Mass General Brigham
Mass General Research Institute

Official Study Title	Effects of Transcranial Electrical Stimulation on Task Performance in Healthy Adults
ClinicalTrials.gov Identifier (NCT)	NCT06995560
Study Sponsor	Massachusetts General Hospital
Principal Investigator	Gary E. Strangman, PhD
Affiliation	Massachusetts General Hospital / Harvard Medical School
Study Type	Interventional Study
Intervention	Transcranial Electrical Stimulation (tES)
Primary Outcomes	ROBoT-r Task Performance (During and Post-Stimulation)
Secondary Outcomes	tES Adverse Effects Questionnaire; fNIRS Hemodynamic Activation (HbD)
Document Type	Study Protocol
Protocol Date	April 4, 2024

Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: Preliminary investigations of transcranial electrical stimulation effects on neurophysiology and behavior

Principal Investigator: Gary Strangman, PhD

Site Principal Investigator:

Description of Subject Population: Healthy volunteers age 18-64

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about how stimulating the brain may affect your ability to perform specific tasks. This may include complex tasks, such as those used in high performance settings like spaceflight.

How long will you take part in this research study?

If you decide to join this research study, it will require between 1 and 7 visits spanning no more than 11 days. Each visit may require up to 3 hours of your time.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen: (1) one or more sessions will familiarize you with the tasks you will be asked to do and the equipment we will use; (2) one or more sessions performing the tasks while undergoing a brain stimulation procedure called transcranial electrical stimulation (tES); during these sessions we will also monitor brain and blood oxygenation using near-infrared spectroscopy (NIRS), brain activity (EEG), heart activity (ECG), respiration, blood pressure, skin temperature, and/or movement (EMG); (3) up to 6 follow-up sessions involving task performance and monitoring but no further brain stimulation. The specifics of your study are listed later in this document.

Why might you choose to take part in this study?

You will not benefit from taking part in this research study. However, we hope to better understand under what conditions tES can improve your performance, and how it affects brain function, with a possible future use to enhance personal performance or to aid patients.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include discomfort associated with the tES procedure, skin irritation from sensors, and fatigue from performing the tasks. NIRS uses low power laser light. As such, there are risks associated with over-exposing your eyes or skin to the lights, or skin irritation beneath the sensors, but we will limit the exposure so as to protect you against these potential risks. A detailed description of side effects, risks, and possible

discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Gary Strangman, PhD is the person in charge of this research study. You can call him/her at **617-724-0662 [M-F 9-5]**. You can also call **Stijn Thoolen, MD at 857-320-8410 [24 hours a day, 7 days a week]** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Stijn Thoolen, MD at 857-320-8410**.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

We are doing this research to help understand the relationship between brain stimulation, brain activity, and the performance of both simple and complex tasks. The goal is to learn how we can utilize brain stimulation to improve human performance in a wide variety of settings.

Who will take part in this research?

We are asking you to take part in this research study because you are healthy, age 18-64 and do not have medical device implants or other contraindications to participating.

Up to 120 healthy volunteers will take part in this research project, which will be divided into multiple sub-studies.

NASA is paying for this research to be done.

What will happen in this research study?

There will be three phases in this research study. You will serve as your own control, so there is no randomization involved.

After enrollment, there will be 3 phases to the study, as follows

Phase 1: You will participate in one or more sessions to practice the tasks you will be asked to perform. You will also become familiar with the brain stimulation and recording equipment that we will use in the study. This process will take up to approximately 3 hours, and will be scheduled on one day, or multiple days, depending on schedule limitations.

Phase 2: After you are familiar with the tasks and equipment, you will come in for one or more brain stimulation sessions. These will take up to approximately 3 hours. During this time, if applicable, you will first be fitted with the recording equipment. This will involve placing sensors on your head and chest, using either stick-on sensors, tape, straps or caps. The specific procedures are as follows:

Near-infrared spectroscopy (NIRS) – We shine light onto your head so we can monitor blood volume and blood oxygen in your brain.
Eletroencephalography (EEG) – small sensors on your head will record the electrical activity from your brain.
Electrocardiography (ECG) – small sensors on your chest record the electrical activity of your heart.
Muscle/activity– small sensors on your face/head record the electrical activity of the muscles around your eyes (EOG) and cheeks (EMG), as well as the movement of your head.
Transcranial electrical stimulation (tES) – We will also position brain stimulation electrodes over the parts of the brain we plan to stimulate. These do not directly touch the head, but are placed on a wet sponge or gel which touches your head.

Once set up, we will then conduct the brain stimulation procedure and ask you to perform the tasks you practiced (in Phase 1) one or more times. During brain stimulation periods, the stimulation may or may not be turned on. The experimenter will be monitoring but, like you, they will not be able to tell when the stimulation is being applied. You may feel tingling in either case. The brain stimulation will not last more than 60 min on a given day.

Phase 3: You may be asked to remain in the lab for a period—or possibly come back to the lab on up to 6 additional days—to perform the tasks you practiced and undergo physiological monitoring additional times. This will help determine how long the brain stimulation may affect your performance. No brain stimulation will be conducted during these sessions.

Phase 1 (familiarization and training) for your substudy will be conducted over _____ day(s) and up to _____ hour(s) each day.

Phase 2 (brain stimulation and recording) for your substudy will be conducted over _____ day(s) and up to _____ hour(s) each day.

Phase 3 (post-stimulation testing) for your substudy will be conducted over _____ day(s) and up to _____ hour(s) each day.

Thus, your participation will involve a total of ____ hours spread over ____ day(s).

How may we use and share your samples and health information for other research?

The health information collected for this study will NOT be used or shared for other research, even if we remove identifiable information like your name, medical record number, or date of birth.

Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We will study information from many people. It could take years before anyone knows whether the results have any meaning. There is a small chance that we could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more.

What are the risks and possible discomforts from being in this research study?

Performance testing: There are no risks associated with the cognitive testing aside from the possibility of fatigue or boredom.

Transcranial electrical stimulation (tES): tES involves applying a mild electrical current to the skin on the head. Most commonly, subjects may experience tingling, itching and/or discomfort beneath the electrodes during stimulation. Less commonly, a subject may become tired, develop a mild headache or, even less commonly, develop mild nausea after stimulation. Rarely, subjects have reported experiencing insomnia. It is also possible the skin could be damaged (a burn) due to inadvertent direct contact of electrodes with the skin, but this is very rare. To minimize or eliminate the potential for these risks or discomforts, we meet or exceed all of the most current safety guidelines: using a very low electrical current, careful inspection and continuous monitoring of all electrodes, limiting the duration of stimulation, and careful positioning and securing the sensors and electrodes.

Near Infrared Spectroscopy (NIRS): NIRS monitoring requires placing a sensor on the skin on your head, and holding it in place with a cap or strap. The procedure does not cause pain or distress, although extended wearing of the device may lead to discomfort due to the mild pressure. The instrument will not significantly limit head motion. The laser light used by the device has very low power, but you should still not look directly at the sensor pad. It has been designated minimal risk by the MGH IRB.

EEG/EMG/ECG/EOG monitoring requires coupling a sensor to the skin via electrodes. This can cause skin irritation.

What are the possible benefits from being in this research study?

You will not benefit from taking part in this research study. Healthy individuals, high-performers such as astronauts, or even patients may benefit in the future from what we learn in this study.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid $35 per hour of active participation in this study. You will also receive parking vouchers if you drive to the study site.

What will you have to pay for if you take part in this research study?

Study funds will pay for all research-related items and services.

What happens if you are injured as a result of taking part in this research study?

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ _____

Hospital Medical Interpreter Date/Time

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____

Name Date/Time

Consent Form Version: 05/09/2022