

**UNIVERSITY OF WASHINGTON
INFORMATION STATEMENT – FOCUS GROUPS**

Fall-related health outcomes in lower limb prosthesis users

Researchers:

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RESEARCHER'S 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 reason we are doing this study is to learn more about how people who use prosthesis feel about falls, and how concerns about falling can interfere with life activities. We want to find the best way to ask prosthesis users about confidence in performing activities without falling (fall-related self-efficacy) and ways you might avoid participating in everyday activities because of falling concerns (fall-related interference in life activities). You can take part in this study if you use a lower limb prosthesis regularly to transfer or walk.

STUDY PROCEDURES

If you agree to take part in this study, you will be asked to participate in a focus group to discuss falls experienced by people who use lower limb prostheses. The focus group will include between 4 and 8 prosthesis users and will be led by a study researcher. Topics will include the causes of falls and fear of falling. Examples of the questions are: "What makes you more or less likely to lose your balance?", "Have you ever been concerned, worried, or afraid of falling?" and "How does the risk of falling affect your life?" You are free to not answer any question you choose. The focus group discussion will take about 1-2 hours and will be recorded to have an accurate record of the discussion.

Before the focus group discussion, you will be asked to complete a short survey that asks questions about you (such as your ethnicity and highest level of education), your health (such as health conditions you may have), and your fall history (how many times have you fallen in the past year). It will take about 20-25 minutes to complete. You do not have to answer any question for any reason.

We may contact you after the focus group to clarify comments or ask you additional questions about comments you made during the discussions. The follow-up interview will take about 15 minutes. The follow-up discussion is optional.

RISKS, STRESS, OR DISCOMFORT

You may become more aware of your feelings regarding your condition. Some of the questions may be upsetting to you. You are free to share your questions or concerns with research staff following the discussion. 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, as well as the recording of the interview, will be stored in a secure manner.

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. 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 United States Department of Defense (DOD).

CONFIDENTIALITY OF RESEARCH INFORMATION

The researchers will keep your responses confidential. We ask participants to use only their first name in the discussion. You do not need to reveal your name in the focus group. You may use a fake name if you wish. It is possible that the recording may identify you. We will hire someone to transcribe what you say during the focus group discussion. Your name will not be in the transcript. We will assign a unique study code to your responses. Information that identifies you will be kept in a secured location. We may use web-based software to analyze focus group transcripts. The transcripts or analysis will not include any information that identifies you.

Sometimes University of Washington staff will 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 and transcripts that do not identify you may be shared with other researchers at the University of Washington and/or at other institutions.

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 want to withdraw from this study or think you have been harmed by participating in this study, please contact Dana Wilkie at uwcrr@uw.edu or 206-221-2414.

There are no costs for you to be in this study. We will pay you \$50 (by check or Amazon gift card) for completing the survey and participating in the focus group discussion.

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

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.