



SCREENING CONSENT

Department of Physical Therapy

TITLE OF STUDY: PROSthetic PERformance enhancement trial (PROSPER) – Screening.

INVESTIGATOR: Dr. Jenny A. Kent, PhD, CSci.

For questions or concerns about the study, you may contact Dr. Kent at jenny.kent@unlv.edu or 702-895-5949. For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact **the UNLV Office of Research Integrity – Human Subjects at 702-895-2794 or via email at IRB@unlv.edu.**

KEY INFORMATION SUMMARY

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the research is to test a simple walking training program that may improve lower limb prosthesis users' mobility and walking confidence. **This consent form only refers to the screening portion of the study**, which will determine whether you are eligible to participate in the main study.
- The screening will take 15 minutes and you will be asked to answer some questions. The information will be stored for future use, without your name and any identifiers attached to it.
- Risks and/or discomforts may include the risk of breach of confidentiality.
- There is no direct benefit to you from participating in this screening procedure.

DETAILED INFORMATION

PURPOSE OF THE STUDY

The overall goal of our research is to find out if prosthesis users can improve their walking skill and confidence by training on uneven surfaces. As a first step in this research, we have developed a training program and mobility assessments but need feedback from prosthesis users to make improvements. The study will involve four weeks of training at UNLV's Maryland Campus. You would be walking on either a treadmill or a mat, and either on a bumpy or a flat surface. The goal is for you to complete the training sessions three times per week. Additionally, you will also be asked to attend two assessment sessions and to wear an activity monitor for two weeks. We will also ask for your feedback about your experiences with the training and assessments using surveys. You will be compensated up to \$325 in incremental gift card payments for participating in this study.

You are being invited to join this research study because you may fit the eligibility criteria. **The purpose of this screening is to find out whether you are eligible to participate in the main study.** The information you provide will also be used to help us find out more about how we may best adapt the methods of future studies to include people who may benefit from this research.

PROCEDURES DURING THIS SCREENING

To find out whether you are eligible, you will be asked questions about your background, your medical history, and your prosthesis. You will additionally be asked to complete two questionnaires about balance confidence and mobility. After the screening, your responses will be reviewed by study personnel, who may ask you further questions to help determine whether you are eligible for the study.

If you are eligible to be in the study and you are interested in participating, you will be given another consent form to read and sign. That consent form will further explain the procedures, risks, and potential benefits of the main study.

Your study participation in the screening portion of the study will take a total of approximately 15 minutes. The screening procedure will take place either by electronic questionnaire, virtually (by phone or secure video call) or in person.

BENEFITS OF PARTICIPATION IN SCREENING

Participating in the screening procedures will determine whether you are eligible for the study. There is no other direct benefit to you from participating in the screening procedures. If these procedures show that you are eligible and you are considering participating in the main study, then a comprehensive review of the experimental procedures, risks, and potential benefits of the main study will be discussed with you at that time.

RISKS OF PARTICIPATION IN SCREENING

Breach of confidentiality: As with all research there is a risk that confidentiality could be compromised if an unauthorized person gains access to your data. This risk is reduced by our data security measures including password protected logins.

COST /COMPENSATION

There is no financial cost to you, and you will not be paid for taking part in this screening.

CONFIDENTIALITY

Your deidentified screening information will be kept as confidential in a secure, password-protected database and/or locked file cabinets. You will not be identified in any written or oral materials that could link you to this study.

Data from this screening may be shared with the research community at large to advance science and health. We will remove all personal information that could identify you before any data files are shared with other researchers.

This study is classified as a clinical trial and we will publish summary results from the study, including screening data, in scientific journals, and report results at scientific conferences. No screening or study participants will be identified in any of those summary results. In addition to the above, representatives of the Department of Defense are authorized to review research records.

VOLUNTARY PARTICIPATION

Your participation in this screening is voluntary. You may refuse to participate in this screening. The only alternative to participating in the screening procedures is not to participate. You may withdraw at any time without prejudice to your relations with UNLV. If you have questions about the screening

process you are encouraged to contact the study team at humancapabilitylab@unlv.edu or 702-895-1254.

PARTICIPANT CONSENT:

I have read the above information and agree to participate in this screening. I have been able to ask questions about the screening process and the research study. I am at least 18 years of age. A copy of this form has been given to me to keep.

Signature of Participant

Date

Participant Name (Please Print)