Partnered Rhythmic Rehabilitation in Prodromal Alzheimer's Disease

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Title: Partnered Rhythmic Rehabilitation for Enhanced Motor-Cognition in Prodromal Alzheimer's Disease
Short Title: PARTNER
Principal Investigator: [redacted]

Sponsor: National Institute on Aging

You Are Being Asked to Be in a Research Study

For people with early or mild memory complaints, treatment options to prevent declined function are extremely limited. In people with early or mild memory complaints, which we call 'mild cognitive impairment', people may have trouble physically doing things while also thinking, which is necessary for many activities in daily life. This problem might be helped by doing activities that challenge the mind and the body at the same time, so we have developed interventions for this: Partnered rhythmic rehabilitation (PRR), and a Walking Program, both targeting fitness, cognition, mobility and social engagement and which may prevent future functional problems in memory.

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 66 people who are being studied at Emory.

Why is this study being done?
This study is being done to answer the question: What effects will different types of exercise have on the ability to think and move around at the same time? You are being asked to be in this research study because you have been diagnosed with mild cognitive impairment.

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.

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 a minimum of 4 study visits and will attend physical activity classes over 12 months. The first visit will be to determine if you are eligible and the remaining 3 visits are to obtain study information. You will participate in a blood draw, lie in a scanner and perform some mental tasks and some physical tasks. Study visits will take approximately 2.5 to 5 hours for all aspects (MRII, blood draw, assessments, questionnaires). Due to the multiple components, scheduling constraints, and possibility for fatigue, study visits may be split into two days if all required activities cannot be completed on the same day. We will ask you to fill out some questionnaires about how you feel as well as your health and behaviors. We will ask you about your height, weight, resting blood pressures, medications, health history, and about musculoskeletal symptoms at exercise sessions. You will have an assessment of the arteries in your neck, also called carotid artery We will use a sound wave machine or an ultrasound to see if you have hardening of the arteries. We will also measure the degree of hardening of the arteries in your finger and arm. You will have a brain scan, also called MRI, three times during the study (baseline, 3 months and 12 months). The digital pictures of your brain will give us information about your brain and the blood circulating into the various brain areas. A blood sample will be drawn to measure inflammatory biomarkers in the blood that can provide more information about your health and circulation. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. You may enjoy the physical activity classes. You may make friends with others in the group classes. You may or may not benefit from the experience in the study.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The physical activity that is being tested may not work any better than regular care. 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. The most common risks and discomforts expected in this study are:

Neuropsychological (memory and thinking) assessments may be accompanied by anxiety, frustration and overall fatigue.

The attachment and removal of a blood pressure cuff, cuffs for venous occlusion, and pressure probes on the neck may cause mild discomfort. Blood draws may be associated with a small bruise at the site of the needle insertion, and on rare occasions, fainting and infection. Brain imaging may cause boredom and minimal reversible back pain, anxiety or panic reactions.

The less common risks and discomforts expected in this study are: the conductive gel used for the ultrasound procedure may cause a transient skin reaction. Inflation of the cuff for a prolong period may be associated with discomfort, tingling, and discoloration of the skin/bruising.

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.

Alternatives to Joining This Study
Because this is not a treatment study with a drug therapeutic or device, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures.
There is more information in the cost section below.

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.

Title: Partnered Rhythmic Rehabilitation for Enhanced Motor-Cognition in Prodromal Alzheimer's Disease

Principal Investigator: [redacted]
(a) [redacted]
Emory University School of Medicine
(b) Center for Visual and Neurocognitive Rehabilitation
Atlanta VA Health Care System

Sponsor: National Institute on Aging

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

Before making your decision:

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

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

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 determine how different types of physical activities done over a year affect your ability to move and think at the same time. We will also try to understand why people get better at thinking and doing at the same time after doing these activities by administering blood draws, brain activity scans and mental tasks.

What will I be asked to do?
If you are eligible and want to be part of the study, you will participate for 4 study visits and will attend physical activity classes over 12 months. We will ask you about your height, weight, resting blood pressures, medications, health history, and about musculoskeletal symptoms at exercise sessions. You will be assigned to one of two types of physical activity randomly, which is like flipping a coin. The researchers will ask you to do the following: The first visit will be to determine if you are eligible and the remaining 3 visits are to obtain study information. These visits will take place right before you start your physical activity, at 3 months after your start your physical activity class and then again at 12 months. You will participate in a blood draw, lie in a scanner and perform some mental tasks and some physical tasks. We will ask you to fill out some questionnaires about how you feel as well as your health and behaviors. You will have an assessment of the arteries in your neck, also called carotid artery. We will ask you not to eat for at least 2 hours before

this test. We will use a sound wave machine or an ultrasound to see if you have hardening of the arteries. There is no radiation during the ultrasound assessment. We will also measure the degree of hardening of the arteries in your finger and arm. To do so, we will apply a small blood pressure cuff on your arm and inflate it for 5 minutes. We will then release the pressure from the cuff. We will measure the degree of change in the arteries before and after the cuff inflation. These will be done three times during the 1 year period.

We will measure the blood flow in your arm with ultrasound. You will be asked to lie still during the test. The measurement requires a blood pressure cuff to be inflated so that it feels very tight for 5 minutes. The blood pressure cuff will then release. Finger probes may be attached on one finger of both hands. They will continuously record the blood flow in the fingertips. This test will take about 30 minutes and this assessment will be conducted 3 times during this study.

You will have a brain scan, also called MRI, three times during the study (baseline, 3 months and 12 months). The MRI will provide us with detailed information about the health of your brain. The MRI does not use x-rays or radiation. The MRI scans will take about 50-70 minutes. Before you have the scan, you will be asked to remove all metal objects (like earrings or watches) from your body. Throughout the exam, there will be loud thumping noises coming from the wall of the scanner. Earplugs will be provided to help reduce the noise. You may feel a warming sensation in your body during the MRI. You must lie still on a padded table during the scan. The digital pictures of your brain will give us information about your brain and the blood circulating into the various brain areas.

A blood sample will be drawn to measure inflammatory biomarkers in the blood that can provide more information about your health and circulation. Blood will be drawn 3 times during the study period. For the screening visit we will draw 15mL (1 tablespoon) and for all other visits we will draw up to 65mL (4.5 tablespoons) of blood.

Additionally, you may be asked to participate in a focus group for older adults, meeting one instance, to discuss attitudes related to this study and the research process. The focus group will be audio tape recorded.

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. Your blood will be stored indefinitely, and may be used for research purposes by Emory and non-Emory researchers for other research purposes. If you chose to have your samples withdrawn, no further testing will be done, and your samples will be destroyed. Results of any analysis that have already been performed, however, will remain part of the study records.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.
The study will take time. The physical activity that is being tested may not work any better than regular care. 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.
The most common risks and discomforts expected in this study are:

The physical activities could lead to being tired, or feeling lightheaded. There is a very low risk of developing delayed onset muscle soreness. There is a small risk of losing your balance but we will be monitoring you and will try to prevent any events like this.

Neuropsychological assessment may be accompanied by anxiety, frustration and overall fatigue.

The attachment and removal of a blood pressure cuff, cuffs for venous occlusion, and pressure probes on the neck may cause mild discomfort. Blood draws may be associated with a small bruise at the site of the needle insertion, and on rare occasions, fainting and infection. That typically resolves in 2-3 days.

Brain imaging requires the participant to stay still and lie down for prolong time which may cause boredom and minimal reversible back pain. Because of the closed space and noise, undergoing an MRI may be associated with anxiety or panic reactions.

If you participate in the focus group, there is also the risk of breach of confidentiality. Everyone will be asked not to discuss the information shared in the focus group with others, but this cannot be guaranteed because the other participants are not required by law to maintain confidentiality.

The less common risks and discomforts expected in this study are:

In rare instances, the conductive gel used for the ultrasound procedure may cause a transient skin reaction. The procedure will be stopped in that case. Inflation of the cuff for a prolong period may be associated with discomfort, tingling, and discoloration of the skin/bruising.

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?

If you are in the study, you will be helping the researchers answer the study question, which might benefit others in the future. You may enjoy the physical activity classes and might feel better after each class. You may make friends with others in the group classes. You may or may not benefit from the experience in the study.

Will I be compensated for my time and effort?

You will get $50 for each completed study visit where you participate in tests, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $200 total, if you complete all study visits.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. The study doctor will discuss these with you. You do not have to be in this study to be treated for some trouble with memory.

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 deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

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.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

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: your MRI, and your vascular function reports.

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.

In Case of Injury

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

If you believe you have become ill or injured from this study, you should contact [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. "Negligence" is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study drug [or device, as appropriate] or a study procedure, the sponsor will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory employee.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs. Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study. You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

***Due to the COVID-19 pandemic, we are implementing a telehealth approach to administering several of our cognitive and motor assessments in this study. One of the main benefits of telehealth is that we can reduce the time that you will be in the clinic and to reduce risk of potential exposure and transmission of pathogens, helping to ensure your safety.
Although there are benefits of telehealth, there are some difference between in-person visits and telehealth, as well as some risks. For example, there may be technical difficulties or interruptions in using a video conferencing tool, others may get access to our private conversations, and stored data could be accessed by unauthorized parties. However, we will make every reasonable and appropriate effort to eliminate confidentiality risks associated with our telehealth meetings. It is important for you, as a participant, to find a private place for our session where you will not be interrupted and to protect the privacy of our session on your device. If you get injured from performing the assessments, Emory will help you get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. We will make every effort to eliminate your risk of any falls or injury by reviewing the safety of your environment before administering assessments.

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. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

- Imaging, blood draws, mental testing, physical testing.

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

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

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

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

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

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

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

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The NIH is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

  Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

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

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data are correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

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

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
[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 a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

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**