Brief Behavioural Counselling Intervention for Peripheral Artery Disease (BIP)

The Townsville Hospital Site Specific Participant Information Sheet

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You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This study is being done to evaluate the effectiveness of a brief behavioural counselling session delivered by a health worker to improve physical activity in patients with blocked leg arteries. We believe this is an important study since previous work suggests that the counselling intervention being tested can significantly improve mobility in patients with blocked leg arteries. It is important that we now establish whether this initial finding can be confirmed in a wider group of patients. The results of this study might help us understand if the presentation of physical activity recommendations to patients with blocked leg arteries can be improved.

What does participation in this research involve?

If you agree to participate in this research then you will be asked to sign a consent form. You will then be randomly allocated to either the behavioural counselling intervention group or the control group. Participants in both groups will receive information about blood vessel disease, possible treatments, and other lifestyle factors. Participants in both groups will also be provided with counselling advice via face to face or telephone calls. Participants may be

required to attend up to two face to face counselling sessions and receive up to 4 phone calls. The face to face sessions will be 1 hour sessions and the phone calls will only take approximately 10-15 minutes of your time. Follow up appointments will also be made at 4, 12 and 24 months.

You will also be asked to provide blood samples. With consent, we will access your medical file to confirm the lifestyle factors you have mentioned but also, to identify any other factors that may have been missed.

There are no costs associated with participating in this research project, nor will you be paid.

Why have I been invited?

You are being invited to take part in this study because you have blocked leg arteries.

This research is taking place in several hospitals/universities in Australia. Overall, we plan to recruit a total of 200 patients across all sites, who have blocked leg arteries.

Do I have to take part?

It is up to you to decide whether or not to take part. If you are already a patient of the hospital you may have been contacted by mail or a phone call. If you do decide to take part you will then be asked to sign this consent form and return it to the site coordinator. If you aren't already a patient of the hospital, you may be approached in person by a vascular nurse or a member of the research team in an outpatient clinic or by mail or phone if you have responded to a study advertisement. If you are interested, you will be given or sent a copy of the invitation letter and participant information and informed consent form. You will also be given the opportunity to ask a member of the research team any questions that you have relating to the study. If you decide to take part you will then be contacted by phone to arrange a time for your first appointment. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive, from your medical practitioner, your relationship with professional staff, or your relationship with the Townsville Hospital.

What will happen to me if I take part?

If you have been approached in an outpatient clinic and you decide to take part in this study, please tell the nurse or a member of the research team. If you have been initially contacted by mail, the member of the research team will then contact you by phone. They will answer any questions that you may have and will work out a time when you can come in for your first visit.

Visit 1 (2-3 hours):

At your first visit you will also be given a blood request form to take with you to your local blood collection centre. There they will collect a number of routine blood samples plus a number of circulating markers for blood vessel disease. An additional 24mls (equal to 5 tea spoons) of blood will be collected at each visit. The blood will be stored in the Peripheral Vascular Biobank. The Biobank collects blood samples from people with different types of vascular disease. We hope that comparing the results from different groups, it will help us to uncover biomarkers related to this disease.

Your blood sample will be stored indefinitely unless you or the Human Research Ethics Committee instructs the Peripheral Vascular Biobank to destroy the sample. Biomarker testing may result in findings linked to conditions other than cardiovascular disease. If our research uncovers any significant information specific to your health, our Human Research Ethics Committee may decide to authorise someone to contact you and offer you access to this information. You may decline the information. If you wish to be given this information a qualified person will explain it to you. If we need to contact you we will use the contact details that you have provided to us. The Peripheral Vascular Biobank may permit access to and use the samples and/or information by other research organisations within Australia and/or overseas. Samples will only be given to other researchers for projects that have been approved by a Human Research Ethics Committee. Since your blood sample is a donation there will be no financial reward to you for providing it.

At the first visit, you will be asked to lie down in a comfortable position. While in this position we will take some measurements that indicate the health of your blood vessels. The first is autofluoresence which involves a small device, place over your skin at the lower arm, behind your knee, the lower leg and the foot.

Next we will measure the blood flow in your fingers, by attaching a small cuff around your finger. The cuff will put a small amount of pressure on your finger for a short period of time and will then be removed.

Next, we will measure pulse wave velocity. Pulse wave velocity is a well-established technique for obtaining a measure of arterial stiffness between two locations in your blood vessels. The velocity of the pulse wave along an artery is dependent on the stiffness of that artery and arterial stiffness is associated with cardiovascular disease. This test is done whilst you are lying down on a bed. At the beginning of the test your arm blood pressure will be taken. The pressure sensor will then be placed on your carotid artery (on the side of your neck), on your radial artery (at your wrist) and on your dorsalis pedis artery (on the top of your foot) or tibialis (posterior) artery (at your ankle). The examiner will place the pressure

sensor on the areas for long enough to obtain the data required. This test poses no risk or discomfort to you and only takes between 5 and 10 minutes to perform.

Also at the first visit, you will be asked to complete an assessment of your walking ability and cardiovascular fitness using the six-minute walk test. You will also be asked to complete the Short Physical Performance Battery which includes a standing balance test, a timed 4 metre walk test and a timed repetitive chair stand. You will also be asked to complete a number of questionnaires about your health. This testing session will take approximately 2-3 hours.

At the first visit your level of physical activity will be assessed. At this visit you will be asked to wear an activity measurement monitor. This is a small device that will be placed on your thigh. This monitor simply measures what position you are in and how many steps you take per day. You will be asked to start wearing the activity measurement monitor for 7 days after the first visit.

Visit 2 (1 hour):

At the end of 7 days, you will return to the clinic and the activity monitor will be removed. At this time, you will repeat the six-minute walk test and you will also be asked to complete a number of questionnaires about your level of physical activity. The questionnaires will require approximately 1 hour to complete. You will also be asked questions to find out what you normally have for breakfast, morning tea, lunch, afternoon tea and dinner.

Week 1 (10-60 min):

You will either receive a phone call or attend a face to face session with the investigators.

Week 2 (10-60 min):

You will either receive a phone call or attend a face to face session with the investigators.

Week 6 (10-15 min)

You will receive a phone call from the investigators.

Week 12 (10-15 min)

You will receive a phone call from the investigators.

All assessments (Visit 1 and 2) will be repeated at 4, 12 and 24 months.

The face to face sessions and phone calls will be audio-recorded. A member of the research team will analyse a small percentage of these recordings. All other recordings will be destroyed.

Your participation in this study will not affect the clinical care you receive.

Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name removed so that you cannot be recognised from it. All information will be stored securely, and only the research team will have access to the information. Analysed audio-recordings will be kept indefinitely on a password-protected computer system in the Vascular Biology Unit, James Cook University. 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.

The information about you, with your name removed, will be kept in a central, secure location in case we want to do further analysis in the future. Examples would include later analysis of the additional blood samples, or using the data to identify risk factors for blocked leg arteries. Ethical approval will be sought first before the current information is used in future research. If you choose to withdraw from the study at any time, you will be given the option of having the information already collected available for the researchers to use or if you would prefer the information will be destroyed.

What are the possible benefits of taking part?

If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research. We hope that the information learned from this study will help us understand new ways of increasing physical activity in patients with blocked leg arteries.

What if there is a problem?

The risk of harm from the study is expected to be low since it involves only counselling, blood samples and activity assessments. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, please contact Tricia Grady, Research Governance Officer at the Townsville Hospital on (07) 44331351.

Ethical Guidelines

This research project is being sponsored by James Cook University. 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 the Royal Brisbane and Women's Hospital. 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.

Further Information on 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 problems which may be related to your involvement in the project, you can contact Lisan Yip on (07) 4433 1739.

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

Name	Kathleen Gillespie
Position	Coordinator, Human Research Ethics Committee
Telephone	(07) 44331440
Email	TSV-Ethics-Committee@health.qld.gov.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 the Research Ethics Coordinator on (07) 44331440.

STUDY CONSENT FORM

Title of Research: **Brief Behavioural Counselling Intervention for Peripheral Artery Disease (BIP)**

Name of Principal Investigator: **Professor Jonathan Golledge**
Dr Nile Allaf
Dr Ramesh Velu

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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

I agree to the researchers accessing my medical file for reasons related specifically to this project.

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 care.

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

Name of Participant (print)_____

Signature _____ Date _____

Declaration by 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 Researcher† (print) _____

Signature _____ Date _____

† An appropriately qualified 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.

VASCULAR BIOBANK CONSENT FORM

Title of Research: **Brief Behavioural Counselling Intervention for Peripheral Artery Disease (BIP)**

Name of Principal Investigator: **Professor Jonathan Golledge**
Dr Nile Allaf
Dr Ramesh Velu

I, the undersigned (print name) _____

Hereby consent to my involvement in this research project as explained in the Participant Information and Consent Form. I consent to my clinical data and any excess samples not required for this study to be entered into the Vascular Biobank, where they will be stored and used in other studies investigating vascular disease.

- I have read the information sheet and I understand the reasons for this study, I have been given a copy of this document for my records
- The details of the study have been explained to be by a member of the research team, including;
    - The expected length of time it will take
    - The nature of the procedures being performed
    - The nature of any techniques/medications I may be given
    - Any risks of discomforts which I may experience
- My questions have been answered to my satisfaction
- My consent is given voluntarily
- I give permission for my doctors, other health professionals, hospitals or laboratories outside of this study centre to release information to the study team concerning my disease and treatment if required for use in this trial
- I understand I am free to withdraw from this study at any time without having to give a reason and without my medical care or legal rights being affected
- I understand that my normal legal rights to compensation under common law will not be affected by participating in this study
- I understand that the purpose for this research project is to improve the quality of medical care, but my involvement may not be of benefit to me
- I have been given the opportunity to have a member of my family or a friend present while the project was explained to me
- I understand that I am consenting for my samples to be included in the Peripheral Vascular Biobank and that these samples will be stored indefinitely. I understand that the samples will be available for use by scientists researching vascular disease, but may be used for research on other associated diseases in the future. I understand that researchers from other organisations may have access to my samples and that those studies will have been approved by a Human Research Ethics Committee.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to James Cook University concerning my

disease and treatment. I understand that such information will remain confidential and will only be shared outside this research team in the manner described.

SIGNED _____ DATE _ _ / _ _ / _ _ _ _

WITNESS _____ DATE _ _ / _ _ / _ _ _ _

RESEARCHER _____DATE _ _ / _ _ / _ _ _ _

REVOCATION OF CONSENT FORM

Title of Research: **Brief Behavioural Counselling Intervention for Peripheral Artery Disease (BIP)**

Name of Principal Investigator: **Professor Jonathan Golledge**
Dr Nile Allaf
Dr Ramesh Velu

I, the undersigned (print name) _____
hereby wish to **WITHDRAW** my consent to participate in the research trial named above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the study centre the Townsville Hospital. I ask that all data and blood samples collected in this study are hereby destroyed.

SIGNED _____

DATE / /