Plasticity in the Spinal Cord to Enhance Motor Retraining after Stroke

NCT03645122

June 5, 2023

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: SPINAL PLASTICITY TO REDUCE HAND IMPAIRMENT AFTER STROKE

Principal Investigator: Michael Urbin, PhD_____VAMC: Pittsburgh (646)

LAY TITLE: Altered connections in the spinal cord to reduce hand impairment after stroke

KEY ELEMENTS:

The purpose of this research is to see if noninvasive (meaning no needles or surgery are involved) stimulation improves the ability of signals to travel from brain areas controlling movement to muscles weakened by stroke. Your participation in this study is voluntary.

This research includes multiple visits that involve:

- Magnetic and electrical stimulation
- Magnetic resonance imaging (MRI)
- There are risks to this study that are described in this document. Some risks include: seizure, discomfort, claustrophobia, heating of metal implants, and breach of confidentiality. Most study visits are 3 hours long or less. There are up to 30 visits for testing sessions that involve noninvasive stimulation and one visit for MRI. You will be compensated $15/hour for all study visits. Noninvasive stimulation and MRI sessions will be performed at two different locations. If you are interested in learning more about this study, please continue reading below.

STUDY CONTACT INFORMATION:

If you have a general question and/or any concerns or complaints about this research study, you may call the **study coordinator** at **412-822-3700** or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call the Human Engineering Research Laboratories (HERL) at 412-822-3700. If after-hours or on weekends, then please call 1-866-785-9015 and tell the operator that you are a research subject from the Pittsburgh VA and need to speak with Dr. Urbin. The operator will get in touch with Dr. Urbin or another person listed below who will call you back.

Principal Investigator: Michael Urbin, PhD (412)-822-3692

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Principal Investigator: Michael Urbin, PhD_____VAMC: Pittsburgh (646)

Co-Investigators:

Jen Collinger, PhD	(412)-383-1274
George Wittenberg, MD, PhD	(412)-383-1077
Brad Dicianno, MD	(412)-822-3700

STUDY SPONSOR: Veterans Health Administration. Additional information regarding the study sponsor can be provided upon request.

VA research laboratory:

Human Engineering Research Laboratories
Bakery Square, 4th floor
6425 Penn Avenue, Pittsburgh, PA 15206
(412)-822-3700

PURPOSE OF THE RESEARCH STUDY: People often have difficulty using their hands to do everyday tasks after stroke. **The purpose of this research is to see if noninvasive (meaning no needles or surgery are involved) stimulation improves the ability of signals to travel from brain areas controlling movement to muscles weakened by stroke.** These results may provide information that can be used to develop rehabilitation strategies that improve hand and arm function after stroke.

You are being asked to participate in this research study because you have had a **first-ever stroke** at least six months ago and still have **some hand weakness**, or because you have no neurological impairment. Up to 80 individuals will be asked to participate in this research.

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.

DESCRIPTION OF THE RESEARCH STUDY:

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SCREENING EVALUATION

1. To see if you can take part in this study, we must do the following:

   a. ***Pregnancy test:*** If you could become pregnant, you will need a negative pregnancy test to participate in this study. You will also need to use adequate birth control and promptly tell the study staff in case you do become pregnant.

   b. ***Stimulation pre-test:*** Stimulation that is similar to the type used in the research procedures will be done to be sure that it produces appropriate responses. A magnetic pulse will be applied to your scalp that is directed to a specific brain area, and responses will be recorded.

   c. ***Communication test:*** We may ask you to complete simple tasks or repeat information to ensure that you understand instruction.

   d. ***MRI safety screen:*** Individuals who tell us about certain foreign objects in their body must provide documentation or provide written authorization for the study team to obtain medical records so more information can be obtained. Manufacturer information for any device/implant (for example, a metal plate) you may have will be checked to ensure safety with 3-T MRI. Individuals who do not pass the MR safety screen may still be able to participate in other testing sessions that do not involve MRI.

STUDY PROCEDURES

2. The following include procedures for the study. Please note that none of these procedures are standard of care for people with stroke. These are procedures that are only done for research.

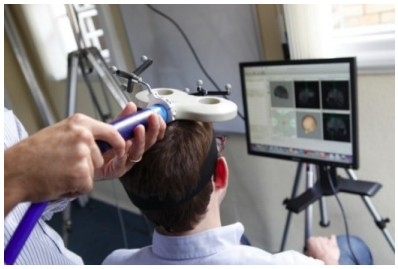
   a. QUESTIONNAIRES: You will complete multiple questionnaires to determine if you are right or left handed and describe your medical history related to stroke. The expected time to complete these questionnaires is 15 minutes.

   b. MEDICAL RECORDS: We may ask you to authorize the release of your medical records related to your stroke history, foreign objects/implants inside of your body, or other conditions which may affect results of the study.

c. MEDICATIONS: We will ask you about certain medications you are currently taking for spasticity (muscle spasms).

d. LAB TESTING: You may participate in up to 30 test sessions, each lasting approximately 2-3 hours or less. We will work with you to schedule time that are convenient for you. Each session will occur at either the Magnetic Resonance Research Center (MRRC) or at the Human Engineering Research Laboratories (HERL). Throughout each testing session, you will be seated. Different types of noninvasive stimulation will be used to record responses from muscles in your hands or arms. Visits will be scheduled based upon the availability of the research team and laboratory space.

Noninvasive stimulation involves magnetic fields or electrical currents



Magnetic Stimulation: A copper coil encased in plastic will be placed over your head or back. When triggered, the device will discharge a magnetic pulse and produce a clicking sound. You may feel a pulling sensation on your skin underneath the area where the coil is placed. You may also feel a small twitch in the muscles of your arm, hand or face. Several pulses will be administered during each testing session. The magnetic stimulator used for this research is made by Magstim Inc. and is an investigational device not currently approved by the FDA.

Electrical Stimulation: A small device or wires will be placed on the surface of your skin that will transmit pulses of electrical current for a fraction of a second. These pulses may produce a vibration or slight pinching sensation, but these sensations only occur for the brief time that the current is applied. The area where the electrical pulses are being placed are designed to activate different parts of the nervous system. The electrical stimulator used for this research is made by Digitimer Ltd. and is an investigational device not currently approved by the FDA.

You will be seated throughout each testing session, but it is important that you remain alert. You may be asked to perform tasks during testing. Breaks will be taken as needed.

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_____**e.** MAGNETIC RESONANCE IMAGING (MRI) SCAN: We may ask you to undergo MRI if it is safe for you to do so. The MRI will take detailed pictures of your brain, providing information about how different brain areas are connected. Individuals who are able to become pregnant will be given a pregnancy test prior to the scan. If pregnant, you will not be scanned. This is the policy of the Magnetic Resonance Research Center.

In the case of an **unanticipated medical finding** during imaging, we will consult with a radiologist and provide you with information to share with your physician. If you cannot have an MRI for safety reasons and you are not pregnant, then you may still complete the non-invasive stimulation portion of this study.

If any data collected are "inadequate" for any reason, we may ask you to repeat the same testing procedures. At the end of the study, your data and study-related information will remain on file at the Human Engineering Research Laboratories. If you participate in the VAPHS Audiology & Speech Pathology Research Registry, data may also be shared with that registry for updating your registry profile. We may contact you in the future about other opportunities to participate in research studies.

STORING DATA FOR FUTURE RESEARCH USE

In the future, study data may be entered into a data repository used in work completed by the Human Engineering Research Laboratories and/or collaborating investigators. No data will be used for future studies until the repository is established and approved by the VA Institutional Review Board and other affiliated IRBs. Data may be transferred outside of the VA for this purpose.

WHAT IS THE PURPOSE OF BANKING MY DATA?

The purpose of entering your data in a repository is to help develop and plan future research studies.

WHAT TYPES OF DATA WILL BE BANKED?

Data from questionnaires, MRI, and other testing sessions may be saved for future use. MRI data contain information about the structure of your brain. Questionnaires include information about whether you are right or left handed and limitations you may have with hand function. Data from other testing sessions contain information about functioning in your nervous system.

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WHERE WILL MY DATA BE STORED AND WHO WILL MANAGE THIS?

All of your data, including that obtained from the Magnetic Resonance Research Center (MRRC), will be stored at the Human Engineering Research Laboratories (HERL) which is part of the VA Pittsburgh Healthcare System. These data will not contain any of your identifiable information. Electronic data will reside on a password protected network. Your paper data will reside at HERL located at Bakery Square, Suite 400, Pittsburgh, PA 15206.

WILL ANY INFORMATION BE STORED WITH ELECTRONIC DATA?

No personal information will be stored with your electronic data. These data will be labeled with a study code unrelated to your personal information.

WHAT WILL HAPPEN TO MY DATA?

Your data will be securely stored until the VA Institutional Review Board authorizes its use for future studies.

HOW LONG WILL MY DATA BE MAINTAINED?

Your data may be stored and maintained indefinitely.

WHO WILL MY DATA BE RELEASED TO?

Data collected from this study will only be released to future research investigators who are authorized to use it for research purposes by the VA Institutional Review Board. It is possible that investigators from outside of the VA may potentially use these data if a Material Transfer or Data Use Agreement is obtained.

WHAT WILL HAPPEN TO MY DATA?

Your data may be used in future research projects but will be identified with a code that does not contain any identifiers such as your initials or date of birth. This code is linked to your identity by members of the

study team who have access to VA-secure identifiable records. Other researchers who receive IRB permission to use these data will only be given the research code, not other identifiers.

WHAT ARE THE RISKS?

There are no known risks regarding future use of your data since no identifiers will be shared.

WHAT ARE THE BENEFITS?

You will not directly benefit. You may however, receive indirect benefit from knowing the contribution you are making to science that may help to advance our understanding of how the nervous system functions and/or recovers from neurological injury.

WHO WILL BE TOLD ABOUT ANY FUTURE RESEARCH RESULTS?

Results may be published in scientific journals. Your identity will not be made known in any published work nor will you receive notification of any published work.

CAN I WITHDRAW MY PERMISSION TO USE MY INFORMATION?

Future use of your data is considered part of this research study. If you would like to withdraw your data in the future, you may submit a request in writing. If you withdraw your consent for use of your data, you may not be able to continue to participate in the research study.

RISKS AND BENEFITS:

Transcranial Magnetic Stimulation (TMS) – Although stimulation techniques used in this study have been used extensively in people for the past 30 years, there are some risks and possible discomforts.

1. There is small possibility that magnetic stimulation can cause a seizure. When we verify your eligibility, questions will be asked to assess your seizure risk.
2. Effects during pregnancy are not well understood. For this reason, individuals who are currently pregnant or are planning to become pregnant in the very near future will not be eligible to participate.

3. It is possible that stimulation can affect certain types of metal implants or foreign objects inside your body. When we verify your eligibility, questions will be asked to assess your risk.
4. Discomforts can include headache or neck pain.

Electrical Stimulation – Electrical stimulation is more easily tolerated in some people than others. Stimulation strength will be increased gradually to allow you to become familiar with it. The potential risks related to electrical stimulation are described below.

1. Temporary pain and/or irritation around the stimulation site.

Magnetic Resonance Imaging (MRI) – MRI is widely used in clinical practice and the risks of MRI are low. There is no exposure to radiation, and contrast is not used. The potential risks related to having an MRI scan are listed below.

1. You may experience anxiety or claustrophobia while in the MRI scanner. If so, you will be able to alert the technician at any point during the scan and it will be stopped.
2. There is a risk of tissue heating and/or loosening of metal objects attached to bone. Standard MRI procedures are not appropriate if there is metal in certain locations within the body (e.g. non-MRI compatible aneurysm clips, foreign body in the eye, or recently placed surgical hardware) or electronic devices (e.g. pacemaker, cochlear implant, Baclofen pump). The MRI scan can interfere with the normal operation of some implanted devices. We collect information about foreign objects and implants to determine if they are safe for use with the type of MRI scan that will be used for this study. Multiple screening interviews will be conducted to identify metal in your body, but it is possible that it could be missed if unreported.
3. There is a potential risk of the strong magnetic field attracting metallic objects toward the magnet (keys, cell phones, jewelry, etc.). You will be asked to leave these items in a locker outside of the MRI room.
4. During the exam, the MRI scanner will make loud noises that could cause discomfort. You will be provided with earplugs during the scan.
5. The rapidly changing magnetic fields used during imaging may stimulate nerves in your body that results in an uncontrolled twitch or sensation around your back and waist. This sensation may

vary from not being present to causing pain. If you experience any type of pain, the scan will be stopped.

6. There are no known risks associated with being scanned during pregnancy. However, it is the policy of the MRRC to provide a pregnancy test using urine analysis to individuals who could become pregnant. If you are pregnant, you will be withdrawn from the study.

There is also the risk that your information may be seen by someone who is not part of the research team, resulting in a breach of confidentiality. To protect your information, an identifiable code will be assigned to your data. Research data are kept in a locked cabinet, and this information can only be accessed by authorized persons.

There may be adverse events or side effects that are currently unknown. Some of these unknown risks could be permanent, severe, or life-threatening. If you believe that the research procedures have resulted in an injury to you, please notify the Principal Investigator or Study Coordinator whose contact information is listed in this consent document.

You will not directly benefit from participating in this study. You may, however, receive indirect benefit from knowing the contribution you are making to science that may help to advance our understanding of how the nervous system functions and/or recovers from neurological injury.

ALTERNATIVES TO PARTICIPATION:

There may be other studies that you qualify for. Talk to your provider about such options. You have no obligation to participate in this research study.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate. Your clinical results from this study will be made available to you upon request.

PREGNANCY: If you are pregnant, planning to become pregnant or nursing, you **cannot** take part in this study. If you can become pregnant (not post-menopausal, have not had tubal ligation (tubes tied) or have not had your uterus or both ovaries removed), you must use an adequate method of birth control. Adequate methods of birth control are hormones (birth control pills or Depo-Provera), an implantable contraception, an IUD (intrauterine device) or double barrier methods (such as a diaphragm plus

condoms). If one of these cannot be used, using contraceptive foam and a condom are recommended. Urine pregnancy tests will be done at the initial visit and during the study. We encourage all women enrolled in this study to use one of the effective birth control methods.

INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent if it is in your best interest, you do not follow the study plan, or you experience a study-related injury. For example, if you experience adverse events or discomfort from stimulation, OR if you are pregnant or plan to become pregnant, you will be withdrawn.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the Department of Veterans Affairs. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA-approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergency as well as medical treatment beyond necessary emergency care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under federal law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please notify the Principal Investigator whose contact information is listed in this consent document. If

compensation is available, the Principal Investigator will provide you with an explanation or where you can obtain further information.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to this research. However, if you are receiving medical care and services from the VA that are not part of this study and you are a Veteran described in federal regulations as a Category 7 Veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

All participants will be compensated for individual testing sessions at a rate of $15 per hour. You will be paid at regular intervals throughout your participation (as often as every visit). Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the VA for study payment. If the total reimbursement for your participation in research is greater than $600 in a year, this may be considered taxable income by the Internal Revenue Service.

Except in limited circumstances, payments issued through VA are generated by Electronic Funds Transfer (EFT) or Direct Express payment cards. Therefore, in order to receive EFT payment associated with your participation in this study, you must be willing to provide banking information to VA, if that information has not already been provided. EFT payments may take up to three weeks. If you do not have a bank account or wish to receive a Direct Express payment card, you will need to provide your social security number. Payment on a Direct Express payment card may take up to six weeks. In addition, due to limitations in the Financial Management System, payments made to you will generate Internal Revenue Service (IRS) Form 1099 regardless of amount. Payments will be reported to the IRS as income and your social security number will be used for this purpose.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

CONFIDENTIALITY AND USE AND DISCLOSURE OF DATA: There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission or 'authorization' for the use and disclosure of information protected by the HIPAA Privacy Rule.

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Principal Investigator: Michael Urbin, PhD_____VAMC: Pittsburgh (646)

The research team working on the study will collect information about you. This includes information learned from the procedures described in this consent form. They may also collect other information including:

- Information from your medical records such as prognoses, progress notes, medications, lab or radiology findings,
- Demographic information such as date of birth, age, race, medical/rehabilitation history,
- Name, address, date of birth, social security number for **study payment**,
- Name, date of birth, height and weight for **MRI**, and
- Name, social security number, date of birth, telephone number, city and state of birth, marital status, legal next of kin, emergency contact, ethnicity (Hispanic or non-Hispanic, Race, and religious preference for your **VA Health Record**, if you do not already have a VA record.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the:

- University of Pittsburgh Magnetic Resonance Research Center (MRRC) for MRI scheduling and safety screening documentation, and
- Other research investigators outside of the VA who collaborate with us for data analysis.

A progress note stating that you are participating in this study will be placed within your medical record. If you do not have a VA medical record, one will be created for you.

In addition, the Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Organization (GAO) may have access to your research records. 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.

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In very unusual cases, your research records may be released in response to an order from a court of law. Also, if the investigators learn that you or someone with whom you are involved is in serious danger of potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law. Finally, you consent to the publication of the study results or release of the data when published, as long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

Confidentiality Risks and Precautions to Decrease Risk: Every effort will be made to ensure that the information about you obtained from this study is kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

Any electronic or hard/paper copies of the information collected about you will be stored in a secure location at the Human Engineering Research Laboratory (HERL). Any copies that contain information that could be used to identify you (such as your name, address, date of birth, etc.) will be stored separate from information that does not contain your identifiers. Only those individuals who are authorized to review your information will have access to it. We will provide your first and last name and phone number to the MRRC **for the purpose of scheduling your MRI scan**.

Your electronic data will be processed and analyzed at the Human Engineering Research Laboratories at VAPHS. This data will not contain any of your personal identifiers.

Your name, date of birth, height and weight may be provided to the MRRC to schedule your MRI scan and may be stored with information regarding your safety screening administered prior to the MRI.

Your name, social security number, date of birth, telephone number, city and state of birth, marital status, legal next of kin, emergency contact, ethnicity (Hispanic or non-Hispanic, Race, and religious preference will be collected to establish your **VA Health Record**, if you do not already have a VA record.

Any electronic or hard/paper copies of the information collected about you will be stored in a secured location. Only those individuals who are authorized to review your information will have access to it.

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Future Use: Future use is part of this study. By signing this form, you are authorizing and permitting uses and/or disclosures of your data for future research purposes (e.g., future studies) as described in this document.

Data will be stored in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

Revocation: You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator at the address below. 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 VA patient to treatment or benefit outside of the study.

Michael Urbin, PhD

HERL, Suite 400, 6425 Penn Avenue, Pittsburgh, PA 15206

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned by you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time. Any study information that has been placed into a repository for us in future research will not expire.

RESEARCH SUBJECTS' RIGHTS

You have read or have had read to you all of the above. Dr. Urbin or his authorized representative has explained the study to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: SPINAL PLASTICITY TO REDUCE HAND IMPAIRMENT AFTER STROKE

Principal Investigator: Michael Urbin, PhD_____VAMC: __Pittsburgh (646)_

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions about to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394.

As long as the study is renewed as required by the Institutional Review Board, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

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_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

Version Date May 16, 2023