Participant Information Sheet/Consent Form

Title	A risk-guided disease management and tele-rehabilitation program to reduce re-admissions in coronary artery disease
Short Title	Risk-Guided CAD
Project Number	266/21
Protocol Number	Version 2; 28 May 2021
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Melinda Carrington
Associate Investigator(s)	Professor Tom Marwick, Dr Quan Huynh, Associate Professor Jo-Anne Manski-Nankervis, Professor Brian Oldenburg, Dr Dominika Kwasnicka, Dr Erin Howden, Professor Garry Jennings, Professor David Thomson and Dr Deepak Haikerwal

Part 1 What does my participation involve?

You are invited to take part in this research project. This is because you have recently been hospitalised for coronary artery disease. The research project is assessing a management program to prevent another hospital admission in people who are most likely to be readmitted.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research 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 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 the tests and research 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?

Coronary artery disease (CAD) is the number one killer of Australians with a high risk for a recurrent event(s) and hospital readmission. Many of these readmissions can be prevented with better management to control the problem of CAD. A disease management program, led by nurses who interact with other health professionals/providers, can help with education and counselling, taking medications correctly and making healthy lifestyle changes for higher risk patients. Newer models of disease management programs make use of mobile devices (such as an "app") and telehealth (by phone or video call) to monitor and manage health which could facilitate CAD management. Therefore, the aim of this study is to test this type of disease management program compared to standard care for reducing hospital readmissions or death in people with CAD who are at high risk of being readmitted.

The research team will include approved student researchers, undertaking tasks under appropriate supervision for the purpose of obtaining their degree.

3 What does participation in this research involve?

If you decide you want to take part in the research project, the consent form must be signed prior to any study assessment being performed.

You have been identified by the research nurse as a potential participant because you have been admitted to hospital for CAD.

Risk evaluation (to identify higher risk patients)

Everybody will attend our clinic and have a risk evaluation based on your age, kidney function, prior heart attacks, number of coronary arteries involved in your most recent CAD event and any diagnosed diabetes. Using this risk score, you will be classified as:

1. ***Low risk***: If your score is less than 6 [out of 13] you are considered to be at low risk of being readmitted to hospital and are not required for this study. You will be asked if we can review your medical records only for any hospital readmissions or health outcomes over the following 12 months. This visit will take approximately 30 minutes.
2. ***High risk***: If your score is 6 or higher [out of 13], you are considered to be at high risk of being readmitted to hospital and will be able to take part in this study. You will proceed directly to the health assessment below. This visit will take approximately 1-1.5 hours.

By signing the consent form, you will allow the research team to access your medical notes for details about your hospital stay, blood test results, cardiac function tests, medical history and prescribed medications. We will also ask for some personal details including your ethnicity, relationship status, employment, income and education level.

For high-risk participants only

Clinical trial

If you decide you want to take part in the research project, you will be participating in a randomised controlled research project. Sometimes we do not know which treatment or management approach is best to improve cardiovascular outcomes; to find out, we need to compare different methods. We put people into groups and give each group a different management strategy. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). In this study, the two groups are:

1. ***Usual care*** (the control group) - If you are in the usual care group, the care you will receive will be part of the normal practice for CAD management, typically involving your doctor and cardiologist.
2. ***Nurse-led disease management*** (the intervention group) - If you are in the intervention group, you will continue to receive usual care and will also be assigned a cardiac nurse to help you manage your heart condition. The cardiac nurse will develop a care plan with you and communicate with your GP and/or cardiologist about your management, particularly your medicines to help control risk factors. The cardiac nurse will provide health coaching at pre-specified times over 12 months via telehealth (phone or video call) to ensure that you take your medications as prescribed and to give health education and guidance on lifestyle changes. You will have access to a cardiac rehabilitation program via a smartphone or tablet app (called *SmartCR*). This app monitors health and physical activity, has prompted tasks to do and delivers education via video, audio and written articles. The information from this app can be used by the cardiac nurse during telehealth follow-up. You will also be invited to participate in a supervised 6-week group exercise program which will require extra visits to our on-site gym.

This project will be carried out over 12 months. Everybody will have a health assessment at the start and end of the study in order to assess your health changes. We will review your medical records for any hospital readmissions or health outcomes for the 12 months after enrolling in the program.

You will not be paid for participating in this research project. Most tests and medical care required as part of the research project will be provided to you free of charge. There may be additional costs you will have to pay for that are associated with attending GP visits or paying for some medicines according to Medicare.

We recommend that you inform your doctor of your decision to participate in this research project.

4 What do I have to do?

Everybody will be required to attend at least 2 clinic appointments (at the start and end of the study) to have a health assessment. You will need to complete all questionnaires that you may be given. You may be required to have some blood tests which will require you to fast overnight for approximately 8 hours for more accurate blood processing. You should attend all appointments scheduled with your GP and other health professionals for the duration of the study.

Health assessment (all participants)
You will be asked to complete some brief questionnaires about depression, anxiety and your general well-being via an on-line survey. We will measure your blood pressure and heart rate by inflating and then deflating a cuff that is placed around the top of your arm. Your height and weight will be measured wearing loose clothing with no shoes using a height meter and digital weigh scales. We will perform a test to assess your cognitive skills (such as your memory and thinking). We will arrange for you to have a cardiopulmonary exercise test (CPET) to assess the performance of your heart and lungs at rest and during exercise. This requires you to perform mild exercise on an upright bicycle whilst breathing through a mouthpiece and having a heart tracing (ECG) recorded using sticky dots that will be placed on your chest and limbs. We may perform an ECG and ultrasound (echocardiogram) if you did not have one in hospital. We may take a small amount of blood (estimated 15-45 ml) to test for markers of cardiac disease and other indications of disease such as liver and kidney function that were not collected in hospital.

***For participants assigned to the intervention group only*:**
You will be involved in a total of 10 telehealth Zoom video-conferencing (telephone or video) calls by a cardiac nurse lasting around 15-20 minutes. You will be required to engage with the *SmartCR* cardiac rehabilitation app and you will be encouraged to participate in a supervised 6-week group exercise program which will require regular extra visits to our gym. The cardiac nurse may recommend that you seek advice from another health care professional for treatment or management.

5 Other relevant information about the research project

A total of 270 participants will be required to participate. Of these, 135 will be assigned to the usual care group and 135 will be assigned to the intervention group. This project involves researchers from the Baker Heart and Diabetes Institute, The University of Melbourne, HeartWest and Queens University Belfast.

You may be selected (20 participants are required in addition to other GPs, cardiologists and nurses) to have an interview with a member of the study team to discuss your experiences and satisfaction with the program. If you do not wish to take part in this evaluation, you do not have to. This interview will be recorded either via Zoom or a digital audio recorder and later transcribed. Information gathered will be secured stored in a password protected folder on the Baker Heart and Diabetes network with access restricted only to authorised study personnel.

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 Sheet/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 the Baker Heart & Diabetes Institute or HeartWest.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive management for CAD. Participation will not replace any usual treatment you would receive. You can still get treatment as usual from various health providers such as hospital care, specialist medical practices (e.g. HeartWest) and primary health care (e.g. your GP or pharmacist). Ongoing nurse co-ordinated care is less likely to be provided to you via these options. You can discuss this alternative with your health care team.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will gain anything from this research. However, possible benefits may include better management of your CAD that prevents being readmitted to hospital and an improvement in your quality of life. You may also learn more about CAD and how to manage it in the best possible way.

9 What are the possible risks and disadvantages of taking part?

While this research does not involve any interventional treatment, you may be receiving medical treatments that cause side effects. You may have none, some or all of the effects and they may be mild, moderate or severe. If you experience any side effects or are worried about them, talk with the cardiac nurse during any of your visits or via telephone, or talk with your GP.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the cardiac nurse or your doctor immediately about any new or unusual symptoms.

Possible risks, side effects and discomforts include:

- blood pressure cuff inflation may cause mild discomfort as a result of restricting blood flow and may cause some local skin irritation which will usually resolve within 60 seconds once the cuff is removed.
- having blood taken may cause moderate discomfort at the site of needle insertion for approximately 60 seconds. Sometimes mild to moderate bruising or inflammation at the spot from which blood is taken can last 2-3 days. Some people may feel lightheaded when having blood taken and may occasionally faint. Rarely, there could be infection or bleeding. If this happens, it can be easily treated.
- mild skin irritation from the sticky dots used for the ECG in people with sensitive skin.
- chest pain, light headedness or shortness of breath from starting physical activity after CAD. This risk can be minimised by seeking approval from your GP first and starting to exercise gradually, under supervision by a specialist trained person (e.g. an exercise physiologist).
- distress at being asked to recall details of your most recent CAD event. If you become upset or distressed as a result of your participation in the research, the cardiac nurse is able to arrange for counselling or other appropriate support via referral to your GP. Any counselling or support will be provided by staff who are not members of the research team. In addition, you may prefer to suspend or end your participation in the research if distress occurs.

Many side effects go away shortly after the test ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the cardiac nurse may need to stop investigations. The cardiac nurse or your GP will discuss the best way of managing any side effects with you.

The research study may reveal health problems that have previously not been diagnosed and that may affect insurance in the future.

10 What will happen to my test samples?

You will be asked to provide consent for the collection of your blood during the research project as it is a mandatory component of the project. The use of your blood is for both routine care and research purposes; we do not propose to store any of your blood samples for future research. Your venous blood sample will be individually identifiable for analysis by a certified pathology laboratory and the sample destroyed after use.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the management that is being studied. If this happens, the research nurse will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, the study nurse will make arrangements for your regular health care to continue. If you decide to continue in the research project you may be asked to sign an updated consent form.

Also, on receiving new information, your GP might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you will be able to take all of the medications or treatments you have been taking for any condition you may have or for other reasons. It is important to tell the cardiac nurse about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the nurse about any changes to these during your participation in the research project. Your research nurse should also explain to you that no treatments or medications need to be stopped for the time you are involved in the research project, unless recommended by a GP or health professional.

It may also be necessary for you to take medication during or after the research project to address any risk factors that you may have. You may need to pay for these medications and so it is important that you discuss this possibility with your GP.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team when you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study nurse and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured accurately. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. We would still like to review your medical records for any hospital readmissions or health outcomes for the 12 months after enrolling in the program. If you do not want them to do this, you must tell them upon withdrawing.

14 Could this research project be stopped unexpectedly?

It is unlikely that early termination of the project is necessary. There are minimal risks inherent to this kind of nurse-led disease management given that it involves close communication with other health care professionals and specialists and provides individualised and flexible health care.

15 What happens when the research project ends?

At the end of the 12 months, there will be no ongoing follow-up by the study team and the health care program will no longer be available. Any continued care and treatment after this time will be available from your GP and specialist.

Upon completion of the study, a summary of results of the study will be sent to all participants and made available on the Baker website (www.baker.edu.au) in approximately mid 2023.

16 What if I get injured in the research?

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. As 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.

Part 2 How is the research project being conducted?

17 What will happen to information about me?

By signing the consent form, you consent to the research nurse and relevant research staff collecting and using personal and health information about you for the research project. Information about you may be obtained from your health records held at this and/or other health services for the purpose of this research. By signing this consent form you agree to the research team accessing health records if they are relevant to your participation in this research project. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or to comply with law. Your information will be collected under unique study identification

numbers that you will be assigned but can be re-identifiable (If required identification numbers can be retraced to your data/information). Your venous blood test sample will be individually identifiable for pathology processing. All electronic data at Baker Heart & Diabetes Institute is stored on a dedicated mass storage device and is protected from unauthorised external access via networks through the use of firewalls and secure encrypted access pathways. Only specially trained and employed research personnel will have access to research data.

Personal information and data collected by © Cardihab in the *SmartCR* cardiac rehabilitation app will be securely stored on a Cloud based server in Australia. This information will only be accessible to permitted individuals in the research team or clinicians given access by the research team. Data stored on the app will remain for as long as you have the app on your phone. Data is synced to cloud storage and will be retained indefinitely as per Australian Privacy Act Cth(1988) and Health Records Act.

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

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

In accordance with relevant Australian and/or Victoria 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.

18 Who is organising and funding the research?

This research project is being organised by Associate Professor Melinda Carrington from the Baker Heart and Diabetes Institute. This research has been funded by the National Heart Foundation (APP ID 104773), the HCF Research Foundation, the Baker Department of Cardio-metabolic health and Perpetual IMPACT funding (IPAP 2020/0606).

19 Who has reviewed the research project?

The research project has undergone rigorous peer review by the above organisations for funding approval.

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 Alfred Hospital Ethics Committee

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.

20 Who should I contact if I have concerns about the conduct of the study?

The person you may need to contact will depend on the nature of your query.

If you would like any further information concerning this project you can contact:

Name: Carla Duarte
Position: Study Coordinator/Research Assistant
Telephone: 03 8532 1283
Email: carla.duarte@baker.edu.au

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, please quote the Project number 266/21 and you may contact:

HREC office/complaints contact person
Position: Complaints Officer, Office of Ethics & Research Governance, Alfred Health
Telephone: 03 9076 3619
Email: research@alfred.org.au

Or

Site complaints contact person
Name: Human Governance Manager
Position: Manager, Human Research Governance, Baker Heart & Diabetes Institute
Telephone: 03 8532 1709
Email: governance@baker.edu.au

Consent Form

Title	A risk-guided disease management and tele-rehabilitation program to reduce re-admissions in coronary artery disease
Short Title	Risk-Guided CAD
Project Number	266/21
Protocol Number	Version 2; 28 May 2021
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Melinda Carrington
Associate Investigator(s)	Professor Tom Marwick, Dr Quan Huynh, Associate Professor Jo-Anne Manski-Nankervis, Professor Brian Oldenburg, Dr Dominika Kwasnicka, Dr Erin Howden, Professor Garry Jennings, Professor David Thomson and Dr Deepak Haikerwal

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Declaration by Participant

I have read the Participant Information Sheet.

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

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

I understand that, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/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 Research Nurse (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for withdrawal of participation

Title	A risk-guided disease management and tele-rehabilitation program to reduce re-admissions in coronary artery disease
Short Title	Risk-Guided CAD
Project Number	266/21
Protocol Number	Version 2; 28 May 2021
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Melinda Carrington
Associate Investigator(s)	Professor Tom Marwick, Dr Quan Huynh, Associate Professor Jo-Anne Manski-Nankervis, Professor Brian Oldenburg, Dr Dominika Kwasnicka, Dr Erin Howden, Professor Garry Jennings, Professor David Thomson and Dr Deepak Haikerwal

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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 Baker Heart Diabetes Institute.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/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 Research Nurse (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.