Participant Information Sheet/Consent Form
Non-Interventional Study - Adult providing own consent

Title: The development of a walking test to measure shortness of breath in Cardiopulmonary Disease

Short Title: Measuring exertional breathlessness with the Dyspnea Challenge

Protocol Number: 55714

Principal Investigator: Professor Norman R. Morris (PhD, BAppSc Physio)

Associate Investigators: Ms Tanya Palmer (GradCertTEd, BPthy, BExSci)
Mr Craig Aitken (BExSci, MSc ExPhys)
Dr Surendran Sabapathy (PhD, Acc ExPhys)
Dr James Walsh (PhD, BPthy)
Ms Menaka Sabaratnam (BPthy)
Dr Glenn Stewart (PhD, BExSci)
Dr Martin Strahan (MB BS DrPH FRACP FRCP FACPM FAFPHM)
Dr Siva Sivakumaran (MBBS, MRCP (UK), FRACP, FCCP)

Location: Choose an item.

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project because you have been referred for or have completed a pulmonary or cardiac rehabilitation program at the Choose an item.. This research project is aiming to compare two walking tests (the Six-minute walk test (6MWT) and the Dyspnea Challenge in order to evaluate their measures of breathlessness during activity. Furthermore, the ability of the Dyspnea Challenge to detect acute and longer term changes in breathlessness will be explored.

This Participant Information Sheet/Consent Form tells you about the research project. It explains all the procedures involved in our study. 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.

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 the Consent Form, you are telling us that you:
• Understand what you have read

• Consent to take part in the research project
• 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?

The primary aims of this research study are to:

i. To evaluate whether six-minute walk distance (6MWD) is an adequate measure of exertional dyspnea when compared to the dyspnea challenge.
ii. To assess the sensitivity of the dyspnea challenge to changes in exertional dyspnea via changes to the gradient of the treadmill.
iii. Compare the efficacy of the dyspnea challenge across a range of cardiopulmonary disease.
iv. To assess the responsiveness of the dyspnea challenge to changes in exertional dyspnea experienced post an acute intervention and exercise rehabilitation programs (Pulmonary and Heart Failure rehabilitation programs).

Background

The purpose of the research is to evaluate the design of the 'dyspnea challenge', a two-minute treadmill protocol which has been developed to measure exertional dyspnea (ED) (*"breathlessness"*). ED is the feeling of discomfort in breathing during exercise/physical activity and it is the most common symptom of chronic heart and lung disease. Current testing procedures involve questionnaires or poorly controlled exercise tests which may not give reliable results. It is important that a test is designed to precisely measure changes in ED over time as this will allow for the mechanisms behind ED to be better understood and for treatment pathways to be evaluated with greater accuracy.

Benefits of our Study

Whilst it is unlikely that you will have any direct benefit from participating in this study, it will provide important information that will further develop the safety and reproducibility of the dyspnea challenge test. An improved methodology will enable researchers and clinicians to specifically investigate therapeutic interventions proposed to ease symptoms of ED. From participating in the study, you will gain information regarding your levels of ED and your heart and lung responses to exertional activities.

3. What does participation in this research involve?

If you consent, you will be asked to undertake the walking tests described below and complete a couple of questionnaires. The study is made up of three parts, you may be asked to complete more than one part of the study. Parts A and B of the study there will be a total of 6 visits, each approximately 1.5 hours long. Part C of the study will be completed over 3 visits, 2 visits before commencing and 1 visit at completion of your Pulmonary or Heart Failure Rehabilition program, each visit approximately 1 to 1.5 hours long. However we understand that time may be a constraint, participation in all parts will be discussed with you at your initial visit.

You will be asked for written consent prior to any participation in this study. If you do not want to take part in this study, please tell the staff.

You will be eligible to participate in our study if you are:

- An adult over 18 years living at home
- Agree to participate in the study
- Able to tolerate an oxygen type face mask on your face during the walking tests
- Able to tolerate a chest wall binder fitted tightly around your chest during walking tests

There are no costs, other than parking associated with participating in this research project, nor will you be paid. You may be provided with parking cost for the purpose of this research if required.

With your consent, we will enter all information collected into an excel database so that we can analyse and publish outcomes. Please note that outcomes would be entered under a coded number and by patient group to de-identify you. At no time will you be identified in any publication of results that are planned at the close of the study.

4. What do I have to do?

You have been recruited from the Choose an item.and data collection will take place at Choose an item.. There are three parts to this project– the first part (Part A) involves 3 visits which includes a familiarisation, two 6MWT and two 2-minute walking tests on a treadmill. The second part (Part B) involves 3 visits during which you will do two 2-minute treadmill walks at different grades. The third part (Part C) involves 3 visits during which you will do 2-minute treadmill walks pre and post an acute intervention (a fitted chest wall binder, COPD patients only), and prior to and after completion of a 8-10 week Pulmonary or Heart Failure Rehabilitation program. Each visit will be approximately 1.5 hours long. Ideally, we would like you to undertake all visits, however, if this is too much, you may choose just to participate in a single part. Even after starting the study you have the right to withdraw at any point and this will not affect any relationship you have with the researchers or your medical team. Each visit is explained below:

Part A

Visit 1 (Pre-screening, assessment and familiarisation) – The first visit is to familiarise you with all equipment and procedures to ensure your safety during the study. Firstly, the study and objectives will be explained to you, if you are happy to continue witnessed informed consent will be obtained, a pre-assessment health screening and a couple of questionnaires; St George Respiratory Questionnaire (COPD) or Kansas City Cardiomyopathy Questionnaire (HF), medical research council dyspnea questionnaire, Dyspnoea-12 questionnaire, Baseline Dyspnoea Index (BDI) and the hospital anxiety and depression questionnaire will be completed. Next, you will take part in pulmonary function testing which requires you to blow into a tube at maximum force. Although a maximal force is required, this part of the testing is not too taxing. Before taking part in any exercise, you will have your resting heart rate and blood pressure measured to ensure you are physiologically safe to perform exercise. You will also have your anthropometric (height and weight) assessment done. Next you will be familiarised to both exercise tests and all equipment that will be used over the remaining visits. Firstly, you will be asked to perform a six-

minute walk test, following by 20-30-minute rest, and then a 2-minute dyspnea challenge treadmill test. Totalling an exercise time of between 8-9 minutes. The protocol will be demonstrated to you before you perform them. During the six-minute walk test you will be asked to walk up and down a 30m long corridor for six minutes with the objective to walk as far as you can. Each minute you will be asked about your breathlessness. During the dyspnea challenge you will be asked to walk at a speed of 3m.h at a gradient of 4% for 2 minutes. During this time, you will be rating your own breathlessness on a computer monitor in front of the treadmill.

During both tests you will have several pieces of equipment to wear. These are; an electrocardiogram to measure both heart rate and heart rhythm, a PhysioFlow to measure cardiac output and stroke volume, a metabolic system to measure cardio-pulmonary factors such as oxygen use, a forehead probe to measure arterial blood saturation and a portamon device which will be strapped to your calf which will measure muscle tissue oxygenation. At the end of both tests you will be asked to rate your leg fatigue on a 0-10 scale and familiarised to the multi-dimensional dyspnea profile questionnaire which you will complete at the end of all exercise tests.

Visit 2 and Visit 3 – During these visits you will be asked to complete 4 exercise tests (2 on each visit). You will be asked to complete 2 six-minute walk tests and 2 dyspnea challenges. One of each test will be completed with all the equipment on from the familiarisation session. The other you will only be required to wear an electrocardiogram, and a forehead oximeter to measure heart rate, rhythm and arterial oxygen saturation. These four tests will be performed in a random order. At the end of each test, as in the familiarisation test, you will be asked to complete the multi-dimensional dyspnea profile.

Part B

Visit 4-6 – During these visits you will be asked to complete 6x2-minute dyspnea challenges, at 3km/h at differing gradients. The gradients you will complete will range from 3-8%. These will be completed in a random order and you will be asked to complete 2 on each visit. During the walk you will be fitted with an electrocardiogram to measure heart rate, an oximeter to measure oxygen saturation, the Physioflow to measure cardiac output and stroke volume and a calf oximeter to measure muscle tissue oxygenation. You will be asked to rate your dyspnea at 10 second intervals throughout the DC by using a 0-10 scale displayed on a PC based system. At the end of each DC you will be asked to complete a multi-dimensional profile (MDP) questionnaire.

Part C

Visit 7 and 8 (COPD Participants Only) – Will be completed prior to commencing Pulmonary or Heart Failure Rehabilitation programs and the wearing of chest wall binders will only be completed by COPD participants. During these visits you will be asked to complete 4 exercise tests (2 on each visit). You will be asked to complete 2 dyspnea challenges. Each test will be completed wearing a forehead oximeter to measure heart rate, rhythm and arterial oxygen saturation. Two of the four tests you will be required to also wear a chest wall binder. These four tests will be performed in a random order. At the end of each test, as in the familiarisation test, you will be asked to complete the multi-dimensional dyspnea profile.

Visit 9 – Will be completed after the completion of Pulmonary or Heart Failure Rehabilitation programs by participants. During this visit you will be asked to complete 2 exercise tests. You will be asked to complete 2 dyspnea challenges. Each test will be completed wearing a forehead oximeter to measure heart rate, rhythm and arterial oxygen saturation. At the end of each test, as in the familiarisation test, you will be asked to complete the multi-dimensional dyspnea profile and the TDI questionnaire.

5. 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 participate. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. All that we ask in order to withdraw from the study is to complete the withdrawal form as part of this information.

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 **Choose an item.**

6. What are the possible benefits of taking part?

Although this project is directed towards the expansion of medical knowledge, participation in the study may not benefit you directly. However, your participation will contribute to scientific research, which may benefit others in the future.

7. What are the possible risks and disadvantages of taking part?

All measures that will be taken as part of the familiarisation testing and during each visit are non-invasive and painless procedures that are not associated with any known health risks. Blood pressure measurements may cause a mild degree of discomfort, during cuff inflation, however this is a normal and common sensation.

During exercise you may experience symptoms such as abnormal heart rate and rhythms, shortness of breath, dizziness, light-headedness, confusion and nausea. However, these exercise tests mimic walking in everyday life such as walking on a flat surface (6MWT) and walking uphill (dyspnea challenge). The chest wall binder may cause a mild degree of discomfort during periods of heavy breathing, this is to be expected but can quickly be removed with instant relief given. Your tests will be performed and supervised by experienced investigators who will be present to prevent or manage any problems that may arise. If you find the discomfort associated with any of the walk tests intolerable, please inform the investigators and the test will be stopped immediately. Some patients may experience chest pain, change of heart rhythm, breathlessness, musculoskeletal, balance, calf pain or excessive sweating. Physiotherapy staff experienced in the conductance of these walk tests and emergency equipment will be available during the walking tests and several safety strategies are undertaken to minimize risks associated with these tests.

8. What if I withdraw from this research project?

Should you decide to withdraw from the study you may do so at any time, without giving a reason, by informing the researcher (section 11 of this form) by phone or filling in the revocation form attached. Such withdrawal will not affect your relationship with those treating you or your relationship with **Choose an item.**.

Part 2 How is the research project being conducted?

9. What will happen to information about me?

By signing the consent form, you consent to the relevant research staff collecting and using your demographic and physical performance information collected during the tests for the research project. Any information obtained that could identify you, will be kept confidential. All data collected will be stored securely in a locked filing cabinet in the physiotherapy research office on a computer that requires a password for access that will only be known to the assessing researchers.

Your information will be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Details of any data collected about yourself will be kept confidential, and any demographics that may identify you, will be de-identified before any information is published. Your information will not be shared with other participants. The overall findings of the study could be made known to you on request but no comments about individual participants will be provided. In addition, the de-identified information may be used for other research-related purposes following further approval by the Metro North Health Human Research Ethics Committee B.

Information about you may be obtained from your health records held at this health service 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.

In accordance with Griffith University and Queensland Health 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 any study team member named on this document if you would like to access your information.

10. 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 Metro North Health HREC B, Bundaberg Health Promotions, Griffith University and Central Queensland 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.

11. Further information and who to contact

If you want any further information concerning this project or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Primary Investigator
Professor Norman Morris
School of Allied Health Sciences
Telephone: 07 5552 8921
Email: n.morris@griffith.edu.au

Associate Investigator
Ms Tanya Palmer
School of Allied Health Sciences
Telephone: 07 4150 7005
Email: t.palmer@cqu.edu.au

If you wish to discuss your involvement in the project or any concern with someone not connected with the study, you may contact the ethics department:

Metro North Health HREC B, Telephone: (07) 3646 5280, Email: MetroNorthResearch-Ethics@health.qld.gov.au

Participant Consent Form
Participant Copy

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Dr Siva Sivakumaran (MBBS, MRCP (UK), FRACP, FCCP)

Location: Choose an item.

Declaration by Participant

I have read the Participant Information Sheet, or someone has read it to me in language that I understand. I have had an opportunity to ask questions and I am satisfied with the answers I have received. I understand the purposes, procedures and risks of the research described in the project.

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 the quality of treatment provided to me.
I have been informed that my refusal to consent to participate in the study will not affect in any way the quality of treatment provided to me.

I understand that confidentiality will be maintained in respect of any information obtained during the project. I understand that I will be given a signed copy of this document to keep.

Name of participant: ..... **Signature**: ..... **Date**: _ _ /_ _ /_ _ _ _

Declaration by Investigator

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 Investigator: ..... **Signature**: ..... **Date**: _ _ /_ _ /_ _ _ _

Participant Consent Form
Investigator Copy

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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 the quality of treatment provided to me.
I have been informed that my refusal to consent to participate in the study will not affect in any way the quality of treatment provided to me.

I understand that confidentiality will be maintained in respect of any information obtained during the project. I understand that I will be given a signed copy of this document to keep.

Name of participant: ..... **Signature**: ..... **Date**: _ _/_ _/_ _ _ _

Declaration by Investigator

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 Investigator: ..... **Signature**: ..... **Date**: _ _/_ _/_ _ _ _

Form for Withdrawal of Participation - Adult providing own consent

Title: The development of a walking test to measure shortness of breath in Cardiopulmonary Disease

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Location: Choose an item.

Declaration by Participant

I hereby wish to WITHDRAW from participation in the above research project and understand that such withdrawal WILL NOT affect my routine treatment, my relationship with those treating me or my relationship with Choose an item..

Name of participant: ..... **Signature**: ..... **Date**: _ _ /_ _ /_ _ _ _

Declaration by Investigator

I have given a verbal explanation of the implications of withdrawal from the research project, and I believe that the participant has understood that explanation.

Name of Investigator: .....**Signature**: .....**Date:** _ _ /_ _ /_ _ _ _

This Revocation of Consent should be forwarded to:
Professor Norman Morris or Ms Tanya Palmer
The Prince Charles Hospital
Physiotherapy Department
Rode Rd, Chermside, QLD 4032