NCT05048979

Telehealth to Improve Functional Status and Quality of Life in Veterans with PAD

ICF 06/2/2023

Participant Name:	**Date:**
Study Title: *Telehealth to Improve Functional Status and Quality of Life in Veterans with PAD*	
Principal Investigator: [redacted]	

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Department of Veterans Affairs	Research Informed Consent Form	
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Principal Investigator: Jorge Antonio Gutierrez, MD	**VAHCS**: Durham VAMC

OVERVIEW AND KEY INFORMATION

Please read this form carefully. You are being asked to participate in this research study because you have peripheral arterial disease – a condition where blockages occur in the arteries of your legs. This study is voluntary and will include only people who choose to take part. Please ask us to explain any words or information that you do not understand. It is important that you understand the information on this form.

The purpose of this study is *to show that a telehealth-based exercise program can improve physical function, quality of life, and reduce the risk of heart disease in Veterans with peripheral arterial disease.*

Your participation in this study will involve *being part of a 3-month, 3 day a week exercise group delivered through a telehealth application on an Apple iPad.* You will also be asked to complete questionnaires regarding your health and improvement of health throughout this program.

The greatest risks of this study involve muscle fatigue and soreness during or after exercise. There may be a loss of confidentiality since you will be working in groups during the exercise classes.

The investigator may withdraw you from the study without your consent for one or more of the following reasons: You have serious side effects to exercise, your condition worsens, or your study doctor decides it is no longer in your best interest to continue in the study, or failure to follow instructions of the investigator and/or study staff.

WHY IS THIS STUDY BEING DONE?

Veterans experience heart disease more often than non-veterans. Peripheral arterial disease (PAD), a disease where blockages occur in the arteries of the legs, among Veterans is similar. Veterans with PAD are 10 times more likely to require a procedure such as needing a stent or amputation when compared with civilians with PAD. Two possible explanations for the increased rates of complications among Veterans may be related higher number of risk factors, such as diabetes, and/or poor access to care. One way to change this is to increase the

availability of treatment. We believe, the lack of a readily available exercise program within our area contributes to the decline in our Veterans with PAD. Therefore, the three reasons for this study are:

1. There is a need for a supervised exercise training program for Veterans with PAD at the Durham VA Medical Center and surrounding area.
2. North Carolina has the largest number of individuals living in rural areas.
3. There is an increased risk for procedures needing to treat PAD among Veterans living in rural areas.

The study is being done to develop a telehealth supervised exercise program for Veterans with PAD that serves as a model for future programs at VAs across the country.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

154 people will be ***enrolled*** in this study at the Durham VA Health Care System.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last ***one year.***

WHAT IS INVOLVED IN THIS STUDY?

Upon agreeing to participate in this research study and signing this consent form you will be enrolled into one of two groups: Group 1 will participate in a virtual supervised exercise training program and Group 2 will not receive any supervised training. If enrolled in Group 1, you will participate in an exercise program 3 times a week for a total of 12 weeks. During these sessions you will coached remotely by a study member through a telehealth application on a VA issued Apple iPad. This will allow you to exercise at a location of your choice. Participants in Group 1 will be required to attend 3 in-person visits over a year: 1 at the beginning of the study; 1 at the end of the 3-month exercise program; and 1 at 12 months. Participants in Group 2 will be required to attend 2 in-person visits: 1 at the beginning of the study and 1 at 12 months.

Exercise Training Program

You will exercise in a safe location of your choosing. Exercise will consist of walking until you feel moderate discomfort (can be pain, cramping, burning, or aching) or fatigue. At this point you will be instructed to stop walking and rest until this discomfort resolves. Once your symptoms return to baseline you will then resume walking until moderate discomfort or fatigue reoccurs. This cycle of walking and rest will be repeated for at least

30 minutes in the first few sessions of the program. In subsequent visits the goal will be able to walk 5-10 minutes longer than your prior sessions without
experiencing discomfort in your legs. The entire exercise training program will consist of 3 exercise sessions a week, for 12 weeks. Each session will be at least 30 minutes but no more than 60 minutes. During your exercise session you will be supervised by study member in real time through an application on your VA issued Apple iPad. This study member will serve as a trainer providing encouragement throughout your exercise session.

Note that you will be part of an exercise group of no more than 6 people. You will be able to see those in your group and they will be able to see you through the telehealth application on your VA issued iPad. The sessions are not recorded so there is no saved photographs or video. The purpose of the video is that it feels like you are participating in person. These sessions will not be shared other than during the class. Both the telehealth application and the Apple iPad will be provided free of charge.

Group 1 visits

Visit 1

At visit 1 we will perform the following tests: baseline characteristics, six-minute walk, and Gerofit functional assessment, walking impairment questionnaire, vascular quality of life questionnaire, and flourish measure. Explanations of these tests are listed in the following paragraphs. We also will measure your height, weight, and blood pressure and you will complete the three questionnaires. Please note that you will also have your blood drawn (blood draws are not optional).

Ankle brachial index

An ankle brachial index test is a simple way for your doctor to check how well blood is flowing in your legs. They use this test to check for peripheral artery disease (PAD). When you have this condition, it means you have blockages in the arteries of your arms and legs.

Six minute walk test

You will be asked to walk in an unobstructed 100-ft hall for 6 continuous minutes with the goal of walking the greatest distance possible. You are allowed to stop and rest (standing or sitting), but the stopwatch will continue to run. The key outcome is distance walked.

Functional assessment

This evaluation consists of testing all of the following: 1) Gait speed - usual walking speed will be measured from an 8-ft walk test in seconds with a manual stop watch. 2) Balance - assessed by timing the ability to stand in three different positions for 10 seconds. 3) 30-sec arm curls - number of 5-lb arm curls completed in 30 seconds. 4) 30-sec chair stands - number of chair stands completed in 30 seconds. 5) 8-ft get up and go – time it takes to

go from sitting in a chair, standing up, and walking at usual speed to a marked distance of 8 ft, turning around, returning to chair, and sitting down again.

Blood sample collection

We will ask you to give a blood sample. We will use a needle to draw about two (2) teaspoons of blood from your arm. This blood will be used to measure your kidney function and assess risk factors for diabetes. Note that blood will be drawn by a VA phlebotomist.

Visit 2 includes baseline characteristics, six-minute walk, Gerofit functional assessment, and VA home health telehealth satisfaction survey assessed, walking impairment questionnaire, vascular quality of life questionnaire, and flourish measure will be evaluated.

Visit 3 will include the only the functional assessment and questionnaires.

Each visit will last approximately one hour. Blood draws will occur at all three visits.

Group 2

Will only have 2 visits: at beginning and end of the study (12 months). At both visits, we will measure your height, weight, and blood pressure. Blood will also be drawn and questionnaires on how well you feel and function at home will be completed. There will be no exercise classes in this group.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

If you choose to take part in this study, you are at risk for the following risks or side effects.

Exercise.
You may experience fatigue, pain, or discomfort from the exercises.

Blood drawing

Risks of drawing blood Pain, bruising, and rarely, fainting or infection.

There are no other physical risks associated with this study. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some questions asked as part of this study may make you feel uncomfortable or increase distress. This discomfort or increased distress is usually temporary and well tolerated. You do not have to answer questions and you can take a break at any time. You can call the study team at any time if you experience any discomfort related to the research.

There may be risks and discomforts that are not yet known. If you experience any discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

This research study involves participating in an exercise program. As such, you may experience immediate and long-term benefits from routine exercise. According to the US Centers for Disease Control and Prevention this includes the following: improved cognition, quality of life, improved mood, and quality of sleep; reduced short and long-term feelings of anxiety; weight loss; improved ability to perform daily activities and prevent falls; and increase chances of living longer by reducing your risk of heart disease and diabetes. There is the possibility, although small, that you may not personally benefit from the exercise, but your participation will lead to knowledge that will help people in the future.

WHAT OTHER OPTIONS OR ALTERNATIVES DO I HAVE?

Taking part in this study is your choice. You may choose to not participate.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Your information used for this study will be kept confidential as required by law. The results of this study may be used for scientific purposes or for publication, but these results will not include any information that can identify you. Your identity will not be disclosed without your consent, or unless
required by law. Your research records will be maintained and destroyed according to VA records retention requirements.

Data will be stored electronically on VA servers in folders only accessible to study team members: Access to the data is only granted to IRB-approved study personnel via approved software applications used for study participant tracking, data collection, and reporting. All study personnel working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. Access to study data will be removed for all study personnel when they are no longer part of the research team. Some information (name and address) will be shared electronically through a VA LEAF request to the Deputy of Supply Chain Management in order for the $25 payments to be sent via check.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections, the VA Office of the Inspector General, and the Office of Research Oversight. We will not share any information with these groups outside the VA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

FUTURE USE OF DATA AND CONTACT FOR FUTURE RESEARCH:

THE DATA COLLECTED DURING THIS STUDY MAY BE USED FOR FUTURE RESEARCH.

If data collected during this study is used in future studies, it will have all private identifiable information removed. This means no one will be able to find out which participant it came from. Please note that additional permission to use this data in future studies will not be obtained from participants or *legally authorized representatives*.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING? There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

Costs incurred due to economic burden for participation will be reimbursed. You will be reimbursed $25 following the first and last completed in-office study visit. We also will offer a conditional payment for the 3-month follow up visit, which includes: (1) you live more than a 45-minute commute (most direct or quickest route) and (2) we are unable to coincide the 3-month follow-up with a pre-existing appointment at the Durham VA.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VA Medical Center or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at [redacted].

WHAT ARE MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You can choose to not be in this study, or, if you agree to be in the study, you can withdraw at any time. If you withdraw from the study, no new data about you will be collected for study purposes. We will keep and use the data that we already collected before you withdrew your consent.

If you choose to not be in the study or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

The investigator may withdraw you from the study without your consent for one or more of the following reasons: you have serious side effects, your condition worsens, or your study doctor decides it is no longer in your best interest to continue in the study, or failure to follow instructions of investigator and/or study staff.

We will tell you about new information that may affect your health, condition, welfare, or willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

The primary clinical endpoints of the present study are exercise related. Changes in exercise capacity as a result from the intervention, will be disclosed to participants during their 3-month follow-up visit at the completion of their exercise program.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

None of the investigators have financial interest in this study.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

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.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact [redacted] during regular business hours or at [redacted] after hours. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service

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at [redacted], extension [redacted]. If you would like to check that this study is approved by the Durham VAHCS's Institutional Review Board, please call the research office at [redacted] or [redacted], extension [redacted].

AFFIRMATION FROM PARTICIPANT

I have read this form, or it has been read to me. My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Signature of Participant	**Date**
Signature of Person Obtaining Consent	**Date**