NAU NORTHERN ARIZONA UNIVERSITY
Office of Research Compliance

Title of Research Study: Augmenting ankle plantarflexor function and walking capacity in children with cerebral palsy

Study Principal Investigator: Zachary Lerner, Ph.D.

Gillette Investigator Team Contact Information: Michael H. Schwartz, PhD

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Supported By: This study is supported by the National Institutes of Health

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later in this form.

What is research?

Doctors and researchers are committed to your child's care and safety. There are important differences between research and treatment:

- The goal of research is to learn new things in order to help groups of people in the future. Researchers learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. Your child, as an individual, may or may not be helped by volunteering for a research study.
- The goal of treatment is to help your child get better or to improve your quality of life. Doctors can make changes to your child's clinical care plan as needed.

Why am I being asked to take part in this research study?

We are testing a lightweight, battery-powered ankle brace for research. We are asking you and your child to take part in this study because your child has cerebral palsy.

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What should I know about a research study?

- Someone will explain this study to you and your child.
- Whether or not you take part is up to you and your child.
- You and your child can choose not to take part.
- You and your child can agree to take part and later change your mind.
- Your decision will not be held against you or your child.
- You and your child can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to establish an evidence-based ankle therapy and assistance strategy using a lightweight, battery-powered ankle brace for children with cerebral palsy to see if it can help improve mobility. Although physical therapy (PT) is essential for treating cerebral palsy, we are hoping to find better ways to improve mobility over time.

Our collaborators at BiOMOTUM, Inc. and Northern Arizona University developed the lightweight, battery-powered ankle brace. Currently, the ankle brace is investigational and is not yet approved by the Food and Drug Administration (FDA). The ankle brace is only used for research purposes at this time.

How long will the research last?

This study includes two experiments, both of which have different activities and time commitments. It's possible that you and your child may be asked to only participate in experiment 1:

- **Experiment 1**
  We expect your child will be in this part of the study for up to 39 weeks and it will include up to 25 visits. There will be 3 assessments and up to 16 training visits. Each assessment will take 3 hours and training visits will take approximately 1 hour. Adding up all the visits, you and your child's participation will take about 25 hours. If you and your child agree to participate in this study, your child will undergo 12 weeks of physical therapy (standard of care), a baseline assessment, 8 weeks of functional gait training with or without targeted ankle resistance (light push against), and two follow up assessments.
- **Experiment 2**
  We expect your child will be in this part of the study for up to 3 weeks and it will include one practice session and 4 assistance study visits. Each visit will take about 3 hours. Adding up all the visits, you and your child's participation will take up to 12 hours. If you and your child agree to participate in this study, your child will wear the ankle brace, standard AFOs or no ankle aid while completing sustained, high-intensity and challenging activities.

- **Participating in both Experiments 1 and 2**
  If you and your child agree to participate in both experiments, your child will be in this study for up to 39 weeks. Adding up all the visits, you and your child's participation may take up to 37 hours.

All activities are optional and are for research purposes only meaning they are not part of your child's treatment. You and your child's participation can stop at any time.

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What will I need to do to participate?

If you and your child agree to participate in either or both experiments, you and your child will come to the Gillette Center for Gait and Motion Analysis. Your child will only be asked to complete the study activities for the experiments you agree to participate in. The study activities will include being fit for the ankle brace, standard functional gait training, wearing the ankle brace while moving around, and wearing the ankle brace while being asked to perform specific activities. A comment of study participation will be made in your child's medical record as communication with other hospital staff. More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

Research may include risks to you and your child which are not currently foreseeable. This study has the following risks:

- **Confidentiality**

  There is a small risk of a breach in confidentiality by participating in this study. We comply with Gillette's security standards to secure and protect your information. We will make reasonable efforts to minimize this risk, but there is always a possibility of a loss of confidentiality.

- **Gait and Motion Analysis**

  There is a small risk of tripping or falling when walking and moving around during Gait and Motion Analysis. There will always be a trained study team member to assist with study activities. Additionally, your child can take resting breaks whenever they are needed.

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- **Ankle Brace**

  There is a small risk of tripping or falling while wearing the ankle brace. There are several safety features on the ankle brace system. There will always be a trained study team member to assist with study activities. Additionally, your child can take resting breaks whenever they are needed.

Will being in this study help me in any way?

There are no benefits to you or your child from participating in this study. We cannot promise any benefits to others from you or your child taking part in this study. However, a possible benefit to others is a better understanding of how the powered ankle brace can change mobility for children with cerebral palsy.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect up to 36 individuals will participate in this study at Gillette.

What happens if I say "Yes, I want to be in this research"?

If you and your child agree to participate in this study, our study team will coordinate with you to schedule study visits. The time commitment for each experiment will vary. All study activities are optional and are for research purposes only meaning they are not part of your child's treatment. Your and your child's participation can stop at any time.

During the study visits, the study team may ask to take pictures and videos. This is an optional part of the study. You and your child will have the option to say yes or no to these pictures and videos later in this form.

- **Experiment 1**
  For Experiment 1, following up to 12-weeks of documented physical therapy, you and your child will come to the Gillette Center for Gait and Motion Analysis and complete the following activities listed in the table below. If you and your child miss 2 or more testing visits, the study

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team may remove you from the study.

Week	Training Protocol	Duration	Activities
~1-12	**Standard of Care Physical therapy Sessions (Completed at your normal clinic, not necessarily completed at Gillette unless Gillette is your child's normal clinic)** **(2x/wk for up to 12 weeks)**		
~13	Screening/Baseline assessment (Visit 1)	3 hours	• Brace fitting • Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use o Physical Examination (PE) o Kinematics and kinetics o Energy (6MWT) • Complete mobility test o TUG, GMFM-66
High Intensity Task (Experiment 2/Aim 2)			
~18-25	Targeted Ankle Resistance Training (Visit 6 – 22) (2x/wk for 8 weeks)	1 hour/per visit	• With or without the brace: o Walking on the treadmill for 30 minutes
~26	1-Week follow-up Assessment (Visit 23)	3 hours	• Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use o Physical Examination (PE) o Kinematics and kinetics o Energy (6MWT) • Complete mobility test o TUG, GMFM-66
Last High Intensity Task (Experiment 2/Aim 2)			
~39	3-Month follow-up Assessment (Visit 25)	3 hours	• Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use o Physical Examination (PE) o Kinematics and kinetics o Energy (6MWT) • Complete mobility test o TUG, GMFM-66

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- **Experiment 2**
  You and your child will come to the Gillette Center for Gait and Motion Analysis for research visits. The time commitment for each research visit will vary. The table below outlines each visit, how long they will take, and what activities will be completed. If you and your child miss 2 or more consecutive training visits or more than 3 visits total, the study team may remove you from the study.

Week	Training Protocol	Duration	Task	Condition
~14-15	Practice (Visit 2)	1-2 hours	Practice walking with the device	Adaptive Ankle Assistance
				Standard AFO
				No Ankle Aid
~14-15	High Intensity Task (Visit 3)	3 hours (each)	Graded Treadmill exercise	Adaptive Ankle Assistance
				Standard AFO
				No Ankle Aid
~14-15	High Intensity Task (Visit 4)	3 hours (each)	Graded stair stepping exercise	Adaptive Ankle Assistance
				Standard AFO
				No Ankle Aid
~14-15	High Intensity Task (Visit 5)	3 hours (each)	6-minute walk test	Adaptive Ankle Assistance
				Standard AFO
				No Ankle Aid
~2-week break, then 8-wks. of gait training and 1-week follow up (Experiment 1/Aim 1)				
~27	High Intensity Task (Visit 24)	3 hours (each)	Graded Treadmill exercise	Adaptive Ankle Assistance
				Standard AFO
				No Ankle Aid

What happens if I say "Yes", but I change my mind later?

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You and your child can leave the study at any time and it will not be held against you. If you decide to leave the study, we will use the data we collected up until that point. If you do not want us to use any of the data we have collected, just let us know in writing and we will exclude it from our results. Additionally, if you decide to leave the study or are removed from the study, you and your child will no longer receive compensation.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. In other words, your choice not to be in this study will not negatively affect your child's right to any present or future medical treatment.

Will it cost me anything to participate in this research study?

Participation in this study will ordinarily not lead to any cost to you or your insurance company. However, if an injury occurs, care may be billed to you or your insurance company.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of you and your child's information, including study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may review and copy your child's information include Gillette Research and the University of Minnesota Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives that provide oversight, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP) and Gillette Internal Monitoring Program). The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your child's medical records to conduct and oversee the study. By signing this document, you are agreeing to this access.

Additionally, the information collected for this study will be stored and processed in the Center for Gait and Motion Analysis database. By signing this document, you are agreeing to this storage and access. A description of this study will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you or your child. At most, the website will include a summary of the results. You can search this website at any time.

Additional sharing of your or your child's information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

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- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious, or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Certificate of Confidentiality

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

The Certificate does not prevent a study team member from reporting information learned during study activities when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the study team member from disclosing such information in follow-up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the study.

You also should understand that a Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself, your involvement, or your child's involvement in this study. If an insurer, medical care provider, or other person obtains your written consent to receive study information, then the study team members will not use the Certificate to withhold that information.

Will I receive research test results?

Most tests done in research studies are only for research and have no clear meaning for health care. Because all activities outlined in this form are collected for research only, no individual results will be shared with you or your child.

What will be done with my data when this study is over?

When the study is over, the information we collected for this study will remain in the Gillette Center for Gait and Motion Analysis database. The information we have collected will not be shared in future research without consent. We will remove any information that may identify you or your child before it is shared. This means, nobody who sees the information will know who you or your child are. Additionally, this means neither you nor your child will receive any results or financial benefit from future research using your information.

Will anyone besides the study team be at my consent meeting?

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You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that Gillette and the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g., name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns, or feedback about my experience?

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. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Gillette Patient Representative

If you have any questions or concerns regarding an aspect of this study specific to Gillette Children's and would like to talk to someone other than the study team members, contact the patient representative at Gillette Children's Specialty Healthcare, 200 East University Avenue, St. Paul MN 55101, 651-578-5218 or email qualityrep@gillettechildrens.com. You may also send feedback by going to: https://www.gillettechildrens.org/contact-us/ and completing the feedback form.

Will I have a chance to provide feedback after the study is over?

The University of Minnesota Human Research Protection Program (HRPP) may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team, the Gillette patient representative or the University of Minnesota HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this study results in an injury, treatment will be available. This could include first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary

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manner, to you or your insurance company. If you think that your child has suffered a study-related injury, please let the study team know right away.

Will I be compensated for my participation?

You and your child will be compensated for participating in this study. Additionally, you will be provided with a parking voucher after each study visit. The amount of compensation will depend on which experiments you and your child agree to participate in. If you decide to leave the study or are removed from the study, you and your child will no longer receive compensation.

- **Experiment 1**
  Your child will receive $75 at the end of each assessment and $25 at the end of each training visit. In total, your child could receive up to $625.

- **Experiment 2**
  Your child will receive $75 at the end of each visit. In total, your child could receive up to $375.

For all visits, we will also pay $0.625/mile of fuel reimbursement, up to $40 a visit ($20/each way).

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. You and your child will be given a card at the beginning of the study, and we will add money the same card after each visit. If you lose the card, please contact the study team by phone or email to get a new one.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). Be sure to read the information provided with the card, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your or your child's name, address, phone number, and birthday. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Payment you or your child receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, Gillette is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information

We are committed to respect you and your child's privacy and to keep you and your child's personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child's personal health information that includes health information in their medical records

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and information that can identify them. For example, personal health information may include their name, address, and phone number. Protected health information will not be shared or released.

How will my information be used in publications and presentations?
We may publish the results of this study in scientific, medical, academic, or other journals or reports, or present the results at conferences. Information that makes it easy to identify you or your child (e.g., your and your child's name, contact information, date of birth, and medical record number) will not be part of any publication or presentation. If your child has an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your or your child's identity even without these identifiers.

Optional Elements

The following study activities are optional, meaning that you do not have to agree to them for your child to participate in this study. Please indicate your willingness to participate in these optional study activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may take pictures and videos with audio of my child for use in data analysis. The investigator will share these recordings with their collaborators for these purposes and my child's identity may be shared as part of this activity.
_____	_____	The investigator may take pictures and videos with audio of my child my child for use in journals, reports, or presentations. The investigator will share these recordings broadly for these purposes and my child's identity may be shared as part of this activity. When possible, the study team will de-identify audio records, video records, and pictures.
_____	_____	The investigator for this research and the sponsor may contact me in the future to ask about my research experience. This contact may be via phone or email, as permitted by me.

Signature Block for Parent/Legal Guardian of Minor Participant

Your signature documents your permission for your child to take part in this study. You will be provided a copy of this signed document.

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_____ _____

Signature of Parent/Legal Guardian Date

_____

Printed Name of Parent/Legal Guardian

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent