Participant Information Sheet/Consent Form

Interventional Study - Adult providing own consent

insert hospital

Title	Supervised Early Resistance Training Following Median Sternotomy (SEcReT Study)
Short Title	SEcReT Study
Protocol Number	2017.266
Project Sponsor	The University of Melbourne
Principal Investigator	Prof Colin Royse
Associate Investigator(s)	Miss Jacqueline Pengelly, Dr Doa, El-Ansary, Prof Alistair Royse, Dr David Canty, A/Prof Gavin Williams, A/Prof Adam Bryant, Mrs Lynda Tivendale, Mr Tim Dettmann, Mr Brett Long
Location	The Royal Melbourne Hospital, Melbourne Private Hospital, Kieser Essendon, Kieser South Melbourne, Kieser Caulfield

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are having open heart surgery. The research project is comparing the quality of your recovery after surgery using two different types of exercise. You will either be asked to do light aerobic exercise (i.e. walking) or moderate resistance exercise (i.e. weights).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the consent section.

By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

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

2 What is the purpose of this research?

There are over one million heart operations performed each year. After surgery, many patients report problems with concentration, focus and memory. This can last for 3 months or longer. Exercise is recommended after surgery to lower the risk of having continued heart problems. It has also been shown to maintain or improve brain function. However, the exercise you typically do after surgery, does not make you work hard enough to maximise the quality of your recovery. After open heart surgery, you are asked to also limit the use of your arms and chest/trunk. This is to allow the breastbone to heal following surgery, however we don't know whether these precautions slow your recovery.

The aim of this study is to identify whether the rate and quality of recovery after surgery is different between the two types of exercise programs.

The information obtained from this research will help guide the future care of patients following open heart surgery, and in particular what arm and chest/trunk precautions may be necessary.

This research has been initiated by the study doctor, Professor Colin Royse. It has not been funded. The results of this research will be used by the study exercise physiologist Jacqueline Pengelly to obtain a Doctorate of Philosophy (Physiotherapy).

This research will be conducted at The Royal Melbourne Hospital, Melbourne Private Hospital, and community exercise centres (Essendon, South Melbourne and Caulfield).

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. You will be asked do either the usual exercise advised after open heart surgery or a new exercise program using weights.

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), which is like flipping a coin.

If you agree to participate in this study you will sign a consent form before any study assessments are done. The research team will use eligibility criteria to determine if you are a suitable candidate for participation in the research trial. We will measure aspects of your brain function (cognition) using surveys called the Alzheimer's Disease Assessment Scale-Cognition subscale (ADAS-cog) and the Mini Mental State Examination (MMSE). To measure your quality of recovery, a survey called the Postoperative Quality of Recovery Scale (PostopQRS) is used. We will also be measuring your functional recovery with a survey called the Instrumental Activities of Daily Living scale (IADL) and Functional Disability Questionnaire (FDQs). Each time you do all these surveys, it will take around 60 minutes to complete them (all together).
Once you leave the hospital, we will continue these surveys in addition to some exercise tests to test your strength, breathing and balance. The exercise tests will take around 30 minutes to complete.
At the 3.5 month assessment, we will ask you some questions about the program you completed to see whether you believed it benefited your recovery.
Our research team will contact you to make a suitable time for that. The surveys will be conducted a total of 8 times: before surgery and then at 1, 3 and 7 days; 2 weeks; 2, 3.5 and 6.5 months after surgery. The exercise tests will be conducted a total of 4 times: 2 weeks, 2, 3.5 and 6.5 months after surgery.

Group 1: Aerobic Exercise (Usual care)- After discharge from hospital, you will be referred to a Cardiac Rehabilitation program in a community setting or provided with an individual exercise

program to be conducted at home. This usually involves attending a program in the community 2-3 sessions per week for 6-10 weeks (12-30 sessions). Each exercise session lasts for around 60 minutes. There are usually education sessions as well, which are an additional 60 minutes. You may perform exercises like walking or cycling. If you are doing your own program this will consist of walking 3 to 5 times per week for 40 to 45 minutes.

Group 2: Weight Exercise- After discharge from hospital, you will be asked to attend a Kieser exercise centre. This will involve attending 2 sessions per week for 12 weeks (24 sessions total). Each session will last for around 45 minutes with approximately 30 minutes of this time exercising within the limits of comfort and pain. You will exercise specific muscles of your body one at time (arms, legs and chest/trunk).

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. For this reason, the consenting investigator will remain blinded to the intervention following recruitment. This will mean that he/she will not know which exercise group you are allocated to. Another research staff member will be in contact with you to arrange your exercise testing and exercise training sessions.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and exercise treatment required as part of the research project will be provided to you free of charge.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

If you agree to participate in the research you will be randomised to receive either aerobic exercise (usual care) for 6-10 weeks or weight training (new exercise program) for 12 weeks. Your quality of recovery will be assessed by the researchers using surveys and exercise tests a total of 8 times. All assessments will be done face-to-face, either at the hospital or at the exercise centre.

If you agree to participate in this study, it is expected that you will attend all exercise testing and all training sessions. If at any time you are unable to do this, you must let the research staff know. If you anticipate that you will be unable to attend the Kieser exercise sessions, due to its location or not having transportation available to you, you should not agree to participate in the study. Please note you will not be able to drive for 6 weeks after your surgery and you are required to arrange your own transportation to all appointments.

5 Other relevant information about the research project

This project will be done in collaboration with researchers from The Royal Melbourne Hospital, Melbourne Private Hospital, University of Melbourne and Kieser Australia.

A total of 100 participants will be recruited across the different hospitals.

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 The Royal Melbourne Hospital, Melbourne Private Hospital and Kieser Australia.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include the standard exercise treatment at a community centre, a home-based walking program or not participating in any cardiac rehabilitation/exercise after your surgery. Your study nurse will discuss these options with you before you decide whether or not to take part in this research project.

You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however future patients may benefit from the results of this study.

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

The exercises used are safe, however occasionally exercise can cause some pain or discomfort in your muscles. Sometimes this can occur more with weighted exercise than with aerobic exercise. If you have any pain or discomfort, we encourage your report this to your study nurse or exercise physiologist.

10 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 supervisor 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 supervisor 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 supervisor 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.

11 Can I have other treatments during this research project?

The exercise used in this study will not interfere with any medications you are using and does not prevent you from having other treatments as recommended by your doctor.

12 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.

13 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:
• Unacceptable side effects
• The treatment being shown not to be effective
• The treatment being shown to work and not need further testing
• Decisions made by local regulatory/health authorities.

14 What happens when the research project ends?

Patient participation in the study completes at the 6 month after surgery assessment. At completion of the trial all data will be statistically analysed by the researchers. The results of the study will be presented at scientific conferences and published in scientific journals. Any presentation of the study will only include de-identified data so your personal details are not presented. After completion of the study a summary of the findings of the research can be made available to the participant by contacting the research coordinator whose contact details are listed below.

Part 2 How is the research project being conducted?

15 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. The data is stored on a password-protected computer, which can only be accessed by the researchers. Any paper records are kept in a locked cupboard in a locked room and only able to be accessed by the researchers. De-identified data for the Postoperative Quality of Recovery Scale are stored on a secure database based at City, University of London (www. PostopQRS.com). 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 relevant authorities and authorised representatives of the institution relevant to this Participant Information Sheet, The Royal Melbourne Hospital and Melbourne Private Hospital, 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. Your data will remain confidential as only de-identified group data will be presented or published. Information about participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or Victorian 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 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.

16 Complaints and compensation

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.

17 Who is organising and funding the research?

This research project is being conducted by Professor Colin Royse in collaboration with The University of Melbourne. This project has not received any commercial funding.

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

18 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 Melbourne 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.

19 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 Prof Colin Royse on 8344 5673 or any of the following people:

Clinical contact person

Name	Prof Colin Royse
Position	Principal investigator
Telephone	(03) 383445673
Email	Colin.royse@heartweb.com

Name	Dr Doa El-Ansary
Position	Associate investigator and physiotherapist
Telephone	(03) 383445673
Email	d.el-ansary@unimelb.edu.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Reviewing HREC name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone	(03) 9342 8530
Email	Research@mh.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:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Melbourne Health HREC*
HREC Executive Officer	*Manager HREC*
Telephone	*03 9342 8530*
Email	*Research@mh.org.au*

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

Name	*Director of Research and Ethics*
Position	*Complaints Manager*
Telephone	*03 9342 8530*
Email	*research@mh.org.au*

Consent Form - Adult providing own consent

Title	Supervised Early Resistance Training Following Median Sternotomy (SEcReT Study)
Short Title	SEcReT Study
Protocol Number	2017.266
Project Sponsor	The University of Melbourne
Principal Investigator	Prof Colin Royse
Associate Investigator(s)	Miss Jacqueline Pengelly, Dr Doa, El-Ansary, Prof Alistair Royse, Dr David Canty, A/Prof Gavin Williams, A/Prof Adam Bryant, Mrs Lynda Tivendale, Mr Tim Dettmann, Mr Brett Long
Location	The Royal Melbourne Hospital, Melbourne Private Hospital, Kieser Essendon, Kieser South Melbourne, Kieser Caulfield

Declaration by Participant

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

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

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Royal Melbourne Hospital and/or Melbourne Private Hospital 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, 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 understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (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 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.

Form for Withdrawal of Participation - Adult providing own consent

Title	Supervised Early Resistance Training Following Median Sternotomy (SEcReT Study)
Short Title	SEcReT Study
Protocol Number	2017.266
Project Sponsor	The University of Melbourne
Principal Investigator	Prof Colin Royse
Associate Investigator(s)	Miss Jacqueline Pengelly, Dr Doa, El-Ansary, Prof Alistair Royse, Dr David Canty, A/Prof Gavin Williams, A/Prof Adam Bryant, Mrs Lynda Tivendale, Mr Tim Dettmann, Mr Brett Long
Location	The Royal Melbourne Hospital, Melbourne Private Hospital, Kieser Essendon, Kieser South Melbourne, Kieser Caulfield

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 The Royal Melbourne Hospital or Melbourne Private Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

Description of the circumstances in which the participant has decided to withdraw.

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.