Enhanced Home-Based Exercise Therapy for Peripheral Arterial Disease through Mobile Health and Remote Monitoring

NCT04889105

04/24/2026

U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Informed Consent Template Version 1/10/25

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 85 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

This study is being done to answer the question: How does wearing a daily activity and fitness monitor help patients with peripheral artery disease, or PAD, perform a walking exercise program at their home or in their community? You are being asked to be in this research study because you are diagnosed with PAD.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for 12 months with 2 in-person visits and up to eight phone calls between those visits. The researchers will ask you to do the following: consent to being in the study, be randomized to one of two remote exercise groups, and complete phone call follow-ups in addition to the 2 in-person visits. The in-person visits involve questionnaires, cognitive testing, and physical exercise testing.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. In addition, your PAD may also improve, you may lose weight, and/or experience an improved mood. There may also be additional benefits to you that are not described here.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include injury to

muscles or bones from exercise, heart rhythm problems that can lead to heart attack or death, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the RISKS section of this document.

Alternatives to Joining This Study

Patients with PAD can be treated with medication, lifestyle changes, and surgery. You do not need to be in this study to be treated for PAD

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

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TITLE: Enhanced Home-Based Exercise Therapy for Peripheral Arterial Disease through Mobile Health and Remote Monitoring

SPONSOR'S NAME: US Department of Veterans Affairs Rehabilitation R&D Service

PRINCIPAL INVESTIGATOR: [redacted]

PURPOSE:
You are being asked to volunteer in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

The purpose of this study is to evaluate if a wearable fitness monitor can help patients with PAD perform a walking exercise program at home or in their community, such as at a park or recreational center. Exercise walking programs can help patients with PAD increase how far they can walk, reduce leg pain, and improve their quality of life.

Currently, patients with PAD need to be referred to an outpatient exercise rehabilitation program in order to participate in a walking exercise program, however these programs are not widely available. We would like to learn if a wearable fitness monitor can help deliver this type of rehabilitation program remotely. We plan to enroll about 85 veterans from the Atlanta VA for this study. The study will take 3 months to complete.

We may also invite you for an optional MRI brain scan to help understand how this program, as well as your PAD, relates to the brain.

CLINICALTRIALS.GOV:.



A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time. (NCT04889105)

WHAT WILL I BE ASKED TO DO?: You will be randomized to one of two groups. Randomization means you are placed into a group by change. A computer program will decide your assignment. The researcher, you, nor your doctor can choose the group. You will have an equal (one in two) change of being placed in one of the following groups:

1. **Smart MOVE Group:**

You will participate for 3 months. This includes 2 in-person study visits at the Atlanta VA and up to 8 phone calls or video calls from our team. You will participate in a 12-week home-based individualized walking program that will require your time and commitment. Your assigned walking times will increase over the course of the 12 weeks. You will be given a wearable fitness device to help track your heart rate and walking.

The researchers will ask you to do the following:

1. Attend an initial study visit to assess your fitness level and complete several surveys.
2. Participate in a 12-week home-based exercise program.
3. Wear a fitness monitor daily.
4. Participate in up to 8 phone calls with our team.
5. Return for a follow up visit immediately after finishing the 12-week exercise program to re-assess your fitness level.

2. **General Care Group:**

You will participate for 3 months. This includes 2 in-person study visits at the Atlanta VA and up to 8 phone calls from our team. You will not be asked to participate in a home-based exercise program, but you will be given general health and exercise resources. You will be given a wearable fitness device to help track your heart rate and walking.

The researchers will ask you to do the following:

1. Attend an initial study visit to assess your fitness level and complete several surveys.
2. Wear a fitness monitor daily
3. Participate in up to 8 phone calls with our team.
4. Return for a follow up visit immediately after finishing the 12-week general care program to re-assess your fitness level.

The technology in this study has not been shown to improve medical care and should not take the place of seeking regular medical care. Consenting and questionnaires will be conducted at VAHCS or through video/phone communication.

Description of Study Procedures:

1. Initial Study Visit. Participate in an initial study visit for an interview and an assessment of your level of fitness. This assessment includes one or more monitored exercise tests, such as walking back-and-forth down the hallway, walking on a treadmill, or both. During the test, you may be asked to wear several pieces of equipment to measure your fitness including a face mask to measure your oxygen level, heart monitor, or both. Before and after each exercise test, we may measure the pulses in your feet using an Ankle Brachial Index (ABI) test. You may also be asked to complete several questionnaires and surveys to assess various aspects of your health including your physical, mental, social, and emotional wellbeing. We may also draw labs. These procedures will take place at the Atlanta VA medical center and will take about 2.5 to 3 hours to complete.

2. Home-Based Walking Exercise Program. Complete the home-based walking exercise program which lasts for 12 weeks. These exercises will be unsupervised and consist primarily of walking outside in a safe place (public park, pedestrian walkways, walking trails) or a treadmill if you have access to one. This is a recommended treatment for PAD and considered standard of care.

3. VA MOVE! Program. You may participate in the MOVE! Program, which involves up to 8 group classes that can be taken from the Atlanta VA, your local CBOC, or through telehealth (i.e., Tele-MOVE!). At each session, you will meet with either a nutritionist, pharmacist, and/or social worker to discuss healthy lifestyle choices, such as diet and strategies to become more active. Since MOVE! is a clinical program offered to all Veterans, MOVE! classes are not considered official study visits, but you may sign up at your own convenience. You will also be provided with additional information regarding other VA health-related programs.

4. Wearable Fitness Monitor. You will be asked to wear one or more wearable monitor to monitor your oxygen levels, physical activity, degree of fitness, and sleep patterns. Participants will receive one or more, wearable activity monitor (a LifeQ Moto 360, Bittum Faros, Empatica EmbracePlus, or ActiGraph LEAP). You will be asked to wear this device continuously during the study, including at night. You may remove the device for recharging, bathing, or other personal hygiene activities. You will be asked to return the device at the end of your participation. We will create an account for you as part of this study. In order for you to have the most real-world experience with this device, we will input your name, age, height, and weight into the mobile device app on your phone. The device and the data collection platforms will allow you and the study

team to better track your exercises. When you agree to use the wearable device, you are agreeing to the privacy policy of that company.

5. Exit Study Visit. You will be asked to return to the Atlanta VA for a follow-up study visit after completing the 12-week home exercise program. This will also count as your exit visit from the study. At this visit, we will repeat many of the same tests and surveys from the initial enrollment visit, including exercise tests and lab work. This visit will take place with a member of our study team.

6. Optional Brain Scan. We may invite you for one (1) or two (2) MRI brain scans at the beginning of your participation and also after you finish the exit visit. Each brain scan will involve an additional 1-hour visit to Emory.

After you finish the study, we may continue to monitor your Wearable Fitness Monitor data as long as you continue to wear the device, but not longer than 1 year from the date of your study exit visit. We would like your permission to contact you regarding your condition in the future, even if you sign a consent form but do not qualify for participation in the study due to selection requirements. A member of our study staff may also call you to ask about your progress and any issues you may have had since existing the study. You can opt-out of these phone calls anytime.

Optional Smartphone App:
Some participants may be asked to download a second smartphone app on their phone to help them manage their home walking program. This app is optional, and you do not have to have to download it to participate in this study. You may be asked to sign a separate consent form if you are asked to download the optional smartphone app.

RISKS:

There may be side effects from the study drug or procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

Questionnaires, surveys, and interviews: Being asked questions about the stress in your life may cause you to have unpleasant and/or upsetting feelings. If this happens, then you can take a break from the interviews. You can also slow down and take longer to do the tests. Should you so desire, a counseling session and/or referral for counseling will be made available.

Electrode stickers: They can cause skin irritation in some people.



The less common risks and discomforts expected in this study are:

Exercise test: This study is designed to minimize the risks to you. Patients who exercise on a treadmill may get a muscle or bone injury (like a sprained ankle) or have a change in their heartbeat. Rarely, patients can have a cardiovascular complication. The risk of a serious cardiovascular complications (like a heart attack or stroke) during exercise testing is about 1 in 10,000. A credentialed practitioner will perform the exercise test and your heart and blood pressure will be monitored throughout. You may stop the test at any time.

Wristband fitness tracker: Some people may experience wrist discomfort from wearing the fitness tracker.
Brain scan: The MRI is a large magnet that may move any metal objects in your body. We will review for such risks in advance and only move forward if the risk is minimal. You may also feel uncomfortable from laying in a small tunnel for up to one hour and may stop the scan at any time. Some participants may also find the noises of the scanner uncomfortable.

Rare but possible risks include:

Risk of starting an exercise program: Rarely, physical activity during a cardiac or vascular exercise rehabilitation program causes serious problems. These problems can include injuries to your muscles and bones or heart rhythm problems that can lead to a heart attack or death. Before you start, our team will assess your health and physical fitness to make sure you are healthy enough to begin a home walking exercise program.

There is the potential of a third-party intercepting research and non-research information.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

BENEFITS: Taking part in this research study may benefit you by increasing your cardiopulmonary fitness which can improve how you feel in the short term and other long-term outcomes including a lower risk of hospitalization or worsening of any cardiac or pulmonary conditions. You also may not benefit personally from this study; however, this research study may help us learn new things that may help other people in the future.



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COMPENSATION: You will receive $50 for each study visit. Participants can receive a total of $100 for completing the two (2) required study visits. In addition, we have two optional Brain Scan visits. You have to be invited to participate in the optional Brain Scan visits. For each Brain Scan you complete, you will receive $50.) Participants can receive a total of $100 for completing the two optional Brain Scan visits. You will be paid at the end of your participation using a VA-approved method. It can take six weeks after each study visit to receive your compensation.

COSTS:

You or your insurance will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

You will get necessary medical treatment if you get injured from being in this study. This requirement does not apply to:

(1) Treatment for injuries due to non-compliance by a subject with study procedures;

Or

(2) Research conducted for VA under a contract with an individual or a non-VA institution.

If you believe you have been injured by this research, you should contact [redacted]

ALTERNATIVES:
This study is for research purposes only. The alternative is not to participate in the study. You do not have to be in this study to receive treatment for PAD. You doctors can provide more options about what is specifically available to you, and you may discuss these options with him/her.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED:

We will keep information about you, including any research records we create, strictly confidential to the extent required by law.
We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use [a



study number*] rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results." People other than those doing this research study may have access to your medical and study records including:

- Sponsors, companies or agencies paying for the study
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- Emory University
- Life Q
- ActiGraph
- Empatica
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect



other information including your name, address, date of birth, and information from your medical records such as

- Demographic information including name, age, and race
- Information from your VA health record such as diagnoses, progress notes, medications, allergies, lab results and/or radiology findings
- Billing or financial records
- Drug, alcohol and/or substance abuse
- Mental health treatment
- Questionnaires and/or surveys
- Genetic test results

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Emory University and the Emory University Institutional Review Board (IRB), the Atlanta VA Research Compliance Office, and other federal agencies required to monitor or oversee research such as the Office of Human Research Protections (OHRP), the inspector general, the VA Office of Research Oversight (ORO), the Government Accountability (GAO), the Food and Drug Administration (FDA) and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

<u>While this study is being conducted you will not have access to your research related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.</u>

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.



Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESULTS: In general, we will not give you any individual results from the study of the samples or information you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

IDENTIFIABLE PRIVATE INFORMATION OR IDENTFIABLE SPECIMENS:
Identifiers might be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

CONFLICT OF INTEREST: None

CONTACT PERSONS:
If you have any questions, concerns, or complaints about this study you can call a member of the study staff:

[redacted]

If you have been harmed from being in this study call:

[redacted]

If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at ([redacted] or the Clinical Studies Center Manager at [redacted]

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at ([redacted] or toll free at 1[redacted].

VOLUNTARY PARTICIPATION AND WITHDRAWAL:

The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.



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Your participation is voluntary, and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically returning the devices that were provided for use during the research study.

The study doctor, investigator, or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____
Research Participant's Signature Date

_____ _____
Participant's Legally Authorized Representative Date