Principal Investigator

NCT06284525

1/22/2024

Project Number: 2137420-1
Expiration Date: January 21, 2025
This stamp must be on all consenting documents

NORTHERN ARIZONA UNIVERSITY

Office of Research Compliance

Permission Form

Title of Study: Ankle assistance and resistance in older adults
Principal Investigator: Zachary Lerner, Ph.D.
Sponsor: NAU Foundation

For Adult Consent: "The participant" refers to you.

For Legally Authorized Representative Consent: "The participant" refers to the person for whom the representative is signing.

Key Information

What is the purpose and why is this study being done?

The purpose of this study is to improve walking and running ability in individuals with and without movement disorders through the investigation of wearable assistive devices. Wearable assistive devices (i.e. powered or passive leg braces) offer a promising new means to improve gait (walking) rehabilitation outcomes and meet the increasing demand for therapy. This research study is designed to 1) study the ability of targeted resistance training with biofeedback to improve ankle function and walking performance , or 2) evaluate the ability for assistive orthoses (i.e. powered leg braces) to improve walking performance.

What will happen for the participant who takes part in this study?

The participant will be asked to complete 1-4 visits per week for 3-12 weeks. We will fit them with a powered orthosis device and evaluate how they walk with assistance under several walking conditions (below). A custom schedule will be determined for each participant and visit.

Locations: Study visits will take place at either NAU's main (Flagstaff), Phoenix Biomedical Campuses (Downtown PHX), or Phoenix Children's Hospital depending on your proximity.

What are the major risks and/or benefits?

This study may help determine if targeted resistance training can improve ankle function and mobility or if wearable assistance can improve walking performance. It is possible that this protocol can lead to improved walking ability. There is a risk of falling during walking and of mild discomfort from the leg braces.

Data Collection: We will collect experimental biomechanics data including:

1) *Motion Capture*: Small, cherry sized reflective markers will be placed on the arms, torso, pelvis, and legs to track the body with special infrared cameras.
2) *Oxygen Consumption*: A facemask covering the nose and mouth that is connected to a respirometer will capture breath inhalation/exhalation.

3) *Muscle Activity*: Small, matchbox sized boxes will be place on various leg muscles to measure when they are active using an electromyography (EMG) device that measures the electrical activity that can be recorded during muscle contractions.
4) *Video/Photo Recordings*: A video/photo camera will be used to record all walking trials. You will be given the option whether to allow video/photo recordings to be used in presentations/publications at the end of this form.

Experimental conditions: Several powered orthosis conditions will be tested during several modes of walking or running throughout the course of the study. Trials will take place over-ground and/or on a treadmill. Participants will walk for up to 40 minutes on each visit. Breaks will be provided as needed between trials and conditions to avoid fatigue.

Conditions:
1) Level walking over ground
2) Level walking on a treadmill
3) Walking at a mild incline/decline (0°-15°) on the treadmill
4) "Walking" on a stepmill machine
5) Walking on stairs
6) Balance
7) Outside all terrain walking

Orthosis Conditions:
1) *Walking without assistance/resistance*: We will obtain the normal/representative walking pattern of each participant. This condition will be used to compare the effectiveness of the assistive conditions.
2) *Walking with basic powered orthosis assistance/resistance*: We will provide on/off assistance*/resistance* to the ankle and/or knee joints during walking, depending on the individual's specific gait deficits.
3) *Walking with adaptable powered orthosis assistance/resistance*: We will provide assistance*/resistance* that changes magnitude based on measures of gait performance.
4) *Walking or running with powered assistance/resistance and biofeedback*: We will combine assistance*/resistance* with real-time feedback of walking performance. Individually tuned performance measures will be identified for each participant, and used to identify walking goals. Participants will be instructed to try to meet and maintain their goals.
5) Walking or running with passive (unpowered) orthosis assistance: We will evaluate the ankle's neutral angle and AFO stiffness that is most beneficial for each participant and mode of ambulation.

Mobility analysis:
To assess mobility, participants will undergo the following tests, with or without a powered orthosis, under direct supervision by a research team member, who will be available to spot for safety (heart rate and metabolic cost may be collected):

1) Timed up and go: participants will walk as quickly as possible in a safe and controlled manner to a cone 3 meters away, turn around, walk back to the chair and sit down; 3 – 6 trials will be collected.
2) 6 minute walk test: participants will walk as quickly as possible in a safe and controlled manner for 6 minutes to test walking endurance; 1 – 3 trials will be collected.

Physical activity questionnaire: We may ask participants to answer some questions about their physical activities, in the form of a *Physical Activity Questionnaire,* during the time before and after participation in this study.

Schedule of Visits:

First visit: After consent, participants will undergo a medical history/physical and orthotic (leg brace) device fitting. Following device fitting, the participants will undergo baseline gait analysis and then complete two to four of the experimental conditions. The expected duration is 3-4 hours.

Visits Allocations:

Participants will complete two to four of the experimental powered orthosis conditions and one to five of the experimental conditions on each visit. An "X" indicates which conditions and data collection procedures will take place on a given visit.

	Visit																	
Conditions	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Without Assist																		
Basic Assist																		
Adapt. Assist																		
Assist or resist & Feedback																		
Over ground (level)																		
Treadmill (level)																		
Treadmill (incline/decline)																		
Stepmill walking																		
Over ground steps																		
All terrain (outside)																		
Data Collection																		
Motion Capture																		
Muscle Activity																		
Oxygen Consumption																		
Mobility																		
Usability Log																		

All terrain (outside): The participant may be asked to complete all terrain walking trials that may take place on or off campus in controlled environments. The participant will be monitored and accompanied at all times by the trained safety advocate and study staff during. Trials will include ambulation with and without wearable assistance. On-campus locations will include the north and south quads, and campus walkways and urban trails. Off-campus locations will include Buffalo Park and surrounding Elden trails.

Will there be any cost to take part in this study?
The only cost to participation in this study is a time commitment for which remuneration will be provided.

Will participants be paid to take part in this study?
The participant will receive monetary compensation for their participation in the study. Participants with gait deficits will be compensated $30 per hour. The minimum compensation for a visit is $30, should the participant or investigator choose to stop the study within the first hour, and the maximum is $120/visit; the maximum possible compensation would be $2160 if the participant with gait deficits completes all data collection and the visit durations all last 4 hours.

Participants can elect on the timing (payment at the end of the study or after each visit) and method of compensation, either a check in the mail or an Amazon gift card.

Compensation for participation in a research study is considered taxable income for you. We are required to obtain your name, address, and Social Security number for federal tax reporting purposes. If your compensation for this research study or a combination of research studies is $600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes.

What are the risks and/or discomforts participants might experience when taking part in this study?

Gait Analysis: There is a slight risk of falls during ambulatory activities performed during this protocol, but this risk is not greater than during normal daily life. This risk will be minimized by supervision from a physical therapist or trained safety advocate. If the subject appears unstable, a safety harness will be used to arrest any falls that may occur. Therefore, the risk should be no greater than that of normal daily activities.

Walking with wearable Assistance*/resistance*: There is a mild risk of falling when subjects are walking with passive or motorized assistance/resistance; subjects may feel a slight perturbation from the orthotic device. The device is not designed or able to over-power the user. Safety measures are integrated within the control algorithms used to control the wearable device such that it automatically deactivates during gait disturbances. For initial use, a physical therapist or trained safety advocate will closely monitor each subject while walking with assistance. If the subject appears unstable, a safety harness will be used to arrest any falls that may occur during laboratory

testing. Additionally, a therapist or researcher may hold an emergency switch so the wearable assistance can be immediately deactivated, if needed. For any home/community testing, the participant and parent/guardian (if applicable) will complete extensive training on operation and use of the device.

There is a small risk of pressure by the orthotic braces causing skin irritation. A physical therapist or trained safety advocate will be with the subject throughout the tests, and continuously monitor subject tolerance and inquire about presence of pain, pressure or other complaints to detect any discomfort during testing. If the subject experiences anything beyond minimal discomfort (extra inertia and resistance against movement), we will stop the testing and readjust the device as needed until the problem is resolved. Redness or any other skin problem due to the brace will be inspected at the end of every visit.

Muscle Activity Measurement (EMG): There is minimal risk associated with EMG recording.

Oxygen Measurement: There is minimal risk associated with respirometer recording. If difficulty breathing occurs, the face mask will be removed.

Are there any benefits for the participant if they choose to take part in this research study?
This study may help determine if targeted resistance training can improve ankle function and mobility or if wearable assistance can improve walking performance. It is possible that this protocol can lead to improved walking ability.

Will study-related information be kept confidential?
Efforts will be made to keep the participant's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding participation in this study may be disclosed if required by state law.

Also, the participant's records may be reviewed by the following groups:

- Office for Human Research Protections
- Northern Arizona University Institutional Review Board
- U.S. Food and Drug Administration

Will data be stored for future research?
De-identified motion and gait data may be kept for future research without additional consent.

Study Withdrawal

- Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- All participants may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

- A participant's participation may be stopped by the investigator if the investigator assesses that the participant is at a safety risk or if they are non-compliant with the research protocol; termination will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- There are no consequences of a participant's decision to withdraw from the research. Orderly withdrawal will occur by talking with the principal investigator.

Who can you call if you have any questions?
If you have any questions about this study you can contact the Principal Investigator at 928-523-1787 or Zachary.Lerner@nau.edu.

For questions about participant rights in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.
An Institutional Review Board responsible for human subjects research at Northern Arizona University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Notice of Conflict of Interest: The PI, Dr. Lerner, has an ownership stake in a start-up that is seeking to commercialize wearable assistive devices, like one that may be used in 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.