CONSENT FORM

Study Title: A community-based exercise program to improve walking outcomes in patients with peripheral artery disease

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You are being asked to be in a research study to evaluate the effects of an exercise program on the health of patients with peripheral artery disease (PAD). You were selected as a possible participant because you are at least 40 years old, have been diagnosed with PAD and experience leg muscle pain when you walk, or will be receiving endovascular therapy (procedure in which a catheter is inserted into a blood vessel for the treatment of PAD) or open surgery (surgical procedure in which the blood supply is rerouted around a blocked artery in your legs) to treat your PAD. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Study Purpose
This study plans to learn more about how a community-based exercise program affects walking ability in people with PAD. We also want to know whether a program of walking in community settings will improve quality of life. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Other people in this study
Up to 3 people from your area will participate in the study. You will be placed into an intervention group or a control group. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin. Each group will get slightly different care.

Study Procedures
If you join the study, you will be asked to come to the University of Minnesota for a total of up to 6 visits or 3 study visits over the course of 16 or 20 weeks, depending on whether you are assigned to the intervention group or control group and also depending on whether you are receiving endovascular therapy or open surgery. If assigned to the intervention group, study staff will meet you at a walking location in the community that is convenient for you. If you are assigned to the control group, you will only be asked to take part in 3 visits at the hospital as mentioned above. All visits are described in detail in the **Schedule of Visits** table on page 7. Below is a brief description of the number of visits and timing for each group:

Intervention Group

- Visit 1 (at hospital)
- Visit 2 (at hospital)
- Visit 3 (at hospital)
- Visit 4 (at hospital)
- Visit 5 (at hospital)
- Visit 6 (in the community)
- Visit 7 (in the community)
- Visit 8 (in the community)
- Visit 9 (at hospital, 12 weeks after Visit 2)

Control Group

- Visit 1 (at hospital)
- Visit 2 (at hospital)
- Visit 3 (at hospital, 12 weeks after Visit 2)

Visit 1

- You will discuss and sign a consent form with the study staff. The consent form provides information about the study visits.
- Your demographic and medical information will be reviewed.
- If you are receiving endovascular therapy or open surgery, a blood sample (about 6 teaspoons) will be collected prior to the therapy or surgery (but not at this visit).
- If you are receiving endovascular therapy or open surgery, you will also be asked to not use any nicotine products 3 hours prior to the study visit or alcohol products 24 hours prior to the study visit.
- If you are receiving endovascular therapy or open surgery, your blood glucose will be assessed using a finger stick device (1-2 drops of blood).
- For females of childbearing potential, a urine sample will be collected (<1 cup) to determine if you are pregnant. The results of the pregnancy test must be negative in order for you to continue screening and to be in this study.
- If we do not have medical records for you, a physical examination may be done by a physician, physician's assistant, or nurse practitioner which includes your height and weight.
- You will have your resting heart rate and blood pressure taken while standing and/or lying down.
- A test known as an ankle-brachial index test will be done to measure your PAD. An ultrasound instrument and blood pressure cuff will be used to measure blood pressure in your arms and legs. If the ankle-brachial index is within a certain range, we will have you walk for several minutes and recheck your ankle-brachial index. If your ankle-brachial index test is found to be high, an additional test called a toe-brachial index test will be conducted to measure your PAD. The toe-brachial index test is similar to the ankle-brachial index test but the cuff is placed around your big toe rather than your legs.
- A test known as an electrocardiogram (ECG) will be done to help find any issues with your heart that may prevent you from participating in the study. An ECG is a measure of the electrical activity of your heart. It is taken using small electrode patches attached to the skin of your chest, arms and legs. It is important that the adhesive in the electrode patches make good contact with your skin to get a good reading on the ECG. If you have hair on your chest, we will request that small areas on your chest be shaved just where the electrodes are to be placed. Also, research staff will use small amounts of a mildly abrasive gel at the site of the electrodes to improve the ECG reading ability.

- Inclusion and exclusion criteria for the study will be reviewed. These are items that will tell us if you are eligible to be in the study. They will also tell us if it is safe for you to be in the study.
- If you qualify and are not receiving endovascular therapy or open surgery, you will be finished with Visit 1 and will be scheduled for the next visit.

If you are receiving endovascular therapy or open surgery, and are eligible for the study up to this point during Visit 1:

- You will be asked to complete several questionnaires that ask you about your ability to walk, your general health and an assessment of your local community walking environment.
- You will be asked to perform short distance walking tests equal to about 4 yards at your usual walking speed and then at your fastest walking speed. Each speed will be performed twice for a total of 4 short distance walking tests.
- You will be asked to sit and stand from a chair 5 times in a row as quickly as possible. You will not be able to use your arms for assistance in standing.
- You will be asked to balance while standing without the assistance of the study staff, cane, walker, or any other device. The standing balance task will include three tests in this order: 1) both feet together with your feet side-by-side, 2) feet parallel and toes of one foot next to the heel of the other foot, and 3) one foot directly in front of the other. You will be asked to stand for a maximum of 10 seconds for each test unless you lose your balance and move your feet or grasp the study staff.
- You will walk/rest in a corridor for a total of 6-minutes.
- You will perform walking exercise on a treadmill for several seconds at a time, at different speeds to get you used to walking on a treadmill.
- You will have a walking test on the treadmill. While on the treadmill you will be asked to breathe into a mouthpiece that is connected to a machine that measures the amount of oxygen your body uses. The treadmill will increase in speed and/or grade every few minutes. You will be asked to walk as long as you can on the treadmill, to the point of severe levels of fatigue. ECG monitoring will be done during the test. Your blood pressure will also be measured during the walking test. You will also be asked about any leg muscle pain or general discomfort and fatigue you feel during the test.
- Visit 2 will be scheduled if you are eligible to continue in the study.

Visit 2

- For patients who are receiving endovascular therapy or open surgery, this visit will occur 4-6 weeks following those procedures.
- For patients not receiving endovascular therapy or open surgery, this visit will occur within 1-2 weeks after Visit 1.
- You will be asked to not eat or drink anything (except for water) for at least 10 hours before this visit. We will provide a light snack following the blood draws. If you have diabetes, we will provide you instructions regarding your diabetes medication. We may have you withhold them until after the morning blood draws or the study visit (depending on the type of medication you use). Additionally, we may provide or withhold a light snack depending on your fasting blood glucose levels if you have diabetes.
- You will also be asked to not use any nicotine products 3 hours prior to the study visit or alcohol products 24 hours prior to the study visit.

- You will be asked about changes in your health and any medication changes since the last visit.
- A blood sample (about 6 teaspoons) will be collected for routine laboratory tests.
- Your fasting blood glucose will be assessed using a finger stick device (1-2 drops of blood).
- Your resting heart rate and blood pressure will be measured while standing and lying down.
- You will be asked to complete several questionnaires that ask you about your ability to walk, your general health and an assessment of your local community walking environment.
- An ankle-brachial index test will be done if you have received endovascular therapy, open surgery, or experience leg muscle pain. A toe-brachial index test may need to be performed if the ankle-brachial index test is high.
- You will be asked to perform short distance walking tests equal to about 4 yards at your usual walking speed and then at your fastest walking speed. Each speed will be performed twice for a total of 4 short distance walking tests.
- You will be asked to sit and stand from a chair 5 times in a row as quickly as possible. You will not be able to use your arms for assistance in standing.
- You will be asked to balance while standing without the assistance of the study staff, cane, walker, or any other device. The standing balance task will include three tests in this order: 1) both feet together with your feet side-by-side, 2) feet parallel and toes of one foot next to the heel of the other foot and 3) one foot directly in front of the other. You will be asked to stand for a maximum of 10 seconds for each test unless you lose your balance and move your feet or grasp the study staff.
- You will walk/rest in the hospital corridors for a total of 6-minutes.
- An ECG will be done.
- If you have not received endovascular therapy or open surgery, you will perform walking exercise on a treadmill for several seconds at a time, at different speeds to get you used to walking on a treadmill.
- You will have a walking test on the treadmill. While on the treadmill you will be asked to breathe into a mouthpiece that is connected to a machine that measures the amount of oxygen your body uses. The treadmill will increase in speed and/or grade every few minutes. You will be asked to walk as long as you can on the treadmill, to the point of severe levels of fatigue. ECG monitoring will be done during the test. Your blood pressure will also be measured during the walking test. You will also be asked about any leg muscle pain or general discomfort and fatigue you feel during the test.
- If assigned to the control group, you will be given general advice for walking in the community.
- If assigned to the control group, you will be given an activity monitor (on your ankle) and asked to wear the monitor on your ankle for 5 days per week for 10 hours a day. You will be given advice and an informational handout on how to use this device on your own.
- If assigned to the control group, you will receive 2 new monitors by mail during the course of the remaining study period. We will also provide you with 2 pre-paid mailing packages to use to send us the older activity monitors (2 separate times over the course of 11 weeks).
- If assigned to the intervention group, you will be given additional information about exercise training.
- If assigned to the intervention group, you will then be asked about convenient locations to walk around your home or a place of your choosing such as a mall or recreation center.

Visits 3-5 (additional hospital visits only if assigned to intervention group)

- Your fasting blood glucose will be assessed using a finger stick device if you have diabetes (1-2 drops of blood).
- Your resting heart rate and blood pressure will be taken while standing.
- You will then perform exercise training in the hospital. You will start with a 3-5 minute warm-up on the treadmill at a low speed followed by some light stretching. You will then be asked to walk on a treadmill and rest as needed for a total of 35 minutes. The starting speed of the treadmill will be a low speed. You will be asked to walk at a moderate intensity and study staff will increase or decrease the speed and grade of the treadmill depending on your ability to walk. Study staff will also increase the duration of exercise sessions to no more than 50 min depending on your ability to walk. When you need to rest, study staff will stop the treadmill and allow you to sit in a chair placed on or beside the treadmill.
- Your blood pressure and heart rate will be monitored during the walking exercise.
- You will be asked to wear a pedometer (on your hip) and activity monitor (on the ankle) during these visits. You will be given advice and an informational handout on how to use these devices on your own.
- You will be asked to fill out several worksheets about your walking exercise sessions.
- Study staff will talk to you about the best places for you to walk depending on the place you chose as the most convenient for you.

Visit 6-8 – Community visits (only if assigned to intervention group)

- Your fasting blood glucose will be assessed using a finger stick device if you have diabetes (1-2 drops of blood). This will take place at a location you choose where it is convenient for you to walk.
- Your resting heart rate and blood pressure will be taken while standing prior to walking exercise with study staff.
- For Visits 7 and 8 (1 visit every 3-4 weeks), study staff will collect information from the activity monitor that you were asked to wear on your ankle while walking in the community. Data will be collected from the information sheets you were asked to fill out. Study staff will also provide you a new monitor or reset the one you had been using previously.

Community walking exercise (over the course of 11 weeks)

- You will be asked to walk in the community 3 times per week for 11 weeks (following Visit 5 in the hospital).
- You will be given a lightweight, collapsible chair which you will have the option of carrying for seating during rest periods.
- You will be asked to wear the pedometer and activity monitor and fill out information sheets.
- You will receive weekly phone calls from study staff to discuss the walking exercise goals. Any concerns you may have with the walking exercise will also be talked about. Staff will visit you once every 3-4 weeks as described above (3 total visits over 11 weeks).

Intervention: Visit 9
Control: Visit 3
(12 weeks after Visit 2)

- You will be asked to not eat or drink anything (except for water) for at least 10 hours before this visit. We will provide a light snack following the blood draws. If you have diabetes, we will

provide you instructions regarding your diabetes medication. We may have you withhold them until after the morning blood draws or the study visit (depending on the type of medication you use). Additionally, we may provide or withhold a light snack depending on your fasting blood glucose levels if you have diabetes.

- You will also be asked to not use any nicotine products 3 hours prior to the study visit or alcohol products 24 hours prior to the study visit.
- You will be asked about changes in your health and any medication changes since the last visit.
- A blood sample (about 6 teaspoons) will be collected for routine laboratory tests.
- Your fasting blood glucose will be assessed using a finger stick device if you have diabetes (1-2 drops of blood).
- Your resting heart rate and blood pressure will be measured while standing and/or lying down.
- You will be asked to complete several questionnaires that ask you about your ability to walk, your general health and an assessment of your local community walking environment.
- An ankle-brachial index test will be done to measure your PAD. A toe-brachial index test may need to be performed if the ankle-brachial index test is high.
- You will be asked to perform the short distance walking tests, just as you did in Visit 2.
- You will be asked to sit and stand from a chair 5 times in a row as quickly as possible, just as you did in Visit 2.
- You will be asked to balance while standing without the assistance of the study staff, cane, walker, or any other device. The standing balance tasks will include the same three tests as you completed in Visit 2.
- You will walk/rest in the hospital corridors for a total of 6-minutes just as you did for Visit 2.
- An ECG will be done.
- You will breathe through the mouthpiece and walk as long as you can on the treadmill, to the point of severe levels of fatigue. An ECG will be done during the test. Your blood pressure will be measured during the walking test. You will be asked about any leg muscle pain or general discomfort and fatigue you feel during the test.
- Study staff will collect information from the activity monitor that you were asked to wear.

Schedule of Visits

Procedures	Initial tests		Intervention only		Follow-up[††]
	Visit 1	Visit 2[ΔΔ]	Visits 3-5** (over 1 week)	Visit 6-8[†] (over 11 weeks)	Visit 9 (controls: Visit 3)
Timeline (MM/DD/YR)					
Length of Visits	1.5 -2.5 hrs*	2.5 hrs	1.5 hrs	1.5 hrs	2.5 hrs
Informed consent	X				
Health history forms	X				
Physical exam	X				
Heart rate and blood pressure	X	X	X	X	X
Blood draws	X[‡]	X			X
Finger stick	X[‡]	X	X	X	X
Questionnaires	X[‡]	X			X
ABI	X	X			X
ECG	X	X			X
Treadmill familiarization	X[‡]	X[‡‡]			
Walking, standing and balance tests	X[‡]	X			X
Graded exercise test	X[‡]	X			X
Walking advice		X			
Walking in the hospital (intervention only)			X		
Community visits (intervention only)				X	

*Time of visit dependent on whether receiving endovascular therapy or open surgery following Visit 1.

**Indicates the following (for intervention group only): supervised walking in the hospital setting (3 visits over 1 week)

[†]Indicates the following (for intervention group only): initial community visit and walking (Visit 6); 2nd community visit, 4 weeks into community-based walking exercise (Visit 7); 3rd and final community visit, 8 weeks into community-based walking exercise (Visit 8)

[‡]For patients receiving endovascular therapy or open surgery, instructions will be provided for blood draws to occur prior to the therapy or surgery.

[ΔΔ]4-6 weeks following endovascular therapy, 4-6 weeks following open surgery, **OR** 1-2 weeks after Visit 1 if not receiving endovascular therapy or open surgery.

[‡‡]For patients with leg muscle pain and not receiving endovascular therapy or open surgery

[††]Indicates the following:
Intervention-Visit 9 **OR** Control-Visit 3 = 12 weeks after Visit 2

List of abbreviations
ABI, Ankle-brachial index; *ECG*, Electrocardiogram

Payment for Participation
You will be paid a variable amount for each visit in this study. This will add up to a total of $200 ($220 if receiving endovascular therapy or open surgery with your healthcare provider) if you are assigned to the intervention group and complete all of the visits. If you are assigned to the control group and complete all the visits, this will add up to $80 ($100 if receiving endovascular therapy or open surgery from your healthcare provider). If you leave the study early or if we have to take you out of the study, you will be paid only for the visits you have completed.

You will be paid the following amounts for each visit in this study depending on the group you are assigned to:

Intervention group
- Visit 1: $10 ($30 for endovascular therapy or open surgery patients)
- Visit 2: $30
- Visit 3: $20
- Visit 4: $20
- Visit 5: $20
- Visit 6: $20
- Visit 7: $20
- Visit 8: $20
- Visit 9: $40

Control group
- Visit 1: $10 ($30 for endovascular therapy or open surgery patients)
- Visit 2: $30
- Visit 3: $40

Additionally, if you are assigned to the intervention group you will be allowed to keep the lightweight collapsible chair and pedometer.

*Note that it is important to know that payment for participation in a study is taxable income.

Will I have to pay for anything?
It will not cost you anything to be in the study. However, costs that are related to the standard treatment for your PAD and not related to this research will be billed to your or your insurance company.

Risks/Discomforts
Discomforts you may experience while in this study include the following:

PAD
Your PAD may not get better or may get worse during this study. If your condition worsens, you may experience more pain with exercise or at rest than you do now. There are no data to suggest that participating in this study could cause your disease to worsen; however, there is a theoretical risk that your PAD may progress on its own.

Confidentiality and privacy
The use of questionnaires, interviews, collection of personal medical information and walking in the community imposes a risk to confidentiality and privacy and may cause embarrassment.

Blood Draws
A total of 24 teaspoons of blood will be taken during the study. Drawing blood has a risk of local pain, bruising, swelling, bleeding, and/or infection at the puncture site.

Finger stick
One to two drops of blood will be obtained by finger stick at Visit 2 and each visit thereafter if you have diabetes. This is a standard method used to obtain blood for diabetes screening and to ensure it is safe for you to exercise. You may experience pain when the needle goes into your finger but it should go away momentarily. Although rare, a small amount of bleeding under the skin may occur and produce a bruise and a small scar may persist for several weeks.

Ankle-brachial index and toe-brachial index tests
The ankle-brachial index and toe-brachial index tests have a risk of local pain or bruising where the blood pressure cuffs are placed on your arms, legs and toes.

ECG Risk
Your skin may become irritated from the sticky patches on your chest when the ECG is done. You may feel mild discomfort when the sticky patches are taken off of your skin, like a band-aid being peeled off. If you have an allergy to metal, you may have an allergic reaction to the gel we use to prepare the skin for the electrode.

Treadmill Test Risk
You may feel pain or general discomfort and fatigue in your legs while doing the treadmill test. There are other risks of the treadmill test. These include the possibility of injury if you should fall. Treadmill exercise can be a risk to patients with heart or cerebrovascular disease. Dizziness, shortness of breath, chest pain, changes in the ECG, or rarely, heart attack may occur. The death rate of this test is approximately one in 10,000 tests and the incidence of serious complications including prolonged irregular heartbeats or prolonged chest pain is approximately 4 in 10,000 tests. Your exercise will be at a normal walking pace. Your heart activity will be monitored throughout the treadmill test. The test may be stopped at any time if needed. Other risks that are not serious but may be uncomfortable are dryness of the mouth and throat or bleeding of the gums due to the mouthpiece, which is similar to a snorkel.

Muscle strain
You may experience muscle strains with overtraining and exertion during the exercise intervention. This could occur in any muscle group of the legs.

Exercise Training
The risks associated with moderate exercise are minimal. Exercise is highly recommended for patients with PAD. However, the walking exercise may be difficult and you may rest as needed.

Pregnancy Risk
Women who are pregnant or nursing a child may not take part in this study. If you think that you have become pregnant during the study, you must tell your study doctor immediately. Pregnant women cannot continue in the study.

The study may include risks that are unknown at this time.

Benefits
This study is designed for the investigators to learn more about PAD. If you decide to take part in this study, there is no guarantee that your health will improve.

Alternative Therapy
There may be other ways of treating your PAD. These other ways include: smoking cessation if you are a current smoker, certain medications and vascular revascularization (endovascular therapy and open surgery) procedures. You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Confidentiality
The records of this study will be kept confidential. Your record for the study may, however, be reviewed by the National Institutes of Health, and by departments at the University with appropriate regulatory oversight. We will not include any information in publications or presentations that will make it possible to identify you. Study information will not be recorded in your medical record. If study data is transmitted via the Internet, we will not include any identifying information about you related to study outcomes. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

Compensation for Injury
If you have an adverse reaction (get hurt or sick) as a direct result of taking part in this study, immediate and appropriate medical treatment will be made available. However, you or your insurance carrier will be responsible for all medical costs associated with any adverse reaction or injury while taking part in this study. No compensation is available from the sponsoring agent (National Institutes of Health), except as permitted by law. If you think that you have suffered a research related injury, let the study physicians know right away.

Voluntary Participation/Withdrawal
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.
You may be asked to leave the study for any of the following reasons:

1. Failure to follow the Project Director's instructions
2. A serious adverse reaction which may require evaluation
3. The Project Director thinks it is in the best interest of your health and welfare
4. The study is terminated

Questions
If you have questions about research appointments, the study, research results, or other concerns contact the researchers. You may ask any questions you have now, or if you have questions later, **you are encouraged** to contact them:

Researcher Name (Principal Investigator): Ryan J. Mays, PhD, MPH, MS
Phone Number: 612-625-0430
E-mail Address (if applicable): rjmays@umn.edu

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns.

You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research

You will be given a copy of this form to keep for your records.

Opt In/Out for Receipt of Study Results:
The results of this research will be communicated to you if requested. Please indicate whether you wish to opt in or out of receiving your specific study results (check one box):

☐ Opt In

☐ Opt Out

Statement of Your Consent:

I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. By signing this consent form, I have not waived any of the legal rights which I otherwise would have as a participant in a research study. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

Subject's name (signature)	Print	Date
Consent form explained by (signature)	Print	Date
Principal Investigator (signature)	Print	