Title: Neuroplastic Mechanisms Underlying Augmented Neuromuscular Training

Date: 06/04/2021

NCT#: NCT04069520

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 120 people who are being studied, at Emory.

Why is this study being done?

This study is being done to learn more about how the brain works before and after an augmented neuromuscular training program. You are being asked to be in this research study because we want to find out more about how the brain changes as a result of our training program intervention that you are currently participating in the study entitled "Real-time Biofeedback for Injury Prevention Assessed in Virtual Reality".

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. Before you make your decision, you should take time to learn about the study. If there is a possibility you may be pregnant you should not participate in this study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for approximately 6 weeks to 4 months, in order to complete up to 2 separate study visits (1 pre-training visit and 1 post-training visit).The researchers may ask you to do the following at each visit:

- Anthropometrics (height, weight, hand/leg dominance)
- Computer based reaction time tasks
- Questionnaires
- MRI Imaging

You will be compensated for each study visit that you complete.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include loss of privacy, and

breach of confidentiality. 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
Since this is not a treatment study, the alternative is not to participate.

Costs
Participating in this study will not cost you anything other than time and effort. Your insurance will not be billed for any testing associated with this study.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Neuroplastic Mechanisms Underlying Augmented Neuromuscular Training

IRB #: STUDY00001772

Principal Investigator: Gregory D. Myer, PhD; Department of Orthopedics

Sponsor: National Institutes of Health

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

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. If there is a possibility you may be pregnant you should not participate in this study.

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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to learn more about how the brain works before and after an augmented neuromuscular training program.

What will I be asked to do?
These are the things that will happen to you while you are in the study:

1. Anthropometrics: Your height and weight will be recorded. You will also be asked about your hand and leg dominance.

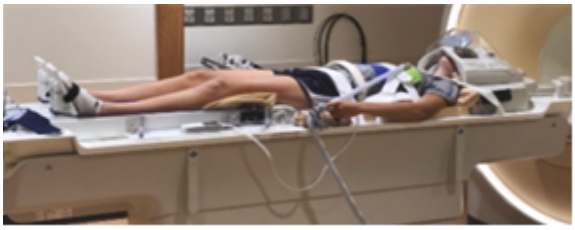
2. Computer reaction time task: You will be asked to look at a computer screen and respond as quickly and accurately as possible to the targets on the screen.

3. Questionnaires: You will be asked to complete a series of non-invasive questionnaires on a tablet/computer pertaining to demographics, general health history and any knee pain.

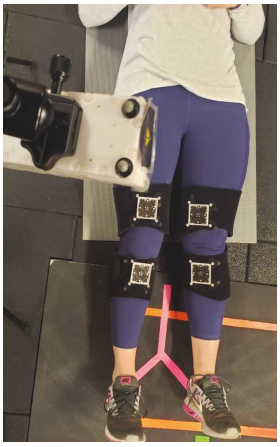
4. MRI Imaging: You will be asked to lie down in a machine that will take images of your brain. For most portions of MR acquisition, you will only be instructed to lie still. For other parts of the acquisition, you will be asked to complete various lower extremity movements such as knee extension/flexion and a combined knee and hip flexion/extension movement. Prior to the imaging appointment, you will be asked to complete a screening questionnaire to ensure that it is safe for you to receive an MRI. For example, if you have any permanent metal dental/orthodontic work, cochlear implant, cardiac pacemakers, recent orthopedic pins/screws/plates, etc., you will not be able to complete this study. A practice session of the different tasks you will be doing while scanned will also be completed just prior to the 'real test scanning' to allow you to ask any questions and be familiar with what we will ask you to do.

    a. Additional MRI Tasks Information:

    During the lower extremity movement tasks we will have you move your legs while we use functional magnetic resonance imaging (fMRI) to look at changes in brain activity. We will ask you to flex and extend your knee (top picture) and flex and extend your knee *and* hip against light resistance (bottom two pictures).



    We may also collect some biomechanics while in the scanner using markers that are attached to Velcro straps around your thighs and calves (shown in the picture below).



Each study visit will last approximately 3 hours. The MRI-specific portion will take no longer than 90 minutes during each visit.

If you sustain a lower extremity injury or concussion you may be asked to repeat your pre-training visit tests as well as participate in longitudinal follow-up brain fMRIs and joint specific structural imaging not lasting more ~45 minutes.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There are no known negative effects from exposure to the magnet or radio waves used in the MRI at this time; however it is possible that harmful effects could be recognized in the future. The tight space of the MRI may make some people feel uncomfortable. One known risk is that the magnet can attract certain kinds of metal. Therefore, we will have all subjects complete a pre-MRI screening questionnaire. If there is any indication from this questionnaire that the MRI is not safe you will not have the MRI testing. The MRI testing will require you to lie on your back and remain still for the duration of the test, which could last up to 90 minutes. Due to the nature of the test, there will be a loud knocking noise that you will hear while the test is being performed. You will be instructed that if at any point during the test you get too uncomfortable, you can signal to the research staff to stop the test immediately.

There is also a minimal risk that the data collected may be viewed by individuals outside the research team. The risk that confidential data may be viewed is relevant for both the written forms and the electronic databases.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. This study is designed to learn more about how the brain works before and after an augmented neuromuscular training program. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

If you agree to take part in this research study, we will pay you $150 ($50 for completing the pre-training testing and $100 for completing the post-training testing) for your time and effort. You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Emory University is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. The participant will need to complete the W9 and will receive the compensation, even if the participant is a minor.

What are my other options?

This study is 100% voluntary. You may elect to not participate in this study or withdraw from the study at any time if you change your mind.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

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

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data to other researchers without your additional informed consent. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

You will be getting a scan for research purposes only. The research does not require health professionals to read the scan. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory 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 Healthcare medical record you have now or any time during the study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include:

- Anthropometrics data
- Answers to any questionnaires
- Data from computer reaction time tasks
- Imaging data

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

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.

The researchers also have the right to stop your participation in this study without your consent for any reason.

These are the expected reasons why the researchers may stop your participation:

- You decide to withdraw from the parent study “Real-time Biofeedback for Injury Prevention Assessed in Virtual Reality”.
- The study team withdraws you from the parent study “Real-time Biofeedback for Injury Prevention Assessed in Virtual Reality” due to non-compliance with the training program.

Contact Information

Contact Dr. Greg Myer at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury, or
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. 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**