Improving mobility in peripheral artery disease using an ankle foot orthosis
NCT02902211
06/01/2020

Department of Veterans Affairs | **VA RESEARCH CONSENT FORM**

Subject Name: **Subject 's Complete SSN:**	
Title of Study: Improving Mobility in Peripheral Artery Disease Using an Ankle Foot Orthosis	**VA Study ID#:** 01082
Principal Investigator: Sara A. Myers, PhD	**VAMC:** NWIHCS-Omaha VAMC

You are invited to take part in this research study. Participation is completely voluntary. The information in the form is meant to help you decide whether you would like to take part in this study. If you have any questions, please ask. This study involves research.

PURPOSE:
The purpose of this research study is to determine if a special device called an ankle foot orthosis (AFO) reduces leg pain during walking to help you walk farther and experience less leg pain during walking. The AFO fits inside your shoe and on the outside of your leg, from the ankle to just below the knee. The study will test walking performance without wearing the AFO, and after you wear the AFO for 3 months. The practicality (how easy it is to use) of this AFO intervention will also be studied.

You are being asked to participate in this research study because 1) you are between 40-85 years old and have symptoms of leg pain during walking that is caused by low blood flow to the legs (commonly known as peripheral artery disease or PAD) or 2) you are a "healthy" individual, meaning that you have no history of chronic leg pain while walking, and you have normal blood flow to your legs, which we will measure for you. Before you enter the study, you must also have stable blood pressure, a cholesterol treatment plan, and diabetes treatment plan for at least 6 weeks.

DURATION:
The study is divided into two groups, a healthy group (also called a control group) and a group that has peripheral artery disease.

If you are a healthy person, you will be part of a control group. You will participate in one walking session that will last approximately 2.5 hours. That will be the total amount of your involvement.

If you have leg pain (PAD), your involvement will last over a period of six months. You will participate in 3 walking sessions and two phone interview sessions. The walking sessions will last around 2.5 hours. The interview sessions will last about 30 minutes. We will also call you once a week during the AFO intervention phase to make sure that the device is not causing any problems.

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You will do this test once without wearing the AFO and once while wearing the AFO (in the same order as the walking distance test above).

The tests listed below are specific measurements that will be done as part of the walking distances/walking function testing described in the sections above:

- Physical activity:

A device, called an *accelerometer* that will measure how much you walk during the day will be given to you to wear. The accelerometer is about the size of a watch or small beeper. You will wear the device during the time you are awake for 7 days in a row before each walking test visit. We will either give you the device in clinic or mail it to you. If you are sent home with the device, we will also give you a postage paid envelope to use to return the device as needed.

You will also be asked to wear accelerometers during the testing at UNO. This will show us the number of steps you take during the testing.

- Quality of Life Questionnaires:

You will be asked to fill out three questionnaires during each walking test visit. These questionnaires ask about your quality of life, physical function, and ability to complete activities of daily living.

- Energy Cost:

You will wear a mask during the walking tests that will measure how much air you are consuming with each breath. This can help determine how much energy you are using while walking.

- Muscle thickness

An ultrasound machine will be used to take pictures of your calf muscles while you are laying on an exam table. Muscle thickness will be calculated from several sites on your leg.

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1. If the AFO intervention is one that you want to use
2. How much you actually wore the AFO
3. Why you did or did not wear the AFO, and
4. Whether you were able to wear the AFO as we wanted you to be able to wear it.

A member of the study staff will ask questions to get this information, and you will be given the chance to share additional information about your experience. Interviews will occur at 1.5 months and after you are done wearing the AFO, unless you are in the control arm. All interviews will take place in a private room in the Biomechanics Research Building or on the phone and will last approximately 30 minutes.

PROCEDURES THAT ARE EXPERIMENTAL:

All procedures involved in this study are considered experimental. Below is a list of procedures and what is being measured:

Walking tests: will measure walking distance, movements and forces acting on the body during walking, activity levels throughout the day, questionnaires about quality of life as related to having leg pain, how much energy is consumed by breathing during the test, muscle thickness, muscular activity during walking, the oxygen present in muscles during walking, and the strength of the muscles that flex and extend the ankle.

Interviews: will measure information about the AFO intervention including if you like using the device, how much you used it, why you did or did not use the AFO, and whether you were able to use the AFO as we would like to use it.

AFO and Control Intervention: you will wear the AFO for three months during the study to see if it helps you walk farther and to assess changes in the walking tests, after wearing it for 3 months. There will also be 3 months when you do not wear the AFO. We will perform the same measurements after this 3-month period as we do after the 3 months of AFO intervention.

RISKS/DISCOMFORTS:

The possible risks/discomforts associated with participating in this research project are as follows for individuals with leg pain:

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study will be in a form that does not identify any participant. 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.

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.

RESEARCH RELATED INJURY:

If you are injured as a result of your participation in research, the VA will provide emergency care and appropriate medical therapy at no cost to you. No other form of compensation is routinely available.

The above requirement does not apply to treatment for injuries that result from non-compliance by a research participant with study procedures.

WHOM TO CONTACT:

For answers to pertinent questions asked about the research and research subjects' rights, to voice concerns or complaints, or in the event of illness or injury that you believe to be related to the study, please contact Dr. Sara Myers at 402-554-3246 during the day and Dr. Iraklis Pipinos at 402-559-4000 after hours. To discuss problems, concerns and questions, to verify the validity of the study, to obtain information or to offer input with an individual who is unaffiliated with a specific research study, contact the Research Administrative Officer at 402-995-3541.

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NUMBER OF SUBJECTS:
The approximate number of subjects involved in this study is 100. Of these subjects, it is expected that there will be 50 individuals with leg pain and 50 healthy individuals.

PAYMENT THE SUBJECT IS TO RECEIVE:
You will be compensated for your time and travel as follows:

- Baseline Visit: $65
- 3 Month Visit: $65
- 6 Month Visit: $65
- Interview at 1.5 months: $30
- Interview after wearing AFO $30
- Wearing AFO $50 per month (up to 3 months)

The maximum amount of stipend for completing all visits/interviews/AFO interventions is $405.

You will only be paid for each visit/interview/AFO intervention month that you complete.

This stipend will be mailed to you in the form of a check from the University of Nebraska. In order to compensate you for your participation, UNO policy requires that you to provide your social security number. Should you decide you do not wish to provide this information, you may still participate in the research, but we will be unable to compensate you.

Initial
☒ Revised Version # 3

Appendix Y

IRB Approval Date: 06/01/2020 DMO *(Initials)*

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I will receive a signed and dated copy of this consent form.

_____ _____

Subject's Signature Date

_____ _____

Name of Person Obtaining Consent (print) Signature of Person Obtaining Consent Date