



Study Title: Optimization of Hip-exoskeleton Weight Attributes

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Consent to Participate in Research

Basic Study Information

Title of the Project: Optimization of hip-exoskeleton weight attributes

Principal Investigator: James Sulzer, Assistant Professor, The University of Texas at Austin

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

What is the study about and why are we doing it?

The purpose of the study is to observe the effect that weight and weight placement has on the way we walk. We are planning on designing a hip exoskeleton that will later serve to help stroke patients recover their ability to walk. To do this, we need to know the best place to put the weight of the exoskeleton that minimizes how much the user's walk is affected.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to walk on a treadmill with sensors attached around your body and up to 8kg of weight attached to your waist in 3 different distributions. The procedure will be as follows:

1. Setup (~30 minutes)
 - a. Remove any loose clothing items and shoes if desired
 - b. Attach Motion Capture EMG sensors, and weight belt
 - c. Calibrate sensors
2. Training (~5 minutes)
 - a. Learn how to stop the treadmill
 - b. Perform Sample Task (detailed below)
3. Data Collection (~40 minutes)
 - a. Complete the walking task for a total of 20 times
 - b. Walking task description:
 - i. Stay still for 15 seconds for recalibration
 - ii. Walk on the treadmill for 1m30s at 1.1m/s
 - iii. Get off treadmill and wait for confirmation of data
 - iv. Change weight for the next task
4. Wrap-Up (~10 minutes)
 - a. Remove Motion Capture and EMG sensors
 - b. After data is verified you are free to leave

How long will you be in this study and how many people will be in the study?

Participation in this study will last 90-120 minutes and will conclude with 40 total subjects.

What risks and discomforts might you experience from being in this study?

There are some low risks you might experience from being in this study. They are:



Treadmill Falling Risk

You will be walking on a treadmill during the study. There is a falling risk associated with this activity. To ensure that falling does not occur, there will be an emergency stop buttons within reach of both you and the researcher while the treadmill is in motion.

Skin Irritation from Attached Sensors

You will be wearing Motion Capture and EMG sensors that may be attached using tape. You may experience discomfort during their removal. If you feel any discomfort, you may ask to remove the sensors on your own accord.

What will happen to the samples and/or data we collect from you?

As part of this study, we will collect biometric data while you walk on a treadmill. These are going to be recorded from the sensors placed on you and include: joint kinematics, muscle activation, and metabolic rate.

How will we protect your information?

There is also the risk of a breach of confidentiality. To combat this, the research team will be removing any identifiable information as soon as possible, and they will keep paper records under lock-and-key access and computer records on an encrypted device.

We will share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you.

A description of this study 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.

What will happen to the information we collect about you after the study is over?

We will keep your research data to use for future analysis on walking with weights attached. Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

How will we compensate you for being part of the study?

You will receive a \$20 Amazon gift card. Payments will occur via email within the next week after the study. You will be responsible for any taxes assessed on the compensation.



Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin.

You are not waiving any of your legal rights by participating in this study.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, your data will be immediately deleted as well as your record of involvement with the study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

James Sulzer
Phone: 512-541-9036
Email: james.sulzer@austin.utexas.edu

Or

Michael Normand
Phone: 817-907-0578
Email: michaelnormand@utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.



Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Printed Subject Name

Signature

Date