Participant Information Sheet/Consent Form
Health/Social Science Research- Adult providing own consent

Title
Cognitive CABG Study

Lead Researcher
Danielle Greaves

Primary Supervisor
Dr Hannah Keage

Locations
Royal Adelaide Hospital and University of South Australia

Participant Information Sheet

Part 1 What does my participation involve?

Introduction

You are invited to take part in the “Cognitive CABG Study”. This is because you are undergoing a Coronary Artery Bypass Grafting (CABG) procedure at the Royal Adelaide Hospital.

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.

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 assessments and research that are described
- Consent to the use of your personal and health information as described

What is the purpose of this research?

Older adults are increasingly having operations on their heart, which improves heart function however in some cases, can lead to problems with thinking and memory (what we call cognitive function). This study aims to improve learning and memory skills using cognitive based interventions both pre and post-surgery. It is hoped that undergoing cognitive based interventions will help thinking and memory skills. This study could also be utilised as a framework in other surgery types where learning and memory problems are seen.

The results of this study will be presented at academic conferences and published within journals and form the lead researcher’s PhD thesis.
What does participation in this research involve?
The following flow chart outlines study assessments and briefly states what will be involved. Further information about assessments is below.

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<td>Start Pre-Surgery Cognitive Training</td>
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| Surgery                                                                                                   |
| Assessment 2 (day after discharge)                                                                     |
| 1.5 hours                                                                                                 |
| Questionnaires, Thinking and Memory Testing                                                             |

| One-month after surgery                                                                                   |
| 1 hour                                                                                                   |
| Start Post-Surgery Cognitive Intervention                                                                |

| Assessment 3 (four-months after surgery)                                                                 |
| 1 hour                                                                                                   |
| Measurements, Questionnaires, Thinking and Memory Testing                                                |

The first assessment will be conducted approximately two weeks before your CABG procedure, at your home (or at a UniSA campus if more convenient for you). After you have consented, relevant information will be collected from your medical notes from your pre-surgery clinic day at the Royal Adelaide Hospital.

This first stage of testing will take 2-3 hours including short breaks. The testing will include:
- Taking measurements of your waist and hip circumference.
- Assessing your thinking and memory skills (paper and computer testing).
- Questionnaires about your general information, general and cardiac health (medical history, in addition to what has been collected from medical records), handedness, psychological well-being, behaviour and activities of daily living.
- Saliva sample

If time permits, and you are interested, we will also measure your brain activity using a non-invasive tool called EEG. This involves wearing a hat (like a swimming cap) on your head. During this time you will be asked to relax and listen to tones from a computer.

Also during the first assessment you will be provided with instructions on undertaking your cognitive intervention. The intervention will involve you performing tasks on a computer or smart device multiple times a week for a two-week period. In this time you will also receive a weekly phone-call to check how the intervention is going and face-to-face support will be provided if needed.
Following your CABG procedure, you will be assessed daily for any confusion or delirium (acute problem with thinking and memory skills). This testing will not affect your care within hospital. These assessments take approximately 20 minutes and also involve asking general questions from your healthcare team, family members if present, and reviewing your medical records. When you have been discharged your hospital records will be reviewed and any medical complications will be recorded if relevant to this study.

A second assessment will be done on the day following your discharge; we will visit your home to assess your thinking and memory skills. This session will take approximately an hour and a half with breaks throughout as needed.

One month following your surgery, you will be visited at your home (or travel to a UniSA campus if more convenient for you) and commence your post-surgery cognitive intervention, which will last for 12 weeks. This intervention will again involve you performing tasks on a computer or smart device multiple times a week, with weekly phone-calls.

A third assessment will be conducted after the completion of your 12-week training intervention, which is four-months after your surgery. You will be scheduled for a home visit follow-up session which will last for approximately an hour with breaks. If more suitable this session can be conducted at a University of South Australia metropolitan campus. This session will include:

- Taking measurements of your waist and hip circumference.
- Assessing your thinking and memory skills (paper and computer testing).
- Questionnaires about your general information (age, medical history, contact details), psychological well-being, behaviour and activities of daily living.

The project will continue data collection for up to 3 years post-surgery. You will be contacted 5-months following your surgery for your interest in participating in these follow-up sessions.

**Additional costs and reimbursements**

You may incur minimal costs associated with travel and parking by participating in this research project. You will be provided with a $20 honorarium in recognition of your time, and to assist with travel/parking costs at each assessment of the study.

**Screening procedures (questionnaire)**

Prior to consenting, you would have been given a questionnaire asking about your personal details and medical history during your pre-surgery clinic day at the Royal Adelaide Hospital. This will determine if you are eligible to take part. Completing the questionnaire takes approximately 2 minutes. If all criteria are met within the screening questionnaire you will be eligible to participate in the research.

Consent and Information _V4 | 6/12/2017
Other relevant information about the research project

The saliva sample collected during this study will be utilised to investigate the genetic markers of cognitive impairment. The collection of saliva is non-invasive and poses no risk to you. The results of this will not be shared with you and will only be utilised for research purposes as the clinical utility of these results is not yet established. Additionally, the results of this sample will only be utilised anonymously and not provided to any third parties; and samples will be destroyed after study completion.

Overall, 120 participants undergoing CABG at the Royal Adelaide Hospital will be taking part in this project. If you are interested, you will also have the opportunity to participate in the six-, twelve-month and three-year follow-up stages of this study. We will contact you 5-months after your CABG procedure to see if you will still be interested in participating.

Do I have to take part in this research project?

Participation in this 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 this project at any stage. Your decision whether to take part or not 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 SA Health. If you do withdraw you may elect to contribute data to the project that was collected, or withdraw the data from the project.

What are the possible benefits of taking part?

A possible benefit of this study is the potential to improve thinking and memory skills. Another important benefit of this study is that it may inform the health system of possible methods to alter or improve health care. Similar methods to this study could be used in different surgery types, like joint replacement surgeries.

By participating in this research, you may have access to additional testing of your memory and concentration. During your hospital stay, we will pass on our results with your clinical care team. If you consent, we will also send any clinically relevant information and your scores on the cognitive tests (collected during your hospital stay and at your home) to your GP.

What are the possible risks and disadvantages of taking part?

This study involves a large time commitment including assessments and interventions. There will be 6 testing session across 3 years as well as two interventions (pre-surgery intervention lasting 2 weeks – 7 sessions and post-surgery intervention lasting 12 weeks -36 sessions).

There may be minimal discomfort related to collecting your saliva and getting your hair wet when measuring your resting brain activity. There are no foreseen risks to being involved within the project. The project will not influence any of your treatments, care provided by SA Health or interfere with your cardiac rehabilitation.
What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. You will be asked to complete and sign a “Withdrawal of Consent” Form.

Part 2 How is the research project being conducted?

Confidentiality and Data Security

Data collected in this study will include: health, psychological and well-being data along with a saliva sample. The data will be collected by the research team directly by asking you, or obtained through health records kept by the Royal Adelaide hospital and other health services. Any information obtained in connection with this research project that can identify you will remain confidential. Data will be entered in a de-identifiable format into a password protected electronic data base. Data can only be re-identified with access to a separate password protected data-base. Data will be kept in a locked cabinet in the researcher’s office (hard copy) and stored on a password protected server (electronic). The researcher and supervisor will have access to hardcopy data, passwords will only be known to the primary researcher and the primary supervisor. Data will be stored for a minimum of 5 years from the study’s completion. For the saliva sample, all of the above applies however the lab technician will additionally have access to the sample. No data will be sent to anyone outside of the research team.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected. You have a right to ask that any stored specimens be destroyed but should be aware that data which has already been derived from those specimens may not be able to be destroyed.

Complaints and Compensation

If you have any complaints regarding this research project please contact the study team as soon as possible. In the unlikely event that you suffer an injury as the result of participation in the study, care would be provided through the public hospital system. The study has been indemnified by SA Health and The University of South Australia but you also have the right to seek compensation through the legal system.

Who is organising and funding the research?

This research is being conducted by Danielle Greaves (PhD candidate, University of South Australia). The study is funded by the principal supervisor, the CAIN laboratory and the University of South Australia. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). The computerised intervention is provided by HappyNeuron who may benefit through acknowledgment within research papers published in association with this study.
**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 have been approved by the HREC of Royal Adelaide Hospital (Reference number: HREC/17/RAH/445), Central Adelaide Local Health Network (Reference number: R20171020) and the University of South Australia Human Ethics Committee (Reference number: 0000034053). 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.

**Conflicts of interest**
The computerised intervention is provided for the study by HappyNeuron Pro at no cost to the research team.

**Further information and contact information**

For further information please contact:

Danielle Greaves  
PhD Candidate and Lead Researcher  
University of South Australia  
Danielle.Greaves@mymail.unisa.edu.au  
(08) 8302 4909

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:

Dr Hannah Keage  
Primary Supervisor  
University of South Australia  
Hannah.keage@unisa.edu.au  
(08) 83024340

Central Adelaide Local Health Network Human Research Ethics Committee  
Health.CALHNResearchEthics@sa.gov.au  
(08) 7117 2229
Title: Cognitive CABG Study

Lead Researcher: Danielle Greaves

Primary Supervisor: Dr Hannah Keage

Locations: Royal Adelaide Hospital and University of South Australia

Consent Form

☐ I have read the Participant Information Sheet and the nature, purpose and risks of the research project has been explained to me. I understand and agree to take part.

☐ I understand the purpose of the research project and my involvement in it.

☐ I understand that I may not benefit from taking part in this study.

☐ I understand that I may withdraw from the research project at any stage and that this will not affect my status now or in the future. Further, I understand that if I withdraw, I may elect to contribute data to the project that was collected, or withdraw the data from the project.

☐ I understand that I can elect to withdraw my data up to one week after my participation.

☐ I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

☐ I understand the statement in the information sheet concerning payment to me for taking part in the study.

☐ I consent to results of the testing being provided to my GP or other treating doctors if they indicate a clinical issue which might be important.

I understand that saliva samples obtained from me during the study may be used to ascertain genetic associations to my test results. Since the clinical utility of the genetic results are not yet established I understand that these results will not be shared with me and only used for research. Results will be used anonymously and not provided to any third parties; and samples will be after study completion.

☐ I give researchers my permission to investigate the influence of my genetics on the test results

☐ I do not give researchers my permission to investigate the influence of my genetics on the test results

Name of participant.................................................................Date..............

Participant’s signature.......................................................... Date..............

I have provided information about the research to the research participant and believe that he/she understands what is involved.

Researcher’s signature.......................................................... Date..............
Participant Information Sheet/Consent Form
Health/Social Science Research- Adult providing own consent

Title: Cognitive CABG Study
Lead Researcher: Danielle Greaves
Primary Supervisor: Dr Hannah Keage
Locations: Royal Adelaide Hospital and University of South Australia

Participant Information Sheet

Part 1 What does my participation involve?

Introduction

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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.

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 assessments and research that are described
- Consent to the use of your personal and health information as described

What is the purpose of this research?

Older adults are increasingly having operations on their heart, which improves heart function however in some cases, can lead to problems with thinking and memory (what we call cognitive function). This study aims to develop knowledge of what factors influence learning and memory skills and how they change post-surgery. This study will provide information about possible risk factors for developing post-surgery thinking and memory skill problems. This information may be utilised to provide a framework to help those at risk in cardiac and other surgeries (joint replacement).

The results of this study will be presented at academic conferences and published within journals and form the lead researcher’s PhD thesis.
What does participation in this research involve?

The following flow chart outlines study assessments and briefly states what will be involved. Further information about assessments is below.

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The first assessment will be conducted approximately two weeks before your CABG procedure, at your home (or at a UniSA campus if more convenient for you). After you have consented, relevant information will be collected from your medical notes from your pre-surgery clinic day at the Royal Adelaide Hospital.

This first stage of testing will take 2-3 hours including short breaks. The testing will include:

- Taking measurements of your waist and hip circumference.
- Assessing your thinking and memory skills (paper and computer testing).
- Questionnaires about your general information, general and cardiac health (medical history, in addition to what has been collected from medical records), handedness, psychological well-being, behaviour and activities of daily living.
- Saliva sample

If time permits, and you are interested, we will also measure your brain activity using a non-invasive tool called EEG. This involves wearing a hat (like a swimming cap) on your head. During this time you will be asked to relax and listen to tones from a computer. Between the first testing session and surgery you will be called weekly and asked about your pain levels.

Following your CABG procedure, you will be assessed daily for any confusion or delirium (acute problem with thinking and memory skills). This testing will not affect your care within hospital. These assessments take approximately 20 minutes and also involve asking general
questions from your healthcare team, family members if present, and reviewing your
medical records. When you have been discharged your hospital records will be reviewed
and any medical complications will be recorded if relevant to this study.

A second assessment will be done on the day following your discharge; we will visit your
home to assess your thinking and memory skills. This session will take approximately an
hour and a half with breaks throughout as needed.
A third assessment will be conducted four-months after your surgery. You will be scheduled
for a home visit follow-up session which will last for approximately an hour with breaks. If
more suitable this session can be conducted at a University of South Australia metropolitan
campus. This session will include:

- Taking measurements of your waist and hip circumference.
- Assessing your thinking and memory skills (paper and computer testing).
- Questionnaires about your general information (age, medical history, contact
details), psychological well-being, behaviour and activities of daily living.

Additional costs and reimbursements

You may incur minimal costs associated with travel and parking by participating in this
research project. You will be provided with a $20 honorarium in recognition of your time,
and to assist with travel/parking costs at each assessment of the study.

Screening procedures (questionnaire)

Prior to consenting, you would have been given a questionnaire asking about your personal
details and medical history during your pre-surgery clinic day at the Royal Adelaide Hospital.
This will determine if you are eligible to take part. Completing the questionnaire takes
appropriately 2 minutes. If all criteria are met within the screening questionnaire you will be
eligible to participate in the research.

Other relevant information about the research project

The saliva sample collected during this study will be utilised to investigate the genetic
markers of cognitive impairment. The collection of saliva is non-invasive and poses no risk to
you. The results of this will not be shared with you and will only be utilised for research
purposes as the clinical utility of these results is not yet established. Additionally, the results
of this sample will only be utilised anonymously and not provided to any third parties; and
samples will be destroyed after study completion.

Overall, 120 participants undergoing CABG at the Royal Adelaide Hospital will be taking part
in this project. If you are interested, you will also have the opportunity to participate in the
six-, twelve-month and three-year follow-up stages of this study. We will contact you 5-
months after your CABG procedure to see if you will still be interested in participating.
Do I have to take part in this research project?

Participation in this 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 this project at any stage. Your decision whether to take part or not 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 SA Health. If you do withdraw you may elect to contribute data to the project that was collected, or withdraw the data from the project.

What are the possible benefits of taking part?

You should not expect to personally benefit from taking part in this study. However, an important benefit of this study is that it may inform the health system of possible risk factors which could be utilised to alter or improve health care. This information could be translatable to different surgery types, like joint replacement surgeries.

By participating in this research, you may have access to additional testing of your memory and concentration. During your hospital stay, we will pass on our results with your clinical care team. If you consent, we will also send any clinically relevant information and your scores on the cognitive tests (collected during your hospital stay and at your home) to your GP.

What are the possible risks and disadvantages of taking part?

The study will involve 3 visits over a 4 month period. If you agree to be part of the long term study there is a significant time commitment including 6 assessment sessions across a 3 year testing period.

There may be minimal discomfort related to collecting your saliva and getting your hair wet when measuring your resting brain activity. There are no foreseen risks to being involved within the project. The project will not influence any of your treatments, care provided by SA Health or interfere with your cardiac rehabilitation.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. You will be asked to complete and sign a “Withdrawal of Consent” Form.

Part 2 How is the research project being conducted?

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Complaints and Compensation

If you have any complaints regarding this research project please contact the study team as soon as possible. In the unlikely event that you suffer an injury as the result of participation in the study, care would be provided through the public hospital system. The study has been indemnified by SA Health and The University of South Australia but you also have the right to seek compensation through the legal system

Who is organising and funding the research?

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Who has reviewed the research project?

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Further information and contact information

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## Consent Form

- I have read the Participant Information Sheet and the nature, purpose and risks of the research project have been explained to me. I understand and agree to take part.
- I understand the purpose of the research project and my involvement in it.
- I understand that I will not benefit from taking part in the study.
- I understand that I may withdraw from the research project at any stage and that this will not affect my status now or in the future. Further, I understand that if I withdraw, I may elect to contribute data to the project that was collected, or withdraw the data from the project.
- I understand that I can elect to withdraw my data up to one week after my participation.
- I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential.
- I understand the statement in the information sheet concerning payment to me for taking part in the study.
- I consent to results of the testing being provided to my GP or other treating doctors if they indicate a clinical issue which might be important.

I understand that saliva samples obtained from me during the study may be used to ascertain genetic associations to my test results. Since the clinical utility of the genetic results are not yet established I understand that these results will not be shared with me and only used for research. Results will be used anonymously and not provided to any third parties; and samples will be after study completion.

- I give researchers my permission to investigate the influence of my genetics on the test results
- I do not give researchers my permission to investigate the influence of my genetics on the test results

Name of participant: 

Participant’s signature: ____________________________ Date: ________________

I have provided information about the research to the research participant and believe that he/she understands what is involved.

Researcher’s signature: ____________________________ Date: ________________