Principle Investigator

NCT06262191

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NAU NORTHERN ARIZONA UNIVERSITY
Office of Research Compliance

Consent to Participate in Research

Study Title: Adjustable ankle orthosis STTR

Principal Investigator: Zach Lerner, PhD

Sponsor: National Institutes of Health

For Parental Consent: "You" or "Your" refers to your child. The child will be asked to provide assent.

For Adult Consent: "You" or "Your" refers to you.

For Legally Authorized Representative Consent: "You" or "Your" refers to the person for whom the representative is signing.

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Why is this study being done?

We have developed a differential and adjustable stiffness AFO (DAS-AFO): Differential stiffnesses allows for customizing the stiffness in the plantarflexor and dorsal directions separately to maximize neuromuscular engagement and positive biological ankle power during push-off; A "real-time" stiffness adjusting slider allows for rapid and easy adjustment for different ambulatory conditions (e.g., walking, stairs, running). The primary goal of this study is to validate the benefits of, and need for, differential and adjustable stiffness AFO features. Our first aim is to confirm that the differential and adjustable stiffness AFO improves plantarflexor push-off power and range of motion compared to standard (physician prescribed) AFOs during walking in cerebral palsy (CP). Our second aim is to confirm that the differential and adjustable stiffness AFO improves plantarflexor muscle activity while maintaining improved posture compared to standard AFOs during walking in CP. Our third aim is to validate the need and usability for real-time stiffness adjustment during play and school activities; obtain feedback from the children and their parents.

What will happen if I take part in this study?

Experimental Protocol for Aim 1 and 2: You will complete two 30-minute practice sessions, and a final assessment. On the final assessment, participants will walk on an instrumented treadmill for 6 minutes with their normal AFOs and with the DAS-AFO

tuned to provide just enough dorsiflexor assistance to address drop foot (if present). Testing order will be block randomized. Treadmill speed will be set to each participant's preference, as will the stance phase plantarflexor stiffness for the DAS-AFO.

Experimental Protocol for Aim 3: You will complete a series of play and school activities using the DAS-AFO and their normal AFOs; order will be block randomized. During the DAS-AFO condition, you will be instructed to adjust stiffness using the simple slider as desired. Activities will include a series of floor-seated, chair-seated, standing, walking, and running (if applicable) tasks to capture the breadth of possible movements encountered during a typical school day. We will use video recording to observe and characterize interactions. These sessions will be followed by dedicated discussion time and validated product evaluation/usability questionnaires.

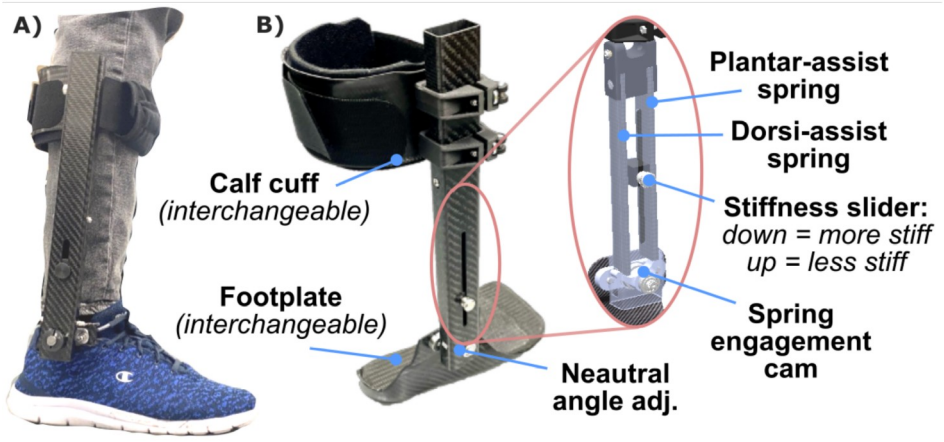

Figure 1. Functional prototypes of the Differential and Adjustable Stiffness AFO (DAS-AFO) with internalized springs.

Outcome Measures: The following experimental data may be collected under each experimental protocol:

- Electromyography
- Ground reaction forces
- Motion capture marker trajectories
- Metabolic cost of transport
- Pictorial pediatric exertion scale
- System Usability Scale questionnaire
- Video recordings

How long will I be in this study?

The study may take up to 2-3 sessions, each lasting up to 3-4 hours, to complete.

How many people will take part in this study?

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Up to 11 people will take part in the study.

What benefits can I expect from being in this study?

There are no anticipated benefits from this study.

What risks, side effects or discomforts can I expect from being in the study?

There may be a small risk of physical discomfort or injury due to rubbing by the device or injury due to falling during walking. We will use a safety tether while you walk on the treadmill if you appear unstable.

What other choices do I have if I do not take part in this study?

Your participation is voluntary. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with Northern Arizona University. If you are a student or employee your decision will not affect your grades or employment status.

When may participation in the study be stopped?

You may be asked to stop your participation if you are not compliant with the research protocol, if the devices used in the study do not fit you, or if you are not able to complete an assigned activity.

What happens if I am injured because I took part in this study?

Injury can happen in any research study. These effects may not be your fault or the fault of the researcher involved. Please seek professional medical assistance if you feel it is necessary. Please let the research team know if you have been injured. Northern Arizona University has no funds set aside for the payment of treatment expenses for this study.

What are the costs of taking part in this study?

If you were to get injured during the study, you may be responsible for payment of any bills not covered by your insurance due to your participation in this research study. Please discuss with the study team what you may be expected to cover.

Will I be paid for taking part in this study?

You will receive $30 per hour. If you voluntarily withdraw, you will not receive the compensation. You may receive $10 of travel compensation for every 25 miles traveled to the facility where the study will take place, with a maximum of $60 per visit. You may be reimbursed up to $120/night of hotel or Airbnb accommodations if an overnight stay is necessary for participation.

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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.

Will my data be stored for future research?
No.

Will I hear back on any results that directly impact me?
No, we do not expect to share any results with you.

Will my study-related information be shared, disclosed, and kept confidential?
Your name will not be used in any report. Identifiable research data will be encrypted and password protected.

If you elect to allow us to take pictures or videos during the study, you may elect to have your face and other features obstructed.

Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups may include:

- Office for Human Research Protections, Food and Drug Administration, or other federal, state, or international regulatory agencies
- Northern Arizona University Institutional Review Board
- The sponsor supporting the study, their agents or study monitors

NIH Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that 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

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research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that 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.

Who can answer my questions about this study?

If at any time you feel you have had a research-related injury, or for questions, concerns, or complaints about the study you may contact Zach Lerner, PhD at 928-523-1787.

For questions about your rights as a participant 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 Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

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.

AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form.

_____
Print Name Participant

_____ Date _____
Signature of Appropriate Signee. Circle the signee type: Parent, Adult Participant, or Legally Authorized Representative

_____
Printed Name of Parent/Guardian (If applicable)

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CHILD ASSENT (If applicable)

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

_____ Date _____

Signature of child

AGREEMENT TO BE VIDEORECORDED OR PICTURED

Signature of Appropriate Signee:_____ Date:_____

Request to obscure facial features? Circle one: Yes/No