Exoskeleton footwear to improve walking performance and subject-reported preference

NCT04337554

January 12, 2022

Participant Name: _____ Date:_____

Title of Study: Exoskeleton Footwear to Improve Walking Performance and Subject Reported Preference

Co-Principal Investigators: Sara Myers, PhD, Iraklis Pipinos, MD VA Facility: NWIHCS-Omaha VA

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

The purpose of this study is to determine the optimal (best) assistance level of an **exoskeleton footwear (EF)** that can help the walking of people older than 40 with and without peripheral artery disease (PAD). The study is funded by the Department of Veterans Affairs. By doing this study, we hope to learn whether wearing the EF helps people older than 40 with and without PAD walk better and what type of assistance with walking is the most helpful. We will test two different groups of people for this study that include: 1) people with PAD, and 2) individuals who don't have PAD.

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

Your participation in this research will involve two visits whether you have PAD or are a healthy subject.

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

Your involvement in this research study will help us learn how to make the EF device more comfortable and effective to help people with and without PAD walk better: for example, walk farther, walk with less pain, walk more comfortably.

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

You may not want to participate in this study because it has no direct benefit for you, and you may experience some discomfot 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 services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The people in charge of the study is Sara Myers, PhD of the University of Nebraska Omaha and Iraklis Pipinos, MD, PhD. 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/her contact information is:

Sara Myers: 402 554-3246
Iraklis Pipinos: 402 559-9549

RESEARCH DETAILS

HOW LONG WILL I BE IN THE STUDY?
You will be asked to participate in two visits. Each visit will last up to 3-4 hours, depending on how much time you need to rest during the testing.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?
You will be asked to go to the University of Nebraska at Omaha to take part in the following tests:

Walking Tests:
You will walk on a treadmill while wearing the EF device in your regular shoe and a laboratory shoe (a shoe given to you at UNO to wear during the testing) and also without wearing the device. You will walk without assistance and with different levels of assistance over flat ground, as well as on the treadmill.

Reflective markers will be placed on your legs so your motion can be recorded by cameras that pick up reflections. These cameras do not identify you; the picture will appear as dots and lines.

Small sensors will be placed on your leg to see how much oxygen your legs are getting while you walk.

You will wear a mask (like an oxygen mask) on your mouth and nose to collect the air you breathe out while you are walking.

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

Questionniares:
You will be asked to fill out two questionnaires. These questionnaires will ask about your quality of life, physical function, and ability to complete activities of daily living. Some people may feel uncomfortable at being asked questions about their views on their healthor quality of life. If, for any reason, you wish not to answer specific questions or you wish you end the session, you will be able to so at any time.

Interview and Survey:
After completing the walking tests, you will be asked to answer some questions and about how the EF device felt while you were walking. You will also be shown a scale to record how you felt while you were walking with the EF. If, for any reason, you wish not to answer specific questions or you wish you end the session, you will be able to so at any time.

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, some, 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 physical activity, such as shortness of breath and pain, muscle soreness, fatigue.

You may also experience discomfort from the mask that will collect the air you breath in and out during the testing.

The interview questions may make you feel uncomfortable when asked questions about your participation.

There is a risk of being uncomfortable with the EF device and it rubbing your foot. To minimize this risk, the device will be properly fitted and adjusted prior to the data collection. Study staff will inspect your feet before and after testing to make sure there is no evidence of the device rubbing your foot.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

While there is no direct benefit to you for participating in this study, your involvement, will help us learn how to make the EF device more comfortable and effective to help people like you with and without PAD walk better: for example, walk farther, walk with less pain, 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 your care and treatment options with your doctor.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Identifiers might 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 be 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 representatives of the sponsor(s) of this study* (National Institutes of Health), 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, 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.

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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 care and medications, you will still pay these co-payments for VA care and medications.

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 $50 (fifty dollars) for each visit. If you live more than 20 miles roundtrip from the site of testing you will receive mileage at a rate of $0 .58 cents per mile, up to a maximum of $50 (fifty dollars) each visit. You will receive a VA voucher after each visit that can be cashed at the Omaha VA. Your social security number will be used for payment purposes.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of your participatioin 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:

DURING THE DAY:

Dr.Pipinos at 402 559-9549

AFTER HOURS:

Dr. Pipinos at 402 880-7148.

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 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 participation.

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 Sara Myers: 402 554-3246 or Iraklis Pipinos: 402 559-9549. 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 402-995-3932 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 there are any significant findings developed during your participation in the research study which may relate to your willingness to continue to be involved in the study, we will provide them to 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 University of Nebraska Omaha 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 that 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 research respository, you can still participate in this study.

WHAT IF I WANT TO BE CONTACTED ABOUT FUTURE STUDIES?
If you would be interested in participating in studies that involve vascular diseases, we would like permission to contact you in the future. In order to do this, we need to keep your name and contact information (phone number, last four of your SSN) securely stored on a VA approved device so we can contact you about future participation in a research 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 research data repository.

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

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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