Plain Language Statement

Department of General Practice, Melbourne Medical School

**Project:** The Assertive Cardiac Care Trial: A randomised trial of an assertive care intervention to reduce cardiovascular risk in people with severe mental illness in the primary care setting

**Short Title:** The ACCT Healthy Heart Study

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**Introduction**

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part.

Please take the time to read this information carefully. You may ask questions about anything you do not understand or want to know more about. If you would like to read through this with a member of the research team, please contact us to do so via one of the phone numbers or email addresses listed above. We can answer any queries you may have.

**Your participation is voluntary**

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study then you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way. At all times your GP will be the person looking after your health. The research team will provide additional support to your GP.

** Withdrawal from the study**

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by notifying the research team and completing the Withdrawal process.
If you withdraw from the study, you will be able to choose whether the study will *destroy* or *retain* the information it has collected about you. You should only choose *one* of the two options. If you withdraw, you will not be required to participate in any other study related tasks. Choosing to withdraw from the study will not affect your relationship with your GP, the research team, or how you should access help for your health.

**What is this research about?**
In this project research nurses will work with General Practitioners to better understand and improve heart health for people who live with complex mental health needs. More effort is needed to improve heart health in people with mental illness as it can be difficult to focus on heart health with so many things going on.

**What will I be asked to do?**
If you agree to take part, we will ask you to complete questionnaires and attend appointments at your General Practice clinic or Community Health Centre for 12 months. For the first meeting your General Practitioner or practice nurse will work with you to complete a Healthy Heart Check. This will involve answering some health questions, completing some questionnaires, blood pressure measurements and may require a blood sample. Once your blood results are available, we will be able to calculate your estimated risk of having cardiovascular disease in the next five years.

You will be randomly allocated to one of two study groups. The decision of which group you are in will be made by chance, like a flip of a coin. In each group participants will be provided with heart health information and will maintain contact with their General Practitioner and will receive different levels of additional contact. Once you are allocated to a group we will provide further information about appointments and contact.

It is important that we have two groups so that we can understand if our new program will improve heart health for people with complex mental health conditions more than the way it is currently managed by GPs. The information we collect from all participants is valuable and is aiming to improve heart health care for people with mental health conditions.

In order to provide safe and whole person care to you, we ask for you to grant us permission to access your medical records at the GP clinic you attend for the period 01 March 2021 to 31 December 2023.

**Audio recording of some sessions.**
Some sessions and phone calls may be audio-recorded for quality purposes (so that we can check that the study is being run correctly and the level of care we are providing is the best it can be). These recordings will only be used by the research team to check
quality and will not be shared with others, including your usual GP or other healthcare providers. You can advise at any time if you do not wish to be audio-recorded, this will not affect your participation in the study.

We will ask for your permission to access government held data about you. We will ask you to provide additional consent allowing the research team to access government held data about the medications you have been prescribed, medical appointments hospital admissions or emergency department presentations. We are asking for this permission as it provides the research team more detailed information on these things than we can get by asking you directly.

You can still participate in the study if you do not wish to provide permission to the research team to access this data.

Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) Consent Form
You will be asked to sign a consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the Department of Human Services who holds MBS and PBS data confidentially. Your MBS/PBS data will only be used for this study and will not be used in any future or unspecified research outside of the approved study.

The MBS/PBS data described above does not include information about any public hospital admissions or emergency department presentations. This information is instead collected through the Centre for Victorian Data Linkage. The process for accessing this information is outlined in the next section.

Victorian Admitted Episodes Dataset (VAED) and the Victorian Emergency Minimum Dataset (VEMD) Consent Form
You will be asked to sign an additional consent form authorising the research team to access information on any Victorian hospital admissions or any presentations to a Victorian public hospital emergency department that you may have in the time you are involved in the study.

This information is collected by the Victorian government and is held by the Department of Health and Human Services.

The consent form will be sent securely to the Centre for Victorian Data Linkage, and the information will be securely provided to the research team for analysis.
Your VAED and VEMD information will only be used in this study and will not be used in any future or unspecified research.

**What are the possible benefits?**
This project aims to test whether our program will improve heart health for people with complex mental health conditions. A heart health check is an important piece of information for you and your GP to ensure your health care is the best it can be. We aim to provide care that may improve your health and wellbeing and if successful could improve heart health for others with complex mental health conditions. You will not be paid to be involved in this study, but we can provide some assistance to attend study-related medical appointments.

**What are the possible risks?**
There is a small risk that changes to your medications and lifestyle can lead to other health issues. Any medication and lifestyle changes will be based on your current level of health and made in consultation with the research nurse and your GP. Through the course of this study your GP will continue to treat you as they normally would plus any additional involvement in the study. In addition, you can contact the research team at any time with any questions or worries. We will be in frequent contact with you over the 12 months you are involved in the study to see how you are.

We will be asking some questions about drug use. We will generally not disclose that information without your consent, but we cannot keep this information confidential if we think you are going to seriously harm yourself or others or if we are required to provide this information by a court of law for legal reasons.

If you give any indication of self-harm or suicidal thoughts, we are required to notify your general practitioner and treating mental health team to provide ongoing treatment according to their clinical judgement. This is to ensure your safety.

There is a possibility that you may experience some soreness or bruising when the research nurse takes the blood sample. This will be minor and should only last a few days. You can contact the researchers if you have any worries about this.

**Do I have to take part?**
No. Participation is completely voluntary. You can withdraw at any time.

**Will I hear about the results of this project?**
The results of this project will be written up as scientific reports and publications. At your 12-month visit we will review some key heart health information that we collected in the study with you. Additionally, we will develop a summary of the study results specifically for study participants and will post these out once the study has concluded (anticipated to be at the end of 2023).
What will happen to information about me?
All information that we collect in this study will only be available to the research team and some information will be shared with your GP. All study data will be securely stored and will only be accessed by researchers involved in the study. You will be allocated a code number only known by the research team and all data will be linked to this code. All data will be stored securely in locked filing cabinets and on password protected servers only accessible by the research team. Some information will be shared with your GP and stored in your medical record at the GP clinic or community health centre. We are planning on writing scientific papers and presenting the results of this study at meetings and conferences. In any work where we use the data collected in the study you will not be able to be identified (all published data is de-identified). The data will be presented for the whole group and individual data will not be identifiable. We may be asked to provide information collected in research to verify our data analysis, but if this is required we will remove any information that could identify you. This is not likely to occur. All data will be stored for 15 years after which it will be securely destroyed.

Who is funding this project?
This study has been funded by the National Health and Medical Research Council (2018-2023).

Where can I get further information?
If you would like more information about the project, please contact the researchers at:
- the study phone number: 1800 431 212;
or
- the study email address: healthy-hearts@unimelb.edu.au

Who can I contact if I have any concerns about the project?
This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.