Title: Cardiac rehabilitation in regional areas: developing a predictive model for ventilatory thresholds and assessing telehealth in phase III cardiac rehabilitation

Short title: Improving exercise prescription in regional cardiac rehabilitation programs

Principal Investigator: Dr Blake Collins

Associate investigator(s): A/Prof Brett Gordon, Prof Michael Kingsley, Dr Daniel Wundersitz, Dr Lisa Hanson, Ms Jacquelyn Dunstan, Dr Simon Nichols and Mr Alasdair O’Doherty

1. Am I eligible to participate?
   Thank you for showing interest in participating in the research project titled “Cardiac rehabilitation in regional areas: developing a predictive model for ventilatory thresholds and assessing telehealth in phase III cardiac rehabilitation”. To participate you must meet the following criteria:
   - Able to understand and respond to spoken English
   - Aged 18 years and older
   - Diagnosed with cardiovascular disease and exiting out-patient cardiac rehabilitation program
   - Available to meet the time commitments and physically able to complete testing

   If you have any difficulty in understanding the requirements of participation, please contact a member of the research team.

2. What is the study about?
   Cardiac rehabilitation is important following a heart attack. However, prescribing the exercise correctly within rehabilitation relies on specialised equipment that may not be available in regional areas. Further, implementing exercise using telehealth may be more appropriate for some people facing barriers to participation. This project involves two experimental phases to understand these issues. The first phase aims to develop a model for prescribing exercise using exercise tests that can easily be conducted in a doctor’s clinic. The second phase aims to assess the benefit of cardiac rehabilitation programs delivered using telehealth compared to in person. The first phase will require you to attend three (3) times within a week:

   - Three (3) laboratory sessions at La Trobe University involve six (6) maximum effort exercise tests through walking, cycling, standing, and stepping. During these sessions we will be collecting information on your general health (via questionnaires) and fitness levels.

Participants who complete the first phase will be invited to complete additional testing (measure of sleep quality, heart function, and blood testing) and a 6-week exercise program conducted either onsite at La Trobe University or at-home via telehealth.

This Participant Information Sheet/Consent Form tells you about the research project, including explaining the tests, activities and your rights as a participant to help you decide if you want to take part in the project. Please read this information carefully. Ask questions about anything that you do not fully understand or if...
you want to find out more information. You may also want to talk about the project with a relative, friend or medical professional before you decide to take part.

Participation in this research is voluntary, if you do not wish to take part you do not have to. If you decide you want to take part, 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 the tests and research that are described
- Consent to the use of your personal and health information as described
- Understand that if eligible you will be invited to participate in the training intervention and additional testing described below

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

3. What is the purpose of this research?

The purpose of this research project is to determine an accurate way of assessing fitness and prescribing exercise for cardiac rehabilitation and to identify if exercise as part of cardiac rehabilitation is beneficial when provided by telehealth.

4. What does participation in the research involve?

If you wish to participate in this research project, and meet the eligibility criteria, you are required to give consent by signing the participant consent form attached to the bottom of this Information Sheet before you participate. There are no costs associated with participating in this research project, nor will you be paid. The project involves:

- Attending La Trobe University Bendigo Campus on three separate occasions to complete baseline testing
- At or prior to the first session, you will complete questionnaires about your current sleep, mental and physical health
- At the first session you will complete two exercise tests
- At the second session you will complete a different two exercise tests
- If you complete the exercise tests in the first two sessions without complication you will complete a final maximum effort exercise test measuring your breathing response
- If you wish to participate in the 6-week exercise program you will have measures of heart function and sleep conducted and undergo a blood test before being randomly allocated the on-site or at-home exercise training study
- If you participate in the 6-week exercise program you will be required to return to the laboratory one final time at the completion of the intervention to repeat exercise and health testing

Volunteering for the initial phase of the research project does not mean you need to participate in the exercise program and are free to withdraw consent and cease participation at any time.
Details of the testing session are explained below:

**First Laboratory Testing Session (La Trobe University Bendigo, Exercise Physiology Laboratory)**

In the first session you will undertake three (3) activities for a total duration of 45-50 minutes

1. **Activity One** – you will be asked to complete seven (7) questionnaires:
   a) General health questionnaire
   b) ESSA Adult Pre-exercise Screening System
   c) Duke Activity Status Index
   d) New York Heart Association Questionnaire
   e) Short Form 36 Questionnaire
   f) International Physical Activity Questionnaire
   g) Depression Anxiety Stress Scale

   You will then be randomly allocated two (2) of four (4) submaximal functional exercise tests. Listed below are examples of the potential order testing may occur.

2. **Activity Two** – Six Minute Walk Test (6MWT), a safe well-tolerated method to assess functional exercise capacity. You will be asked to cover as much distance as possible on an indoor walking track in 6 minutes.

3. **Activity Three** – Incremental Shuttle Walk Test (ISWT), after a recovery period you will be asked to complete the ISWT. Another commonly used functional exercise test where you will be instructed to complete laps (of a 10m track) in time with an external pace (beeps) that progressively gets faster until you can no longer keep up with the pace. Because of the external pacing, this test is considered a maximal test of fitness

**Second Laboratory Testing Session (La Trobe University Bendigo, Exercise Physiology Laboratory)**

In the second session you will undertake two (2) activities for a total duration of 35 minutes

1. **Activity One** – Astrand-Ryhming submaximal cycle test will require you to cycle on a stationary bike at a predetermined resistance while maintaining a consistent pedal rate, for 6 minutes. Exercise heart rate and rating of perceived exertion is collected in the final two minutes and used to predict maximal capacity.

2. **Activity Two** – Chester Step Test will require you to step onto and off a step according to an external pace in the form of a metronome recording. The test includes five (5) 2-minute stages but can be stopped early.

**Third Laboratory Testing Session (La Trobe University Bendigo, Exercise Physiology Laboratory)**

1. The time frame and activities for the third session you will depend on your participation in the exercise program. If you consent to participate in the 6-week exercise program, you will complete activities three to six below (30 minutes combined time). Activity One – you will be asked to complete a 30
second sit-to-stand (STS) test which involves you rising from a seated position before sitting back down as quickly and safely as possible in 30 seconds.

2. Activity Two - Maximum effort exercise test will involve a riding on a stationary bike with resistance regularly increasing until you feel that you can no longer continue. You will be required to wear a heart rate monitor and facemask (similar in size and shape to an oxygen mask) that will record how much air you breathe during exercise (20 minutes).

3. Activity Three – A blood test collected from a needle inserted into a vein in your arm (usual blood test procedure). Two small tubes of blood (approximately 15 ml in total) will be collected to determine your cholesterol profile

4. Activity Four – you will wear a 5-lead Holter monitor (portable ECG) to record and measure heart function

5. Activity Five – You will be required to lay on your back while a blood pressure cuff is placed around your upper arm and thigh. The time between heart beats will be measured by a device touching the skin over a vein on your neck.

6. Activity Six – you will wear a watch-like device for seven (7) days and record sleep quality in a sleep diary.

Exercise Program

If you volunteer to participate in the exercise program, you will be randomly allocated an onsite intervention (conducted at La Trobe University Bendigo) or at-home intervention conducted via a telehealth program. Telehealth component will involve patients remotely monitoring and logging training sessions (training diary) and attending a weekly virtual appointment with a member of the research team to discuss the training progress. The exercise program will involve three weekly sessions of aerobic exercise (i.e. walking) for up to 60 minutes per session. Following the 6-week exercise program you will be required to return for one final laboratory testing session.

Final Laboratory Testing Session (La Trobe University Bendigo, Exercise Physiology Laboratory)

In the final session you will repeat the testing activities in Session Three, with the addition of questionnaires from the first laboratory session a total duration of 60 minutes

1. Activity One – you will be asked to complete seven (7) questionnaires:
   a) General health questionnaire
   b) ESSA Adult Pre-exercise Screening System
   c) Duke Activity Status Index
   d) New York Heart Association Questionnaire
   e) Short Form 36 Questionnaire
   f) International Physical Activity Questionnaire
   g) Depression Anxiety Stress Scale

2. Blood testing

3. 5-lead ECG
4. Wearing a watch for seven (7) days

5. What will I be asked to do?

To fully participate in this study, you need to agree to the following restrictions:
- Time commitment of initial testing is three (3) laboratory sessions totalling approximately 2-3 hours
- Time commitment of the exercise program is sixty (60) minutes three times a week for six (6) weeks plus an additional sixty (60) minute post testing session. Training will be conducted onsite at La Trobe University or at-home via telehealth (requiring you to keep a log of training sessions and attend a weekly, online visit)
- A watch and recording sleep in a diary is recorded for a total fourteen (14) days, seven (7) days each pre and post exercise

6. What are the benefits?

The proposed research project has potential benefits to both you as an individual and the wider community. Firstly, exercise-based cardiac rehabilitation has been demonstrated to improve individual functioning, quality of life and reduce risk of future heart problems. While these results cannot be guaranteed, enrolment in initial testing and exercise program has the potential to improve important health measures. During the project you will also have access to additional testing, resources and support you may not otherwise receive. These include assessment by an Accredited Exercise Physiologist, measure of cardiac fitness and supervised exercise programs (onsite or at-home). Finally, your participation will benefit the wider community as results from this project will inform future research projects and cardiac rehabilitation programs.

7. What are the risks?

With any study there are (1) risks we know about, (2) risks we don’t know about and (3) risks we don’t expect. If you experience something that you aren’t sure about, please contact us immediately so we can discuss the best way to manage your concerns.

Potential risk for participants involved in the proposed research project include sustaining musculoskeletal injury during fitness testing or the subsequent exercise program. To complete exercise testing and the exercise program participants will be required to exert a level of physical effort that be considered uncomfortable and has a risk of muscular pain and/or injury. To minimise the risk of musculoskeletal injury volunteers will be recruited following referral to and discharge from Phase II cardiac rehabilitation programs and prescribed exercise training by their health care professional. Further assessment of disease severity and risk of exercise participation will be conducted by an Accredited Exercise Physiologist and the project is designed in such a way that submaximal exercise testing is conducted first to inspect participant functionality and response to increasing exercise loads.

Participants are exposed to an additional risk of physical injury during blood collection. Blood collection will involve a blood sample being taken from a vein in your arm using a needle, which is associated with a level of discomfort and potential risk of infection. Physical injury during the collection of blood is addressed by having the collection procedure conducted by trained and experienced researchers. Researchers will use appropriate personal protective equipment including gloves, alcohol wipes to disinfect the collection site and sterilised, sealed single-use material which is disposed of in puncture resistance biohazard containers. Finally, the smallest size needle that allows for adequate flow will be used to minimise discomfort during the collection procedure.
Finally, disclosing sensitive personal information may cause distress for participants undergoing rehabilitation programs for clinically significant cardiovascular conditions. Distress may be related to acknowledging risks associated with current conditions including the risk of future morbidity/mortality and anxiety about how the information may be used. To address the issue of potentially distressing information you will be encouraged to discuss involvement in the research project with the research team and your health care provider before commencing the project. During this time the treatment/storage/presentation of collected data will be explained to potential volunteers with an opportunity to ask questions or voice their concerns. Further, we will be checking in with you toward the end of the study to see if you would like your own customised report on your results.

**What if you become upset or distressed as part of this research?**
We do not anticipate any risks arising as a result of your participation in the study. However, if you become upset or distressed as a result of your participation in the research, and wish to talk to someone, we encourage you to contact your local GP, Lifeline (call 13 11 14 or visit [https://www.lifeline.org.au/](https://www.lifeline.org.au/)), Beyond Blue (call 1300 22 4636 or visit [https://www.beyondblue.org.au/](https://www.beyondblue.org.au/)) or another support service (see [https://www.healthdirect.gov.au/mental-health-helplines](https://www.healthdirect.gov.au/mental-health-helplines)).

**What happens if a medical emergency occurs?**
If something unexpected happens during experimental procedures, trained first aiders will be on hand to immediately assist and notify emergency services. The member(s) of the research team will not leave your side and will provide support to the best of their abilities.

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>How often is it likely to occur?</th>
<th>How severe might it be?</th>
<th>How long might it last?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Side effects related to exercise testing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discomfort (sitting on bike for 6h)</td>
<td>Unlikely to occur</td>
<td>Mild</td>
<td>Several minutes</td>
</tr>
<tr>
<td>Dizziness</td>
<td>Unlikely to occur</td>
<td>Mild</td>
<td>Several minutes</td>
</tr>
<tr>
<td>Muscle soreness</td>
<td>Somewhat likely</td>
<td>Mild</td>
<td>Several days</td>
</tr>
<tr>
<td>Heart palpitations</td>
<td>Very unlikely</td>
<td>Mild</td>
<td>Several minutes</td>
</tr>
<tr>
<td>Muscle injury</td>
<td>Very unlikely</td>
<td>Moderate-severe</td>
<td>1-4 weeks</td>
</tr>
<tr>
<td>Heart attack</td>
<td>Very unlikely</td>
<td>Severe</td>
<td>Lifelong</td>
</tr>
<tr>
<td><strong>Side effects related to taking blood samples</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minor infection</td>
<td>Unlikely to occur</td>
<td>Moderate</td>
<td>1 – 7 days</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Unlikely to occur</td>
<td>Moderate</td>
<td>Several minutes</td>
</tr>
<tr>
<td>Bruising</td>
<td>Somewhat likely</td>
<td>Moderate</td>
<td>1 - 7 days</td>
</tr>
<tr>
<td>Discomfort</td>
<td>Unlikely to occur</td>
<td>mild</td>
<td>Several minutes</td>
</tr>
<tr>
<td><strong>Side effects related to wearing the 5-lead Holter</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin irritation</td>
<td>Somewhat likely</td>
<td>Mild</td>
<td>1 – 14 days</td>
</tr>
</tbody>
</table>
8. What will happen to information about me?

Electronic and (where necessary) hard copy information is being collected as part of this research project. Where hard copy information is collected, the information will be transferred to an electronic format. The hard copies will be destroyed with electronic copies stored on password protected computers and destroyed fifteen years after publication.

All information will be stored in a re-identifiable format (name and personal identifying information removed) using a unique participant number assigned by the Chief Investigator. Only one File (participant identification code sheet) will be kept that can link you to your stored samples. Upon completion of the research project, the participant identification code sheet will be securely destroyed, resulting in the previously re-identifiable data now de-identifiable. Electronic files with re-identifiable data will be stored on the University P drive requiring permission to access, of which only investigators and medical professionals at Bendigo Health and St John of God will have access to the information. Re-identifiable data collected during the research projects will be stored using Cloudstor online with the University research data management policy. All files will be on password protected computers. Summary data (group averages and standard deviation of datasets) will be uploaded to an online institutional repository (OPAL) in the interest of collaboration and shared data.

Blood samples are being collected to analyse for markers of future cardiac risk and are stored in the same coded manner to protect your individual privacy for fifteen years in accordance with the University Research Data Management Policy. Any samples of written information linking you to the coded samples will not be released and the lead researcher will do everything possible to ensure privacy and confidentiality is maintained.

The results from the research project are expected to be published in peer reviewed journals and presented at research conferences. The format the data is presented in is non-identifiable group average ± standard deviation with no personal details reported anywhere in the documents. This project does not involve the collection, storage, or analysis of genetic testing that would result in information about an identifiable future health risk to themselves or relevant health information for their family members who are not part of the project.

It is also our responsibility to inform you that any issues requiring mandatory reporting will be acted upon by the lead researcher who will report it to the necessary authority as required by law. The personal information you provide will be handled in accordance with applicable privacy laws, any health information collected will be handled in accordance with the Health Records Act 2001 (Vic). Subject to any exceptions in relevant laws, you have the right to access and correct your personal information by contacting the research team.

9. Will I hear about the results of the study?

At the end of the study, you will be asked if you wish to receive your personal result collected during the research project including individual aerobic capacity (fitness), sleep quality and heart function data. If you express interest in receiving a copy, you will be emailed a de-identified and summated report at the conclusion of the research project with confidentiality and anonymity maintained at all times. If interested in the overall results, you will be given access to the published data following peer review and publication process. In the event any data is collected with possible prognostic outcomes, the research team will contact you with the relevant information and encourage you to discuss the results with your medical professional, as interpreting such results are outside the research team’s expertise.
10. What if I change my mind?
You can choose to no longer be part of the study at any time until four weeks following the collection of your data. You can let us know by:
1. Completing the 'Withdrawal of Consent Form' (provided at the end of this document);
2. Calling us; or
3. Emailing us

Your decision to withdraw from the project will not affect your routine treatment, your relationship with those treating them, or your relationship with Bendigo Health, St John of God Health Care or La Trobe University. If you decide to withdraw, you will be informed if there are any special requirements linked to withdrawing and arrangements will be made to collect any experimental devices they may have. If you choose to withdraw during the project, we will stop collecting information from you, however any information collected up until that point will form part of the research project. If you withdraw after data analysis has commenced, we can only remove your name and contact details.

11. Who can I contact for questions or want more information?
If you would like to speak to us, please use the contact details below:

<table>
<thead>
<tr>
<th>Name/Organisation</th>
<th>Position</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Blake Collins</td>
<td>Holsworth Research Initiative – Research Officer</td>
<td>0409598135</td>
<td><a href="mailto:b.collins@latrobe.edu.au">b.collins@latrobe.edu.au</a></td>
</tr>
</tbody>
</table>

12. What if I have a complaint?
If you have a complaint about any part of this study, please contact:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Telephone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Research Ethics Advisor</td>
<td>Senior Research Ethics Advisor</td>
<td>(03) 9479 1443</td>
<td><a href="mailto:humanethics@latrobe.edu.au">humanethics@latrobe.edu.au</a></td>
</tr>
<tr>
<td>Research Governance Manager</td>
<td>Bendigo Health Human Research Ethics Committee</td>
<td>(03) 5454 6412</td>
<td><a href="mailto:researchofficer@bendigohealth.org.au">researchofficer@bendigohealth.org.au</a></td>
</tr>
</tbody>
</table>
Consent Form – Adult providing own consent

Title
Cardiac rehabilitation in regional areas: developing a predictive model for ventilatory thresholds and assessing telehealth in phase III cardiac rehabilitation

Short title
Improving exercise prescription in regional cardiac rehabilitation programs

Principal Investigator
Dr Blake Collins

Associate investigator (s)
A/Prof Brett Gordon, Prof Michael Kingsley, Dr Daniel Wundersitz, Dr Lisa Hanson, Ms Jacquelyn Dunstan, Dr Simon Nichols and Mr Alasdair O’Doherty

Consent Agreement
I have read the Participant Information Sheet, or someone has read it to me in a way that I understand.

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

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 participation in Phase Three will be offered to eligible participants.

I understand I am free to withdraw at any time during the project without effecting my future health care.

I understand that I will be given a copy of this document to keep and will be offered the opportunity to access a customised report of test results at the conclusion of the project.

I am aware that if I decide to withdraw in future that data collected by the researchers up to the time of withdrawal will form part of the research project results.

I agree to have blood samples collected and understand the risks involved (please tick one); Yes ☐ or No ☐

I understand that my data collected during this project including blood samples will be stored for 15 years post publication before being disposed of.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) ________________________________________________

Signature ___________________________________________ Date _____________________________

Declaration by Senior Researcher

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 Senior Researcher (please print) ________________________________________________

Signature ___________________________________________ Date _____________________________
Form for Withdrawal of Participation – Adult providing own consent

Title: Cardiac rehabilitation in regional areas: developing a predictive model for ventilatory thresholds and assessing telehealth in phase III cardiac rehabilitation

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Principal Investigator: Dr Blake Collins

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Declaration by Participant

I 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 Bendigo Health, St John of God Health Care or La Trobe University.

I understand that the data collected up until this stage will form part of the research project results.

Name of Participant (please print) __________________________________________________________

Signature ___________________________________________ Date _____________________________

Declaration by Senior Researcher

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 Senior Researcher (please print) ______________________________________________________

Signature ___________________________________________ Date _____________________________