Home-based exercise to improve functional outcomes in Veterans with recently healed diabetic foot ulcer

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Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: Home-based exercise to improve functional outcomes in Veterans with recently healed diabetic foot ulcer

Principal Investigator: Mary-Claire Roghmann Facility: VA Maryland Health Care System

IRB Study Number: HP-109576
Sponsor: VA Office of Rehabilitation Research and Development

INTRODUCTION

You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

CONCISE SUMMARY

The purpose of this research study is to see if a home-based exercise program can increase mobility and function after the healing of a foot ulcer, foot infection, or foot amputation in Veterans with diabetes. Participation in this research study is voluntary. Over the course of up to 31 weeks, participants will have up to 8 study visits. Each visit will take between 30 minutes – 3 hours. At the first study visit, we will ask you questions about your medical history and perform a physical exam. At the second visit, participants will be randomized, like flipping a coin, to participate in the at-home exercise group of the study for 12-weeks or continue with your normal care. Those randomized to the home-based exercise intervention will exercise five days a week. During the study, we will test your mobility and strength, perform a fasting blood draw to test your blood sugar levels, educate you on foot care, and educate those in the intervention group on the at-home exercise regimen. We will text you to remind you to exercise weekly if you are in the exercise group and will text you to remind you to check and clean your feet if you are in the standard of care group. All participants in the study will receive a Fitbit to track steps per day. All participants are expected to enroll in Podimetrics SmartMat program for remote sensing of foot health.

Key risks for participation in this study are those that are common for an exercise intervention including blisters on the foot, falling, muscle soreness, muscle fatigue, and joint pain. Risks for the blood draw include bruising, swelling at the site of the needle stick, and fainting. There is a risk of loss of confidentiality and loss of privacy. There is no guarantee that you will receive a direct benefit from participating in this study. All study participants are compensated for their time of up to $375.

RESEARCH DETAILS

PURPOSE OF THE STUDY

You have been invited to take part in this research study because you have diabetes and had a past healed foot ulcer, a foot infection or a foot amputation. We are studying new ways to increase mobility and function in those with past foot ulcer, foot infection or foot amputation. The purpose of this research study is to see if a home-based exercise program can increase mobility and function Veterans with diabetes and a past foot ulcer, foot infection or foot amputation. You will randomly be assigned to the home-based exercise intervention or standard care- like flipping a coin. There are up to 50 participants being enrolled for this study, with 25 being randomized.

STUDY PROCEDURES

The research will be done at the VAMHCS (Baltimore VA Medical Center, Loch Raven Medical Center or Baltimore VA Annex- depending on what is most convenient for you and staff availability)

- The research will take 14-31 weeks to complete.
- All study visits will occur in the Baltimore VA Medical Center, Loch Raven, or the Baltimore VA Annex
- There will be a total of 8 visits for those in the intervention group and 6 for those in the standard care group. The first, second, and seventh visits will take about 2-3 hours. The third, fourth, fifth and sixth visits will take 30 minutes to 1 hour. If you are in the intervention group, you will be asked to take part in an eighth visit for a phone interview of your opinion on the home-based exercise regimen.
- The home-based exercise regimen includes the currently recommended 5 days per week of exercise. Seated cycling exercise will be performed 3 days a week (for example-Monday, Wednesday, and Friday), and strength/balance exercise will be

performed 2 days a week (for example-Tuesday and Thursday). The strength and balance portion will be done as a virtual group exercise session (45-60 minutes).

- We will also ask you to enroll in a VA-approved Annie App text program . You will receive one weekly text to remind you to exercise if you are in the exercise intervention group. If you are in the control group, you will receive one weekly text to remind you to check your feet. Texts will end with the study. You will not be required to download anything on your phone. Information on the Annie App can be found: https://mobile.va.gov/app/annie-veterans.

At the first visit, the following will happen:

- We will explain the study to you. If you agree to be in the study, you will be asked to sign this informed consent form. We will make a copy for you to keep for your records.
- We will ask you questions about your medication use, medical problems, and foot care. You will also have a physical performed.
- We will give you information about caring for your feet.
- We will test your mobility and strength using walking and strength tests.

At the second visit (about a week after the first), the following will happen:

- We will ask you to come to this visit fasting (no food or drink other than water for at least 8 hours before the test) and to not take any vasodilator medication (if prescribed).
- We will take a blood sample (less than 3 tablespoons) to check your blood sugar levels and test for markers of health. We will give you something to eat.
- You will be asked about your foot care since the last visit as well as any medical changes since the last visit.
- We will finish any mobility and strength testing not done at visit 1 using walking and strength tests.
- We will measure blood flow in your foot.
- We will give you a Fitbit with an anonymous account to track daily step counts.
- You will randomly, like flipping a coin, be assigned to the at home-exercise intervention or extra foot monitoring and assessment of walking level. Neither you nor your doctor will choose what treatment group you will be in. You will have a three to one chance of being in the exercise intervention group.

At the third visit (a few days to a week after the second visit), the following will happen for those in the intervention group only:

- Your foot health will be checked.
- We will check that your Fitbit is working and the anonymous account is recording your steps per day
- You will receive one-on-one education on the at-home exercise regimen. You will also receive any equipment that is needed for the at-home tests including a under desk-bike and TheraBand strength bands.

At the fourth-sixth visits (every 3 weeks for 2 months), the following will happen:

- We will ask you a few questions about your medication use and medical problems since the last visit.
- We will ask you about your foot care since the last visit.
- We will record steps taken from your Fitbit.
- For those in the intervention, we will review your exercises and collect any exercise logs.

At the seventh visit (about 12 weeks after the second visit), the following will happen:

- We will ask you to come to this visit fasting (no food or drink other than water for at least 8 hours before the test) and to not take any vasodilator medication (if prescribed).
- We will take a blood sample (less than 3 tablespoons) to check your blood sugar levels and test for markers of health. We will give you something to eat.
- You will be asked about your foot care since the last visit as well as any medical changes since the last visit.
- We will test your mobility and strength using walking and strength tests.
- We will measure blood flow in your foot.

At the final visit (about 2 weeks after the end of the intervention) which could happen by phone or in person, the following will happen for those in the intervention only:

- We will ask you to take a brief survey about the exercise intervention.
- We will ask you questions and your opinion about the exercise intervention.
- We will audio record the interview. We will not refer to you by name and will save the recording under your study ID behind the VA firewall. We will transcribe the audio recording to text.

Although unlikely, we may ask you to come in for additional visits if the mobility and strength testing cannot be done in the allotted visits.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?
If you take part in this research, you will be responsible to:

- Come to all study visits.
- Follow the directions of the research staff.
- Respond to contact from study staff.

POTENTIAL RISKS/DISCOMFORTS

- Common risks for the exercise intervention are those that are common for any exercise which may include blisters on the foot, falling, muscle soreness, and rarely cardiovascular events. There is also the potential for exercise-induced hypo or hyperglycemia in participants with type 2 diabetes.
    - At the beginning and end of each study visit, we will examine your feet for skin integrity. If there is evidence of skin breakdown, the exercise regimen will be paused, and the participant evaluated by Podiatry. Participants will also be monitored via the SmartMat Program.
    - The risk for a cardiac event is estimated to be <1 event per 10,000-man hours of exercise.
    - We will ask you to monitor blood sugar before and after the exercise sessions.
- For muscular strength testing, there is risk of muscle fatigue, joint pain, and an unlikely risk of tendon rupture.
- When collecting the blood sample, there is a risk of bruising, swelling at the site of the needle stick, fainting, and possible infection at the needle stick site.
- When fasting, there is risk for low blood sugar. To minimize this, we will schedule the appointments in the morning and do the blood draw and blood flow testing first. We will also give you food immediately afterward.
- There is a risk that your health information could be accidentally shown to others outside the study and there is a potential for breach of privacy. We will protect your privacy to the fullest extent allowed by law. The records from this research study will be kept confidential. Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet and electronic data will be password-protected.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

New findings developed during the course of the research that may affect the participant's willingness to continue participation will be provided to the participant.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: [redacted]

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. You will receive information on foot self-care. This study will provide knowledge to determine whether an at-home exercise program can increase mobility and strength in Veterans that had a past healed foot ulcer, foot infection or foot amputation.

COSTS TO PARTICIPANTS

You will not be charged for any treatments or procedures that are performed for research purposed in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

It will not cost you anything to participate in this study. Your study visits will be coordinated with your regular outpatient visits if possible.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

You will be compensated $50 for each study visit and $25 for the end of study interview for those in the intervention for a total of $375. Compensation will be provided to you in the form of a voucher to be redeemed for cash through the VA Agent Cashier. Compensation for each study visit will be provided to you at the end of each study visit.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or stopping your participation in the study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS. If you are a VA employee, refusal or withdrawal from this study will in no way influence your employment or ratings.

If you withdraw from the study, you will still keep the Fitbit and exercise equipment if you have received it from the study team before withdrawal.

You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. [redacted].

There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal

- If you turn out not to be eligible for the study
- If you fail to show up for appointments
- If you fail to follow the directions of the research staff, or
- If the person in charge decides that the research study is no longer in your best interest

The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

CONFIDENTIALITY AND ACCESS TO RECORDS

Confidential information from your medical record that is not related to this study will not be accessible to anyone outside of the VAHMCS. This information may only be shared with those outside the VAHMCS if you consent to it in writing, or if it is required by law or regulation. Your medical record may be viewed or copied by the VAHMCS Institutional Review Board of record (University of Maryland IRB). If this were to happen, your data would be kept confidential to the fullest extent allowed by law.

This study involves confidential information. Only study staff will have access to this information. Study data will be coded with a study ID. Confidential information and study data will be stored in a secure location such as a locked office and locked cabinet and electronic data will be password-protected. Any audio recordings from the interview will be saved behind the VA firewall labeled with study ID. Audio recordings will be deleted according to the VA records control schedule. The Fitbit device does not collect GPS data, however, if you connect this device to your phone it may collect GPS data that may be collected by Fitbit.

We will include information about your study participation in your medical record. Labs will be performed in the VA and will become a part of your clinical record. Blood samples will be stored in the VA for future tests for this study and will be stored with a coded number. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization such as the University of Maryland IRB, VA Office of Research and Development, VA Office of Research Oversight, VA Office of Inspector General, Office of Human Research Protections, and VAMHCS Office of Research Compliance.

The monitors, auditors, and the IRB will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access.

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

Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The “records control schedule” is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS “HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research”. However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

WILL ANY OF MY DATA OR BIOSPECIMENS BE STORED FOR FUTURE USE BEYOND THE PURPOSES OF THE CURRENT STUDY?

By enrolling in this study, you are agreeing to the storage, sharing, and use of the data. Information for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent. De-identified data will be stored on the VA servers and only the study team will have access. Those who wish to use data for future research studies will need to ask the investigators for access.

Blood samples will be saved, but only for the purposes of this study. They are saved in case re-testing for blood sugar levels or additional testing such as testing for inflammatory markers is needed.

WILL I BE RECONTACTED AFTER THE STUDY?

Please read each sentence below and **initial** next to "YES" or "NO". No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

May the investigator or its research partners in this study contact you after this research study is over to participate in other studies?

_____**YES,** I consent to be re-contacted.
_____**NO,** I do not want to be re-contacted.

HEALTH INSURANCE 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 medical history, or lab 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 Institutional Review Board (IRB), VAMHCS Office of Research Compliance (ORC), Office of Human Research Protections (OHRP), VA Office of Research Oversight (ORO), and Government Accountability (GAO).

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.

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.

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] 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.

CONTACTS AND AGREEMENT

WHO ELSE CAN I CONTACT ABOUT THIS STUDY?
The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB-approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Research Protections Officer (RPO).

VAMHCS Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
443-421-5602

The VAMHCS RPO may contact you in the future to ask you about your experiences with this research study. **AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible

benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date