Principal investigator: Joyce Gomes

Protocol Title: Assessing Cognitive Improvements, Brain Neuroplasticity and the Role of Genetic Factors After Aerobic Exercise in Sedentary Adults

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Permission to Take Part in a Human Research Study

Title of Study: Assessing Cognitive Improvements, Brain Neuroplasticity and the Role of Genetic Factors After Aerobic Exercise in Sedentary Adults

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Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We ask you to take part in a research study because you are a healthy adult 55 years or older who is not regularly performing physical exercise**.**

What should I know about this research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to see if aerobic exercise can improve the ability of your brain to change and learn (brain plasticity) and improve your cognition or thinking ability. Exercise is effective at improving cognition and supporting brain health, but we still do not fully understand how much exercise is needed or how exercise can improve our cognition. This study will see how exercise may improve cognition and if this is related to how your brain is able to change and learn (brain plasticity).

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 10 weeks for a total of 29 or 31 visits.

You will be asked to take part in the in a pre-test assessment where we will measure your brain plasticity which is how your brain is able to change and learn. We will also measure your cognition or thinking ability and aerobic capacity or fitness, and a take a small sample of blood. Then you will be asked to perform aerobic exercise 3 times per week for 8 weeks. After completing the exercise sessions you will perform a post-test that is the same as your pre-test assessment.

More detailed information about the study procedures can be found later in this document under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are some risks possible from the brain plasticity assessment, most commonly people may have a short lasting minor headache but there are other very rare risks that will be discussed in greater detail.

The American Heart Association recommends regular exercise for all people. However, while exercise may be very beneficial there are some risks such a pain or a muscular problem, or in rare cases chest pain, heart attack or even very rarely, sudden death. To minimize these risk you will be evaluated for your readiness to participate in exercise and will always exercise with a trained member of our study team.

More detailed information about the risks of this study can be found later in this document under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved fitness and feelings of well-being from participating in exercise.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Student Rights

If you are a student, your decision not to participate or to withdraw from the study will not affect your grades or other academic standings at the University of Miami.

Employee Rights

If you are an employee of the University of Miami, your decision not to participate or to withdraw from the study will not affect your employment at the University of Miami.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

PURPOSE

The purpose of this research study is to learn about the effects of exercise on your cognition. Research studies have shown that exercise has beneficial effects on cognition. The goal of this study is to see if 8 weeks of aerobic exercise, in people who currently are sedentary, affects:

- Brain plasticity (the ability of your brain to change and learn)
- Cognitive function (your ability to think and perform mental tasks)

Additionally, we are interested in how your genes may influence your brain plasticity and cognitive response to the exercise training.

Brain plasticity is measured using a non-invasive type of brain stimulation called transcranial magnetic stimulation (TMS). TMS uses a magnetic field to cause activity in the brain. The magnetic field is produced by a coil that is held next to your scalp. In this study, we will use TMS to create activity in your brain. We will measure your brain's response to the activity. This is how we measure brain plasticity.

TMS is used in this study as an investigational device, which means that TMS is being investigated in research studies, and is currently not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study.

Transcranial Magnetic Stimulation (TMS) is a device approved by the Food and Drug Administration (FDA) used in the treatment depression and is approved for individuals with depression. TMS is used to elicit small intensity electrical currents in the brain that allow one to assess brain activity, or transiently modify brain activity. In this study, however, TMS is considered an investigational device because it is not being used as a treatment, and rather to assess brain activity in people who are neurologically healthy.

If you decide to be in this study, you will be one of about 80 people in this research study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (305) 243-0741.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

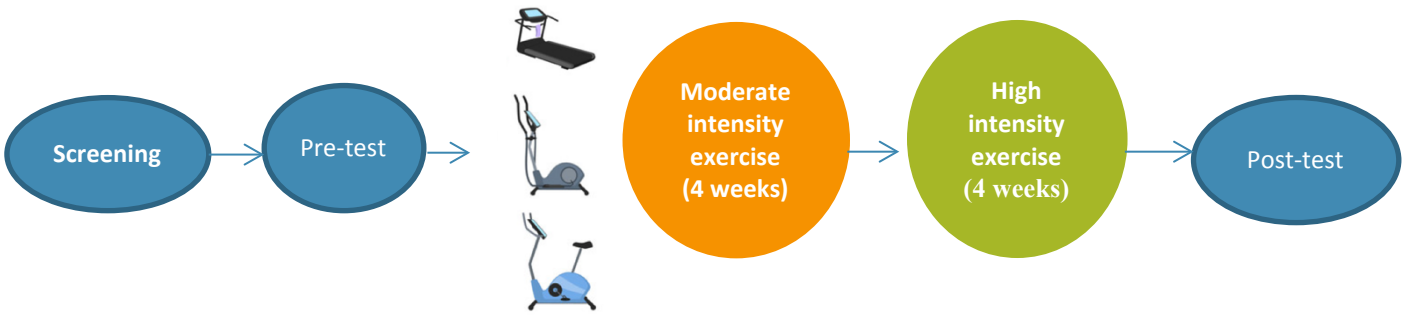
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 80 people here will be in this research study.

What happens if I say yes, I want to be in this research?

You will be approached by a member of the study team. You will be given information about the study and then screened for eligibility. If you are interested in the study we will enroll you, and then procedure with our testing procedures including a measure of brain plasticity and cognition. Then you would exercise 3x per week with a member of our study team for 8 weeks. Upon completion you would repeat the assessment of brain plasticity and cognition again.



Visit #1: Screening process (estimated time: 40 minutes)

- Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. Some of these procedures may be performed on the phone, but at least one visit in person will be necessary. For this research study, the screening procedures include:
    - Your demographic information. For example your age and occupation.
    - Your medical history and any medication that you may be currently taking.
    - TMS screening and description of the study and overview of the inclusion and exclusion criteria.
    - Physical ability readiness questionnaire and vital signs.
    - Physical Activity Level using the International Physical Activity Questionnaire (IPAQ) and self-report body mass index (BMI) measurement

Research Procedures: If you qualify to take part in this research study you will undergo these research procedures.

Visit #2 Pretest assessment- Part 1 Assessment of Brain Plasticity, Blood Sample, and Gait and Postural control assessment (estimated time: 3 hours)

- Blood sample collection for genetic testing
    - We will collect approximately 20 mL (a little over 1 tablespoon) of blood through a needle in your arm.
- TMS Brain Plasticity Procedures
    - We will place 2 electrodes on your hand. These electrodes are used to record electrical activity in your muscles and nerves. We will record signals from the electrodes while the electromyography (EMG) is in place during the TMS testing.
    - A member of the research team will place a coil that is about the size of a shower head against your head.
    - The coil is made of wires that are covered in plastic.
    - The coil will be held firmly, but comfortably, against your scalp.
    - The coil produces a magnetic field that will briefly affect your brain. The magnetic field is about the size of the tip of your finger.
    - You will know that the magnetic field is on because you will hear a clicking noise. You might feel a tap or a pinch at the place that we are holding the coil. You may also feel a twitch of your face or scalp muscles.
    - We will apply single “pulses” TMS to the area of your brain responsible for movement in your hand. There are times that your fingers will twitch when the magnetic pulse is given. This movement will be measured by the EMG. This helps us measure the strength of TMS that we use to stimulate your brain. In addition to the single pulses of TMS, you will receive Thetaburst Transcranial Magnetic Stimulation (TBS). TBS is like TMS except that the trains of magnetic pulses will be close together in a rapid sequence over a short period of time. We will measure how your brain responds to the TBS by using single pulses of TMS. Study staff will ask you to respond to a TMS side

effect questionnaire before and after this TMS session. You will be asked to wear ear plugs during the TMS sessions.

- Gait and postural assessments
    - You will perform tests of physical function such as sitting down in a chair and getting up, as well as standing and walking. During one of the walking tests, you will be asked to do a mental task that requires you to count backwards.

Visit #3 Pretest assessment- Part 2 Cognitive and Exercise Testing (estimated time: 1.5 hours)

- Cognitive test battery
    - We will do paper and pencil test to assess your cognition.
- Exercise Testing
    - You will perform a progressive shuttle walking test along the 10-meter course, keeping to the speed indicated by the bleeps on the audio recording to assess your aerobic capacity.
- Exercise Questionnaires
    - You will answer questionnaires about your knowledge of exercise and activity levels.

Visits #5-16: Physical Exercise Intervention-Moderate Intensity (estimated time per visit: 60 minutes 3 times per week for a total of 4 weeks of Moderate Intensity Exercise)

- We will assess your blood pressure and heart rate after you sit for 3 minutes.
- We will put a heart rate monitor around the lower part of your chest.
- You will choose to perform exercise on a bike, elliptical, or treadmill. You will do a total 60 minutes of aerobic exercise at a moderate intensity. All of your sessions will be supervised by a trained member of our study team.
- We will reassess your heart rate after you finish exercise.

Visits #17-28: Physical exercise Intervention-High Intensity (estimated time per visit: 60 minutes for 3 times per week for a total of 4 weeks of High Intensity Exercise)

- We will assess your blood pressure and heart rate after you sit for 3 minutes.
- We will put a heart rate monitor around the lower part of your chest.
- You will choose to perform exercise on a bike, elliptical, or treadmill. You will do a total 60 minutes of aerobic exercise at a high intensity. All of your sessions will be supervised by a trained member of our study team.
- We will reassess your heart rate after you finish exercise.

* Exercise sessions may be scheduled at the University of Miami (Miller School of Medicine Wellness Center or Coral Gables Campus), whichever location is most convenient for you.

Visit #29 Posttest assessment- Part 1 Assessment of Brain Plasticity and Blood Sample (estimated time: 3 hours)

- You will repeat the brain plasticity measure using TMS, blood sample, and Gait and Postural control assessment exactly as performed on visit #2.

Visit #30 Posttest assessment- Part 2 Cognitive and Exercise Testing (estimated time: 1.5 hours)

- You will repeat the cognitive, exercise testing, and exercise questionnaires exactly the same as you did on visit #3.

Optional Testing Procedures and Visits:

- An additional testing combining TMS and EEG (electroencephalogram) during pre and post testing will be offered to participants. This testing is performed to gather information about direct measure of neuronal activity. This would add approximately two hours to each visit.

Additional Visits:

Visit #4: TMS/EEG pretesting measure: In addition to the TMS Plasticity Measure procedure, an EEG cap will be placed at the beginning of the session and will remain on for the duration of the visit. You will be seated during the test for about 2 hours.

Visit #31: TMS/EEG post testing measure: You will repeat the procedure described in the pretesting.

I agree to participate in the Optional Testing Procedures and Visits.

Yes ☐ No ☐

_____ _____

Name of Patient Date (dd-mm-yyyy)

_____

Signature

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to come to all study visits and be compliant with the exercise training.

What happens if I say yes, but I change my mind later?

You can leave the research at any time, it will not be held against you.

Any data we have already collected this time will still be used for study related purposes.

Is there any way being in this study could be bad for me? (Detailed Risks)

Because of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

TMS Side Effects:

More Common Side Effects

Pain:
As many as 20-40% of subjects undergoing TMS experience headaches, that is up to 4 in 10 participants. You may have pain, such a headache, pain in your face or pain in your neck during or after TMS. We will offer you acetaminophen (Tylenol) or ibuprofen if you experience pain.

Rare Side Effects:

Seizures:
TMS may sometimes cause a seizure. This is rare and occurs in less than 1 in 1000 participants. A seizure may be thought of as a convulsion where a person's body shakes. Many seizures are not like this. Some have very mild symptoms. If you have a seizure, we have emergency equipment and you will receive immediate medical care.

Experiencing a seizure caused by TMS does not mean that you will have another seizure. Participants who had seizures from TMS have not had any continued seizure related health problems.

Hearing problems:
TMS produces a loud clicking sound. It is possible that you could experience a temporary change in your hearing or ringing in your ears. Wearing earplugs will prevent the risk of hearing changes.

There is one report of someone whose hearing protection fell out who experienced permanent hearing loss from TMS. You will have earplugs in place during the TMS. This will reduce the noise to prevent the risk of hearing problems.
We will ask you to let us know immediately if:

- your earplugs loosen
- your earplugs become detached
- your earplugs fall out

You will be promptly referred for auditory assessment if you experience hearing loss, ringing in the ear or ear fullness following completion of TMS.

Syncope (Fainting):
It is possible that you could faint during the TMS. This happens in less than 1% of people. Fainting can happen if you are anxious, nervous or have not eaten. You should immediately tell the study staff if you feel:

- Dizzy
- Lightheaded
- That you might pass out

If you have the above symptoms, the TMS will be stopped. You will be monitored until you are feeling better.

Memory:
TMS could cause changes in your memory, your attention and your thinking. These changes would be very mild. If this occurs you will experience these changes temporarily. These changes happen very rarely.

Mood:
TMS could cause changes in your mood. These changes happen very rarely, and you will be monitored throughout the study. In case this happens to you, the TMS will be immediately stopped.

Dental Pain:
Rarely, some participants have reported dental pain. Please tell the study team member if you have pain. The TMS will be immediately stopped. Your dental pain may indicate you should see a dentist.

Pregnancy:
Because the effects of TMS on the developing fetus are not known, you may not participate in this study, if you are pregnant. The use of the study device may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study. In order to reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable for use during this study. If, during this study, you become pregnant, you should notify the study doctor as soon as possible. Your participation in this study will end.

Electroencephalography (EEG): There are no risks associated with an EEG. The test is painless and safe.

Risks of Gait and Postural assessment, Exercise Testing and Physical Exercise
Potential risks of gait and postural assessment, physical exercise and exercise testing include fatigue, muscle strains, sprains, muscle soreness and light-headedness. There are possible, but infrequent complications of the training exercises such as dizziness, fainting, fall, irregular heartbeat, and very rarely, heart attack, cardiac arrest, or death.

A trained study team member will supervise you at all times during these tests. There will always be someone from the study team who is trained in Basic Life support or Cardiopulmonary Resuscitation (CPR) and First Aid on site during exercise sessions. Typically, muscle soreness is temporary and is resolved within a few days, but if muscle soreness persists, we will do our best to accommodate a "make up" session.

The standard procedure for handling emergencies at both locations where the exercise sessions will take (University of Miami Wellness Center [Medical Campus and Coral Gables campus] is to call 911 (emergency response system).

Blood draw risks: Drawing blood may cause temporary pain from the needle stick, bruising or swelling at the site, and rarely, infection or fainting.

Electromyography (EMG):
The sticky pads used for the test may cause skin irritation or redness. Taking the sticky pads off causes discomfort like when taking off a Band-Aid.

Neuropsychological (Cognitive) Testing:
You may feel tired or frustrated during the cognitive tests, and will be given breaks as needed.

Psychological Stress
Some of the questions we will ask you as part of this study may make participants feel uncomfortable. You have the option to refuse to answer any of the questions and take a break at any time during the study.

Unforeseeable Risks

There may be unforeseen risks that the investigators are unaware of. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

You or your insurance company may be responsible for medical costs of participating in this research study. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay.

What if I get hurt as a result of my participation in this study?

If you are hurt or get sick as a result of being in this study, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality. Your information will be shared with the sponsor of this study, if any. Organizations that may inspect and copy your information include the University of Miami IRB and other representatives of this organization. Your information may be looked at and/or copied for research, regulatory or other purposes by:

- The Food and Drug Administration (FDA);
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes;
- other organizations collaborating in the research;
- your health care providers.

Will the information collected be used in future research?

Data will be stored indefinitely at Lois Pope Life Center located at 1095 14th Terrace, 1st Floor, Miami, FL 33136. Data will be stored in a secured area within a locked cabinet accessed by only IRB-approved personnel. Blood samples will be stored indefinitely at the John P. Hussman Institute for Human Genomics, University of Miami located at 1501 NW 10th Ave, Miami, FL 33136.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if the study team thinks it is not safe for you to continue or you do not show up for study visits.

You cannot withdraw your samples and information from studies that have already begun. We cannot get samples and information back once they are shared with other researchers. Also, it may not be possible to remove your genetic information from scientific databases once it has been distributed.

What else do I need to know?

If you agree to take part in this research study, we will pay you a total of $120 ($60 after completing the baseline assessment and $60 upon completing the full study) for your time and effort. Additionally, we will pay you for parking or transportation costs of $2 per visit (parking payments will be given at the end each week based on the number of study visits attended).

This study also involves genetic testing. Genes control how your body grows and changes, and how your body reacts to certain things. Genes are what we get from our parents that help make our bodies what they are. For example, eye and hair color depend on the genes we received from our parents. Genes are made up of DNA (deoxyribonucleic acid), which can be collected from blood, saliva, or other tissue samples. We want to find out how genes work in your response to exercise on your cognition and brain plasticity measure. It may be true that some people are more likely to respond differently exercise or brain plasticity measurements because of their genes and we would like to learn more about this.

As part of this study, a blood sample will be obtained and DNA from your blood sample will be purified. As part of this research project, your DNA will be studied in an effort to find out how your genes are related to your responses to exercise. Because we do not know how the results of this DNA study relate to your individual health, the results of the research will not be given to you or your study doctor without your permission. These results will also not be placed in your medical records.

We will not tell you what we find out about your genes. For example, we might find out that you have a certain kind of gene. We may know that if people have this gene, they sometimes get a certain disease or do not respond to treatment. You could have a gene that makes it more likely that you will have a health problem. However, that does not mean you will get that health problem. You should ask the study team or a genetic counselor if you have any questions about genetic research.

Your sample will not be stored with your name or other identifying information and health information linked to it. We will not share your name, or other information that identifies you, unless it is required by law. Since your genetic sample is linked to identifying information, should you choose to withdraw your consent to use the sample at a later date, please contact the study team. The study team will remove your sample from the research and immediately destroy it so that it can no longer be used. Please understand that part of your sample may have been used prior to the withdrawal of your consent.

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

• Health insurance companies and group health plans may not request your genetic information that we get from this research.

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies, group health plans, and employers as outlined above must follow this law. Please note that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Instead of being in this research study, your choices may include to not participate.

Any blood, urine, tissue, or other biological specimens obtained for the purposes of this study become the exclusive property of the University of Miami. The University of Miami may retain, preserve, or dispose of these specimens and may use these specimens for research which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research, with your identifiable information or samples, gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You will likely have to pay for those additional services yourself.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Permission to Take Part in a Human Research Study

Title of Study: Assessing Cognitive Improvements, Brain Neuroplasticity and the Role of Genetic Factors After Aerobic Exercise in Sedentary Adults – **Option B**

Principal Investigator: Dr. Joyce Gomes-Osman, PT, PhD
Department: Physical Therapy and Neurology
Phone Number: Office Phone: (305) 284-2632, Cell Phone: (786) 376-6844 (24-hour number)
Email Address: j.gomes@miami.edu

Study Contact Name: Jordyn Rice, PT, DPT
Study Contact Telephone Number: Lab Phone (305) 912-7871, Cell Phone: (702) 349-7632
Study Contact Email: j.rice5@umiami.edu

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We ask you to take part in a research study because you are a healthy adult 55 years or older who is not regularly performing physical exercise and have expressed interest in participating in an exercise program that can be done safely at home.

What should I know about this research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to see if aerobic exercise can improve the ability of your brain to change and learn (brain plasticity) and improve your cognition or thinking ability. Exercise is effective at improving cognition and supporting brain health, but we still do not fully understand how much exercise is needed or how exercise can improve our cognition. This study will see how exercise may improve cognition and if this is related to how your brain is able to change and learn (brain plasticity).

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 10 weeks for a total of 29 or 31 remote sessions.

You will be asked to take part in the in a pre-test assessment where we will measure your brain plasticity which is how your brain is able to change and learn. We will also measure your cognition or thinking ability and aerobic capacity or fitness. Then you will be asked to perform aerobic exercise 3 times per week for 8 weeks. After completing the exercise sessions, you will perform a post-test that is the same as your pre-test assessment.

More detailed information about the study procedures can be found later in this document under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are some risks possible from the brain plasticity assessment, most commonly people may have a itching or tingling sensation that will be discussed in greater detail.

The American Heart Association recommends regular exercise for all people. However, while exercise may be very beneficial there are some risks such a pain or a muscular problem, or in rare cases chest pain, heart attack or even very rarely, sudden death. To minimize these risks, you will be evaluated for your readiness to participate in exercise and will always be supervised by a trained member of our study team.

More detailed information about the risks of this study can be found later in this document under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved fitness and feelings of well-being from participating in exercise.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Student Rights

If you are a student, your decision not to participate or to withdraw from the study will not affect your grades or other academic standings at the University of Miami.

Employee Rights

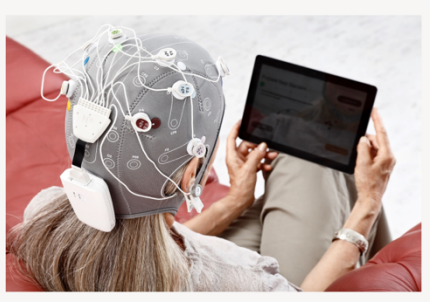
If you are an employee of the University of Miami, your decision not to participate or to withdraw from the study will not affect your employment at the University of Miami.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

PURPOSE

The purpose of this research study is to learn about the effects of exercise on your cognition. Research studies have shown that exercise has beneficial effects on cognition. The goal of this study is to see if 8 weeks of aerobic exercise, in people who currently are sedentary, affects:

- Brain plasticity (the ability of your brain to change and learn)
- Cognitive function (your ability to think and perform mental tasks)



Brain plasticity is measured using a non-invasive type of brain stimulation and monitoring with real-time remote supervision called transcranial alternating current stimulation (tACS). tACS uses a painless and very minimal low intensity electrical current that is applied to the scalp through a cap that you will wear. We will use tACS to create activity in your brain. We will measure your brain's response to the activity with non-invasive surface Electroencephalography (EEG) electrodes that are inside the cap. This is how we measure brain plasticity.

The device used in this study is the STARSTIM®-Home (Neuroelectrics, Inc), a tACS home-based system that recently received Food and Drug Administration (FDA) approval to treat patients with Major Depression Disorder (MDD) due to COVID-19 related restrictions.

In this study, tACS is considered an investigational device because it is not being used as a treatment, but rather to assess brain activity in healthy people. tACS is currently not approved by the FDA for the way that it is being used in this research study.

If you decide to be in this study, you will be one of about 80 people in this research study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (305) 243-0741.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

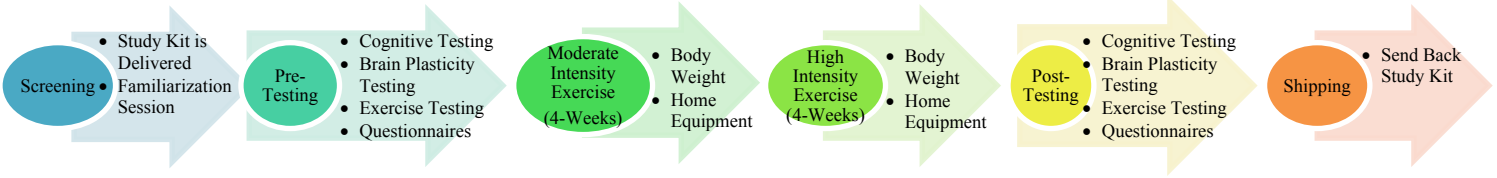
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 80 people here will be in this research study.

What happens if I say yes, I want to be in this research?

You will be contacted by a member of the study team. You will be given information about the study and then screened for eligibility. If you are eligible and interested in the study, you will sign this informed consent form. Once you are enrolled in the research study, we will send you a study kit to your home. You will participate in a familiarization session over a Zoom video call to ensure you know how to properly use the items in the study kit and then we will proceed with our testing procedures, including a measure of brain plasticity and cognition. The program requires that you exercise under the supervision of a member of our study team, 3 times per week for a total of 8 weeks. Upon completion you would repeat the assessment of brain plasticity and cognition again. Once this is concluded, you will send back the study kit using the provided return label.



<u>Session #1a: Screening process (estimated time: 40 minutes)</u>

- Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. These procedures will be performed using a secured video call. For this research study, the screening procedures include:
  - Your demographic information. For example, your age and occupation.
  - Your medical history and any medication that you may be currently taking.
  - tACS screening and description of the study and overview of the inclusion and exclusion criteria.
  - Physical ability readiness questionnaire and vital signs (blood pressure, heart rate).

- Physical Activity Level using the International Physical Activity Questionnaire (IPAQ) and self-report your height and weight to calculate your body mass index (BMI).

Research Procedures: If you qualify to take part in this research study you will undergo these research procedures. A study kit will be mailed to your place of residence.

Session #1b Familiarization Session- Review items delivered to place of residence using secured zoom (audio and video)

- Heart rate monitor and activity tracker
  - How to put on and take off the heart rate monitor and activity tracker
- Blood pressure
  - How to take blood pressure using an automatic blood pressure machine
- Oxygen saturation
  - How to use a pulse oximeter to measure your oxygen levels
- STARSTIM device and tablet
  - How to put on and take off the STARSTIM cap (tACS/EEG) and use the tablet
- Practice how to log into secured zoom for testing and exercise sessions

Session #2 Pretest assessment- Part 1 Assessment of Brain Plasticity, Exercise Testing, and Gait and Postural control assessment (estimated time: 3 hours)

- tACS/EEG Brain Plasticity Procedures
  - You will join a video call session with a trained study member. The study member will walk you through the set-up process for the test.
  - You will be asked to put on the STARSTIM cap.
  - A low intensity electrical current is applied to the scalp and the EEG electrodes in the cap measure your brain's response.
- Gait and postural assessments
  - You will perform tests of physical function such as sitting down in a chair and getting up, as well as standing and walking. A study member will teach you how to set up a small space in your home to complete this test. They will confirm your address and phone number. You will need a chair and materials provided to you in the study kit. During one of the walking tests, you will be asked to do a mental task that requires you to count backwards.
- Exercise Testing
  - You will perform a 1-minute sit-to-stand test. A study member will confirm your address and phone number in the event that the video connection is interrupted. They will then guide you in putting on your heart rate monitor, taking your blood pressure, oxygen saturation, and explain the test to you. During the test you will be asked to sit down and stand up several times during 1-minute.

Session #3 Pretest assessment- Part 2 Cognitive Testing (estimated time: 1.5 hours)

- Cognitive test battery
  - We will do a test using a secured video call to assess your cognition.
- Exercise Questionnaires
  - You will answer questionnaires about your knowledge of exercise and activity levels.

Sessions #4-16: Physical Exercise Intervention-Moderate Intensity (estimated time per visit: 60 minutes 3 times per week for a total of 4 weeks of Moderate Intensity Exercise)

- You will log on to a secured zoom video call and confirm your location and phone number to the study member.
- You will put on a heart rate monitor and activity monitor.
- You will assess your blood pressure, oxygen saturation, and heart rate after you sit for 3 minutes and report measurements to the study member. You will also complete a daily exercise screening with the study member.
- You will choose to perform exercise using equipment you have at your place of residence or utilizing body weight exercise given to you by the study member. The study member will guide you through the exercise session. You will warm up for 5 minutes, do a total 50 minutes of aerobic exercise at a moderate intensity, with 10 minutes for water breaks and rest built into the session, and you will cool down for 5 minutes. The total session will last about 60 minutes. All of your sessions will be supervised by a trained member of our study team during the entire session.
- You will reassess your blood pressure, oxygen saturation, and heart rate after you finish exercise.

Sessions #17-28: Physical exercise Intervention-High Intensity (estimated time per visit: 60 minutes for 3 times per week for a total of 4 weeks of High Intensity Exercise)

- You will log on to a secured zoom video call and confirm your location and phone number to the study member.
- You will put a heart rate monitor and activity monitor.
- You will assess your blood pressure, oxygen saturation, and heart rate after you sit for 3 minutes and report measurements to the study member You will also complete a daily exercise screening with the study member.
- You will choose to perform exercise using equipment you have at your place of residence or to perform exercises that do not require equipment that will follow an exercise plan that will be given to you by the study member. The study member will guide you through each exercise session. You will warm up for 5 minutes, do a total 50 minutes of aerobic exercise at moderate to high intensity, with 10 minutes of water breaks and rest built into the session, and you will cool down for 5 minutes. The total session will last for about 60 minutes. All of your sessions will be supervised by a trained member of our study team during the entire session.
- You will reassess your blood pressure, oxygen saturation, and heart rate after you finish exercise.

Session #29 Posttest assessment- Part 1 Assessment of Brain Plasticity, Exercise Testing, and Gait and Postural control assessment (estimated time: 3 hours)

- You will repeat the brain plasticity measure using tACS/EEG, Exercise testing, and the Gait and Postural control assessment exactly as performed on session #2.

Session #30 Posttest assessment- Part 2 Cognitive (estimated time: 1.5 hours)

- You will repeat the cognitive and exercise questionnaires exactly the same as you did on session #3.
- You will send back the study kit using the pre-paid shipping label.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to attend all study sessions and be compliant with the exercise training.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

Any data we have already collected this time will still be used for study related purposes.

Is there any way being in this study could be bad for me? (Detailed Risks)

Because of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

tACS/EEG Side Effects:

Possible Side Effects:

Itching and tingling:

You may experience a mild itching and/or tingling sensation at the start period of the assessment which typically fades away after a few seconds.

Temporary Redness:

You may have some redness under on your scalp from the cap, which is temporary.

Pregnancy:

Because the effects of tACS on the developing fetus are not known, you may not participate in this study, if you are pregnant. The use of the study device may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby) or nursing infant. Therefore, if you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study. In order to reduce the risk of pregnancy, you must use an effective method of birth control while you are participating in this study. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable for use during this study. If, during this study, you become pregnant, you should notify the study doctor as soon as possible. Your participation in this study will end.

Electroencephalography (EEG): There are no risks associated with an EEG. The test is painless and safe.

Risks of Gait and Postural assessment, Exercise Testing, and Physical Exercise

Potential risks of gait and postural assessment, physical exercise and exercise testing include fatigue, muscle strains, sprains, muscle soreness and light-headedness. There are possible, but infrequent complications of the training exercises such as dizziness, fainting, fall, irregular heartbeat, and very rarely, heart attack, cardiac arrest, or death.

A trained study team member will supervise you at all times during these tests. Typically, muscle soreness is temporary and is resolved within a few days, but if muscle soreness persists, we will do our best to accommodate a “make up” session.

The standard procedure for handling emergencies is to call 911 (emergency response system) and provide them your current location.

Neuropsychological (Cognitive) Testing:

You may feel tired or frustrated during the cognitive tests. You will be given breaks as needed.

Psychological Stress

Some of the questions we will ask you as part of this study may make participants feel uncomfortable.

You have the option to refuse to answer any of the questions and take a break at any time during the study.

Unforeseeable Risks

There may be unforeseen risks that the investigators are unaware of. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

You or your insurance company may be responsible for medical costs of participating in this research study. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay.

What if I get hurt as a result of my participation in this study?

If you are hurt or get sick as a result of being in this study, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages, and other damages caused by injury are not available.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality. Your information will be shared with the sponsor of this study, if any. Organizations that may inspect and copy your information include the University of Miami IRB and other representatives of this organization. Your information may be looked at and/or copied for research, regulatory or other purposes by:

- The Food and Drug Administration (FDA);
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes;
- other organizations collaborating in the research;
- your health care providers.

Will the information collected be used in future research?

Data will be stored indefinitely in our electronic data capturing system, REDCap, and at Lois Pope Life Center located at 1095 14th Terrace, 1st Floor, Miami, FL 33136. Data will be stored in a secured area within a locked cabinet accessed by only IRB- approved personnel

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if the study team thinks it is not safe for you to continue or you do not show up for study sessions.

You cannot withdraw your samples and information from studies that have already begun. We cannot get samples and information back once they are shared with other researchers. Also, it may not be possible to remove your genetic information from scientific databases once it has been distributed.

What else do I need to know?

If you agree to take part in this research study, we will pay you a total of $120 in the form of a gift card, upon completing the full study, for your time and effort.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will know that I can download a copy of this consent form after I sign it and may request a printed copy mailed to my address.*

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Permission to Take Part in a Human Research Study

Title of Study: Assessing Cognitive Improvements, Brain Neuroplasticity and the Role of Genetic Factors After Aerobic Exercise in Sedentary Adults – **Option B**

Principal Investigator: Dr. Joyce Gomes-Osman, PT, PhD
Department: Physical Therapy and Neurology
Phone Number: Office Phone: (305) 284-2632, Cell Phone: (786) 376-6844 (24-hour number)
Email Address: j.gomes@miami.edu

Study Contact Name: Jordyn Rice, PT, DPT
Study Contact Telephone Number: Lab Phone (305) 912-7871, Cell Phone: (702) 349-7632
Study Contact Email: j.rice5@umiami.edu

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We ask you to take part in a research study because you are a healthy adult 55 years or older who is not regularly performing physical exercise and have expressed interest in participating in an exercise program that can be done safely at home.

What should I know about this research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to see if aerobic exercise can improve the ability of your brain to change and learn (brain plasticity) and improve your cognition or thinking ability. Exercise is effective at improving cognition and supporting brain health, but we still do not fully understand how much exercise is needed or how exercise can improve our cognition. This study will see how exercise may improve cognition and if this is related to how your brain is able to change and learn (brain plasticity).

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 10 weeks for a total of 29 or 31 remote sessions.

You will be asked to take part in the in a pre-test assessment where we will measure your brain plasticity which is how your brain is able to change and learn. We will also measure your cognition or thinking ability and aerobic capacity or fitness. Then you will be asked to perform aerobic exercise 3 times per week for 8 weeks. After completing the exercise sessions, you will perform a post-test that is the same as your pre-test assessment.

More detailed information about the study procedures can be found later in this document under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are some risks possible from the brain plasticity assessment, most commonly people may have a itching or tingling sensation that will be discussed in greater detail.

The American Heart Association recommends regular exercise for all people. However, while exercise may be very beneficial there are some risks such a pain or a muscular problem, or in rare cases chest pain, heart attack or even very rarely, sudden death. To minimize these risks, you will be evaluated for your readiness to participate in exercise and will always be supervised by a trained member of our study team.

More detailed information about the risks of this study can be found later in this document under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improved fitness and feelings of well-being from participating in exercise.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Student Rights

If you are a student, your decision not to participate or to withdraw from the study will not affect your grades or other academic standings at the University of Miami.

Employee Rights

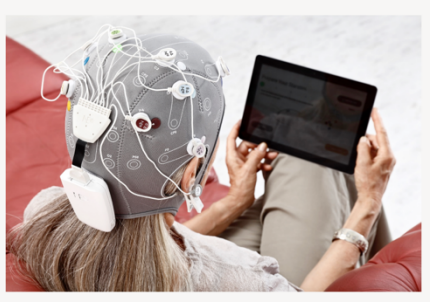
If you are an employee of the University of Miami, your decision not to participate or to withdraw from the study will not affect your employment at the University of Miami.

Detailed Information: The following is more detailed information about this study, in addition to the information listed above.

PURPOSE

The purpose of this research study is to learn about the effects of exercise on your cognition. Research studies have shown that exercise has beneficial effects on cognition. The goal of this study is to see if 8 weeks of aerobic exercise, in people who currently are sedentary, affects:

- Brain plasticity (the ability of your brain to change and learn)
- Cognitive function (your ability to think and perform mental tasks)



Brain plasticity is measured using a non-invasive type of brain stimulation and monitoring with real-time remote supervision called transcranial alternating current stimulation (tACS). tACS uses a painless and very minimal low intensity electrical current that is applied to the scalp through a cap that you will wear. We will use tACS to create activity in your brain. We will measure your brain's response to the activity with non-invasive surface Electroencephalography (EEG) electrodes that are inside the cap. This is how we measure brain plasticity.

The device used in this study is the STARSTIM®-Home (Neuroelectrics, Inc), a tACS home-based system that recently received Food and Drug Administration (FDA) approval to treat patients with Major Depression Disorder (MDD) due to COVID-19 related restrictions.

In this study, tACS is considered an investigational device because it is not being used as a treatment, but rather to assess brain activity in healthy people. tACS is currently not approved by the FDA for the way that it is being used in this research study.

If you decide to be in this study, you will be one of about 80 people in this research study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (305) 243-0741.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs.

Please call the HSRO at 305-243-3195 if:

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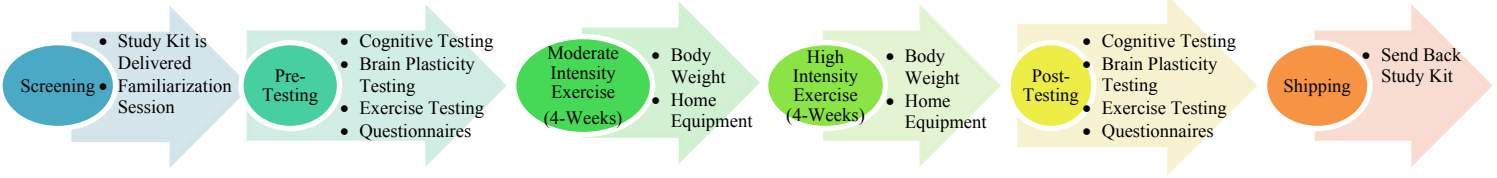
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 80 people here will be in this research study.

What happens if I say yes, I want to be in this research?

You will be contacted by a member of the study team. You will be given information about the study and then screened for eligibility. If you are eligible and interested in the study, you will sign this informed consent form. Once you are enrolled in the research study, we will send you a study kit to your home. You will participate in a familiarization session over a Zoom video call to ensure you know how to properly use the items in the study kit and then we will proceed with our testing procedures, including a measure of brain plasticity and cognition. The program requires that you exercise under the supervision of a member of our study team, 3 times per week for a total of 8 weeks. Upon completion you would repeat the assessment of brain plasticity and cognition again. Once this is concluded, you will send back the study kit using the provided return label.



<u>Session #1a: Screening process (estimated time: 40 minutes)</u>

- Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. These procedures will be performed using a secured video call. For this research study, the screening procedures include:
  - Your demographic information. For example, your age and occupation.
  - Your medical history and any medication that you may be currently taking.
  - tACS screening and description of the study and overview of the inclusion and exclusion criteria.
  - Physical ability readiness questionnaire and vital signs (blood pressure, heart rate).

- Physical Activity Level using the International Physical Activity Questionnaire (IPAQ) and self-report your height and weight to calculate your body mass index (BMI).

Research Procedures: If you qualify to take part in this research study you will undergo these research procedures. A study kit will be mailed to your place of residence.

Session #1b Familiarization Session- Review items delivered to place of residence using secured zoom (audio and video)

- Heart rate monitor and activity tracker
  - How to put on and take off the heart rate monitor and activity tracker
- Blood pressure
  - How to take blood pressure using an automatic blood pressure machine
- Oxygen saturation
  - How to use a pulse oximeter to measure your oxygen levels
- STARSTIM device and tablet
  - How to put on and take off the STARSTIM cap (tACS/EEG) and use the tablet
- Practice how to log into secured zoom for testing and exercise sessions

Session #2 Pretest assessment- Part 1 Assessment of Brain Plasticity, Exercise Testing, and Gait and Postural control assessment (estimated time: 3 hours)

- tACS/EEG Brain Plasticity Procedures
  - You will join a video call session with a trained study member. The study member will walk you through the set-up process for the test.
  - You will be asked to put on the STARSTIM cap.
  - A low intensity electrical current is applied to the scalp and the EEG electrodes in the cap measure your brain's response.
- Gait and postural assessments
  - You will perform tests of physical function such as sitting down in a chair and getting up, as well as standing and walking. A study member will teach you how to set up a small space in your home to complete this test. They will confirm your address and phone number. You will need a chair and materials provided to you in the study kit. During one of the walking tests, you will be asked to do a mental task that requires you to count backwards.
- Exercise Testing
  - You will perform a 1-minute sit-to-stand test. A study member will confirm your address and phone number in the event that the video connection is interrupted. They will then guide you in putting on your heart rate monitor, taking your blood pressure, oxygen saturation, and explain the test to you. During the test you will be asked to sit down and stand up several times during 1-minute.

Session #3 Pretest assessment- Part 2 Cognitive Testing (estimated time: 1.5 hours)

- Cognitive test battery
  - We will do a test using a secured video call to assess your cognition.
- Exercise Questionnaires
  - You will answer questionnaires about your knowledge of exercise and activity levels.

Sessions #4-16: Physical Exercise Intervention-Moderate Intensity (estimated time per visit: 60 minutes 3 times per week for a total of 4 weeks of Moderate Intensity Exercise)

- You will log on to a secured zoom video call and confirm your location and phone number to the study member.
- You will put on a heart rate monitor and activity monitor.
- You will assess your blood pressure, oxygen saturation, and heart rate after you sit for 3 minutes and report measurements to the study member. You will also complete a daily exercise screening with the study member.
- You will choose to perform exercise using equipment you have at your place of residence or utilizing body weight exercise given to you by the study member. The study member will guide you through the exercise session. You will warm up for 5 minutes, do a total 50 minutes of aerobic exercise at a moderate intensity, with 10 minutes for water breaks and rest built into the session, and you will cool down for 5 minutes. The total session will last about 60 minutes. All of your sessions will be supervised by a trained member of our study team during the entire session.
- You will reassess your blood pressure, oxygen saturation, and heart rate after you finish exercise.

Sessions #17-28: Physical exercise Intervention-High Intensity (estimated time per visit: 60 minutes for 3 times per week for a total of 4 weeks of High Intensity Exercise)

- You will log on to a secured zoom video call and confirm your location and phone number to the study member.
- You will put a heart rate monitor and activity monitor.
- You will assess your blood pressure, oxygen saturation, and heart rate after you sit for 3 minutes and report measurements to the study member You will also complete a daily exercise screening with the study member.
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- You will reassess your blood pressure, oxygen saturation, and heart rate after you finish exercise.

Session #29 Posttest assessment- Part 1 Assessment of Brain Plasticity, Exercise Testing, and Gait and Postural control assessment (estimated time: 3 hours)

- You will repeat the brain plasticity measure using tACS/EEG, Exercise testing, and the Gait and Postural control assessment exactly as performed on session #2.

Session #30 Posttest assessment- Part 2 Cognitive (estimated time: 1.5 hours)

- You will repeat the cognitive and exercise questionnaires exactly the same as you did on session #3.
- You will send back the study kit using the pre-paid shipping label.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to attend all study sessions and be compliant with the exercise training.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you.

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tACS/EEG Side Effects:

Possible Side Effects:

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You may experience a mild itching and/or tingling sensation at the start period of the assessment which typically fades away after a few seconds.

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Electroencephalography (EEG): There are no risks associated with an EEG. The test is painless and safe.

Risks of Gait and Postural assessment, Exercise Testing, and Physical Exercise

Potential risks of gait and postural assessment, physical exercise and exercise testing include fatigue, muscle strains, sprains, muscle soreness and light-headedness. There are possible, but infrequent complications of the training exercises such as dizziness, fainting, fall, irregular heartbeat, and very rarely, heart attack, cardiac arrest, or death.

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There may be unforeseen risks that the investigators are unaware of. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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- The Food and Drug Administration (FDA);
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes;
- other organizations collaborating in the research;
- your health care providers.

Will the information collected be used in future research?

Data will be stored indefinitely in our electronic data capturing system, REDCap, and at Lois Pope Life Center located at 1095 14th Terrace, 1st Floor, Miami, FL 33136. Data will be stored in a secured area within a locked cabinet accessed by only IRB- approved personnel

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if the study team thinks it is not safe for you to continue or you do not show up for study sessions.

You cannot withdraw your samples and information from studies that have already begun. We cannot get samples and information back once they are shared with other researchers. Also, it may not be possible to remove your genetic information from scientific databases once it has been distributed.

What else do I need to know?

If you agree to take part in this research study, we will pay you a total of $120 in the form of a gift card, upon completing the full study, for your time and effort.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will know that I can download a copy of this consent form after I sign it and may request a printed copy mailed to my address.*

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent