Improving Walking in Peripheral Artery Disease Using Specially Designed Assistive Shoes

NCT05103280

June 22, 2022

Participant Name: _____ Date:_____

Title of Study: Improving Walking in Peripheral Artery DiseaseUsing Specially Designed Assistive Shoes

Principal Investigator: [redacted] VA Facility: NWIHCS- Omaha VA

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

The purpose of this study is to evaluate the ability of different **specially designed tennis shoes** to improve the walking performance and muscle oxygen levels of patients with peripheral artery disease (PAD). The study is funded by the University of Nebraska Medical Center and the University of Nebraska at Omaha. The shoes we will be testing are made to propel the person wearing them forward with each step. By doing this study, we hope to learn whether wearing the **specially designed shoes** helps people with PAD walk better and which type of specially designed shoe is the most helpful. In this study we will test people with PAD while wearing different types of tennis shoes including: 1) your own walking shoes, 2) shoes with carbon fiber and shock-absorbing foam in their soles, and 3) shoes with shock-absorbing springs in their soles.

About **30** subjects will participte in this study at Nebraska Western Iowa Health Care System (VA-NWIHCS).

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will involve one or two visits to the Omaha VA Medical Center.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your involvement in this research study will help us learn which specially designed tennis shoes are more comfortable and effective to help patients who have PAD, like yourself, walk better: for example, walk farther, more comfortably and with less pain.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to participate in this study because you will need to spend some of your time testing the shoes and because you may experience some discomfort with the walking tests.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any of the services, benefits or rights you would normally have if you choose not to participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Sara A. Myers of the VA Nebraska-Western Iowa Health Care System (VA NWIHCS). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is:

[redacted], PhD:

During the Day: [redacted]; After Hours: [redacted]

Participant Name: _____ Date:_____

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to evaluate the ability of different **specially designed tennis shoes** to improve the walking performance and muscle oxygen levels of patients with peripheral artery disease (PAD). The study is funded by the University of Nebraska Medical Center and the University of Nebraska at Omaha. The shoes we will be testing are made to propel the person wearing them forward with each step. By doing this study, we hope to learn whether wearing the **specially designed shoes** helps people with PAD walk better and which type of specially designed shoes are the most helpful. In this study we will test people with PAD while wearing different types of tennis shoes including: 1) your own walking shoes 2) shoes with carbon fiber and shock-absorbing foam in their soles, and 3) shoes with shock-absorbing springs in their soles.

HOW LONG WILL I BE IN THE STUDY?

You will either participate in one or two visits. Each visit will last up to two hours.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

You will be asked to go to the Omaha VA Medical Center and take part in the following tests:

You will choose whether you want to participate in one or two visits for this research study. You will choose to participate in the either the Baseline Phase or the Intervention Phase as described below:

The **Baseline Phase** involves the following:

- **Walking Test:**
  You will walk on a treadmill while wearing your own walking shoes and the specially designed tennis shoes (carbon fiber insole shoe and spring loaded shoes). You will walk without assistance on the treadmill.

- **Muscle Oxygen:**
  Small sensors will be placed on your legs to see how much oxygen your legs are getting while you walk on the treadmill.

- **Interview and Survey:**
  After completing the walking tests, we will ask you some questions about how your own walking shoes felt and how the specially designed shoes felt while you were walking. We will also show you a scale to record how you felt while you were walking with your own walking shoes and the specially designed shoes. If, for any reasonyou wish not to answer specific questions, you may decline to answer. If, for any reason, you wish to end the session, you will be able to do so at any time.

You will not keep the tennis shoes that you wear to walk on the treadmill.

The **Intervention Phase** will involve 2 separate visits that will occur about 3 months apart. You will do the following tests at each of the visits:

- **Walking Test:**
  You will walk on a treadmill while wearing your own walking shoes and the specially designed tennis shoes (carbon fiber insole shoe and spring loaded shoes). You will walk without assistance on the treadmill.

- **Muscle Oxygen:**
  Small sensors will be placed on your legs to see how much oxygen your legs are getting while you walk on the treadmill.

- **Physical Activity:**
  You will be asked to wear small devices called accelerometers for 7 days in a row before the testing. The accelerometers are about the size of a watch or small beeper that will measure how much you walk during the testing.

- **Interview and Survey:**
  After completing the walking tests, we will ask you some questions about how your own walking shoes felt and how the specially designed shoes felt while you were walking. We will also show you a scale to record how you felt while you were walking with your own walking shoes and the specially designed shoes. If, for any reason you wish not to answer specific questions, you may may declinie. If, for any reason, you wish to end the session you will be able to do so at any time.

  Wear the Tennis Shoes:
  At the first visit, you will choose which tennis shoes you like the best, and you will be given these new shoes to keep permanently. You will be asked to wear these shoes for the next 3 months. At the end of the 3 months, we will schedule you for a second visit, and you will be asked to wear the tennis shoes during the second visit.

- **Phone Interview Session:**
  We will call you six months after you complete both of the intervention phase visits to see if you are wearing the tennis shoes or not wearing the tennis shoes and the reason you may not be wearing them.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

The walking tests have the same potential risks as you may experience during normal walking or other physical activity, such as leg discomfort or fatigue.

The interview questions may make you feel uncomfortable, having to give answers about your participation.

There is a risk of being uncomfortable with the specially designed tennis shoes or having them rub your foot. To minimize this risk, the specially designed tennis shoes will be properly fitted and adjusted prior to data collection. Study staff will inspect your feet before and after testing to make sure there is no evidence of the shoes rubbing your foot.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be some direct benefit to you for participating in this study because you may discover that there is a particular type of shoe that actually improves your ability to walk. Furthermore, your involvement will help us learn if the specially designed tennis shoes are effective to help people like you with PAD walk better: for example, walk farther, walk with less pain and walk more comfortably.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. This study does not involve any type of treatment so you should discuss treatment options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Identifiers will be removed from the identifiable private information or identifiable data that is collected. After that removal, information 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.

Any information obtained about you in this study will be treated as confidential and will safeguarded in accordance with the Privacy Act of 1974 and HIPAA. Identifiers might be removed from the identifiable private information. Information published or presented about the results of the study will be in a form that does not identify any particular participant. The information 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. You understand that, in order to comply with federal regulations, records identifying you may be inspected by the representative of the sponsor(s) of this study the VA NWIHCS and the University of Nebraska at Omaha and professional or government organizations that conduct and oversee the conduct of research activities (e.g.,Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA)), an accrediting organization currently under contract with the VA, and the VA Research Service and its nonprofit research organization. By signing this document, you consent to such inspection. Destruction of the research records will be in accordance with the VA record control schedule. The FDA may choose to inspect research records that include the subject's individual medical records.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There is no cost to you for your participation in the study. This study does not involve any treatment or medications so if you usually pay co-payments for VA medications, you will still pay these co-payments for VA care and medications.

Participant Name: _____ Date:_____

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Principal Investigator: [redacted],PhD VA Facility: NWIHCS- Omaha VA

WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?
You will be compensated for your time for participating in this study. You will receive $100 (one hundred dollars) for participating in the Baseline Phase visit.

If you participate in intervention phase, you will receive $50 for each of the Intervention Phase visits and you will keep the tennis shoes. You will receive a check in the mail after your visit.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of your participation in the research, the VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). No other form of compensation is routinely available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: [redacted] MD (Co-Investigator) at [redacted]

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?
Your participation in this research study is voluntary. Your refusal to take part in this research study will involve no penalty or loss of benefits to which you are otherwise entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION
You may be withdrawn from the study if you are unable to complete the testing or if the investigator feels that it is in your best interest to stop participating.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?
If you have any questions, complaints, and concerns about the research or related matters, please contact [redacted] If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the IRB Committee Coordinator at [redacted] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?
If during your participation in the research study we discover new knowledge that relates to your willingness to continue to be involved in the study, we will share it with you.

FUTURE USE OF DATA AND RE-CONTACT
If you agree to future contact, we will store your study and health information in a data base called a research data repository. Your information will be de-identified, which means that it will be assigned a special code that will not identify you. The data will be stored in a special VA research drive that only authorized research personnel is allowed to access. If you agree to have your information stored in the research data repository, this means you agree that we can use your information for future studies about PAD or other vascular diseases and that other investigators may get permission from the VA's

Institutional Review Board, that oversee's all VA research, to use your information for future research involving vascular diseases.

If you agree to have your information stored in a research data repository, you will be asked to sign a special HIPAA form that grants permission.

If you do not wish to have your information stored in a data repository, you can still participate in this study.

Please initial your preference on the lines below to indicate your preference on future contact and storing your information in a research data repository:

_____YES, I agree to future contact about research studies.

_____ NO, I do not agree to future contact about research studies.

_____YES, I agree to have my information stored in a reseach data repository.

_____NO, I do not agree to store my information in a data research repository.

Participant Name: _____ Date:_____

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____, who is a member of the research team who is authorized to obtain informed consent has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I 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

Identification of Person Obtaining Consent.		
_____ Name of Person (Print)	_____ Signature of Person	_____ Date