Stimulation combined with externally powered motorized orthoses for stroke

NCT04116671

October 31, 2022

Participant Name: _____ Date:_____

Title of Study: Stimulation combined with externally powered motorized orthoses for stroke

Principal Investigator: [redacted] VA Facility: VANEOHS

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Rehabilitation Research and Development Service of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

You are being asked to participate in a research study because you have difficulty walking after suffering a stroke. By doing this study, we hope to learn the best way to control a neuromechanical gait assist (NMGA) device and if combining surface electrical stimulation applied to muscles that move the leg and a powered motorized knee brace improves walking.

Your participation in this research would last up to a year. During this time, you would be asked to come to the VA once or twice a week, but no more than eight times per month, to test your muscle strength and tone and develop and evaluate muscle stimulation patterns and controllers for walking with NMGA. The timing for different sessions in the study schedule is flexible.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The NMGA device combining muscle stimulation and motorized knee control has the potential to improve your walking, especially, if your walking is very slow because you have problems with moving and coordinating your leg while making a step, catching your toes, and maintaining weight on your affected leg. The knowledge gained here will help researchers develop a device to help people walk after stroke.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to participate in this study if you are comfortable getting around in the community on your own or with an ankle foot orthosis or a peroneal nerve stimulator to prevent foot drop. Further you may not want to participate in this study if you find electrical stimulation painful or cannot tolerate wearing a motorized brace on your leg. Additionally, you may not want to participate in this study if you find it difficult to travel to the Cleveland VA Medical Center or arrange a ride.

You may choose not to participate in this study. If this is your decision, there are other choices such as an ankle brace or peroneal nerve stimulation to prevent drop foot. Alternatively, a device such as Biomess L300 Go can stimulate the peroneal nerve in

combination with either knee extensors or flexors. Commercially available motorized robotic devices are designed and used primarily for inhouse rehabilitation, but not as assistive orthotic devices for everyday community use. Other alternative methods for stiff-legged gait correction are performing surgery or chemical nerve block to limit knee extension, however this can compromise knee stability during stance, thus limiting effectiveness of these procedures.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] at the Cleveland VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: phone #[redacted].

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DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn how to best control a NMGA device combining muscle stimulation and motorized bracing that assists ankle, knee and hip movement and whether it improves walking in people after stroke. There are a number of devices used to improve walking in the community for people with stroke, but they only assist a small number of movements or require a full lower limb exoskeleton attached to both legs. All devices currently available either use bracing or stimulation to control or one two movements or use motors to control multiple joints. This study is designed to develop a device called NMGA that uses both stimulation and motorized bracing to assist your own effort and use your own muscles as much as possible and use motor assistance only as needed to initiate and coordinate your leg movement to improve walking. Sensors on the device measure movements and we will determine which signals indicate when to turn stimulation and motor assistance on or off. During the process, we will ask for your feedback about the device design. We will also test whether the device allows you to walk farther and faster with less effort.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project would last up to a year based on your availability. Sessions would be about once or twice a week, but the scheduling is flexible. There will be up to ten subjects participating in this study developing the NMGA over the four-year study period.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Screening

After signing the informed consent form, you will undergo screening to determine if you are eligible to participate in the study.

During screening, the study physician will review your medical history. The physical therapist will test how strongly you can push with your legs and how tight your muscles are by moving your joints. Joint stiffness will also be measured by a machine that moves your leg while measuring how hard it has to push while moving the leg. The research team will also observe your walking to assess your coordination, step symmetry, walking speed and distance. If you meet inclusion criteria and there are no exclusions, you will be asked to participate in the study.

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Once you agree to participate, you will be scheduled for baseline testing. All procedures performed as part of this study are experimental, performed by the study team, for research purposes only and independent of your clinical care. None of the appointments are time critical. Thus, if you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment. While in this study, you should discuss with the research team before taking part in other research studies. For your safety, you should tell the investigator or research staff if you believe you might be pregnant since the effect of stimulation on a fetus is unknown and you need to be put on an inactive status until the pregnancy is completed.

Baseline testing

This testing will assess your muscle strength and tone, walking ability, and effort required for walking. Muscle strength and tone will be assessed on a Biodex device. This will require you to sit on a Biodex chair with your leg strapped to the Biodex arm and push as hard as you can to measure muscle strength or relax and let the Biodex arm move your leg to measure muscle tone. Muscle testing will require one visit lasting about two hours. In addition, there will be two kinds of walking tests. The first are short walks in the laboratory to measure your walking speed, task transitions, and detailed information about your movements. Small reflective markers will be placed on your body to measure movements during walking and small electrodes placed over your muscles to measure their activity known as electromyograms (EMG) while you walk. Muscle and walking tests will define your impairment and provide baseline information for the NMGA controller design. Second, walking tests will be performed in the hospital hallways to measure your walking speed, distance and number of steps during a 6-minute test. We will also measure your blood pressure before and after the walk and your heart rate for the duration of the test. We will repeat the 6-minute test while you are wearing a mask and a small device strapped to your chest to measure the amount of oxygen you consume which relates to your effort required to walk. Each walking test will require one visit lasting about two hours.

In addition to baseline testing, we will collect information about your leg and foot size to ensure we have an appropriately sized motorized brace for controller development. The brace will have a foot plate attached to the ankle joint connected to the power unit at the knee. Above the knee attached to the power unit is a cuff that wraps around your thigh to hold the brace in place. Surface electrodes can be attached directly over the muscles to be stimulated or they can be integrated into the shank and thigh cuffs.

NMGA Fitting and Tuning

Next, the study team will work with you to fit the device and determine appropriate stimulation patterns to assist walking. Fitting includes choosing brace components that fit well without causing you discomfort during walking. A physical therapist and biomedical engineer will

stimulate your muscles that were determined to be weak or paralyzed or that you have difficulty coordinating during walking. They will place round or square gel electrodes over your muscle and then determine the appropriate stimulation parameters that produce good movements without you experiencing discomfort. Stimulation patterns will be generated specifically for you to help you with your muscle weakness and improve leg coordination. Stimulation will target movement at the hip, knee, and ankle on your affected leg. During stimulation tuning we will adjust surface stimulation electrode locations as well as stimulus timing and intensity during walking. This may take several sessions lasting about two hours to achieve the best response for your walking. The muscle and walking tests may be repeated with assistance of surface muscle stimulation.

Controller Development

The research team will use information from your muscle and walking tests to design NMGA controllers. They will then schedule you to come to the lab multiple times (up to 16 sessions based on your availability) to test and refine controllers by having you walk with the NMGA while collecting data similar to the walking tests conducted during your baseline evaluation. They will also ask for your impression on how easy or difficult it feels to walk with the device. The NMGA device is designed to use your muscles first and add stimulation and motor assistance to help you complete the movement during the step. The goal is for the power unit to help complete the movement in a more natural motion.

While you are walking, stair climbing, and standing up and sitting down the study team will record from sensors mounted on the brace or inside your shoes to modify and refine controllers that coordinate stimulation with motorized bracing. The physical therapist will spot you to prevent falls or we can use a harness system during testing and controller tuning. Activities will take place over several sessions each lasting about two hours.

Gait Training

After the research team refines the controller and the NMGA device, there will be six sessions of training preferably over a three-week period to use the device for walking, stair climbing, and sit-to-stand assistance. Gait training will be conducted by the study physical therapist in the gait laboratory, hospital hallways, and surrounding outdoor spaces. The physical therapist will provide standby assistance, monitor your vital signs, record your progress and solicit your feedback on the use of the NMGA. Training will focus on increasing walking speed while maintaining safety, specifically toe clearance in swing, stability in stance, and situational awareness to the surrounding environment. You will provide feedback about when during the training period you feel comfortable putting on, taking off, and using the device without study staff assistance.

Post-Training Assessment

Following training with the NMGA, you will be asked to come to the lab up to six times within a month for final testing. This will include repeating the baseline testing both with and without the device to see if the NMGA device allows you to walk faster, longer and with less effort. You will also be given a questionnaire to assess your satisfaction with the NMGA device. You can either complete the questionnaire in the lab or take it home and mail it back to us. You are free to skip any question you would prefer not to answer. This will complete your participation in the study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- **Skin irritation:** The conductive gels and adhesives used with surface EMG and stimulating electrodes routinely used in clinics and therapy can irritate your skin. This may cause a temporary redness from either the tapes used to secure surface electrodes to your body or the heat generated by the stimulation. Any redness should fade shortly after testing/stimulation and there should be no long-term effects of the heating. There is also a risk of abrasion or pressure from the straps and pads used to secure your legs in measurement devices and the NMGA. The research staff will check your skin at regular intervals and discontinue testing if there is any evidence of irritation or potential skin breakdown. This risk is common, mild and short-lived.

- **Burn and other risks with the use of electricity:** There is a possibility of electrical shock hazard, including electrical burn, whenever electricity is used. Stimulators are

designed to prevent any current flow at levels that could damage your skin, so the risk of an electrical burn has been minimized. Therefore, a burn from a surface electrode is possible, but unlikely. It is also possible to receive a chemical burn if the material inside the battery in the external control unit should leak and come in contact with your skin. The batteries are sealed inside the enclosures of external controllers or other devices used for testing and evaluation, therefore, a chemical burn from a battery is very unlikely. All instrumentation used in the study is tested for current leakage to ensure safety by the safety officer in this study. This risk is very unlikely but could be severe.

- **Discomfort and unpleasant sensation:** You may experience discomfort during electrical stimulation. The stimulus will be adjusted to find comfortable levels. After comfortable levels are found, there should be no discomfort when stimulation is applied. If you experience unpleasant sensation during stimulation, alert the study team and it will be discontinued. In addition, there may be discomfort from wearing the brace. Padding and proper fitting by an orthotist should minimize the chance of discomfort. These risks are uncommon, momentary and mild.

- **Risks to the heart and nervous system:** There is a potential risk of causing an abnormal heart rhythm with electrical stimulation. Therefore, if you have a history of cardiac problems, you will not be a candidate for this study without consulting your cardiologist and informing the research team. This risk is very rare but could be severe.

- **Fractures and falls:** There is a risk of sprain or fracture if you should fall during gait training or evaluation procedures. These risks will be minimized by an overhead harness and/or physical therapist walking and spotting you during all training and evaluation procedures. All experimental procedures will use standard clinical equipment and any external electric or mechanical testing devices will be set up and tested in advance, so the safety officer associated with our research group can qualify their safety. This risk is very rare with experimental precautions but could be severe.

- **Injuries resulting from wearing the NMGA:** There is a risk of sprain due to operation of the motor driven knee joint. In addition, there is a risk of electrical shock from power applied to the motorized joint. The risk of sprain is minimized by hard mechanical stops that limit the device range of knee motion to your own range of motion. Second, the assist mechanism can only provide about a fourth of the normal joint moment ensuring an additional safety factor. Third, the motorized assist mechanism will be within an electrically insulated enclosure protecting you from electrical shock and any potential current leakage. The study orthotist will ensure proper fitting and make sure there are no sharp edges that would cause pressure points, cuts or abrasions. The electrical

safety officer will ensure there is no current leakage between you and the device. This risk is unlikely with the electromechanical design but could be severe.

- **Blood pressure changes and muscle fatigue:** Dizziness associated with lower blood pressure can occur while you are standing and walking. If this occurs, further attempts to walk will be made with your consent only after resting, drinking fluids and consulting a medical professional. Fatigue and shortness of breath can result from walking. The walking required for these studies has been shown to be well below the threshold for such a response for persons with stroke. Although a certain amount of fatigue is anticipated, the experiments will be terminated immediately upon your request if you show any signs of discomfort. Any soreness of the muscles should go away with rest. This risk is uncommon and moderate; however, this risk is no greater than you are exposed to in daily life.

- **Risks to an unborn child:** If you are a female of childbearing age, you should know that risks of the electrical stimulation to an unborn child are unknown. You should avoid becoming pregnant for the time you will participate in this study and immediately inform the study physician or study team if you suspect being pregnant.

- **Other potential discomforts or risks:** One potential risk is that you develop unreasonably high expectations of the NMGA that may lead to depression if your expectations are not met. This is a research and development study and there is no guarantee that the NMGA will improve your walking or any other function. If you should get depressed because of participating in this project, you will be referred for counseling.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

Photographs or videotaping

By signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or video recordings to be made of you by the VA Northeast Ohio Healthcare System while you are participating in this study. Pictures and video recordings of

you are intended for documenting and analyzing your walking and for presentation in scientific journals and at conferences, presentation to Veteran organizations and student visitors. You will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to stop being filmed, photographed or recorded, and may withdraw your consent for up to a reasonable time before the picture or video recordings are used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits from NMGA may include being able to walk faster and farther with less effort with a more normal, safer gait. In addition, you may experience some carry-over therapeutic benefits from training with the NMGA that improves your ability to walk on your own without the device. Secondary benefits may include improved cardiovascular fitness from walking. In addition, the information we get from this study might assist development of devices to improve walking for stroke survivors.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as an ankle brace or peroneal nerve stimulation to prevent drop foot. Alternatively, a device such as Bioness L300 Go can stimulate the peroneal nerve in combination with either knee extensors or flexors. Commercially available motorized robotic devices are designed and used primarily for inhouse rehabilitation, but not as assistive orthotic devices for everyday community use. Other alternative methods for stiff-legged gait correction are performing surgery or chemical nerve block to limit knee extension, however this can compromise knee stability during stance, thus limiting effectiveness of these procedures.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We will include information about your study participation in your medical record.
While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

A description of this clinical trial will be available on 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.

If you are a non-Veteran or a Veteran who does not receive medical care from the VA Northeast Healthcare System, a Notice of Privacy Practices will be provided to you separately and documented.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records relevant to study eligibility.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: The Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO), the VA Institutional Review Board, the Internal Revenue Service (IRS), the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility o you can ask a member of the

research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, [redacted] and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

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Financial Considerations

- You will be reimbursed for cost of travel expenses from and to your place of residency at the current government rate per mile.

- You will be reimbursed for your time and inconvenience at $50 per completed study session. Payments will be made either by electronic transfer to your account or by check sent to your address. You should be aware that the Financial Management System, payments made to you through Austin Financial Services Center, will generate Internal Revenue Service Form 1099 regardless of amount and will be your tax obligation. If this payment is more than $600.00 in any one calendar year, it will be reported to the Internal Revenue Service (IRS) on a 1099 (Miscellaneous Income) form. This form will be issued to you and a copy will be sent to the IRS.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

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Effective Date: November 10, 2022

Financial compensation for such things as lost wages, disability, or discomfort due to an injury may not be available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

[redacted] and

AFTER HOURS:

[redacted].

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is strictly voluntary and refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you terminate your participation in the study, you will not be requested to return for follow-up testing or observation. The research team may continue to review the data already collected on you for the study but will not and cannot collect further information.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

While unlikely, the investigators may stop your participation in this study without your consent, for example, if they think that it will be in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

To answer questions about the research or if you sustain a research related injury contact the following:

- During the Day: [redacted]
- After Hours: [redacted]

For answers to questions about rights as a research participant or to voice a concern or complaint contact the following:

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- The Research Administrative Officer at [redacted]
- The VA Northeast Ohio Healthcare System Patient Representative at [redacted]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Institutional Review Board at [redacted] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Any new findings developed during the course of the research that may affect your willingness to continue participation will be provided to you as it becomes available.
The research team will share data on your progress during evaluation session and when presented for publication.

WHO COULD PROFIT FROM THE STUDY RESULTS?

No payments are being made to investigators. The researchers have submitted invention disclosures related to the device being developed. Data will not be used for commercial profit.

FUTURE USE OF DATA AND RE-CONTACT

Your study data will be retained based on the Veterans Health Administration Records Control Schedule after the study ends. Records will be maintained at the Cleveland VA in locked cabinets and on password protected computers. The research team will have access to the data.

If you express interest in participating in follow up studies, we will use your contact information to re-contact you about additional development and study for the NMGA device.

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Participant Name: _____ Date:_____

Title of Study: Stimulation combined with externally powered motorized orthoses for stroke

Principal Investigator: [redacted] VA Facility: VANEOHS

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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