Participant Name: _____ Date:_____

Title of Study: Customizable cooperative multi-joint control to enhance walking mobility after stroke

Principal Investigator: Nathaniel Makowski, PhD VA Facility: LSCVAMC

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the National Institutes of Health. 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. This study is also being conducted at MetroHealth Medical Center. Up to 30 participants will be enrolled.

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

This study is to determine your eligibility for another study titled “Understanding and Enhancing Human Health and Movement” also being done at the Louis Stokes VA Medical Center (LSCVAMC). This study is will be explained to you in a separate information sheet. Your participation in this research may take place over several days but should last no more than sixteen weeks. Screening may take longer depending on your individual circumstances.

Screening will include a physical examination, review of your medical history, and the evaluations described below will determine if you are physically eligible to participate in surface stimulation and/or in a separate study that would include the surgical implantation of a neuroprosthesis. If you are qualified to volunteer, you will be extended an invitation to enroll.

The purpose of this research is to determine if you qualify for a study that will gather information on the safety and effectiveness of an implanted neural stimulation system. The U.S. Food and Drug Administration (FDA) allows the limited investigational use of the implanted stimulators for persons with limited movement due to weakness because of a neurological disorder, such as stroke.

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research participants.

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

There are no benefits to participating in this study, but if you are eligible and choose to volunteer to enroll in “Understanding and Enhancing Human Health and Movement”, we may be able to help mobilize your lower limbs to enhance your everyday activities.

For a complete description of benefits, see below.

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

You may experience some adverse sensations while the proper levels of current are determined during electrical stimulation.

For a complete description of risks, see below.

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Effective Date: June 13, 2024

Participant Name: _____ Date:_____

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Principal Investigator: Nathaniel Makowski, PhD VA Facility: LSCVAMC

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 Nathaniel Makowski, Ph.D. at LSCVAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is 216-791-3800 x63135.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This is a screening study to determine if you are eligible to enroll in VA study “Understanding and Enhancing Human Health and Movement”.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the screening phase of this project may take place over several days but should last no more than 4 months. Screening may take longer depending on your individual circumstances.

If you successfully complete the screening and evaluation process as described in this consent form, you will be considered for the “Understanding and Enhancing Human Health and Movement” study to receive an implanted device or use surface stimulation to assist walking. This research study is expected to last approximately 5 years and enroll up to 30 people who have hemiparesis.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

After you sign this consent form the study staff will review your medical history to make sure that you do not have any medical problems that would exclude you from being a volunteer in this study.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

If you are a female of childbearing age you will be screened for pregnancy. If you do not want a pregnancy test you must provide documented proof of an effective birth control method. A positive pregnancy test will exclude you from further evaluation.
After your physical examination and reviewing your medical history, you will have assessments done to determine if you would be a good candidate for surface stimulation and/or surgical implantation. You might not have to do all the assessments to determine if you are eligible. Each assessment is described below and will be explained to you before it is done.

Motor and Sensory Evaluation
A doctor or other members of the research team will examine you to assess your current, or "baseline," motor and sensory status. This involves putting your arms and legs in different positions and asking you to make voluntary movements. If you have sufficient control of your muscles, their strength and endurance will be measured by a special machine called a dynamometer. Similarly, the natural electrical activity of your muscles (the electromyogram, or EMG) will be recorded. EMG recording will be done either with surface or intramuscular electrodes, both of which are commonly used in general medical practice. Surface electrodes are small patches of conductive material that stick to the skin over each muscle to be monitored. Intramuscular electrodes are used when more specific recording of your muscle activity is required. They are thin, sterile wires that are inserted with a hypodermic needle after the skin has been properly cleaned. They are left in place for the duration of testing and then removed. Test objects will be pressed or brushed against your skin to determine the extent of your sensation. Your reflexes, coordination and spasticity will also be evaluated by standard methods such as tendon tapping, moving your joints or EMG recording.

Nerve Excitability
The response of your nerves and muscles to small electrical currents will be tested by applying stimulation to the surface of your skin. A trained therapist or other member of the research staff will conduct these tests. Surface electrodes are small patches (typically 2" x 2") of conductive material that are applied to the surface of the skin, similar to electrodes used to record electrical signals from the heart during an electrocardiogram (EKG). Conductive gels or water will be used to improve the contact between the electrode and the skin surface. One to eight sets of these electrodes will be applied at a single time to allow the research team to assess the contraction of a single muscle, or to activate a group of muscles at the same time. Walking may also be tested with surface stimulation as part of the screening process.

If your response to surface stimulation is weak, painful or includes unwanted reflexes, fine wire or thin needle probes will be inserted into your muscles to deliver stimulation. Electrical pulses will be sent through the probes to test if your nerves can be stimulated to produce useful muscle contractions. The wire or needle probes will be removed after the testing is finished. Depending on your level of sensation you may be given a local topical anesthetic or by injection by a trained individual.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

Stimulation will be applied while you are lying on an examination table, sitting in a chair, or performing an activity such as stepping. To further document the quality of your stimulated contractions, your muscle strength and endurance will be measured with a dynamometer. The naturally occurring electrical activity (EMG) of other muscles may also be recorded at the same time to further assess your muscle activity.

Movement Analysis

Baseline information about how you move will be necessary to determine your initial movement ability and if it changes as a result of participation. Movement data can be collected with a system using lightweight markers or other special sensors taped to your skin or clothing. The position of your limbs will be monitored by a video system and the naturally occurring electrical activity of your muscles may be recorded simultaneously as you make various movements or perform activities such as walking. The markers and recording devices will be removed at the end of the test, which will last no more than two hours. Surface stimulation of key muscles may be incorporated during motion analysis to provide additional information on your potential response to having an implant. . Walking may be tested over different types of flooring (e.g. carpet, tile, obstacles) and include standing up, walking, turning, around, sitting down and going up and down stairs. Walking may also be tested on a treadmill while movement is changed to evaluate your balance. This could be done by changing the speed of the treadmill or by gentle pulls from a rope attached to a belt on your waist.

Muscle Conditioning

If you respond to surface stimulation you will have an option for an exercise program using surface stimulation to strengthen and condition your muscles. These exercises may use weights, resistance bands or other exercise equipment. Surface electrodes will be positioned on the surface of your skin to activate the nerves and muscles. The surface electrodes will be connected to an external stimulator customized for your needs. You will be instructed on how to use the stimulator and about the stimulation exercise program you are to perform at home to improve your strength and endurance. Before you take the stimulator home you will be asked to demonstrate how to use the device to show you understand all instructions. You may be asked to keep a daily log of your system use and respond to phone inquiries by the research staff.

Pre-surgical Rehabilitation

You may be asked to practice walking and work on therapeutic activities with the study physical therapist for up to 12 weeks (24 sessions). Each session will be about two hours long. You will be asked to come for therapy about one to three times a week. This training period will help maximize your walking ability before potential participation in “Understanding and Enhancing Human Health and Movement” and confirm that improvements in walking function result from the stimulation and not simply gait training. Walking assessments will be repeated after completing the therapy sessions.

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VANEOHS IRB
Effective Date: June 13, 2024

If you are found to be eligible for the next study and you would like you volunteer, you will be asked to sign another consent for the next study. If you are invited to participate and interested in receiving an implanted neuroprosthetic device, you will move on to an implant study: "Understanding and Enhancing Human Health and Movement".

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

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

- 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.
- Alert the study staff immediately if you feel any pain or discomfort or notice anything abnormal during or after the evaluations.
- Tell the investigator or research staff if you believe you might be pregnant.
- Complete your questionnaires as instructed.
- 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.

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.

Adverse sensation

You may experience discomfort or pain during electrical stimulation while the proper levels of current are being determined. Finding comfortable stimulus parameters should take no more than several minutes per electrode and involves slowly adjusting the stimulation so you can identify tolerable levels. After comfortable levels are found, there should be no additional discomfort or pain when the stimulation is applied.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

Burns and electrical hazards

There is a possibility of electrical shock, including electrical burn, whenever electricity is used to power the instruments necessary to record test results. Measurement instruments are designed with protective devices that try to prevent current flow at levels that could produce tissue damage thereby minimizing the risks of electric shock and/or burns. To further minimize these risks, the safety officer associated with the research group will check all pieces of laboratory instrumentation for electrical safety before they are applied to you. It is also possible to receive a chemical burn if the material inside the batteries of measurement and/or stimulating devices comes in contact with your skin. The batteries are sealed inside cases and contain materials that are less likely to cause chemical burns.

Risks to the heart and nervous system

There is a risk of heart or nervous system problems such as abnormal rhythms or autonomic dysreflexia (sudden increases in blood pressure) with electrical stimulation. The electrical stimulation used in this study is similar to that routinely used on a therapeutic basis in the general medical practice. If you have had a history of cardiac problems, you will not be a candidate without consulting your cardiologist and informing the research team.

Nerve or vessel injury

If nerve excitability or muscle activity is tested with fine wire or needle probes, the usual dangers of any hypodermic injection are present. These include puncture of a blood vessel, irritation of a nerve or breaking of the needle inside the body. Individuals taking blood-thinning agents such as coumadin or aspirin may have increased risk of bleeding. Although it is possible to injure a nerve during probing, there have been no instances of permanent nerve damage from the procedure.

Skin irritation or inflammation

The conductive gels and adhesives used with surface electrodes and the tapes or adhesives used to secure sensors to your body can irritate your skin. You may experience a temporary redness of your skin from the heat generated by electrical stimulation. This redness should fade within a few hours of testing and there should be no long-term effects of the heating. There is also a risk of abrasion or pressure from the surface electrodes, sensors, or the straps and pads used to secure your limbs in measurement devices. If you have any known tape allergies, please inform the research staff. The research staff will check your skin at regular intervals and discontinue testing if there is any evidence of irritation or potential skin breakdown.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

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.

Bone or joint injury
There is a risk of fracture, sprain, and joint or ligament damage during some of the testing procedures. All testing is designed to minimize the stress on the bones, joints, and soft tissues and will be performed by trained professionals experienced with the testing equipment and knowledgeable about the precautions to take while manipulating your extremities. There is also a risk of injury from a fall during maneuvers that might be part of the evaluation procedure. You will be closely supervised by the research staff during these procedures to minimize this risk.

Metabolic testing
Metabolic testing involves using a nose clip and mouthpiece that might cause claustrophobia or discomfort in some individuals. The metabolic tests will be short and they will be stopped if you find them to be intolerable.

Pregnancy risks
The effects of electrical stimulation on an unborn child or a pregnant woman are unknown. It is possible that the electrical currents used to stimulate the nerves and muscles of a pregnant woman could induce premature labor contractions or a miscarriage, cause a birth defect in the unborn child, or result in other unknown or unanticipated side effects in the unborn child and/or mother. If you know or suspect you are pregnant, notify a member of the research team immediately.

EMG
There is a risk of pain, infection, bleeding and bruising where a needle is inserted.

Questionnaires
Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Unanticipated risks
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.

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VANEOHS IRB
Effective Date: June 13, 2024

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, audiotaping, or videotaping

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the VA Northeast Ohio Healthcare System while you are participating in this study. The picture, video, and/or voice recording is intended for educational purposes and may be used in presentations, conferences, publications, or for training.

The study team has also explained that 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, video or voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in the evaluation stage of this research. The procedures described in this consent form will not improve your condition. However, the information we get from this study might help investigators develop newer technologies that may help paralyzed people to move and exercise in the future.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this study will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your research records will be labeled with a code number and will be stored in a protected computer file that only the study team has access to. The paper research records will be kept in a locked filing cabinet in a locked office. Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Identifiersmight be removed from your identifiable private information, and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

A description of the clinical trial that this study is part of 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.

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.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: National Institutes of Health (NIH) (study sponsor), Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO), the VA Institutional Review Board, the local VA medical facility Human Research Protections Program, the Cleveland VA Medical Research and Education Foundation, and Greephire and their contractors– provider of Clincards for payment.

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.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

If you revoke this authorization, Nathaniel Makowski and his 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.

You will be reimbursed for your milage to and from your baseline evaluations and pre surgical rehabilitation sessions at the current standard medical milage rate. If you are unable to provide your own transportation and need to pay a transportation service to take you to and from your study appointments, you will be eligible to be reimbursed up to $6,400 (or about $200 per session).

Payment will be given to you in the form of Clincard, a reloadable debit card. The money will be loaded onto a ClinCard that you will use throughout the entire study. Protect this card like cash. If you lose the ClinCard, please contact the study team, they are able to provide you with a new one that will transfer any monies you have available.

Greenphire ClinCard Reimbursement Program:
Greenphire is a company working together with CVAMREF to manage your compensation and/or transportation. You will be issued a Greenphire ClinCard, which works like a debit card. About once a month, funds will be loaded and approved onto your card. The funds will be available within 1 business day and can be used at your discretion. In order for Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from the study team, including your name, address and date of birth.

All information about you is stored in a secure fashion and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties (including the sponsor) and will be kept completely confidential.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

By signing this consent form, you consent to providing all the before mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program. You may be required to provide your taxpayer ID (Social Security #) if thresholds for IRS (Internal Revenue Service) reporting are met. This will only happen in the event that you receive a total of $600 in a year while participating in any research study at VANEOHS.

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.

Signing this form does not indicate that you have given up any legal rights nor does it release the VA from any liability.

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

DURING THE DAY: 216-791-3800 x 64909
AFTER HOURS: 216-402-0190

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

You have the right to refuse to participate or withdraw from this study at any time without any adverse effects on your health or welfare. The investigator may review data that has already been collected prior to your withdrawal, but cannot collect further information, except from public records, such as survival data.

FOR IRB USE ONLY

VANEOHS IRB
Effective Date: June 13, 2024

Participant Name: _____ Date:_____

Title of Study: Customizable cooperative multi-joint control to enhance walking mobility after stroke

Principal Investigator: Nathaniel Makowski, PhD VA Facility: LSCVAMC

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: Nathaniel Makowski, PhD at 216-791-3800 x 63135.

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 VA Northeast Ohio Healthcare System IRB. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call them at (216) 791-3800 x64658 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the study team 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.

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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VANEOHS IRB
Effective Date: June 13, 2024