Novel Spatial-Motor Approaches to Improve Spatial Neglect and Walking Deficits Post-Stroke

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 15 people with a history of stroke who are being studied at Emory University.

Why is this study being done?
This study is being done to determine the effects of prism adaptation therapy and electrical stimulation on the visual attention, connections between the brain and muscles, and walking ability.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do you have to do if you choose to join this study?
If you are eligible and want to be part of the study, you will participate in about 2-3 sessions lasting up to 4 hours each. Before the session, we will observe your walking and leg strength. During the session, you will be asked to do the following: complete some questionnaires, complete some paper and computer tests, walking assessment and prism adaptation training with electrical stimulation delivered to your arm muscles; noninvasive stimulation will be delivered to your brain to measure the strength of connections within your brain and between your brain / spinal cord and your muscles. Non-invasive brain stimulation (transcranial magnetic stimulation (TMS) will be performed with you seated and standing quietly. These assessments will be repeated after a period of 3 weeks.

How is this study going to help you?
You may not benefit from joining the study. If you are in the study, you will be helping the researchers answer the study question. While there is no direct benefit to you, you may experience short-term improvements in your walking ability and visual attention.

What are the risks or discomforts you should know about before deciding?
All studies have some risks. Some risks are relatively small, like being bored or losing time.

- Risks related to TMS such as headache, scalp pain, toothache, or scalp numbness.
- Prism adaptation treatment, walking training and evaluation sessions may cause discomfort or minor risks.
- At times, the questions may be difficult to answer, and you may become anxious.
- Some are more serious – for this study, these include risk of falls, muscle soreness or injury, fatigue, skin irritation or burns, headaches, dizziness, other risks associated with walking exercise, loss of privacy, and breach of confidentiality with your data.
- A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
Participation in this study is completely voluntary. The alternative is not to participate.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

What Should You Do Next?
Read this form carefully, or have it read to you. Ask questions about any part of the study you are concerned (e.g., time commitment, unfamiliar words, or more details on specific tasks you will be asked to complete). Take time to think about the study parts and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / IIHI Authorization

Title: Novel Spatial-Motor Approaches to Improve Spatial Neglect and Walking Deficits Post-Strokes
IRB #: 00005012

Principal Investigator:
[redacted] PT, PhD.
Associate Professor, Department of Rehabilitation Medicine
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Project Title: Novel Spatial-Motor Approaches to Improve Spatial Neglect and Walking Deficits Post-Stroke**.**
PI Name: Aloba, Olufisayo Olukemi
FOA: [PA21-052]
NIH Appl. ID: 10606908
Application ID: 1 F31 NS131020-01

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to understand how participation in prism adaptation training or walking training in a treadmill changes visual attention and walking dysfunction.

What will you be asked to do?

Study Visit	Activity	Time	Location
Screening	Study eligibility and scheduling	Up to 30 minutes	Via phone
Consent & Baseline (VISIT 1)	Informed consent & Baseline Physical Therapy Assessment	Up to 2 hours	EUH

PRE- and POST Training (Visit 2)	TMS and movement measures before and after prism adaptation training and walking	Up to 4 hours	EUH
PRE and POST Training **⩾3 weeks after** (Visit 3)	TMS and movement measures before and after prism adaptation training and walking	Up to 4 hours	EUH

If you are eligible and want to be part of the study, we will request you to visit our laboratory at Emory for sessions or visits that will last about 2.5 to 4 hours. The researchers will ask you to do the following: answer questionnaires regarding your health and physical activity status, clinical evaluation of your motor and cognitive function, complete some paper and computer tests, walking assessment and prism adaptation training with electrical stimulation delivered to your arm muscles; noninvasive stimulation will be delivered to your brain to measure the strength of connections within your brain and between your brain / spinal cord and your muscles. Non-invasive brain stimulation (transcranial magnetic stimulation (TMS) will be performed with you seated and standing quietly. These assessments will be repeated after a period of 3 weeks.

Evaluation and Training:
The evaluation sessions will be conducted as follows:

Visit 1: The day before starting the PAT OR walking training, we will conduct a series of evaluations to measure (1) clinical tests of leg function, (2) movement patterns while you walk (walking quality), and (3) the severity of stroke and spatial neglect.

(1) Clinical tests of leg muscle function: A physical therapist will check how strong your leg muscles are, your leg function and walking function. In addition, we may ask you to complete some questionnaires about your activity levels, community participation, cognition, etc. This part may take 45 minutes to 1.5 hours.
(2) Measurement of balance and walking function on treadmill: We will measure your sitting then standing balance. Then we will measure how your walking is on a treadmill for about 1-2 minutes using motion sensors placed on your shoulder, back, hip, knee and ankle. While walking, a safety harness suspended from the ceiling will be used for safety. If you are unable to walk, we will measure your sitting then standing balance as you are able to tolerate.
(3) Measurement of severity of Spatial Neglect: If you have spatial neglect, we will measure the severity of your spatial neglect. You will be asked to complete several paper and pencil tests and computer tests to measure the severity of your spatial neglect. This part may take 45 minutes to 1 hour.

Visits 2 & 3:
Noninvasive brain stimulation: Before and after your training sessions, we will measure the strength of the connections between your brain and muscles using something called Transcranial Magnetic Stimulation (TMS). We will record your muscle's responses to TMS pulses through small EMG sensors attached on the skin of your legs and/or arms. We will use one or more large figure 8-shaped coil(s) to deliver very short (less than half a second long) electromagnetic pulses to the top of your head. The coil will touch your head during the stimulation. We will locate the areas of your brain that control the leg and/or hand muscles that we are measuring as well as cognitive regions we are measuring. While the electromagnetic pulses are being delivered, we will monitor your muscle's activity and may provide you with cues to help you better relax the muscle or to lightly activate your muscle. You will hear a click every time the electromagnetic pulse is delivered and may feel a gentle tap on your head. We will deliver single-pulses or a pairing of 2-pulses. Your shoulder, leg, hand, and/or face muscles may twitch in response to the electromagnetic pulse delivered to your brain. In addition, in the same session, we may pair TMS pulses with balance and cognitive tasks.

Measuring muscle activity: As part of the non-invasive brain stimulation (TMS), we will measure your muscle activity. To do so, we will tape electrodes to your skin over certain muscles. The electrodes are the same ones used to monitor heartbeats and are simple adhesive tabs with small metal snaps. These will not be able to shock you. It may be necessary to shave a 3-inch × 3-inch region of hair off the skin in certain areas and/or apply a small amount of gel to your skin. This ensures that the electrodes maintain good contact with the skin. The areas to be shaved will be over the major muscles of the legs, index finger, and possibly the lower back and abdomen. Each skin area will be rubbed clean with an alcohol wipe before applying electrodes. Short electrical leads or wires will be attached to each electrode and plugged into 3 small boxes of electronics which we will strap on your arms and legs using Velcro straps.

Training tasks to be performed:

Prism Adaptation Therapy: You will be asked to perform Prism Adaptation Therapy (PAT) with electrodes attached to your arm for stimulation. The prism adaptation training involves pointing movements while wearing prism goggles for 20 minutes. You will be asked to point at targets on a table and cross out different shapes on paper using a marker pen with your right arm and/or point with your right leg while seated.

Walking: You will also complete multiple 30-seconds to 4-minute bouts of walking on the treadmill or overground at speeds ranging from self-selected to fast speeds (faster than comfortable self-selected speed), with rest breaks between bouts. While walking on a treadmill, a safety harness suspended from the ceiling will be used for safety. The training will take approximately 1.5-2.5 hours including rest breaks. We may measure your walking patterns using motion capture and muscle activity using sensor markers placed on your shoulder, back, hip, knee and ankle. While walking, a safety harness suspended from the ceiling will be used for safety.

If you are unable to walk, we will measure your sitting and standing balance.

Who owns your study data?

If you join this study, you will be donating your data. You will not be paid if your samples or data are used to make a new product. If you withdraw from the study, you will be asked to complete a revocation form that allows you to decide whether we may use the data we have collected up to the point you withdrew from the study.

What are the possible risks and discomforts?

Risk associated with TMS: There is a potential but very rare risk of causing a seizure in people with a history of seizures (e.g., epilepsy). There has never been a confirmed report of a seizure associated with the type of TMS to be delivered in this study (i.e., single, and double pulse TMS). To prevent this risk and exercise additional caution, you are not eligible to participate in this study if you have a history of seizure uncontrolled by medication in the past 6 months. The clicks associated with TMS are loud. To minimize this risk, participants may be asked to wear earplugs during the testing session. Some people experience discomfort, twitches, headache during the TMS. We also exclude you if you have unexplained dizziness or loss of consciousness in the past 6 months. Furthermore, safety standards for the application of TMS have been established and will be followed. Trained operators will follow these standards during this study to minimize the risk.

Risk associated with spatial neglect assessment and prism adaptation are minimal. However, they may include but not limited to becoming frustrated or tired during the study assessments, and administration of the prism adaptation treatment, anxiety, and loss of privacy/breach of confidentiality.

Risks associated with clinical testing, gait training, and motion analyses include falling, fatigue, poor heart rate and blood pressure response to walking and minor skin irritation from the adhesive tape. To minimize risk, you will wear a safety harness during the treadmill testing and will be given a rest break whenever requested. Heart rate will be monitored continuously, and blood pressure will be monitored at rest breaks. If heart rate exceeds 80% of age predicted heart rate maximum, walking will be stopped until it returns to baseline. If your blood pressure exceeds 190/100 mmHg, the session will be stopped, and it blood pressure will be continually monitored until it returns to baseline. Your primary or referring

physician will be notified. Throughout the experiment, the experimenter has access to an emergency safety switch that can be used to stop the treadmill immediately.

Risks associated with electrical stimulation: During electrical stimulation, the potential for equipment malfunction is also present, which might result in burns to the skin. However, the equipment used is reliable and prolonged exposure necessary to cause the risk of skin damage is highly unlikely with our stimulation parameters. After electrical stimulation to the leg or arm muscles, there is a small chance that you may experience some muscle soreness or minor skin irritation. We have over 15 years of experience using electrical stimulation, and we will take all measures to minimize risk.

Will you benefit from the study?

This study is not designed to benefit you directly. Your walking speed or function may improve while you are in this study, but it may not, and it may even get worse. This study is designed to learn more about how prism adaptation training and walking training changes the strength of brain circuits in the visuo-spatial system, walking patterns and function, and strength of circuits that control walking. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will be compensated for your time in this study. You can receive up to $75 for completion of this study. You will receive $25 for the baseline session (visit 1), $25 for the 1st training session (visit 2) and $25 for the 2nd training session 3-weeks later (visit 3). If you do not finish the study, we will compensate you for the visits you have completed. Payment will be through an Amazon, Walmart, or Target gift card at the end of each session.

What are your other options?

If you decide not to enter this study, there is care available to you outside of this research study. For example, you may be able to enroll in walking rehabilitation or physical therapy at a clinic. The study doctor will discuss these with you. You do not have to be in this study to be treated for rehabilitation of walking after a stroke.
If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

How will your private information be protected?

The study staff will keep your identifiable information in a locked cabinet or computer file with restricted access. We will use a study number rather than your name on study records, when we can. Your name and other facts that might point to you will not appear when we present this study or publish results. Only select members of the research staff will have access to your records

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.
The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data with restricted access. We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study. Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Medical Record

If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.
Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

Costs

There are no costs, research or standard of care related, associated with the study. There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty, this is completely voluntary. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your PHI from health care entities and to use and disclose your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:
The IIHI that we will use or disclosed for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Video and images of experimental procedures.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and disclose your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will disclose your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.

The following people and groups will use your IIHI to make sure the research is done correctly and safely:

- Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration
- Public health agencies
- Research monitors and reviewer
- Accreditation agencies

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be disclosed to the new institution and the institution's oversight offices.

Expiration of Your Authorization

Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at:

[redacted], Department of Rehabilitation Medicine, Division of Physical Therapy, Emory Rehabilitation Hospital, [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the IIHI already collected as described in this Authorization. If you revoke your authorization, you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact [redacted] at [redacted]

- if you have any questions about this study or your part in it
- if you have questions, concerns or complaints about the research Contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted]:
- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at [redacted] or [redacted] or [redacted].

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**