



INFORMED CONSENT

Department of Physical Therapy

TITLE OF STUDY: Motor Learning in Individuals with Lower Limb Loss and Chronic Diabetes

PRINCIPLE INVESTIGATOR: Szu-Ping Lee

For questions or concerns about the study, you may contact:

Szu-Ping Lee 702-895-3086 (office), 352-870-4767 (cell), szu-ping.lee@unlv.edu

NCT number: NCT03989063

Date of initial IRB approval: December 23rd, 2019

Date of the most recent IRB approval: April 26th, 2021

For questions regarding the rights of research subjects, any complaints or comments regarding the study, contact the UNLV Office of Research Integrity – Human Subjects at 702-895-2794, toll free at 888-581-2794 or via email at IRB@unlv.edu.

It is unknown as to the level of risk of transmission of COVID-19 if you decide to participate in this research study. The research activities will utilize accepted guidance standards for mitigating the risks of COVID-19 transmission: however, the chance of transmission cannot be eliminated.

Purpose of the Study:

We invite you to participate in this research study. The purpose of this research is to evaluate two training programs for balance and walking.

Participants:

You are being asked to join the study because you fit the following:

1. Have above or below the knee amputation on one leg,
2. Age >18 years,
3. Are fitted with a walking prosthesis and use it regularly and proficiently (we will test you to see if you are a good candidate to participate in this study),
4. Able to stand for at least 5 minutes without using an assistive device or experiencing excessive fatigue,
5. Willing to travel to UNLV 3 times for training and testing.

You are not eligible to join the study if you have any of the following:

1. Have other concurrent central nervous system diseases (such as stroke) that influence your walking and balance.
2. Have leg/foot ulcer or other conditions that cause pain that affects your ability to stand or walk.
3. Have cardiovascular, respiratory or other critical health conditions that preclude moderate physical activity.

Procedures:

If you volunteer to join this study, you will visit a laboratory on UNLV campus and do the following:

Please wear loose and comfortable clothes (such as exercise clothes) and bring your regular walking prosthesis. In your first visit, we will interview and ask questions about your demographics (age, sex, etc.), medical history, and current health and physical status to determine if you are appropriate to join this study. You may not join the study if we believe there is reason (such as safety) not to enroll you. If you are deemed appropriate to join the study, you will do the following:

- Complete surveys (including amputee-specific questionnaires) to assess your current quality of life and mobility functions.
- Perform a walking test (Timed Up and Go test).
- Perform a sensory test of your feet using 2 different thin plastic wires.
- Perform a sensory test where you will sit in a chair and have your leg connected to a bar that moves (Cybex Norm dynamometer). We will move your leg to different positions and ask you to replicate these positions without looking at your leg.
- We will introduce you to the balance task which requires you to stand on an unstable platform (Lafayette Instrument; Figure 1) for 30 seconds at a time. The platform will tilt from side to side and your goal is to stay in balance while standing on it. We will give you instruction on how to do it. You will wear a harness so you will not fall even if you lose balance. You can rest as much as you need between tries.
- We will also ask you to walk on the treadmill (also wearing the harness; Figure 2).

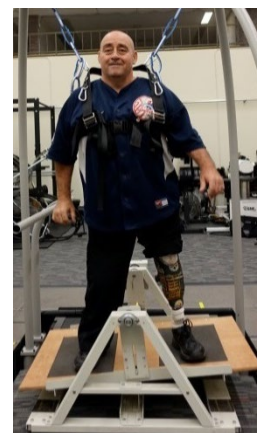


Figure 1: Balance Task

This first visit will take up to 180 minutes

If you are interested and eligible to the training portion of the study, we will contact you to schedule times for training.

For the training portion of the study, you will come back to the laboratory 2 more times in the next 1-2 weeks for balance training and testing. You will do the following:

- Balance training on the same platform as in the first visit. We will give you specific instructions on how to do it. On each of the two training days, you will practice the balance task 30 times (30 seconds each). During training, you will wear shorts and sleeveless shirts provided by us. Each day of training will take up to 120 minutes.

At least one week after the second training day, you will come back to UNLV for the final test (visit 3). We will look at your balance and walking again and discuss the training with you.

During the balance and walking tasks in your visits, we may place small reflective markers on your legs and body using double-sided tape so we can see how you walk and do the balance task. The 12 cameras in the lab will detect the location of the markers. This will not affect how you move.

Summary of the visits:

Visit 1 (up to 180 minutes): screening interview, survey, introduction to the balance and walking tests

Visit 2 (approximately 60 minutes): balance training

Visit 3 (at least 7 days after visit 2, up to 180 minutes): balance and walking tests, debriefing interview



Figure 2: Treadmill Walking

If you are available, we will ask you to come back 2 months later to repeat the visits (for up to 6 visits total).

Benefits of Participation:

There will not be any direct benefit to you as a participant in this study.

However, through your participation you may improve your physical mobility (walking and balance).

We also hope that the knowledge gained from this study will help to improve the quality of life of those with lower limb loss in the future.

Risks of Participation:

This study may involve the following risks and discomforts.

- Injury or soreness:
All physical activities involve some risk of injury. Although you will perform the walking tests in a controlled environment, you run the risk of sustaining muscle soreness, sprain, cardiovascular event, or falling. To minimize these risks, we will conduct all testing with proper safety equipment and spotters. Researchers will monitor and guard you during the testing and training.
- Reflective markers will be attached to your body, legs, and prosthesis using double-sided tapes. There is a small risk of experiencing minor skin allergy to the glue (red marks).
- After the training and testing, you may experience minor joint pain, sprain, muscle strain, soreness, and fatigue. The safety harness may cause some chaffing, but we will do our best to ensure it is properly fitted and adjusted to minimize this.

- The level of risk for transmission of COVID-19 during participation in this research study is currently unknown. However, we will follow all current CDC guidelines to keep you safe and healthy. All investigators will be screened for COVID-19 symptoms daily including temperature checks, and will follow the COVID-19 mitigation best practices during our interaction with you:
 - We will screen you for COVID-19 symptoms prior to your visit to the lab.
 - We will provide hand sanitizer and a mask to you. All investigators will wear masks and clean our hands prior to interacting with you. All touching surfaces in the exam room will be cleaned with disinfecting spray prior to your arrival.
 - Social distancing of at least 6 ft. will be maintained. No more than two investigator will be in the laboratory with you.

Cost /Compensation:

There will not be financial cost to you to participate in this study. We will pay you for your time with \$30 for each time you come to UNLV (if you do all 6 visits, we will pay you \$180 total). If there are additional transportation costs (i.e. Uber rides) of traveling to UNLV, we will reimburse your cost (based on the receipts) up to \$20 per trip. The amount will be loaded into a VISA card that will be given to you. If you need to drive to UNLV, a parking pass will be provided at no cost to you.

We will do our very best to prevent any injury from happening to you. However, UNLV may not provide compensation if unanticipated injury occurs in the course of the research. Depending on the data obtained from the first 3 visits, two additional training days may be offered to some participants. Participation in these additional days will be optional and not compensated.

Confidentiality:

We will keep all information gathered in this study confidential. All records will be stored in a locked facility at UNLV for five years after completion of the study. After the storage time, all information gathered including any recorded videos or images will be destroyed. The study is conducted by researchers from UNLV, and your information will not be disclosed to your clinicians (doctors, physical therapists...etc.) or affect your medical treatment.

Voluntary Participation:

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with UNLV. There is no penalty if you withdraw from this study. You are encouraged to ask questions about this study at the beginning or any time during the research study.

More Information:

The National Institute of Health funds this study. 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.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions or concerns about the study, you may contact Dr. Szu-Ping Lee 702-895-3086 or email at szu-ping.lee@unlv.edu. For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted you may contact the UNLV Office of Research Integrity – Human Subjects at 702-895-2794 or toll free at 888-581-2794 or via email at IRB@unlv.edu.

Participant Consent:

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

Signature of Participant

Date

Participant Name (Please Print)

Audio/Video Taping

This study may involve audio/video taping. It is my understanding that I will appear within the field of view of the camera. And I agree the researchers may use my images for academic purposes only.

Name of Research Participant

Signature

Date Signed