Study Title: Optimizing Ankle Exoskeleton Assistance for Walking Across the Life Span

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CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: Optimizing ankle exoskeleton assistance for walking across the life span

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Protocol and Consent Title: IRB_Consent_Form_Nov22 v2

You are being asked to be a volunteer in a research study.

Purpose:

The purpose of this study is to evaluate whether the ankle exoskeleton parameters (stiffness) that make walking the easiest for young adults is the same or different for older adults. We expect to enroll 60 people in this study; 30 young adults (18-45) and 30 older adults (65+).

Exclusion/Inclusion Criteria:

Participants in this study must:

1) Be able to walk for ≥60 minutes in a 90-minute time frame.
2) Be between 18 and 45 years of age, or be at least 65 years old.

Participants will be excluded from this study if they:

1) have dementia or an inability to give informed consent, 2) have an injury or feel pain while running, 3) have a history of dizziness and/or balance problems, and 4) have cardiovascular, heart, metabolic, or renal disease, or respiratory problems 5) smoke cigarettes, 6) asthma, 7) Feel pain or discomfort in the chest, neck, jaw, arms during rest of exercise, 8) have orthopnea or paroxysmal nocturnal dyspnea 9) have ankle edema 10) have palpitations or tachycardia 11) have a heart murmur 12) have had a heart attack 13) have diabetes 14) have unusual shortness of breath with usual activities 15) have a pacemaker, 16) are a minor, 17) or do not speak or understand English.

Procedures:

If you decide to be in this study, your part will involve four visits: each visit will take place on a separate day. In the first session, we will look at your calf muscle and tendon characteristics. To do this, you will perform ankle dorsiflexion (pulling toes up) and ankle plantar flexion (pointing toes down) trials using a dynamometer. You will perform these trials, at multiple different angles. You will perform trials where you push down as much as you can with your foot in a fixed position. You will perform trials where you push down with your foot at a medium and light effort. You will be given time to rest between trials as needed.

During these trials, we will place an ultrasound probe over the skin of your calf (non-invasive), allowing us to track your calf muscle or tendon movement during each trial. We will also place small electrodes over the 3 leg muscles, which tell us how much you are using each muscle during each trial. We will also place small reflective markers at select bony locations (e.g. ankle joint center) and track them with cameras to capture leg movement during each trial.

In the second visit, you will be asked to perform multiple walking trials that last 7 minutes each and a 5-minute standing trial. Each trial's walking speed will be the speed that most people use to walk during everyday activities. You may rest in between trials as desired. You will use a different exoskeleton condition for each walking trial. Exoskeletons are devices that you wear that aim to improve your movement. For this study, you will wear an exoskeleton that can change how to assist you. One type of assistance acts like a spring that you stretch during the first half of stance, and then the "spring" shortens and aids ankle push-off during the second half of stance. The second type of assistance acts like a powered device that has previously been optimized for walking in young adults. The last type of assistance is no assistance at all, just the exoskeletons turned off. The amount of each exoskeleton assistance will be varied. During these treadmill walking trials, you will wear a mask that covers the nose and mouth, enabling us to measure how much energy you use during each trial.

In the third session, you will begin each type of exoskeleton assistance (spring, powered, and unpowered) with a 6-minute trial to adjust to the device. You will then walk a 2-minute trial for each condition varying exoskeleton assistance type and amount. The trials will be randomized. During these trials, we will use the same equipment as in session 1 to assess the effects of the different exoskeleton conditions. Walking speed will be a typical walking speed (1.25 m/s) for all trials. You will perform 2 contractions as hard as you can in the same manner as session 1. You may rest as desired between walking trials.

In the fourth session, you will perform a 5-minute standing trial and a 6-minute treadmill walking trial for each exoskeleton assistance type to adjust to the device. You will then walk a 6-minute trial for each condition varying exoskeleton assistance type and amount in a randomized order. During these treadmill walking trials, you will wear a mask that covers the nose and mouth, enabling us to measure how much energy you use during each trial. After all treadmill trials, you will walk in the hallway to assess the speed you prefer to walk at for the same exoskeleton conditions. You may rest as desired between walking trials.

All 4 sessions will last less than or equal to 6 hours each. For all sessions, you may stop at any time and for any reason. For all sessions, walking speed will be at an easy effort. Session order may vary.
Please note that the investigational device is for research purposes only and has not been approved by the FDA.

Risks or Discomforts:
The following risks or discomforts may occur as a result of your participation in this study.

There is a risk that you may fall during treadmill walking. To protect you from falling, you will wear a safety harness and we can stop the trial at any time. You may experience slight facial discomfort wearing the mask, you may remove the mask and rest at any time. You may experience discomfort from light skin exfoliation of the area the electrodes will be placed. There is also a very small possibility of allergic reaction to the adhesive residue or impression marks on the skin upon the removal of the surface electrodes or ultrasound probe. You may feel slight discomfort using the ankle exoskeleton. You may stop during any trial and choose to adjust your footwear to reduce discomfort. There may be a risk of dehydration during our protocol. To mitigate this, you are free to drink water prior to and throughout the study. There is a risk of fainting due to exhaustion. To mitigate fatigue, you can stop during any trial at any time and rest. Also, between each trial, you will be allowed to rest for as long as you desire.

Benefits:
Aside from a modest amount of physical exercise, you are not likely to benefit from participating in this study. We hope that this study will inform future exoskeleton designs to make walking easier.

Compensation to You:
You will be compensated $10 per hour upon your completion of the study. If you decide to leave the study at any time prior to performing all testing sessions, you will be compensated $10 per hour of testing that you completed.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing your Information:
Your participation in this study is gratefully acknowledged. It is possible that your information/data will be valuable for other research purposes. By signing below, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Use of Photographs, Audio, or Video Recordings:
To track your body movements through each trial we will record you with

cameras during each trial. With these recordings, we will be able to use computer software to calculate many of your biomechanical measures, such as knee joint angle and the rotational force exerted at your ankle. All recordings, will only be accessed by research personnel. All recordings will be de-identified using an alpha-numeric coding system. and saved on computers with passwords that only lab personnel have access. Since these recordings are necessary for our biomechanical analyses, they will be treated as data, and stored on an external hard drive in a locked cabinet in our lab for three years following the end of our study.

Also, we may want to take and use some of the photographs, audio, or video recordings of you in public presentations related to the research. The attached MODEL RELEASE FORM outlines several possible uses and asks for your specific written consent to use these items in each way. We will not use any photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.

Confidentiality:

The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept in locked files and unless you give specific consent otherwise, only study staff will be allowed to look at them. Your name and any other fact that might point to you will not appear when results of this study are presented or published. The Georgia Institute of Technology IRB, the Office of Human Research Protections, and/or the Food and Drug Administration may look over study records during required reviews.

We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Costs to You:

None.

Questions about the Study:
If you have any questions about the study, you may contact Gregory S. Sawicki Ph.D., the Principal Investigator at, telephone: (919) 448-5099.

In Case of Injury/Harm:
If you are injured as a result of being in this study, please contact Principal Investigator, Gregory S. Sawicki Ph.D., at telephone (919) 448-5099. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

Questions about Your Rights as a Research Participant:

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research subject, you may contact Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature Date

_____ _____
Signature of Person Obtaining Consent Date

Consent to Store and Share your Information:

I agree that my de-identified information/data may be stored and shared for future, unspecified research.
SIGNATURE _____

I do not allow my de-identified information/data to be stored and shared for future, unspecified research. These may only be used for this specific study.
SIGNATURE _____