Study Title: Powered Hip Exoskeleton for Stroke Survivors With Gait Impairment

Document Title: Consent Form

NCT: NCT03924765

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Key Information for: Powered Hip Exoskeleton for Stroke Survivors with Gait Impairment:

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. The name of the study is listed above. This document has important information about the reason for the study such as what you will do if you choose to be in this research study, and the way we would like to use information about you and your health. Your participation in this study is entirely voluntary.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of this study is to see if using a powered hip exoskeleton will help you to move better. We will have you walk with the robot across different walking conditions such as walking up/down a ramp. While walking, you will be provided with a hip assistance from the robot. Additionally, we will have different sensors attached to your body to record your movement. Your participation in this study will have 2 sessions total with each experiment lasting no more than 4 hours.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

Common risks of using an exoskeleton are fall and stumble. We will have safety harness and handrails available to you. Additionally, we will have an emergency stop next to you at all time. Another common risk is skill irritation from wearing the exoskeleton. We will make sure that the thigh and waist cuffs are properly fitted. Also, we will check your skin after each trial to make sure that you are okay. During the experiment, you can stop the experiment at any time if you feel any discomfort.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. However, your participation in this study will assist researchers in understanding how to better program and build exoskeleton devices to help people with neurological disorder to move better. As compensation for your time, we will pay $20/hour.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology
Project Title: Lower Limb Powered Exoskeleton Device for Gait Assistance
Investigators: Aaron Young, PhD; Inseung Kang MS; Yi-Tsen Pan, PhD; Kinsey Herrin, MSPO, C/LPO, FAAOP; Remi Onifade, PT, DPT

Protocol and Consent Title: Powered Hip Exoskeleton for Stroke Survivors with Gait Impairment
Version: 3/26/2020

Supporting Funding Source: National Institute of Health – Improving Community Ambulation for Stroke Survivors Using Powered Hip Exoskeletons with Adaptive Environmental Controllers

You are being asked to be a volunteer in a research study. This document has important information about the reason for the study such as what you will do if you choose to be in this study. This document also contains the way we would like to use information about you. Your participation in this study is entirely voluntary.

Purpose:
The purpose of this research study is to develop a smart robot for helping you to walk better. The study will have participants up to 20 individuals.

You are being asked to participate in this study because you have a history of stroke that limits movement in your lower body. Once you participate, you will be walking with a hip exoskeleton robot. We will be recording data from sensors placed on the robot and/or your body to measure different information when you move. This will be done by comparing how you walk with and without the robot while you do different tasks such as walking, going up and down the stairs and ramps etc. From this study, we will use the data to make our robot smarter and more efficient.

Exclusion/Inclusion Criteria:
You can participate in this study if you are a subject between 18-85 years of age who had stroke previously with a physician's approval that you can safely perform the experimental activities. The stroke must have occurred at least 6 months prior to study involvement. You can participate in the study if you scored greater than 17 on the mini-mental state examination (MMSE). You must be able to sit unsupported for minimum of 30 seconds. You must be able to follow a 3 step commend. The walking criteria are listed as below.

1. Ability to walk without support (a rail as needed is allowed), with a walking speed of at least 0.4 m/s (limited community walking speed)
2. Ability to walk for at least 6 minutes

3. Willingness and ability to participate over a 1-4 hour experiment, with breaks enforced regularly and as needed
4. Ability to transfer (sit-to-stand and stand-to-sit) with no external support (arm rests support allowed)
5. Ability to walk over small slopes (3 degrees) and a few steps (6 steps)

You will be excluded from the study if you have any loss of sensation in the legs, a complete spinal cord injury, history of concussion in the last 6 months, history of any severe cardiovascular conditions, severe arthritis, or orthopedic problems that limit lower body movement, other neurological disorders such as Parkinson's disease, Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), dementia, history of head trauma, lower extremity amputation, non-healing ulcers of a lower extremity, renal dialysis or end state liver disease, legal blindness or severe visual impairment. In addition, you will be excluded from the study if you use a pacemaker or have metal implants in the head region, medications that lower seizure thresholds. Lastly, if you are participating in another clinical study and/or your physical condition is limited to do different tasks, in the opinion of the Principal Investigator (PI), would likely affect the study outcome or confound the results, you will be excluded from the study.

Procedures:

After you consent to the experiment, the exoskeleton robot will be adjusted in size so that it comfortably fits your body size. Back of the exoskeleton robot is attached with a back plate piece which holds the electronics such as the computer and the battery. This plate is attached with shoulder straps which can be worn to make sure that the device is not too heavy for you to wear. Additional sensors, such as motion and muscle sensors will be placed on the surface of your leg and/or exoskeleton robot. Video cameras will record your movement and record the sensor data placed on your body. You will also be asked to wear a tightly fitted face mask that tells us how much energy you are using (metabolic cost) while you walk with the exoskeleton robot. The metabolic mask will be adjusted so that it does not give you any discomfort in both skin and breathing.

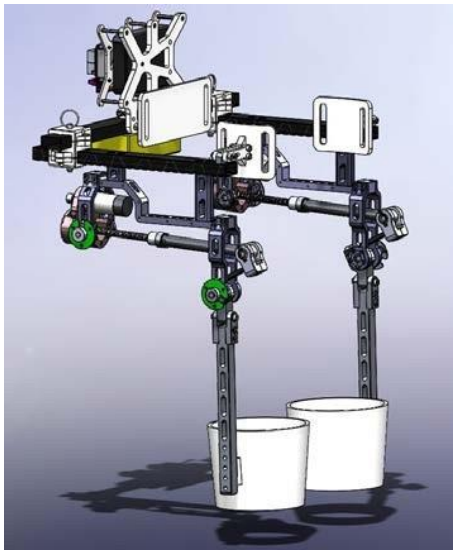

Figure 1Powered Exoskeleton

After you are fitted with exoskeleton robot, you will be asked to walk on a treadmill. You will have a safety rail along the treadmill for assistance during this time. Initially, you will be asked to walk at a comfortable speed on a leveled treadmill. When you become comfortable and showed that you can walk safely with the robot without stumbling, you will be asked to walk at different walking speeds and inclination levels. This range of levels will only change within your walking capability and you will not be asked to walk in a condition which can cause discomfort. If you feel comfortable using the exoskeleton robot, you will be asked to complete simple

activities such as walking over a ground, walking up and down the ramps, walking up and down stairs, stepping over obstacles, and standing up and sitting down. While you do these different tasks, we will change the robot to behave differently to test our controllers. As you complete these activities, you will be provided assistance with hand rails, personnel to provide supervised guarding as needed. A safety harness will be utilized at all times to make sure that you are safe from falling. When you practice doing these activities, we will make some adjustments to the exoskeleton robot so that it works the best for you. After, if you feel comfortable doing so, we will ask you to walk outside the laboratory such as a building stairwell and/or outdoor terrain on the Georgia Tech campus. This will let you practice walking in a more realistic environment.

You can choose to not do any of these activities you do not feel comfortable with. You will have as much time as you like to practice doing these activities. If you need more than four hours of practice or it takes longer than four hours for us to have you adjust to exoskeleton robot, we will ask you to come in on another day to continue the experiment. These do not need to be consecutive days. Data that will be recorded from you while you practice these tasks help us adjust the robot better. After you have finished practicing, we will collect the data for the actual experiment. We will ask you to complete each task that you have practiced multiple times. You will be given rest periods in between repetitions. The number of visits required to come to the lab depends on the amount of time it takes to adjust the robot for you and the amount of time you need to practice the activities with the robot. You will need to visit us a minimum of 2 times for experimental data collection and practice using the exoskeleton. Each visit will last between 1-4 hours and will not involve more than 30 minutes of continuous movement. We estimate the total time commitment to be between 10-25 hours.

Risks or Discomforts:

The exoskeleton robot has motors and sensors. The investigational device being used in this study is low-risk and is being used for research purposes only. Safety and efficacy of the device have not been determined and the device has not been approved by the FDA. Although these procedures are very safe and commonly used in our lab, your participation in this study will involve the following risks: falls resulting in injury, muscle soreness and/or fatigue, skin irritation, and bodily discomfort from wearing equipment. The primary risk of injury in this protocol would be due to falls, regardless of the device being used. To minimize this risk, you will be asked to wear a safety harness and initially walk with handrails until you become comfortable using the exoskeleton device(s) and demonstrate that you can use it without falling. Should you stumble/trip/lose balance during this familiarization session, the harness will support and prevent you from falling to the ground. When walking outside of the treadmill, you will still have the assistance with wearing the safety harness, access to hand rails and/or other walking aids, and will be supported by staff members providing supervised guarding using a gait belt if needed as you complete the activities. Also, along with safety harnesses, there will be a physical emergency stop button that can shut down the entire device when activated. The experimenter can easily access this stop button during any time of the experiment to shut down the machine if you feel uncomfortable and/or in danger. A second risk is minor muscle soreness and fatigue. Muscle soreness is a common problem when walking with a new wearable device. To prevent

this, experimental sessions will be kept as short as possible, adequate rest periods will be provided between trials, and you will be questioned often about any discomfort. A third risk is skin irritation. Skin can become irritated while using any exoskeleton and it can also cause blisters where the thigh and waist cuffs touch the user's body. To avoid the risk of skin irritation, you will use properly fitted user cuffs constructed by a trained lab member. Additionally, the limb will be checked periodically for skin irritation. The metabolic system you will be asked to wear tells us how much energy you are using while you walk. This system is safe, but may be uncomfortable for you to wear as it involves a mask over the face and must be tight to create a seal. There will be different size masks that can be optimally fit to you. The metabolic mask will be adjusted so that it does not impede your vision during the experiment. Risks include transmission of communicable diseases and discomfort. To protect you against infection, the mask and monitor will be properly disinfected between uses, and will always be handled with disposable sanitary gloves. Also, antibacterial filters will constantly be used within the metabolic mask.

Benefits:

Lower limb exoskeletons are designed to improve a person's ability to move and perform tasks. These s devices can be used to enhance both able bodied individuals and patients with gait deficiencies to overcome their current limitations by assisting joint motion with power through the robotic device. They can even allow disabled individuals with complete loss of movement (i.e. spinal cord injury patients) to regain walking abilities. Different controllers implemented in the exoskeleton device are necessary to effectively understand the user's current state. This study is focused to maximize the exoskeleton technology to enhance user's movement by intellectually understanding the user's intention of different movements.

Compensation to You:

You will not be charged for any study-related procedures. We will compensate fee that occurs during your visit (i.e. your time, inconvenience, and transportation fee etc). You will be compensated $20/hr.

The Finance Department at Georgia Tech will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. 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 enormously valuable for other research purposes. By signing the consent form, 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:
We may want to 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 videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.

Confidentiality:
The only possible identifier linking you to this study is the video and photographs taken during testing. The video will only be published if you give permission (permission form listed below). Your face can be blocked out upon request. You will be given a research subject number that will be used instead of your real name in potential published studies. Research records including the video will be stored in a password protected secured network where only the research members can have an access. Only the Principal Investigators and direct research study personnel will have access to the research records that include your personal information. After completing the study, videos may be used in teaching, publications or presentations. You can refuse permission for us to use your video in these settings. You will need to give or refuse permission for these at the end of this form. This consent form will be filed securely in the locked cabinet where only the PI will have an access to it. People who have access to your information include the Principal Investigators and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration, and entities such as the Georgia Tech Office of Research Integrity Assurance can access your records to make sure the study is being run correctly and that information is collected properly. Information about you related to this study will be kept confidential to the extent required by law.

Costs to You:
There are no costs to you, other than your time, for being in this study.

Participant Rights:
• 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.

Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant's identifiable or sensitive information (data and/or biospecimens):

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.

Clinically Relevant Information:

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.

As a part of this study, we will be collecting different measurements relating to your body movement. However, it is important for you to know that these results will not be disclosed to you under any circumstances, even if the results prove to be clinically relevant. If you are concerned about your health, we recommend you contact your personal healthcare giver.

Questions about the Study:

If you have questions or concerns, or any illness or injury during your time in this study, you should call us promptly. Aaron Young, PhD is in charge of this research study and can be reached at telephone number 404-385-5306 or by e-mail at aaron.young@me.gatech.edu.

In Case of Injury/Harm:

If you are injured as a result of being in this study, please contact Principal Investigator, Aaron Young, Ph.D., at telephone (404) 385-5306. 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:

If you have any questions about your rights as a research participant, you may contact Ms. Melanie Clark, Georgia Institute of Technology Office of Research Integrity Assurance, at (404) 894-6942.

[or]

Ms. Kelly Winn, Georgia Institute of Technology Office of Research Integrity Assurance, at (404) 385- 2175

_____

Participant Name (printed) Date

_____

Participant Signature Date

_____

Participant's Legal Authorized Representative 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 _____

(if yes, on media usage) block face? (Signature, Yes/No)

Yes / No