Chief Science Officer

NCT04516343

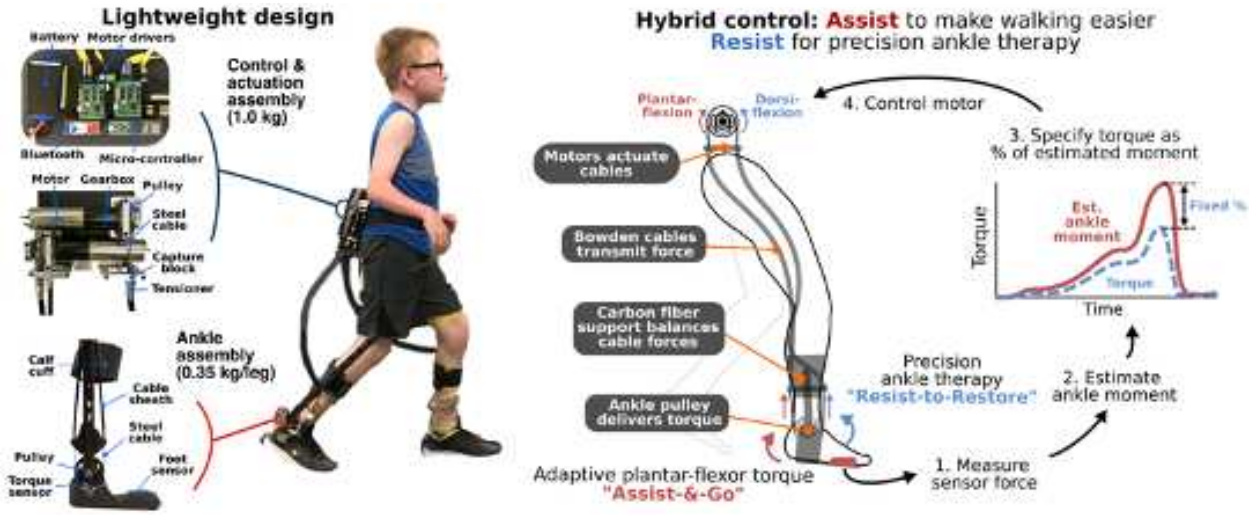
6/10/2024

Title of Research Study: Evaluation of the Safety and Efficacy of the Lower Extremity BiOMOTUM Exoskeleton in the Pediatric Population with Cerebral Palsy

Principal Investigator:

Arun Jayaraman, PT, PhD

Supported By: This research is supported by the National Institute of Child Health and Human Development.



Key Information about this research study:

The following is a short summary of this study to help you decide whether to permit your child to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study to determine the safety and benefit of the BiOMOTUM RAAD/BiOMOTUM SPARK/other similarly updated BiOMOTUM robotic exoskeleton device to provide resistance as a tool used in walking training intervention in the pediatric cerebral palsy population. The research is also looking to compare the use and benefit of the BiOMOTUM RAAD/BiOMOTUM SPARK/other similarly updated BiOMOTUM model in a supervised physical therapy setting versus parent-led sessions.

- The BiOMOTUM RAAD/BiOMOTUM SPARK/other updated BiOMOTUM model is a lightweight device that has the capability of providing robotic assistance and/or resistance at the ankle joint to facilitate walking training for children with cerebral palsy. It is an investigational device and is not approved by the U.S. Food and Drug Administration (FDA).

- Your child will first participate in an initial screen. If your child meets the eligibility criteria, a baseline assessment will be conducted. Your child will then participate in 12 training visits (3 times per week for 4 weeks, missing no more than 3 session's total). At minimum, 9 training visits can occur over 8 weeks. Once the 12 sessions are complete, post assessment evaluations will occur 3-7 days as well as 3 weeks following training session conclusion. Up to an additional 3 training visits and/or 2-3 weeks may occur should the BiOMOTUM

RAAD/BiOMOTUM SPARK/other similarly updated BiOMOTUM device require maintenance or updates during your child's participation. Additional visits should only be required if adjustment is needed to ensure safety following changes.

- We expect that your child will be in this research study for up to 7 months.

- The primary potential risks of participation are risk of falling, discomfort caused by the device, skin irritation from the sensors, blood pressure instability associated with exercise, risk of further moving or stretching their leg joint or muscle, spasms triggered by joint movement in the device, fractures, device malfunction, as well as any unforeseeable risks associated with the device itself. All these risks are minimized by having trained research staff present for all activities.
- The main benefit of being in this study is to better understand the use of the technology to enhance walking ability for kids with cerebral palsy.

Why is my child being asked to take part in this research study?

We are asking your child to take part in this research study because your child has a diagnosis of cerebral palsy which has affected your child's ability to walk and balance.

How many people will be in this study?

We expect about 30 children will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- Your child can choose not to take part.
- Your child can agree to take part and later change their mind.
- Your child's decision will not be held against them.
- You and your child can ask all the questions you want before you decide.
- Your child does not have to answer any question they do not want to answer.

If you say that "Yes, you want your child to be in this research," here is what your child will be asked to do:

- Screening:
  First, an initial screen will be completed to ensure your child is interested and meets eligibility criteria. We will also obtain medical clearance from your child's physician prior to any testing and device training. Once screening is complete to confirm qualification for the study, your child will be placed into one of two groups.
    - Group 1: All training sessions will be completed using the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUM model in resistance mode, with the direct supervision of a physical therapist.
    - Group 2: All training sessions will be completed using the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUM model in resistance mode, with 1 session per week directed by a physical therapist, and the other 2 sessions each week completed with parent supervision. (These sessions will still take place on the 11th floor of the Shirley Ryan AbilityLab.)

- Training Sessions:

If your child meets eligibility criteria and other screening items, they will participate in 12 training sessions, 3 times per week for 4 weeks. At minimum, your child must complete 9 sessions over 8 weeks. Each session will last approximately 1 hour. During each session, your child will participate in walking-based training in the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUM model, in resistance mode.

- During training sessions, the device has sensors which send information about your child's ankle position to the iPad which controls the device. This information is stored and will be utilized to inform how the training went as well as future development of the device.
- Training sessions will occur at Shirley Ryan AbilityLab flagship hospital, in the Center for Bionic Medicine.
- Group 1 will have all sessions completed under direct supervision of a physical therapist.
- Group 2 will have 1 session per week performed by a physical therapist, and the other two sessions completed with parent supervision (to simulate home-use).

- Evaluation Sessions:
  Your child will participate in walking and balance tests as well as questionnaires that ask about walking, balance, and quality of life. As the parent/guardian, you may be asked to complete some questionnaires asking about your child's walking, mobility, and quality of life. This will occur at different time points throughout the study. We will also collect information such as the medications that your child is taking. These time points are: at the very beginning of the study, 3-7 days after the last training session, and then 3 weeks after all training sessions are completed. Evaluation sessions may take up to 4 hours.
  - Evaluation sessions will occur at the Shirley Ryan AbilityLab flagship hospital, in the Center for Bionic Medicine.

Outcome Measures:

- During evaluation sessions, the outcome measures that will be assessed include:
  - 10-meter walk test: A measure of walking speed (< 5 min)
  - 6-minute walk test: A measure of how far your child can walk in 6 minutes (6 min)
  - Timed up and go test: A measure of your child's falls risk (< 5 min)
  - GAITRite Data Collection: Your child will walk over a mat that contains sensors that measure gait quality with relation to time and space (~10min)
  - Maximal isometric strength: measuring the maximum strength of your child's leg muscles (< 5min)
  - Gross Motor Function Measure (GMFM-66): A measure that evaluates changes in your child's mobility status according to activities such as walking, running, or jumping (< 45min)
  - Child and Adolescent Scale of Participation: A comprehensive measure of activities and participation (6-30min)
  - Range of Motion (ROM) performance: measure of joint movement in your child's legs
  - Patient's motivation: estimation of users motivation in 0 to 10 scale
  - Numeric Pain Rating Scale / Wong-Baker Faces scale: to let us know if your child is experiencing any discomfort or pain while in the device
  - Electromyography (EMG): small sensors placed on your child's thighs and lower legs that indicate amount of muscle activation. This may be applied during walking tests.

Your child may also be wearing different types of sensors to measure muscle activity and body movement. These sensors are placed on the skin and secured with tape. Your child may also wear a Cosmed unit to measure breathing and amount of energy used during walking. This is worn as a rubber mask that goes over the nose/mouth that your child breathes into while walking.

Will being in this study help my child in any way?

We cannot promise any benefits to your child or others from taking part in this research. However, possible benefits include improvements in your child's walking.

Is there any way being in this study could be bad for my child?

- The risk of falling: This could be caused by loss of control during walking by your child or therapist as well as malfunction of the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUMmodel itself. The risk of falling will be minimized by having experienced SRALAB research personnel conduct all sessions, and as needed overhead attachment with a safety harness and/or gait belt during over-ground gait training.
- Discomfort, scratches, bruising, pain, or unusual swelling caused by the device which has the potential to lead to skin breakdown, redness, or scratches. This risk will be minimized by a thorough skin check performed by experienced research personnel at each training session. Adjustments to the device fit and additional padding will be assessed to decrease the risk of skin breakdown as well.
- There may also be a risk of skin irritation caused by the adhesives used to secure the sensors to the participant. This will be reduced by careful monitoring of skin when these devices are utilized.
- Blood pressure instability during use of the device related to standing and walking activities during testing and training procedures. This risk will be reduced with frequent subjective assessment of patient's symptoms as well as assessment of blood pressure and heart rate prior to training, as necessary during training and following training. Activity will be stopped in the event of instability of vital signs and as recognized by experienced research personnel. Medical clearance will be required prior to any study related activities.
- Risk of exceeding range of motion: This would be caused if any device moves the participant beyond the normal range of motion, resulting in a strain, sprain or fracture. For the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUM model, this risk is lessened by mechanical hard stops that prevent the device from exceeding a normal human range of motion even in the event of an electrical or software failure. Software systems are also in place to further reduce range of motion to improve fit and comfort during walking. Participants will be evaluated by clinicians who will eliminate participants from being included in the study if participants cannot meet the required range of motion. For all other devices, this risk will be mitigated through proper settings by the physical therapist in charge of participants treatment.
- Spasms triggered by joint movement in the device. This risk will be reduced through screening prior to enrollment in the study. Participants cannot take part if the participant's muscles are too stiff.
- There is a risk of fractures when participating in a therapy program: this will be minimized by requiring medical clearance if participants are at risk for severe osteoporosis.
- The device itself could malfunction. All activities will be performed with close supervision from trained research personnel to monitor device function during use.
- The use of the BiOMOTUM RAAD/ BiOMOTUM SPARK/other similarly updated BiOMOTUMmodel may involve risks that are currently unforeseeable as this is a trial to assess

use of the BiOMOTUM RAAD device/ BiOMOTUM SPARK/other similarly updated BiOMOTUM model in the pediatric population with cerebral palsy.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

What happens if I do not want my child to be in this research, or my child and I change our minds later?

Participation in research is voluntary. You can decide to permit your child to participate or not to participate. If you do not want your child to be in this study or withdraw from the study at any point, your decision will not affect your child's relationship, including healthcare services, with Northwestern University/Northwestern Memorial Healthcare or the Shirley Ryan AbilityLab.

Your child can leave the research at any time and it will not be held against them.

If you choose to withdraw your child, or your child decides to withdraw from this study, the researchers will ask you if information already collected from you can be used.

How will the researchers protect my child's information?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this institution.
If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). 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. 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 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.

Data collected during the study will be transferred to the study monitor electronically and/or by paper hard copy with no protected health information, using only a study code. The "master list" linking personal information to the code will not be shared and will be kept by the study team in a secure location.

The sponsor BiOMOTUM, Shirley Ryan AbilityLab, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your child's medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your child's name and other identifying information confidential.

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 will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- Collaborating researchers at other institutions who are involved with this study.
- The research team may give information to appropriate authorities for reasons of health and safety – for example, if you indicate that you plan to harm yourself or others, or for public health reasons.

If we learn about current or ongoing child abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Most tests done in research studies are only for research and have no clear meaning for developmental, educational or health care. If the research results have meaning for your health, the researchers will contact you to let you know what they have found.

How might information collected in this study be shared in the future?

We will keep the information we collect about your child during this research study for study recordkeeping. Your child's name and other information that can directly identify your child will be stored securely and separately from the rest of the research information we collect.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. We will remove or code any personal information that could directly identify your child before the study data are shared. Despite these measures, we cannot guarantee anonymity of your child's personal data. The PI would like to retain your contact information to contact you about future research opportunities for your child. This information will not be shared with other researchers, but will only be retained for potential interest in research with this PI. We will ask for your consent to do so at the end of this form. Your child can be in this current research study without agreeing to future research use of your identifiable information.

The results of this study could be shared in articles and presentations, but will not include any information that identifies you unless you give permission for use of information that identifies you in articles and presentations.

Will my child be paid or given anything for taking part in this study?

If you agree for your child to take part in this research study, your child will receive $50 for each session that they attend (total of $800). These funds are provided to help support you with time and travel associated with your participation.

Your child will still receive compensation for each session that they participant in, even if participation for that particular session must be ended early.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded and can be used at your discretion. Either your child's name or your name (parent/guardian) can be used to activate the ClinCard.

You will be issued one card for the duration of your participation. If your card is lost or stolen, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

Here is some other information that is useful for you and your child to know:

We are committed to respect your child's privacy and to keep 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 your child's medical records and information that can identify you. For example, personal health information may include your child's name, address, phone number or social security number. Your child's health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Records about study devices
- Billing information

The following clinical providers may give the researchers information about your child: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your child's name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study.
- Study monitors and auditors who make sure that the study is being done properly,
- BiOMOTUM, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your child's health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your child's information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Arun Jayaraman, PT, PhD
Institution: Shirley Ryan AbilityLab
Department: Max Nader Center for Rehabilitation Technologies and Outcomes, Center for Bionic Medicine

Address: 355 E. Erie Street, Suite 1402, Chicago, IL 60611

You do not have to authorize the use or disclosure of your child's health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your child's health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your child's eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your child's medical records and may be seen by your insurance company

Who can I talk to?

If you or your child have questions, concerns, or complaints, you can contact the Principal Investigator Arun Jayaraman, PT, PhD. You can call him at 312-238-6875 during normal business hours Monday-Friday.

If your child has any illness or injury during your child's time on this study, you should call us promptly. You can contact the research team: Allie Lynott, PT at 312-238-7401, Jen Traines, PT at 312-238-8423, Kristine Buchler, PT at 312-238-7114, Matt McGuire, PT at 312-238-3457.

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at irb@northwestern.edu 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.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order for your child to participate in the research study. Please indicate your permission for your child to participate in these optional activities by placing your initials next to each activity. Your child will have the opportunity to agree or disagree with the same elements after you have indicated what you are willing to give permission for:

Parent:

I agree	I disagree	
_____	_____	The researcher may audio or video record my child to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record my child for use in scholarly presentations or publications when showing my face or hearing my child's voice might serve to help other professionals understand the research. My child may be identifiable as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in

my child participating in other research studies by the principal investigator of this study.

Child participant:

I agree	I disagree	
_____	_____	The researcher may record my voice or take video of me during the project. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may record my voice or take video of me for use in presentations or publications when showing my face or hearing my voice might serve to help other professionals understand the research. People may be able to see my face and hear my voice as part of this activity, although the researcher will attempt to limit this.
_____	_____	The researcher may contact my parent in the future to see whether I may be interested in participating in other research studies by the principal investigator of this study.

Parent Permission and Child Assent 12 or older

Your signature documents your permission for the named child to take part in this research.

_____ _____
Signature of child/student Date

_____
Printed name of child/student

_____ _____
Printed name of parent [ ] or individual legally authorized [ ] giving permission for the child to participate Date

_____ _____
Signature of parent [ ] or individual legally authorized [ ] giving permission for the child to participate Date

_____ _____
Signature of person obtaining permission Date

_____
Printed name of person obtaining permission

Adult Consent Form – Experimental Phase

Title of Research Study: Development of robotic ankle assist device to improve mobility in individuals with movement disorders

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:

Investigator: Michael H. Schwartz, PhD **Investigator Departmental Affiliation:** Director of Bioengineering Research – Gillette; Associate Professor – University of MN **Phone Number:** 651-229-3929 **Email Address:** MSchwartz@gillettechildrens.com	**Research Coordinator:** Stacy Ngwesse **Phone Number:** 651-578-5059 **Email Address:** StacyENgwesse@gillettechildrens.com

Supported By: This study is supported by the National Institutes of Health Small Business Innovation Research program

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 (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 to take part in this study because you have cerebral palsy.

What should I know about a research study?

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

Why is this research being done?

The purpose of this study is to test a lightweight, battery-powered ankle brace for children and adults 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. As part of this study, we are testing the safety and efficacy of the ankle brace for children with cerebral palsy.

How long will the research last?

If you do not have any previous data in the Gait and Motion Analysis database that we can use to determine eligibility, you will be asked to come in for a screening visit. At this visit we will take some measurements and fit the device. Participants who come in for a screening visit will be asked to complete this consent form regardless of whether they are enrolled into the study or not.

This study includes two experiments, both of which have different activities and time commitments. You will have the option to choose which experiments you would like to participate in:

- **Experiment 1**
  We expect you to be in this part of the study for up to 4 weeks and it will include 4 visits. Each visit will take between 1 and 1 ½ hours. Adding up all the visits, your participation will take 4-6 hours. If you agree to participate in this study, you will wear electromyography sensors (EMG) placed by a licensed physical therapist and the ankle brace while practicing walking activities when it is turned off, turned on, providing assistance (light push forward), and providing resistance (light push against). EMG is typically collected as part of standard of care for a complete gait and motion analysis. It will help us track your muscle activity as you complete the walking activities. You will complete 1 baseline visit, 1 visit to test ankle brace assistance, 1 visit to test ankle brace resistance, and 1 visit that will be like a typical PT visit. The study team will also ask you about your experience using the ankle brace through a series of questionnaires.

- **Experiment 2**
  We expect you will be in this part of the study between 9-13 weeks and it will include 11-15 visits. Each visit will take between ½ and 3 hours. Adding up all the visits, your participation will take up to 15 hours. If you agree to participate in this study, you will wear electromyography sensors (EMG) placed by a licensed physical therapist and the ankle brace while practicing walking activities. EMG is typically collected as part of standard of care for a complete gait and motion analysis. It will help us track your muscle activity as you complete the walking activities. Additionally, you will have study visits not wearing the ankle brace. You will complete 1 baseline visit, 8-12 training visits providing assistance (light push forward), and 2 follow-up visits. One follow-up visit will be 3 days after the last training visit, and one will be 3 weeks after the last training visit. The study team will also ask you about your experience using the ankle brace through a series of questionnaires.

- **Participating in both Experiments 1 and 2**

If interested, you will have the option to participate in both experiments. If you agree to participate in both experiments, you will be in this study between 13-17 weeks. Adding up all the visits, your participation may take up to 21 hours.

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

What will I need to do to participate?

If you agree to participate in either or both experiments, you will come to the Gillette. You 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, wearing the ankle brace while moving around, and wearing the ankle brace while being asked to perform specific activities. Some of these activities will include sitting, standing, walking at your regular speed, and walking slower or faster.

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 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, you can take resting breaks whenever they are needed.

- **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, you can take resting breaks whenever they are needed.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from you taking part in this study. However, a possible benefit to you and others is a better understanding of how the powered ankle brace can change mobility for children and adults with cerebral palsy. Additionally, you may observe some improvement in your walking.

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 30 individuals will participate in this study at Gillette.

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

If you agree to participate in this study, our study team will coordinate with you to schedule study visits. If you do not have any previous data in the Gait and Motion Analysis database that we can use to determine eligibility, you will be asked to come in for a screening visit. 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 treatment. Your 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 will have the option to say yes or no to these pictures and videos later in this form.

- **Experiment 1**
  For Experiment 1, you will come to the Gillette for all 4 research visits. The table below outlines each visit, how long they will take, and what study activities will be completed. If you miss 2 or more testing visits, the study team may remove you from the study.

Week	Visit	Time	Activities

1	Baseline visit	1 – 1 ½ hours	• Brace fitting
			• While wearing the brace:
			  ○ Practice sitting, standing, and walking
			  ○ Walk with brace resistance (light push against)
			  ○ Walk with brace assistance (light push forward)

2	Testing visit 1
	
	Assistance or Resistance or Research PT
		1 – 1 ½ hours	• While wearing the brace:
			  ○ Walk for 10 minutes
			  ○ Walk on the treadmill for 10 minutes
			  ○ Practice walking skills for 15 minutes

3	Testing visit 2
	
	Assistance or Resistance or Research PT
		1 – 1 ½ hours	• While wearing the brace:
			  ○ Walk for 10 minutes
			  ○ Walk on the treadmill for 10 minutes
			  ○ Practice walking skills for 15 minutes

4	Testing visit 3
	
	Assistance or Resistance or Research PT
		1 – 1 ½ hours	• While wearing the brace:
			  ○ Walk for 10 minutes
			  ○ Walk on the treadmill for 10 minutes

			○ Practice walking skills for 15 minutes

After the baseline visit is complete, the order of the 3 Testing visits will be assigned randomly by the study team.

- **Experiment 2**
  For Experiment 2, you will come to Gillette for all 15 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. You must complete at least 1 visit per week. If you miss 2 or more consecutive training visits or more than 3 visits total, the study team may remove you from the study.

Week	Visit	Time	Activities
1	Baseline visit	2 – 3 hours	• Brace fitting • While wearing the brace: ○ Practice sitting, standing, and walking • While not wearing the brace: ○ Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use ○ Complete tests for sitting, standing, walking, running, and jumping
2 – 5*	Training visits 1 - 12	½ hour (each)	• While wearing the brace: ○ Walk with brace assistance (light push forward) for 15-20 minutes
6*	3-Day Follow-up visit	2 – 3 hours	• While not wearing the brace: ○ Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use ○ Complete tests for sitting, standing, walking, running, and jumping
8-9*	3-Week Follow-up visit	2 – 3 hours	• While not wearing the brace: ○ Complete a full gait analysis to measure your movement, how your muscles work, and how much energy you use ○ Complete tests for sitting, standing, walking, running, and jumping
* There is an option to extend the duration of the Training Visits to accommodate the patient's schedule. Please discuss with research coordinator			

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

You 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 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 right to any present or future medical treatment.

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

Taking part in this study will not lead to any cost 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 your 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 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 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. Our collaborators will also have access to your information collected as part of this study, including study and medical records. 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. 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:

- 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.

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. Some of the information we have collected may be shared in future research. We will remove any information that may identify you before it is shared. This means, nobody who sees the information will know who you are. Additionally, this means that you will not receive any results or financial benefit from future research using your information. This information may be shared with other researchers or institutions outside of Gillette. We will not ask for your consent before using or sharing this information.

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

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?

University of Minnesota Human Research Protections Program

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. 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 the study 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 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 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 manner, to you or your insurance company. If you think that you have suffered a study-related injury, please let the study team know right away.

Will I be compensated for my participation?

You 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 agree to participate in. If you decide to leave the study or are removed from the study, you will no longer receive compensation.

- **Experiment 1**
  You will receive $50 at the end of each of the 4 study visits. In total, you could receive up to $200. Additionally, you will be reimbursed for your roundtrip mileage at the current federal rate. We will also cover hotel and parking for individuals traveling overnight from a distance of 100 miles or more at the current allowed federal rate for your hotel stay of up to 1 night per week for 4 weeks. A Gillette travel agent will help to book your stay.

- **Experiment 2**
  You will receive $40 at the end of each of the 15 study visits. In total, you could receive up to $600. Additionally, you will be reimbursed for your roundtrip mileage at the current federal rate. We will also cover hotel and parking for individuals traveling overnight from a distance of

100 miles or more at the current allowed federal rate for your hotel stay of up to 3 nights per week for 4 weeks. A Gillette travel agent will help to book your stay.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. You 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 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 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 respecting your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in their medical records and information that can identify them. For example, personal health information may include your name, address, and phone number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

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 (e.g., your contact information, date of birth, and medical record number) will not be part of any publication or presentation. If you have 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 identity even without these identifiers.

Optional Elements

The following study activities are optional, meaning that you do not have to agree to them for you 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 you for use in data analysis. The investigator will share these recordings with their collaborators for these purposes and your identity may be shared as part of this activity.
_____	_____	The investigator may take pictures and videos with audio of you for use in journals, reports, or presentations. The investigator will share these recordings broadly for these purposes your 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 to take part in this study. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent