take them off to shower.

Participation in the exercise sessions and assessments may cause some inconvenience. The researcher can arrange to meet you at a more convenient location for your first assessment (e.g. at a café or library). You will be offered a total of $90 to compensate you for your time in completing the study assessments.

Your personal questionnaire results and physical measures (activity monitor data, weight, waist etc) can be provided to you on request. We can also provide you with a summary of the overall study results at completion of the study, which can be mailed out to you at your request.

**Do I have to take part?**

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 research at any time without consequence. If you withdraw from the research, data you provide up until that point will be used in the study assessment. If you do decide to take part, you will be given a Consent Form to sign and a copy of this Information Sheet to keep. Please advise your psychologist or case manager if you are willing to be involved. With your permission, they will pass your contact details on to the researcher (Justin), and he will call you to arrange a time to meet.

**Complaints and Compensation**

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

**Who has reviewed this 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 Royal Brisbane Women’s Hospital. 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.

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| --- | --- |
| Reviewing HREC name | *The Royal Brisbane and Women’s Hospital* |
| Telephone | *(07) 3646 6132*  |
| Email | *RBWH-Ethics@health.qld.gov.au* |

Please contact the principal researcher if you would like further information:

**Dr Justin Chapman**

QIMR Berghofer Medical Research Institute

Telephone: 0432 299 240

Email: Justin.chapman@qimrberghofer.edu.au

**Participant Consent Form**

**Study title**: ***Physically active one way or another***

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The investigators of this study conform to the principles governing the ethical conduct of research, and will protect the safety, interests and wellbeing of subjects at all times. This form contains an outline of procedures involved.

1. I have read and understand the information sheet for this study and are aware of the risks involved.
2. I give permission for my doctor (*Doctor* \_
3. *Clinic address*: ) to be contacted to obtain medical information about my suitability to participate in this program.
4. 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.
5. I acknowledge that I’ll be asked to complete questionnaires on physical activity and mental health, and that information about my diagnosis will be obtained from a mental health clinician involved in my care.
6. am aware that I can withdraw from the study at any time without it affecting my treatment, and without prejudice form the researchers or participating organisations.
7. I understand that the data I provide will be treated as confidential and will not be available in an identifiable manner.
8. I have been given the opportunity to discuss the study contents with one of the research staff prior to starting the study, and all questions I have asked have been satisfactorily answered.

**Name**:

**Signed:** **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.

**Name of researcher**:

**Signed:** **Date:**