Cover Page for ClinicalTrials.gov

Study Title: Ankle Robotics for Error Augmentation after Stroke

Document: Informed Consent Form Official

NCT Identification Number: pending

HP-00108406

Document Creation Date: May 26th, 2026

UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Ankle Robotics for Error Augmentation after Stroke

Study No.: HP-00108406

Principal Investigator: Kelly Westlake, PT, PhD, 410-706-5919

CONCISE SUMMARY:

Researchers at University of Maryland School of Medicine and NextStep Robotics are conducting a study in individuals who have suffered a stroke and have ankle weakness to evaluate the effectiveness of a new portable ankle robot that provides ankle resistance training during walking.

This is a thirty-visit study. Each session will involve a 45-60 min training session, which includes two x 10 min bouts of treadmill walking and one x 10-minute bout of overground walking while wearing the ankle robot. The robot will provide resistance to the ankle and assessments will be conducted during the training session to monitor any resulting changes in ankle muscle control. Assessments of functional leg movements and walking ability will be added to visits one, fifteen, and thirty over an additional 30 mins.

Possible risks of participating in this study are described in this document. The greatest risks include the risk of falling, muscle soreness, and skin irritation. The study team takes all precautions to mitigate these risks during each visit. Before starting, you will have a medical history and assessments performed to determine if this study is safe for you. All sessions will be assisted by trained research personnel and all therapy is under the supervision of a physical therapist, with other medical personnel on site.

If you are interested in learning more about this study, please continue reading.

PURPOSE OF STUDY

You have been invited to take part in this study because you are between 18 and 88 years of age, you have suffered a stroke greater than 6 months ago and have been diagnosed with foot drop, and previously participated in the protocol HP-00084830 involving the AMBLE device.
Foot drop means that you have reduced ability to lift the foot after the stroke and this impairs your walking. This study is designed to see if the resistance provided by a portable ankle robot worn over the shoe can enhance short term ankle muscle control and walking ability.

This is a single group study, meaning that your baseline assessment results during visit one will be compared to your results at the end of the training session on visits fifteen and thirty. This

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research project will be conducted at the University of Maryland Rehabilitation and Orthopaedic Institute (UM Rehab) and the University of Maryland School of Medicine, Department of Physical Therapy and Rehabilitation Science. You will be one of approximately 15 individuals from the Baltimore, Maryland area recruited to participate in this study. Your participation is voluntary in this study.

Note that some members of the study team, excluding the principal investigator, are employees and have financial interests in NextStep Robotics, developer of the AMBLE device.

PROCEDURES

If you meet the eligibility requirements, this study will require **30 visits** of 45-90 minutes in duration. The visits will be conducted within a 8-9 week period. Study procedures are solely for research purposes.

- You will attend thirty sessions
  - During the first session, after informed consent procedures, you will undergo baseline tests of your leg function and walking ability with and without the ankle robot. Prior to walking with the robot, you will be seated and fitted with the ankle robot. During the fitting process, the ankle robot will be secured to your stroke affected lower leg using a modified shin guard that has Velcro straps. You will wear your regular shoes. Your "shoe covered" affected foot will be inserted into a modified slipper. You will be asked about comfort of the fit. Should you have any discomfort or feeling like the ankle robot device is rubbing on your skin, padding will be applied to protect your skin.
  - During all thirty sessions, the ankle robot will provide resistance to your ankle while you walk on the treadmill or overground. You will be under the direct supervision of a physical therapist during this session. You will wear a safety harness while walking on the treadmill for safety. The physical therapist controls the ankle robot settings using a computer tablet (iPad) that sends messages to the device, while the device sends information to the therapist on how your ankle is performing while you are wearing it. The research team will periodically collect your heart rate and blood pressure measurements and ask how hard you are working and how you feel during various physical therapy tasks.
- The following assessments will be conducted during baseline testing at visit one and after training at visits fifteen and thirty:
  - Standardized tests of walking and balance to grade your ankle and whole body mobility function.
  - Timed walking tests (10 meter) will be performed under supervision with and without your assistive walking devices, and with the ankle robot both assisting and not assisting.

- If you give permission, we will photograph/videotape some of your training sessions and test visits, to provide you and researchers with feedback on your progress during the study.



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- You have the option of allowing these photographs/recordings to be kept by the research team for use in future presentations (slideshows, conferences, etc.) and to educate others about this research study.

  Please initial your choice below for study photographs/videotaping:
  ____ *Yes*, I agree to be photographed/videotaped during my training sessions and testing visits to provide myself and researchers with feedback on my progress during the study. I understand that only the PI/researchers will have access to these photos/videotapes; they will be stored in the secure research office, and photos/videotapes will not be destroyed.
  _____ *No*, I do not agree to be photographed/videotaped for this study.

  If Yes to photographs/videotaping:
  ____ *Yes*, I agree to have my photos/video tapes used for future publications and/or presentations related to this study. I understand that only the PI/researchers will have access to these photos/videotapes; they will be stored in the secure research office, and they will not be destroyed.
  ____ *No*, I do not agree to have my photos/videotapes used for future publications/presentations related to this study only. All recordings will be destroyed when my study participation ends.
  -

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH STUDY?

If you take part in this study, you will be responsible to:

- Participate in this study for thirty visits.
- Attend thirty sessions over approximately 8-9 weeks that will last 45-90 minutes at University of Maryland Rehabilitation and Orthopedics Institute or the University of Maryland School of Medicine Department of Physical Therapy and Rehabilitation Science.
- Perform walking tests with and without your usual assistive walking device.
- Walk on a treadmill with the ankle robot on your foot.

POTENTIAL RISKS/DISCOMFORTS:

This study exposes you to several risks:

- ***Skin irritation***: There is a risk that wearing the ankle robot may cause skin irritation with repeated ankle movements. The research team will check your skin before and after each training session for signs of skin redness or irritation. Foam padding will be used to provide protection to your skin if needed. The padding will be adjusted, if you develop any discomfort during any training visits or testing sessions.
- ***Fall risk***: You could fall during the treadmill training or walking tests. All physical therapy sessions are directly supervised by a physical therapist using best care practices to prevent falls and any kind of injury. You will wear a harness for safety during walking



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assessment and training to protect against falls. Research staff will also reduce the likelihood of falling by having 2 research team members present at all sessions.

- ***Muscle discomfort***: You may experience muscle soreness. Research staff and your physical therapist will monitor your muscle soreness during and between sessions. Your physical therapist will address muscle soreness by adjusting your stroke rehabilitation according to best practice as they see fit.
- ***Joint pain***: There is a very slight risk that the robot could move the foot in the wrong direction, causing joint discomfort. This is extremely unlikely, as maximal force outputs by the robot are not sufficient to cause injury to a muscle, tendon, or ligament. Further protection is provided by fail-safe switches that quickly turn the robot off in 2 milliseconds. Trained research staff engineer technician will perform service checks (calibration and operational) to the robot device before and after each session. Your physical therapist will be in charge of managing joint pain in consultation with the research staff rehabilitation medicine clinician (doctor) that provides continuous medical oversight for the study.
- ***Privacy and confidentiality***: Research staff will collect personal information about you during this study. This information will be protected; however, we cannot be assured of absolute privacy. This data will be kept locked in a research space at the University of Maryland School of Medicine Department of Physical Therapy and Rehabilitation Science.
- Your personal data (name, address, and other identifiers) will remain strictly confidential. Your data will be coded to protect your privacy. This coded data will be used in scientific publications and presentations, and you will not be personally identified. The risk of loss confidentiality will be minimized by storing data, photos, and any recorded imaging in a secure location in a locked office within a locked cabinet, with access restricted to research staff.

Unknown risks: In addition to the risks described in this form, there may be risks in this study which are not yet known.

- The research staff will update you on any new information that may affect your health, welfare, or decision to stay in the study.

POTENTIAL BENEFITS

You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study. This means that you may not benefit from wearing the robot during the treatment session. Your participation may help us to learn more about how ankle robotics can be used as an exercise device by physical therapists to reduce foot drop, and help stroke survivors recover their mobility with safer and better walking and balance.

ALTERNATIVES TO PARTICIPATION

Participation is voluntary, and the alternative is not to participate. Conventional therapy may be an alternative to taking part in this study.



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COSTS TO SUBJECTS

There will be no fee to enroll in the study. However, you or your insurance will be billed, in accordance with applicable law and policy, for any costs of medical care that may be required by the study. You or your insurance will also be billed for costs of medical care, including tests and procedures, that you would have needed or received if you were not in the study. These costs may include co-insurance, deductibles, and co-pays. You may also incur additional ancillary costs such as travel, lodging, parking, meals, etc.

Talk to your insurance plan and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this research study. Also, find out if you need approval from your plan before your plan will agree to pay for any costs of this research study.

PAYMENT TO SUBJECTS

You will be paid $300 for taking part in this study. In addition, you will receive parking voucher for each visit if you are driving yourself or be reimbursed the cost of travel up to $10 per visit if you are using alternative transportation.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. <u>If you have an emergency, call 911 or go to the nearest emergency room</u>. You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the principal investigator. UMB, if requested, will assist you to get medical care or referrals.

If you are injured as a result of being in this study, you or your insurance will be responsible for paying your medical expenses. Neither the hospital nor UMB has agreed to pay for the cost of medical care or other costs arising from an injury. However, you do not give up any of your legal rights by being in this study, and you may choose to pursue legal action if you are injured by being in the study.

CONFIDENTIALITY AND ACCESS TO RECORDS

- Efforts will be made to limit disclosure of your 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 information include the IRB and other representatives of the University of Maryland, Baltimore (UMB), or the study site.
- This study will involve the collection of confidential information about your medical health. The principal investigator and members of the research team will have access to this information stored in binders identified by code numbers and not by name. These binders will be kept in locked cabinets in a locked research space at the University of



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Maryland School of Medicine Department of Physical Therapy and Rehabilitation Science.

- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted, and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this study. You are free to withdraw your consent at any time. Your refusal to take part or your decision to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a study-related injury, please contact the investigator, Kelly Westlake, at 410-706-5919. There are no adverse consequences (e.g., physical, social, economic, legal, or psychological) of your decision to withdraw from the study. Note that the data that was collected prior to your withdrawal will be used in the data analysis for this study and will continue to be stored in a secure location in a locked cabinet in a locked room at the University of Maryland School of Medicine Department of Physical Therapy and Rehabilitation Science.

CAN I BE REMOVED FROM THE STUDY?

The person in charge of the study or the sponsor can remove you from the study without your approval. Possible reasons for removal include not following study-related directions to related to research participation, a new treatment becomes available for your foot drop, or you have a new medical illness. The principal investigator will tell you about this, and you will have the chance to ask questions if this happens.

UNIVERSITY STATEMENT

The University of Maryland, Baltimore (UMB) is committed to providing subjects in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research study subject. The contact information for the IRB and the HRPO is:



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University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

CONSENT TO PARTICIPATE – SIGNATURE PAGE

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

RESEARCH PARTICIPANT
If you agree to participate in this study, please sign your name below.

Subject's Signature	Date	Printed Name

INVESTIGATOR OR DESIGNEE OBTAINING CONSENT

Signature of Investigator or Designee	Date	Printed Name



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HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
AUTHORIZATION TO OBTAIN, USE, AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Subject:_____

Date of Birth: _____ **Medical Record Number: __N/A_____**

NAME OF THIS RESEARCH STUDY: **Ankle Robotics for Error Augmentation after Stroke**

UMB IRB APPROVAL NUMBER: *HP-00108406*

RESEARCHER'S NAME: *KELLY WESTLAKE*

RESEARCHER'S CONTACT INFORMATION:

Department of Physical Therapy & Rehab Science
University of Maryland School of Medicine (UMSOM)
100 Penn street, suite 305D
Baltimore, MD 21201
(410) 706-5919

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Research tests, which include a medical screen to ensure study eligibility as well as tests of physical function and movement and a questionnaire related to fear of falling.*

Federal laws require this researcher to protect the privacy of this health information. The researcher will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. *Westlake* and the study team.

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. The researcher will stop collecting health information about you. This researcher might not allow you to continue in this study. The researcher can use or share health information already gathered.

ADDITIONAL INFORMATION:

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- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University of Maryland Faculty Physicians, Inc. (FPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask the researcher how to get a copy of this information from the study.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above.

Subject's Signature	Date	Printed Name

Relationship to Subject:_____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.



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