

**TITLE:** Exercise rehabilitation for patients with critical limb ischemia peripheral arterial disease after revascularization: a single center pilot randomized controlled trial assessing quality of life and functional capacity after a 12-week rehabilitation program compared with best medical therapy

**PRIMARY INVESTIGATOR:** Dr. Randy Moore

**COMMUNICATING INVESTIGATORS:** Dr. Matthew James, Dr. Andrea Devrome

**ADDRESS OF SITE:** Peter Lougheed Centre

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**CONTACT TELEPHONE NUMBERS:** 403-943-4588 or 403-943-5467

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

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## **BACKGROUND**

Peripheral arterial disease (PAD) affects more than 200 million people worldwide. This disease occurs with narrowing and occlusion of arteries supplying oxygenated blood to the organs and limbs. Symptomatic patients typically experience leg pain with physical activity. More advanced disease states are referred to as critical limb ischemia (CLI), where patients may have leg pain at rest or non-healing wounds.

Primary treatment of PAD involves risk factor management; smoking cessation, management of blood pressure, blood cholesterol, diabetes, and exercise prescription. Patient with CLI typically require surgical intervention (revascularization) to reestablish blood supply to their limbs. There is currently minimal understanding of the role for exercise rehabilitation after revascularization procedures in this vulnerable population. This study aims to better understand the role of exercise in this population. We hypothesize exercise rehabilitation after revascularization would likely improve quality of life and functional capacity in these patients.

You have been diagnosed with critical limb ischemia which is a severe form of peripheral arterial disease (PAD). This means that you have narrowing of your blood vessels (atherosclerosis) which is preventing adequate oxygenated blood flow to your feet causing severe pain and non-healing wounds. You require an intervention, either open surgery or endovascular, to restore adequate blood flow to your legs. Without an intervention, you will continue to have pain and are at a risk of losing part of your affected limb(s). This intervention must be accompanied by appropriate medications to control your cholesterol, blood pressure and blood sugar as well as risk factor management including stopping smoking and engaging in exercise once you have recovered from surgery.

Exercise rehabilitation has shown to be an effective treatment for PAD in the early stages, and is considered first-line therapy. In patients with critical limb ischemia, it is not clear what role exercise plays in the post-revascularization period, after wounds have healed.

## **WHAT IS THE PURPOSE OF THE STUDY?**

The purpose of this study is to develop a better understanding of the role for supervised exercise rehabilitation programs in critical limb ischemia patients after revascularization.

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## **WHAT WOULD I HAVE TO DO?**

After agreeing to participate in this study, you will be randomly assigned to one of two groups:

- 1) Best medical therapy (BMT)
- 2) Best medical therapy (BMT) and post-revascularization supervised exercise program (SEP)

You will then undergo your revascularization procedure as discussed with your surgeon. This treatment will involve either open surgery or endovascular management. If you have any non-healing ischemic wounds, they will be treated with appropriate wound care.

Approximately four to six weeks after your revascularization treatment, you will be assessed by your vascular surgeon to confirm that you have recovered sufficiently to continue with participation in this study. You will also be seen by a specialist in vascular internal medicine to confirm you are medically fit to participate. The internal medicine specialist will also review your prescribed medications and ensure that you are receiving the ideal combination based on your individual risk profile.

After you have been cleared to go ahead by your vascular surgeon and internal medical specialist, you will be seen by a clinical study coordinator. You will undergo an assessment where we will collect the following information:

- 1) Blood Pressure
- 2) Height
- 3) Weight
- 4) Waist circumference
- 5) Six-minute maximum walking distance.
- 6) Two questionnaires: Health status survey, and quality of life questionnaire.

The above data will be collected at the Peter Lougheed Center, and should take approximately 30 minutes.

If you were randomly assigned to the BMT group, you will receive the following information and tools which is the current standard of care:

- 1) Instructions to take your prescribed medications
- 2) Information tools for smoking cessation and diabetes management (if applicable to you)
- 3) Information tools on exercises that you should be doing, at least 30min 5-times per week.

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- 4) You will receive a log book to record your daily medications and daily physical activity for 12 weeks.

If you were randomly assigned to the SEP group, you will receive the following information and tools:

- 1) Instructions to take your prescribed medications.
- 2) Information tools for smoking cessation and diabetes management (if applicable to you).
- 3) Information tools on exercises that you should be doing, at least 30min 5-times per week.
- 4) You will receive a log book to record your daily medications and daily physical activity for 12 weeks.
- 5) You will return to the Total Cardiology Rehabilitation facility three times per week for 12 weeks, to participate in a supervised exercise program. As part of the program, you will have the option to attend educational sessions on various topics such as proper nutrition, smoking cessation and strategies for diabetic control.

After 12 weeks, you will return for a second assessment session at the Peter Lougheed hospital where we will repeat the measurements that we recorded at your first visit.

If you are one of the first 10 patients assigned to the SEP group, we will request that you participate in a short 30-minute exit interview to describe your experience with the supervised exercise program. With your permission, the interview will be recorded using a digital recording device. We may use direct quotes from these interviews. Your identity will remain confidential in any published material.

### **WILL YOU BE COLLECTING ANY ADDITIONAL HEALTH INFORMATION?**

We will also collect relevant data related to your overall health. This information is collected as the standard of care for critical limb ischemia. We will collect the following data:

- 1) Medication list
- 2) Surgical procedure reports (related to your vascular disease)
- 3) Related medical conditions (For example: high blood pressure, previous heart attack, lung disease, diabetes, kidney disease, history of stroke etc.)

By signing this consent form, you authorize access to your electronic medical records (Sunrise Clinical Manager and Netcare), as well as your outpatient chart to obtain the above information. Authorization to access this information will allow

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us to conduct the research project as explained during the informed consent process.

### **WILL YOU USE ANY OF THIS INFORMATION/DATA IN THE FUTURE?**

Data obtained from this study may be used in future related research. Your consent and to participate in this study represents your consent and authorization to the use of your data in future related research. The results from this study may be reanalyzed at a later date and may be combined with the results of other studies.

### **WHAT ARE THE RISKS?**

Supervised exercise rehabilitation programs have been well studied and are generally considered safe for participants. While the risks are low, they are not non-existent. The most common risk for participants is muscle or joint related discomfort or injury that may occur during or after physical activity.

There is also a small risk of lightheadedness, cardiovascular and respiratory complications. You will be under the supervision of trained health professionals. If you do find that you are feeling any chest pain or shortness of breath, you will be instructed to cease the activity immediately and notify one of the supervising staff members.

### **WILL I BENEFIT IF I TAKE PART?**

You may or may not personally benefit from participating in this study. You may reasonably expect to have your peripheral arterial disease treated according to current best medical practice. By serving as a study volunteer you may contribute new information, which may benefit patients in the future.

### **DO I HAVE TO PARTICIPATE?**

No, participation is completely voluntary. Whether or not you choose to join the study is up to you. Whatever choice you make, your decision will not have any effect on your current or future medical treatment or health care. If you choose not to participate, you do not have to explain why. You can also ask to be removed from the study at any time without giving a reason. If you choose to withdraw from the study before you have completed the exercise program, we request that you allow us to use your data so that we gain a better understanding

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of challenges patients may face with a supervised exercise program. If you would like us to withdraw your data, you may do so the data analysis has been completed and submitted for publication. Once the analysis is complete, the data will be used for publication at conferences and in journal manuscripts. Once the data has been published it will not be possible to remove individual data from the results.

If you choose to participate, but then change your mind, you should notify the investigator or study staff immediately at 403-943-4588. For your safety, you may be asked to return for final examinations and tests but these are considered standard of care and not part of the research.

The study investigator may remove you from the study at any time if it continued participation does not appear to be in your best medical interest.

We are trying to develop a better understand about barriers that patients may face regarding exercise rehabilitation. If you choose not to participate in this study, would you be willing to provide a brief written statement to explain why not? We will not collect any personal data regarding this statement, and the information will remain anonymous.

Are you willing to provide a statement regarding why you do not want to participate in this study? (CIRCLE ONE)

YES

NO

**WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?**

You will not be paid for participating in this study. You will not have to pay for any study-related medical care. Your hospitalization and all of your tests will be covered by Alberta Health and Wellness (or your provincial health insurance if you are from out of province) as they are considered part of the standard medical care required to treat your medical condition. You will be provided with a 25\$ pre-paid Visa Card to offset any additional cost for parking.

You will not be required to pay anything for participating in this study.

**WILL MY RECORDS BE KEPT PRIVATE?**

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Every reasonable effort will be made to protect the confidentiality of your records, however, such protection cannot be guaranteed. Study investigators and the study team may look at and copy the health information created or collected about you as part of this study, both to assure quality control and to analyze the information. The results of this study or other research conducted by the Investigator and the study team may be published or presented at meetings but will not include your name or reveal your identity. The University of Calgary Conjoint Health Research Ethics Board may access your records to validate the ethical treatment of study participants and the scientific merit of the study.

### **IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?**

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

If, at any time, you believe you have developed a research-related problem, you should contact one of the investigators Andrea Devrome at 587-227-8642, Dr. Randy Moore at 403-943-5467 or the research coordinator, Christi Findlay at the Peter Lougheed Centre at 403-943-4588.

### **SIGNATURES**

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

If you have further questions concerning matters related to this research, please contact: Andrea Devrome at 587-227-8642, or Christi Findlay at the Peter Lougheed Centre at 403-943-4588

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Participant's Name

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Signature and Date

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Investigator/Delegate's Name

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Signature and Date

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Witness' Name

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Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

If you have any questions concerning your rights as a possible participant in this research, please contact The Chair of the Conjoint Health Research Ethics Board, University of Calgary, at 403-220-7990.

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