***The MOVEMENT study***

*Improving quality of life in people with severe mental illness*

**Participant Information Sheet**

|  |  |
| --- | --- |
| **Principal researcher** | Dr Justin Chapman |
| **Associate researchers** | Dr Meg Doohan, Professor Amanda Wheeler, Professor Dan Siskind, Dr Kylie Burke, Dr Marianne Wyder, Dr Stephen Parker, Dr Geoffrey Lau, Dr Urska Arnautovska, Dr Nicole Korman, Dr Yong Yi Lee, Dr Mary Lou Chatterton, Dr Eva Malacova |
| **Location** | *[Insert site]* |

**Introduction**

This Information Sheettells you about this study. This research being conducted by Griffith University, Metro South Addictions and Mental Health Service, Metro North Mental Health Service, Monash University, QIMR Berghofer, Queensland Centre for Mental Health Research, Communify Queensland, Stride, Neami National and Richmond Fellowship Queensland.

This study is for people who are 18+ years of age and accessing support for mental health. Your participation is completely voluntary, and your decision to participate or not will have no impact on services you may be receiving or any involvement you may have with the above organisations.

Please read this information carefully and ask questions about anything you want to know more about. If you agree to participate you will be asked to sign the Participant Consent Form.

**What is the research study about?**

The aim of this study is to evaluate the influences on quality of life in people with severe mental illness, and the role that exercise can have in recovery.

If you decide that you want to be involved, you will be asked to confirm that you understand the possible risks and benefits of taking part, and consent to participate You will be given a copy of this participant information sheet and consent form to keep.

**What does participation involve?**

***Part 1***: Participation in this research involves completion of both survey and physiological assessments at three (3) time-points, each three (3) months apart. These assessments include questionnaires related to quality of life, metabolic health, medications, psychological distress, health service utilisation, resource use, sense of belonging, social connection, unmet needs, alcohol intake, nutritional intake, physical activity, and sleep quality. Physiological assessments will include measurements of height, weight, waist circumference, blood pressure, and a fasted finger-prick blood test to assess your cholesterol and blood glucose. The finger-prick test will be scheduled before eating breakfast to ensure eight (8) hours of fasting. You may also be invited to an interview about what you think is most important for supporting quality of life and recovery. You will be offered a $50 Coles/Myer gift card to recompense you for your time at each of these assessment points.

***Part 2***: If you agree to Part 1, you may also participate in Part 2 if you wish. Part 2 is an optional exercise program held at a local gym and delivered by an exercise physiologist. The program will be available for six (6) months and involves at one 1-hour exercise session per week at a community gym in groups of up to 10 people. The exercise physiologist will complete a medical history screening form and develop a personalised exercise program with you at the gym. At each session, we will record attendance, exercises completed, perceived exertion, and any pain or injuries. Please note, the exercise program is an optional part to this study.

**Do I have to take part in this research study?**

No, participation is completely voluntary, and you can withdraw at any time. Your decision not to participate or to withdraw from the study will not affect the mental health services you receive*.* If you decide to withdraw from the study, the researchers will not collect additional information from you. At this time, you may request that any of your personal information not be used; however, once the responses are included in the overall findings, we will not be able to alter the results or conclusions. You can withdraw your consent by advising the researcher either verbally, via email, or by completing and returning the ‘Participant Withdrawal of Consent Form’ that is supplied herein.

**What are the possible benefits?**

This research project will allow us to better understand the influences on quality of life for people with severe mental illness, and the role that exercise can play in recovery. You may feel satisfaction in contributing to research and helping to improve our understanding about services that can assist recovery. If you decide to participate in the exercise program, you may enjoy getting a personalised exercise plan and support from an exercise physiologist and exercising in a group. To compensate you for your time, you will be offered a $50 gift card for completing each assessment session.

**What are the possible risks?**

The assessments include questionnaires and physiological measures. Completing these measures will take 60-90 minutes at each assessment point, which can cause inconvenience. The finger-prick blood test will need to be fasted, so the test will be scheduled before you have breakfast to reduce the impact on your routine. This is like a blood sugar test that people with diabetes may do using equipment purchased from the chemist. The test will be arranged at a venue comfortable for you, such as your residence or the organisation at which you receive mental health care.

Any exercise has a risk of injury; however, if you participate in the exercise program, an exercise physiologist will conduct a medical history check with you and communicate with your general practitioner if you have any health concerns. Exercise physiologists are university trained health professionals, and the exercise program will be individualised to suit your abilities and preferences.

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

This research involves the collection, storage, and use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements.

The data you provide for this study will be stored in a secure database and used for other ethically approved trials aiming to improve our understanding of the factors related to recovery and quality of life in people with severe mental illnesses, which may involve linking data across different studies. As required by Griffith University, all research data will be retained in a password-protected electronic drive at Griffith University. In accordance with data security guidelines, all electronic and hard-copy data will be stored securely for 15 years. After this time, the data will be destroyed. Further information can be found in the University's Privacy Plan: [www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan](http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan). If you agree to being approached for future research opportunities, we will use your personal contact information to re-contact you if future research opportunities arise for which you may be eligible.

A de-identified copy of the data may be published in an open access repository. This allows other researchers to access and use the data to advance understanding in this field. All data will be anonymized or de-identified before being published. This means that all potentially identifying information will be removed so it will not be possible to identify who provided the data.

**Will I receive the results of the study?**

Yes. The research team will send a lay summary of the aggregated/averaged data to all participants that provide their contact details. The research team also intend to publish and report the results of the research study in journal articles and conference presentations.

**What should I do if I have further questions about my involvement in the research study?**

If you require further information or if you have any questions about this research, you can contact the following member of the research team:

|  |  |
| --- | --- |
| **Name** | Justin Chapman |
| **Position** | Principal Researcher |
| **Telephone** | 0432 299 240 |
| **Email** | justin.chapman@griffith.edu.au |

**What if I have a complaint or concern?**

Any concerns or complaints about the conduct of this study should be directed to the:

MSH - HREC Coordinator

Metro South Human Research Ethics Committee

*Email*: msh-research@health.qld.gov.au.

*Phone*: (07) 3443 8065

Any complaint will be investigated promptly, and you will be informed of the outcome.

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**Participant Consent Form**

|  |  |
| --- | --- |
| **Principal researcher** | Dr Justin Chapman |
| **Associate researchers** | Dr Meg Doohan, Professor Amanda Wheeler, Professor Dan Siskind, Dr Kylie Burke, Dr Marianne Wyder, Dr Stephen Parker, Dr Geoffrey Lau, Dr Urska Arnautovska, Dr Nicole Korman, Dr Yong Yi Lee, Dr Mary Lou Chatterton, Dr Eva Malacova, Andrea Baker  |
| **Location** | *[insert site]* |

I confirm that I have read and understood the information provided, and I consent to the following:

* Participation involves three (3) assessment sessions, each three (3) months apart.
* Assessments will consist of questionnaires about physical and mental health, and physiological measures, including a fasted finger-prick blood test.
* The assessment sessions will take 60-90 minutes, and I will be offered a $50 gift card for completing each assessment session.
* I will have the option to participate in an exercise program delivered by an exercise physiologist within two weeks of signing this form, which may require obtaining medical clearance from a general practitioner.
* The exercise program consists of weekly group-based exercise sessions over six (6) months and involves an individualised exercise program developed for my abilities, preferences and goals.
* I have had an opportunity to ask questions, and I am satisfied with the answers I have received; if I have any additional questions, I can contact the research team.
* Data collected for this study will be saved on Griffith University password protected drives and destroyed after 15 years.
* I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members.
* I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on (07) 3735 4375 or email (research-ethics@griffith.edu.au) if I have any concerns about the ethical conduct of the project.
* **I consent to be contacted to be invited to other ethically approved trials:** o*Yes*o*No*

## Participant Consent

*Participant name*

*Signature* *Date*

*Email* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*Phone*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Researcher Declaration**: I have given a verbal explanation of the research project its procedures and risks and I believe that the participant has understood that explanation

*Signature* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Date* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Withdrawal of Consent Form**

|  |  |
| --- | --- |
| **Principal researcher** | Dr Justin Chapman |
| **Associate researchers** | Dr Meg Doohan, Professor Amanda Wheeler, Professor Dan Siskind, Dr Kylie Burke, Dr Marianne Wyder, Dr Stephen Parker, Dr Geoffrey Lau, Dr Urska Arnautovska, Dr Nicole Korman, Dr Yong Yi Lee, Dr Mary Lou Chatterton, Dr Eva Malacova, Andrea Baker  |
| **Location** | Metro South Health |

This form is to be used if you have decided to stop participating in the research study.

I hereby **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the participating organisations.

Research Participant Name *(Print)*

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Research Participant Signature Date

You can withdraw your participation consent by advising the researcher verbally, via email, or by returning this completed form using the below details.

|  |  |
| --- | --- |
| **Name** | Justin Chapman |
| **Position** | Principal Researcher |
| **Telephone** | 0432 299 240 |
| **Email** | justin.chapman@griffith.edu.au |
| **Mailing address** | Dr Justin ChapmanGriffith University170 Kessels rdNathanBrisbane 4111 |