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**Participant Information Sheet and Consent Form**

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| **Title** | Comparing the physiological and haemodynamic responses to the sit to stand test and the six minute walk tests in heart failure |
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| **Protocol Number** | GU Ref No: 2021/451  Norm |
| **Coordinating Principal Investigator**  **Principal Investigator** | Norman Morris  Norman Morris (Principal Supervisor) |
| **Co-Investigators** | Ms Dongyi Chen (student researcher); Ms Menaka Louis; Dr Julie Adsett; Dr Llion Roberts; Mr Craig Aitken (student researcher); Dr Pramod Sharma |
| **Location** | Griffith University |

**Part 1 What does my participation involve?**

**You are invited** to take part in a study looking at the usefulness and accuracy of two different exercise tests to measure fitness in people with heart failure.

**1 Introduction**

You are invited to take part in this research project because you have heart failure. The research project is testing an exercise test commonly used in people with other conditions, to measure fitness.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Exercise is commonly recommended for people with heart failure as it has been shown to improve fitness and to reduce symptoms such as breathlessness and fatigue. To enable Physiotherapists to determine the correct type and intensity of exercise, an assessment is often conducted prior to the people with heart failure commencing their exercise programme. Traditionally, this assessment includes a review of your medical history, as well as measures of fitness and strength. Fitness is usually measured by a test called a six minute walk test (6MWT). This test requires people to walk up and down a 30 metre track for a period of six minutes, during which time, the distance that you walk and your blood pressure, heart rate and oxygen levels are recorded.

Whilst the 6MWT is used all over the world to measure fitness in people with heart failure, it is limited it in that it cannot easily be performed in peoples’ homes. During the COVID-19 pandemic, it became obvious that additional tests are needed which do not require people to attend their local health facility for this assessment. Conducting the assessment in people’s homes, or via a video link, would enable Physiotherapists to obtain the information that they need about a person’s fitness, without the person having to leave their own home.

The 60 second sit to stand test (STST-60) and the 30 second sit to stand test (STST-30) aresimple tests which requirepeople to repeatedly move from sitting to standing for a period of 60 seconds and a period of 30 seconds. Whilst this test is commonly used in people with other medical conditions, the effort required by someone with heart failure to perform this test, has never been measured. This research project is therefore designed to evaluate whether the STST-60 and STST-30 would be useful and accurate measure of fitness for people with heart failure. In particular, we hope to identify how hard this exercise is by measuring simple heart and lung measures.

This research project will be conducted in Building G02, Room 2.44, the School of Physiotherapy, Griffith University, Gold Coast. The researchers include Physiotherapists with expertise in prescribing exercise programmes for people with heart failure and a Physiotherapy student, conducting this study as part of her Honours degree. The study has been reviewed and approved by the Human Research Ethics Committees at Griffith University and Gold Coast University Hospital.

**3 What does participation in this research involve?**

For this study, we will enroll 25 people with heart failure over a period of 12 months. All participants will be people managed by the Heart Failure Service at the Robina Health Precinct.

The Heart Failure team at Robina Health Precinct will identify people who are eligible for the study, and the Physiotherapist on this team will provide information about the study and what is involved. If you agree to participate, you will be asked to sign a consent form and to attend two appointments spaced one week apart, at Griffith University. We will also let your specialist team and general practitioner know that you are involved in our study.

*Appointment 1*

At the initial appointment, you will be asked a number of questions about your medical conditions and your symptoms, and you will be asked to complete one questionnaire and two physical tests. The questionnaire, called the Kansas City Cardiomyopathy Questionnaire, takes five minutes to complete and asks questions about your quality of life. At this same appointment, we will also ask you to complete two walking tests (the 6MWT described above), as well as two tests to measure your leg strength. We anticipate that it will take up to ninety minutes to complete all tests for this appointment.

Even though these tests are quite short, it is possible that they may make you tired the next day. For this reason, the remaining tests will be done one week later to give you plenty of time to recover. We will also ring you one day after your appointment to ask about your leg fatigue.

*Appointment 2*

One week after attending your first appointment, you will return to Griffith University to complete the final tests. We anticipate that this appointment will only require 20- 30 minutes of your time.

At this appointment, you will complete one 60 second sit to stand test (STST-60) and one 30 second sit to stand test (STST-30)as described above. The STST-60 requires you to repeatedly move from sitting to standing as many times as you can in 60 seconds, without using your arms to help push, while the STST-30 requires you to repeatedly move from sitting to standing as many times as you can in 30 seconds, without using your arms to help push Both the total numbers of stands in the 60 seconds and 30 seconds are recorded. After sufficient rest, we will ask you to repeat the test for a second time.

As for appointment one, we will ring you one day after your appointment to ask about any leg fatigue that you are experiencing.

*Equipment*

To measure how hard the 6MWT, STST-60 and STST-30 are for you to perform, we will ask you to wear some monitoring devices during each of these tests (appointment 1 and appointment 2). These monitoring devices provide us with information about your heart rate, blood pressure and heart pumping function, as well as breathing function. To do this, we will attach a probe to your finger to measure your blood pressure, and some small electrodes to your chest (similar to an ECG) to measure the amount your heart is pumping (your cardiac output). We will also ask you to wear a mask with light-weight back pack whilst you perform each of the exercise tests. This mask measures the carbon dioxide that you breathe out as well as your breathing rate, and thus helps us to calculate how much energy you expend to perform the tests.

**4 What do I have to do?**

There are no specific requirements for you to consider by being enrolled in this study with the exception of you attending the two appointments, one week apart at Griffith University.

**5 Other relevant information about the research project**

One of the investigator’s on this study is a Physiotherapy Honours student, who will be using the results of this study for her studies. Experienced Physiotherapists will be present at all times to assist with the study.

**6 Do I have to take part in this research project?**

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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Gold Coast Health.

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

We cannot guarantee or promise that you will receive any benefits from this research.

Whilst this study may not benefit you directly, finding measures of fitness which people with heart failure can accurately and safely perform in their own homes, will enable us to deliver a greater range of exercise programmes, tailored to each person’s needs and situation. In so doing, we hope to assist more people to access exercise opportunities which assists to improve their health. If you are injured as a result of taking part of the study we will contact your general practitioner and advise them of the incident and the details. Should you require emergency medical treatment during the study at the University we will follow our emergency procedures and contact the ambulance for immediate treatment.

**8 What are the possible risks and disadvantages of taking part?**

As the tests included in this study are commonly used in exercise programmes for people with chronic heart and lung problems, we anticipate very few risks. To ensure your safety however, we will undertake a number of processes. Prior to performing any of the measures in this study, the heart failure programme staff will determine if you have any particular risks that may impact on your safety. This may particularly be the case if you have low blood pressure which worsens when you stand up or if you have had recent chest pain that may worsen with repeated exercise. In these cases, the programme staff will advise you not to participate in the study. Should your situation change or your symptoms resolve and you remain interested in participating, the programme staff will reassess your suitability at a later time and only allow you to participate if there is no foreseeable risk. All assessments will be supervised by experienced Physiotherapists who are very experienced in managing people with your condition.

Completion of the 6MWT,STST-60 and STST-30 may make you feel more fatigued than usual. To minimise the fatigue that you feel, the tests will be separated by one week to ensure that you are well rested.

For some people with heart failure, repeated exertion can cause temporary increased shortness of breath. If this occurs at a level more than expected, the Physiotherapist will ask you to cease the test you are performing and to rest until your symptoms resolve. The test will only be repeated if it is deemed safe to do so.

**9 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. Your decision to do so is entirely voluntary and in no way will it impact upon the care you receive.

**10 What happens when the research project ends?**

At completion of this study, we hope to disseminate our results to all heart failure and cardiac rehabilitation programmes in Queensland Health. We will also present our findings at local, state-wide and national conferences and forums and we hope to publish these findings in a peer reviewed journal.

Should our results demonstrate that sit to stand tests are safe, relevant and useful for assessment of fitness in people with heart failure, we will recommend that clinicians consider using this test within their rehabilitation programmes where considered appropriate.

**Part 2 How is the research project being conducted?**

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

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project. All information collected about you is confidential. The information will be collected on paper forms which will be stored in a locked cabinet within the School of Physiotherapy at Griffith University. The information will be transcribed into a secure database, which is password protected and only accessible by the study investigators. All information will be kept for at least 15 years, so that we can reliably answer questions that other researchers might ask about our findings. 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.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. When we have completed collecting information about you, we will remove all identifying information (your name, address, DOB) from the data collection forms and database. All correspondence is strictly confidential.

It is anticipated that the results of this study 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 as only grouped information, rather than individual information, will be presented.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future researchthat can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**12 Complaints**

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

All injuries or adverse outcomes will be recorded and communicated to the Human Research Ethics Committee and the research governance unit at each participating site.

You will not benefit financially from your involvement in this research project and no member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**13 Who has reviewed the 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 Griffith University.

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.

Approval has been given by each of the institutions involved in this study.

**14 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. You want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project you can contact any of the following people:

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| *Chief Investigator:* | Prof Norman Morris  Professor of Physiotherapy  School of Health Sciences and Social Work  Menzies Health Institute  Griffith University  Metro North Hospital and Health Service, The Prince Charles Hospital, The Allied Health Research Collaborative  Phone 07 567 80162  Email: n.morris@griffith.edu.au |

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| *Associate Investigators:*  Dongyi Chen | Physiotherapy Honours student  School of Allied Health Sciences  Griffith University  Email: [Dongyi.chen@griffithuni.edu.au](mailto:Dongyi.chen@griffithuni.edu.au) |
| Menaka Louis | Physiotherapist, Robina Health Precinct, Heart Failure Service  Phone 07 5635 6364  Email: Menaka.louis@health.qld.gov.au |
| Dr Julie Adsett | Physiotherapist, Royal Brisbane and Women’s Hospital Heart Support Service  Phone: 07 3636 0286  Email:Julie.adsett@health.qld.gov.au |
| Dr Llion Roberts | School of Health Sciences and Social Work  Menzies Health Institute  Griffith University  llion.roberts@griffith.edu.au |
| Mr Craig Aitken | School of Health Sciences and Social Work  Menzies Health Institute  Griffith University  Metro North Hospital and Health Service, The Prince Charles Hospital,  craig.aitken@griffithuni.edu.au |

If you have any complaints about any aspect of the project or the way it is being conducted, then you may contact:

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| Reviewing HREC name | Griffith University |
| HREC Executive Officer | Ms Kim Madison |
| Telephone | 07 373 54375 |
| Email | k.madison@griffith.edu.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Research Governance Officer) Local HREC Office contact (Single Site -Research Governance Officer)**

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| --- | --- |
| Name | Research Governance Leader |
| Position | Research Governance Officer |
| Telephone | 07 56873880 |
| Email | gchresearch@health.qld.gov.au |

**Consent Form**

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| **Title** | Comparing the physiological and haemodynamic responses to the sit to stand test and the six minute walk tests in heart failure |
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| **Protocol Number** | GU Ref No: 2021/451  Norm |
| **Coordinating Principal Investigator**  **Principal Investigator** | Norman Morris  Norman Morris (Principal Supervisor) |
| **Co-Investigators** | Ms Dongyi Chen (student researcher); Ms Menaka Louis; Dr Julie Adsett; Dr Llion Roberts; Mr Craig Aitken (student researcher); Dr Pramod Sharma |
| **Location** | Griffith University |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Griffith Universityconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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| Name of participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Name of witness to participant’s signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Declaration by Senior Researcher**

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| 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 Study researcher \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |