Austin HEALTH

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Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Austin Health

Title	SMARTphone-Based Cardiovascular Risk Reduction Program in BREAST Cancer [SMART-BREAST]: A Randomized Controlled Trial
Short Title	The Smartphone Cardiovascular Risk Reduction in Breast Cancer Trial
Protocol Number	HREC/47081/Austin-2018
Project Sponsor	Austin Health
Principal Investigator	Dr Matias Yudi
Associate Investigator(s)	Dr Alexandra Murphy, A/Prof Omar Farouque, A/Prof Farshad Faroudi, Dr Belinda Yeo
Location	Austin Health

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have been diagnosed with breast cancer. The research project aims to establish the potential utility of a smartphone based cardiovascular risk reduction program in patients undergoing treatment for breast cancer.

This research project is a pilot study which means that it is a small-scale preliminary study which is conducted in order to find out whether the project is feasible and useful before performing a bigger study.

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?

Heart disease and cancer are the two leading causes of death worldwide. There are a number of common risk factors and as such many patients will have both conditions. Treatments for cancer have improved significantly over recent decades and as a result less patients are dying from their cancer. These treatments however, have been associated with damage to the heart which can manifest in many different ways including heart failure, blockages in heart arteries, and a resultant increase in heart attacks, problems with the electrical system of the heart and even sudden cardiac death. As such it is important for cardiologists and oncologists alike to be familiar with the prevention, diagnosis and management of cardiovascular complications of cancer treatment.

The aim of this study is to establish the utility of a smartphone based cardiovascular risk reduction program in patients undergoing treatment for breast cancer.

This research has been initiated by the study doctor, Dr Matias Yudi.

This research has been funded by the cardiology department at Austin Health.

3 What does participation in this research involve?

You have been screened for this study based on the diagnosis of breast cancer. Your consent for further participation in this study will be required prior to any further involvement.

This study is a randomized controlled study recruiting consecutive patients with newly diagnosed breast cancer. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. 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). You will have a 1 in 2 chance of receiving the intervention which in this study is the smartphone application.

Patients over the age of 18 with a new diagnosis of breast cancer will be eligible for inclusion. The other major inclusion criteria will be personal ownership of a smartphone. Exclusion criteria includes patients with a prognosis of less than 6 months as determined by their treating oncologist.

The artificial intelligence-driven, smartphone-based cardiovascular risk reduction program will be delivered over 12 months starting at time of diagnosis through a smartphone application (app). Participants will download the intervention application (“app”) into their smartphone. They will then receive education on how to use the app. This will take approximately 10 minutes as the app is simple and easy to use. Further assistance can be provided at any time on request. This is a multi-faceted intervention which provides a comprehensive cardiovascular risk reduction program.

Participants will be evaluated at baseline and at 12 months. Baseline assessment will include the following measurements: height, weight, waist circumference, resting heart rate and blood pressure, smoking status, and a blood test measuring fasting cholesterol and glucose levels This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. There are no costs associated with participating in this research project, nor will you be paid.

Timeline:

Assessment	Screening	12-Months
Informed Consent	X	
Demographic Information	X	
Cancer diagnosis details	X	
History and Cardiovascular risk factors	X	X
Weight and Waist Circumference Measurement	X	X
Resting blood pressure and heart rate measurement	X	X
Fasting lipid profile, fasting glucose, HbA1c	X	X
Quality of life assessment (EQ-5)	X	X
Six-Minute Walk Test	X	X
Major adverse cardiovascular event		X
Health care utilization		X

4 What do I have to do?

Your main responsibility is to follow the advice of your treating oncologist. This will include taking your prescribed medication and adoption of healthy lifestyle measures.

In addition, you will receive messages and education to encourage physical activity and cardiovascular risk reduction via the smartphone app.

There are no specific restrictions placed upon you due to your participation in this study.

It is important that participants still adhere to their normal standard of care even if they are participating in this study.

5 Other relevant information about the research project

Approximately 280 people will be enrolled in this study. All participants will be treated at Austin Health (Olivia Newton John Cancer and Wellness Centre).

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 Austin Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. Possible benefits to you would be that if through the tests that are conducted we discover a significant abnormality in your heart, this will be acted upon immediately. Possible benefits to people in the future may be the ability to identify better ways of reducing cardiovascular risk in the breast cancer population.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

Having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

You will be asked to provide additional consent for the collection of your blood during the research project. The samples will be collected by a registered nurse or doctor. The results will remain in the medical records. The blood samples will be processed by Austin Pathology. Samples will not be stored.

11 What if new information arises during this research project?

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

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she 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, it is important to tell your study doctor and the study staff 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 your study doctor about any changes to these during your participation in the research project.

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 before 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 doctor 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 properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Decisions made by local regulatory/health authorities.

15 What happens when the research project ends?

On completion of the research project you will be referred to the outpatient cardiology clinic for any further follow up that may be required.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. 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.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the institution relevant to this Participant Information Sheet, Austin Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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

Data will be collected and stored in a confidential manner. Electronic records will be kept with the principal investigator. Any paper records will be kept in the Cardiology Department at Austin Health. At the completion of the study, the physical records will be kept with the principal investigator for a total of 7 years.

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 research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

Complaints

Any complains which may arise during your participation in this trial can be addressed to the Complaints Contact Person.

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.

Compensation
In the event of injury, you may be able to seek compensation through the courts.

18 Who is organising and funding the research?
This research project is being conducted by Dr Matias Yudi.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 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 Austin Health.

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

If 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, for example, any side effects, you can contact the principal study doctor on 9496 5000 or any of the following people:

Clinical contact person

Name	Matias Yudi
Position	Principal Investigator, Cardiologist
Telephone	03 9496 5000
Email	Matias.yudi@austin.org.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, then you may contact:

Complaints contact person

Name	Complaints Officer
Telephone	03 9496 4090 or 03 9496 3248
Email	ethics@austin.org.au

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Austin Health Human Research Ethics Committee
HREC Executive Officer	HREC Executive Officer
Telephone	03 9496 4090
Email	ethics@austin.org.au

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Protocol Number	
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Location	Austin Health

Consent Agreement

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 Austin Health concerning 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.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process
Name (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.

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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 Study Doctor/
Senior Researcher† (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.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, 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.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

- This specific research project
- Other research that is closely related to this research project
- Any future research.

Name of Participant (please print) _____

Signature _____ Date _____

For participants unable to read the information and consent form

Witness to the informed consent process
Name (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.

Name of Study Doctor/
Senior Researcher† (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.

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Form for Withdrawal of Participation - *Adult providing own consent*

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Location	Austin Health

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 Austin Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

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 Study Doctor/
Senior Researcher† (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.