

UNIVERSITY OF WASHINGTON INFORMATION STATEMENT

Development of a mobility outcome measure for people who use lower limb orthoses

Researchers:

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Researchers' statement

We are asking you to be in a research study. The purpose of this form is to explain the study and help you decide if you want to be in the study or not. Please read the form carefully. If you have any questions, you may contact us at uwcorr@uw.edu or 800-504-0564 (toll free). You might want to ask for more information about why we are doing this study and what you will be asked to do if you decide to be a part of it. You may ask questions about the possible risks and benefits and what your rights are as a volunteer. You may ask any question about the research and ask for help understanding any part of it that is not clear to you. When all your questions are answered, you can decide if you want to be in the study or not. If we get any new information about the study or there are changes to the study in any way, we will let you know right away. This process is called 'informed consent.' You may keep this form for your records.

PURPOSE OF THE STUDY

The purpose of the study is to develop a questionnaire to measure mobility in lower limb orthosis users. You can take part in this study if you have a lower limb impairment and you use an orthosis regularly.

STUDY PROCEDURES

If you choose to take part in this study, we will ask you to complete one survey. You will be asked some questions about you, such as your age and education, and questions about your impairment, orthosis, health, physical activities, and questions about your ability to perform certain activities with your orthosis (such as walking, turning, and transferring). Examples of the questions are: "Are you able to walk across a parking lot?" and "Are you able to carry a tray of food?" You may answer the questions on the computer or on paper. You decide which you would rather do. The survey will take about 30-45 minutes to complete. You do not have to answer any question for any reason. If you have not completed the questions within one week, a research staff member will contact you to see if you still want to be in the study.

Before starting the survey, you will be asked to provide your name, phone number, email, and address. We will only use this information to check for duplicate surveys, contact you if we need to clarify any of your responses, or mail you a check for completing the survey. For quality assurance purposes, we will also collect your Internet Protocol (IP) address if you complete the survey on the computer.

RISKS, STRESS, OR DISCOMFORT

Some of the survey questions in the survey may be upsetting to you. You are free to ask any questions or share your concerns with the research staff while completing the survey. The survey may feel long, and you may become tired. You may take a break anytime you need to. Because this study involves collecting identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a study number. All of the information we collect will be stored in a secure manner.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The alternative to taking part in this study is to not take part in this study.

BENEFITS OF THE STUDY

There are no direct benefits to you for being part of this study. The study results may help us improve questionnaires used by health care providers and make them more relevant to your experiences with your orthosis. Your participation in the study will assist researchers nationwide in making questionnaires used in health care settings shorter, more meaningful and easier to answer.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the American Orthotic and Prosthetic Association (AOPA) and the United States Department of Defense (DOD).

CONFIDENTIALITY OF RESEARCH INFORMATION

The information you provide to us during the study is confidential. We will protect the information we collect about you by assigning a unique study code to your responses. The link between your name and this code will be kept in a safe place.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Study data that do not identify you may be shared with researchers at AOPA and DOD. However, AOPA and DOD researchers will not have access to information that could identify you.

The information that we obtain from you for this study might also be used for future studies. We will remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. You can choose to withdraw your information from future use or sharing. However, once the de-identified information has been shared, you may not be able to withdraw the information.

OTHER INFORMATION

Taking part in this study is voluntary. You can stop at any time. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you do not want your study data to

be shared with other researchers, want to withdraw from this study, or think you have been harmed by participating in this study, please contact Geoff Balkman at uwcorr@uw.edu or 800-504-0564.

There are no costs for you to be in this study. If you have a U.S. or Canadian address, we will mail you a \$50 check for completing the survey. Eligible participants from outside the U.S. & Canada are welcome to take the survey without payment.

We will keep your name and contact information in order to contact you about possible future research.

The decision to join or not join the study will not cause you to lose any medical benefits. If you decide not to take part in this study, your healthcare provider will continue to treat you. If you decide to participate in this study, the answers you provide in the survey will not affect the health care you receive.

If you have questions later on about the study, you can ask one of the investigators listed above. If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at 206-543-0098.