



PARTICIPANT INFORMATION SHEET

Primary care adherence to heart failure guidelines in the diagnosis, evaluation & routine management (PATHFINDER) of heart failure Study.

Principal Investigator: Associate Professor Andrew Maiorana, Allied Health Dept. and Advanced Heart Failure and Cardiac Transplant Service, Fiona Stanley Hospital

Fiona Stanley Hospital, Royal Perth Hospital and Curtin University are undertaking research to evaluate and improve the level of adherence to published guidelines for the management of people who have been admitted to hospital with heart failure, a medical condition in which the heart doesn't pump as strongly as it should. The following information describes what will be involved should you decide to participate in this research project. Please read the information about this study carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend.

BACKGROUND

Heart failure is a common cause of hospital admissions in Australia. However, many of these admissions are preventable with better adherence to published guidelines about heart failure management, such as increased use of appropriate medication, and clear advice to patients on healthy lifestyle (including physical activity) and self-management.

WHAT IS THE PURPOSE OF THE STUDY?

The aim of this study is to evaluate the effects of providing a Heart Health Plan to patients who have been admitted to hospital with heart failure. The Heart Health Plan will involve providing specific information to patients and their nominated GP to support the management of heart failure. This research has been funded by WA Health Translation Network (Rapid Applied Research Translation Grant) through funds provide by the Medical Research Future Fund.

WHAT WILL HAPPEN?

Patients who have been admitted to hospital will be randomly allocated to receive the Heart Health Plan or medical management following standard processes (usual care).



If you agree to take part in the study, you will be asked to complete a walking test prior to leaving hospital. This test involves walking for six minutes as quickly as you're able to, up and down a hospital corridor. In some cases we may ask you to come back to the hospital shortly after you have been discharged to perform the test if you're not able to perform it while in hospital. At the time of each walking test we will also measure your height and weight.

You will also be asked to complete several questionnaires. These should take approximately 20 minutes to complete. We will ask you to repeat these questionnaires when you return for your repeat walking tests.

The questionnaires are:

- i. Kansas City Cardiomyopathy Questionnaire-short version (KCCQ12) – questions about your heart condition and how it affects your life.
- ii. PROMIS Physical Function Short Form 4a, Patient Health Questionnaire (PHQ-2) – questions about how your heart condition affects your ability to do manual chores and physical activity.
- iii. Patient Health Questionnaire (PHQ-2) - two questions about how your heart condition has affected the way you feel over the past 2 weeks.
- iv. Self-care of Heart Failure Index – questions about the behaviours you use to manage your heart condition.
- v. Medication Compliance Questionnaire - questions about your use of medication.

This walking test and questionnaires will be repeated at Fiona Stanley Hospital following 6 months. You will be reimbursed for parking to attend these visits.

If you are randomised to receive the Heart Health Plan you will be given specific information before you leave hospital about self-management of heart failure by a specialist nurse (a Heart Failure Nurse Practitioner), including information about undertaking physical activity suited to your level of fitness. In addition, you will be provided with a form to take to your GP at 7 days, 28 days, 3 months following discharge from hospital to help adjust your medications. If after 3 months post-discharge, you are still having problems with your medications more follow-ups by your GP may be recommended. Your GP will also be given the phone number of heart failure helpline to contact in the event that they need to seek advice (the Nurse Practitioner will work with a Cardiologist in providing this advice).

Patients who are randomised to the usual care group, will receive all the standard care provided to patients following an admission with heart failure at Fiona Stanley Hospital, but won't receive the Heart Health Plan.



We are seeking your permission to review your hospital records to document your medical history and demographic information. If there is some relevant information missing we may need to ask you some questions directly. We also wish to monitor your health into the future, including hospital admissions and if you pass away, so are also seeking your permission to collect this information.

TIME COMMITMENT

The education that will be part of the Heart Health Plan will also take approximately 30 minutes.

The walking test and associated measurements will take less than 30 minutes and the questionnaires will take you around 20-30 minutes to complete. The walking test will be undertaken on two occasions; while you're still in hospital (or soon after you're discharged) and 6 months after you're discharged from hospital. People who live in country areas and are unable to attend the hospital will be mailed the questionnaires but won't need to repeat the walking tests. The questionnaires will be undertaken at hospital and 6 months after you're discharged

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISK OF TAKING PART?

This is a low risk study. Some people may feel self-conscious about answering some of the questions in the questionnaires. However, your responses won't be available to anyone outside the research team and we will use a participant ID code rather than your name so your identity won't appear on your responses.

POSSIBLE BENEFITS

We cannot guarantee that you will receive any benefits from this research; however, we anticipate that findings from the study will help inform better management of patients with heart failure into the future.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary. You do not have to participate and, if you decide to participate, you can stop at any time without explanation. Your decision to participate or not, or to later withdraw from the study, will in no way affect your current or future care at Fiona Stanley Hospital.

WHAT ARE THE COSTS OF BEING IN THIS STUDY?

There are no financial costs associated with participating in the study. You will not be paid for participation, however expenses you incur associated with parking will be reimbursed.

PRIVACY AND CONFIDENTIALITY



The information gathered about you by the investigator or obtained during this study will be held by the investigator in strict confidence. All the people who handle your information will adhere to traditional standards of confidentiality and will also comply with the Privacy Act 1988. If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients.

WHAT IF SOMETHING GOES WRONG?

In the event that you suffer an expected or unexpected side effect or medical accident during this study that arises from your participation, you will be offered all full and necessary treatment by Fiona Stanley Hospital.

WHAT HAPPENS WHEN THE RESEARCH PROJECT ENDS?

You will be provided with a narrative summary of the results by letter in 6 months when the research project is completed.

WHAT WILL HAPPEN TO INFORMATION ABOUT ME?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Upon receipt of consent to take part in the study, participants will be allocated a research code-number. Digital data will be stored on the Curtin Research Drive (R:Drive), a dedicated research drive with password protected access, backup and recovery capabilities. Hardcopies will be stored in locked filing cabinets and computer records will be maintained on password protected secure servers. Only authorised researchers will have access to the data. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

The study data will be retained a minimum of seven years after completion of the project or publication. Disposal of research data and primary materials will be in accordance with the Information Management Policy of Curtin University.



CONTACT INFORMATION

If you have questions about this study, please contact Associate Professor Maiorana on (08) 61521692 or alternatively Zoe Dai on 0413349200.

This study has been submitted to the South Metropolitan Health Service Human Research Ethics and Governance Committee.

Reviewing HREC approving this research:

South Metropolitan Health Service Human Research Ethics Committee

Contact person: Ethics Coordinator Phone: 08 6152 2064.

Email: smhs.hrec@health.wa.gov.au

If you have any concerns about the conduct of the study or your rights as a research participant, please let us know. We will be very glad to answer your queries.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are: Manager, South Metropolitan Health Service Research Support and Development Unit by email SMHS.RGO@health.wa.gov.au or phone 08 6152 3214.



CONSENT FORM

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Principal Investigator: Associate Professor Andrew Maiorana, Allied Health Dept. and Advanced Heart Failure and Cardiac Transplant Service, Fiona Stanley Hospital

I, agree to participate in the above study. I have read and understood the attached information sheet and I have retained a copy of the signed document. I have been given the opportunity to ask questions about the study by the Investigator. I understand that I may withdraw from the study at any time without affecting any future medical treatment, or the treatment of the condition which is the subject of the study.

Signed _____

Date _____

Signature _____

Date _____

of person obtaining consent

Name _____

of person obtaining consent