Partnered Dance Aerobic Exercise as a Neuroprotective, Motor and Cognitive Intervention in Parkinson's Disease

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U.S. Department of Veterans Affairs
Atlanta VA Health Care System

Informed Consent Template Version 1-21-2019

Consent to be a Research Subject

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 102 people who are being studied at the Atlanta VA Health Care System.

Why is this study being done?

This study is being done to show that exercise may slow brain cell death also known as "neurodegeneration" in humans with Parkinson's Disease. You are being asked to be in this research study because you have been diagnosed with Parkinson's Disease.

Do you have to be in the study?

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

What do 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 16-months, which will include Training for 3 months with bi-weekly visits and Maintenance for 13 months with weekly visits. The researchers will ask you to participate in either a Partnered Dance Aerobic Exercise (PDAE) or a Walking Aerobic Exercise (WAE), answer questions about your medical and behavioral history, complete physical assessments, test of vascular health, and lie in a scanner in three visits before, during and after the trial.

***Due to the COVID-19 pandemic, we are implementing a telehealth approach to reduce the time that you will be in the clinic. We will ask you to answer questions about your health and behavioral history remotely. We will work with you to determine if you can do any of the dancing or walking remotely based on several factors that may impact your ability to participate safely from a remote location.

How is this study going to help you?

If you are in the study, you will be helping the researchers who are looking at how exercise may be neuroprotective in humans with Parkinson's Disease. Neuroprotection is an effect that may result in saving, recovering or regenerating the nervous system cells, structure and function.

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

The study will take time. The Aerobic Exercise that is being tested may not work any better than regular care and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time or feeling a little tired and some are more serious. For this study, some risks include exposure to magnetic fields, possible feeling of claustrophobia, exposure to loud noise, dizziness, faintness, discomfort for blood pressure cuff, discomfort to probe over artery, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the RISKS section of this document.

Alternatives to Joining This Study

There are no alternative treatments and/or procedures to those offered in this research study.

What Should I Do Next?

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

TITLE: Partnered Dance Aerobic Exercise as a neuroprotective, motor and cognitive intervention in Parkinson's disease

PRINCIPAL INVESTIGATOR: Madeleine E. Hackney, PhD

SPONSOR'S NAME: Department of Veteran Affairs

PURPOSE:
You are being asked to volunteer in a 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 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.

The purpose of this research study is to learn how exercise affects the brain. Testing will take place at the Atlanta VA Health Care System (AVAHCS) and at Emory University Wesley Woods Health Care Center (WWHC). You are being asked to be in this research study because you have been diagnosed with Parkinson's Disease. We will recruit up to 102 patients who are 40-89 years old. The results of this study should help improve our understanding of how brain changes during exercise

CLINICALTRIALS.GOV:
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 WILL I BE ASKED TO DO?:
Visits will take place at Atlanta VA Decatur Research Center (GRECC) (3101 Clairmont Road Atlanta GA 30329), Atlanta VA Health Care System Movement Studies Lab (MSL) (1670 Clairmont Road NE Decatur GA 30033), and Wesley Woods Health Care Center (WWHC)

(1841 Clifton Road NE, Atlanta GA 30307). The table below is an overview of the study activities. A full description of the activities follows the table.

Overview of Study Activities:

Visit	**Activity**	**Location**	**Time**
Baseline Assessment*	Consenting, Motor/cognitive Testing, Vascular Function Test, Randomization & MRI	GRECC and WWHC	2- 3 hours
Training Phase (3 Months)	PDAE/WAE	GRECC and WWHC	90 Minutes 2x/week
3 Month Assessment*	Motor/cognitive Testing, Vascular Function Test, and MRI	GRECC and WWHC	2-3 hours
10 Month Safety Screening	Vascular Function Test, Motor/Cognitive Testing, PD symptom tests	GRECC and WWHC	2-3 hours
Maintenance Phase (13 Months)	PDAE/WAE	GRECC and WWHC	90 Minutes, 1x/week or 3x/month
16 Month Assessment*	Motor/cognitive Testing, Vascular Function Test, and MRI	GRECC and WWHC	2-3 hours
Monthly Check-in	OFF time assessment and review, medication change review, falls this month review	GRECC and WWHC	30 mins.

**may be split into two visits on two separate days within 3 days of each other.*

***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 differences 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.

Baseline Assessment:
Once consented and before you may begin this study, we will complete screening forms and ask health questions that will determine your eligibility including that you can safely complete the magnetic resonance imaging (MRI) scan. There are medical conditions in which MRI is not safe for you. If it is revealed that you are not eligible or if it is not safe for you to participate in this study, we will not continue. At this visit, we will randomly assign you (like flipping a coin) to either PDAE or WAE.

Medical, Behavioral and Motor Testing:
At the WWHC or GRECC, we will ask you questions about your medical history and medications, stress levels, and mood. We will also:

- Check your blood pressure, height, and weight
- Test your thinking abilities with cognitive (brain function) evaluations designed to examine your memory, processing speed and attention
- Test your physical condition with walking and balance assessments. Walking and balance assessments may be videotaped to be evaluated later by another researcher who does not know what group you have been assigned to.
- Test your cardiovascular function.

Each visit will take approximately 2 hours. You may take rest breaks between tasks or stop at any time.

MRI Scan:

- At WWHC you will go into the MRI scanner, where you will lie still for up to 90 minutes while we take pictures of your brain.
- MRI is safe and non-invasive. During scanning, you will be exposed to a large magnet and radiofrequency magnetic fields.

- You will lie on a special table that slides inside the MRI system or 'magnet' where you will be asked to refrain from moving for the duration of the scan.
- The space within the magnet in which you will lie is somewhat confined; if you feel claustrophobic (uncomfortably confined), you can discontinue the scan at any time.
- A camera that looks like a helmet will be placed around your head to take high quality pictures of your brain. The researchers may place foam padding between your head and the camera to minimize the effect of motion on the brain pictures
- You will hear repetitive tapping noises. Therefore, you will be required to wear earplugs and protective ear coverings for hearing protection to reduce the noise
- Each MRI scan can take up to 2 hours.

Training and Maintenance Phase:
If you are in the *PDAE*, your Training Phase (3 months) will take place at the GRECC or WWHC two times per week for about 90 minutes each time. These dance classes consist of warm-up, new steps and rhythms, and putting steps together in patterns. An experienced instructor will teach the class. Your goal is to attend twenty, 1.5-hour lessons in three months. If you miss a class, research staff will call you to see why and will encourage you to return to class. You should wear comfortable clothes and footwear. Similarly, your PDAE Maintenance Phase (13 Months) will take place at the GRECC or WWHC as outlined above and you will attend a minimum of 3 times per month or up to once a week.

If you are in the *WAE*, you will go to GRECC or WWHC two times a week for about 90 minutes each time. These classes consist of 60 minutes of walking with breaks as needed, and 30 minutes of balance and stretching. If you miss a class, a research team member will call you to see why and will encourage you to return to class. Similarly, your WAE Maintenance Phase (13 Months) will take place at the GRECC or WWHC as outlined above and you will attend a minimum of 3 times per month or up to once a week.

We may take videos or photographs during PDAE or WAE classes to be used in scientific publications or presentations.

IF you are participating in the virtual visits, we will ask you to track certain items while walking such as number of steps, distance, elevation, and time. The study team will work with you to determine the best way to track these items (such as, but not limited to MapMyWalk smartphone app)

3-Month and 16-Month Assessments:
You will repeat Medical, Behavioral and Motor Testing, vascular testing, and MRI scan as outlined above.

10-Month Safety Re-Screen:
You will repeat Vascular Function Test, Motor/Cognitive Testing, and PD symptom tests as outlined above.

RISKS:
There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:
Motor Tests: These tests may cause you to become tired or dizzy. To avoid this, you will have rest breaks as needed.

PDAE/WAE: You may become tired or have muscle soreness during or after the classes. You may stop and rest at any time during the class. The instructor is experienced and will monitor your safety and progress. To prevent falls or balance loss, the instructor and assistants will assist you or stop you if you are doing anything that endangers your safety. You may choose not to perform some activities if you do not feel safe doing them.

MRI: An MRI scan exposes you to strong magnetic fields. There is no evidence that this is directly harmful to you. Strong magnetic fields are capable of moving metal objects. Therefore, if you have any metal objects or fragments in your body, other than dental work, or you have a cardiac pacemaker, you must let us know so we can cancel this test.

The less common risks and discomforts expected in this study are:
Questionnaires: Some of the questions you will be asked on the questionnaire are personal and may make you feel embarrassed. You may skip any questions you do not feel comfortable answering, but it is important for you to give your best effort. Your answers will be kept fully confidential.

MRI: The MRI scan is conducted like a CT scan but the area in which you lie is confining and some people experience claustrophobia, which is discomfort in enclosed spaces. If you are affected in this way, it will be important for you to let us know, as this could adversely affect the results of the study and would lead us to discontinue our research with you.

Vascular Function Test: The attachment and removal of a blood pressure cuffs and probe over an artery may cause mild discomfort.

Rare but possible risks include:
Blood Pressure, Height, and Weight measurements: No known risks are associated with blood pressure, height, and weight measurements. The squeezing of an inflated blood pressure cuff on your arm may be uncomfortable for a few seconds.

MRI: The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of individuals. You will be given hearing protection (ear plugs) to reduce this risk. You may experience a temporary decrease in your hearing abilities accompanied by a ringing in the ears. This should stop within 48 hours from the time you

were scanned. If this does not stop within 48 hours please contact [redacted].

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.

BENEFITS:
Taking part in this research study may not benefit you personally, but we researchers and scientists may learn new things that will help others.

COMPENSATION:
You may be compensated up to a total of $150 for your participation. You will be offered $25 for after your first assessment, $50 after your second assessment and $75 after your third assessment. You will receive a check in the mail from the VA 4-6 weeks after completion of each assessment.

COSTS:
You will not be charged for any treatments or procedures that are part of this study. However, some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services that are not part of this study.

You will get necessary medical treatment if you get injured from being in this study. This requirement does not apply to:

1. Treatment for injuries due to non-compliance by a subject with study procedures; Or
2. Research conducted for VA under a contract with an individual or a non-VA institution.

If you believe you have been injured by this research, you should contact [redacted]

ALTERNATIVES:
There are no alternative treatments [and/or procedures] to those offered in this research study.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED:
We will keep information about you, including any research records we create, strictly confidential to the extent required by law.

We may be required to release your record if we receive a subpoena or a court order. The study staff will keep your study files locked in a file cabinet in a private office. We will use a

study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results. People other than those doing this research study may have access to your medical and study records including:

- Sponsors, companies or agencies paying for the study
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- Emory University
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

All research records and/or identifiers will be destroyed in accordance with the VA record retention schedule.

If you are a veteran who is a patient at the Atlanta VA Health Care System, a copy of your signed and dated consent and HIPAA forms may be placed in your medical record(s). If you are a non-veteran receiving clinical services (i.e., use of the laboratory, radiology, audiology, etc.) as part of this study, you will have an electronic medical record created for you. You will also be given a VA Notice of Privacy Practices (NOPP) and we will ask you to sign a form saying that you have received this notice.

If you are participating in a study where a test and/or procedure may be performed at Emory and you are not and have never been an Emory patient, you do not have an electronic medical record. Please note that an Emory medical record will be created if you have any services or procedures done by an Emory provider or facility for this study.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA):

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the

Government Accountability (GAO), Emory University, and Emory University Institutional Review Board.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Madeleine E. Hackney, PI and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

RESULTS:
In general, we will not give you any individual results from the study or information you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. You may be offered a copy of your MRI scan to take with you but it will not include a clinical diagnosis and is not appropriate for clinical assessment by your doctor.

IDENTIFIABLE PRIVATE INFORMATION OR IDENTFIABLE SPECIMENS:
Identifiers might be removed from the identifiable private information or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

CONFLICT OF INTEREST:
None

CONTACT PERSONS:
If you have any questions, concerns, or complaints about this study you can call a member of the study staff [redacted] or [redacted]

If you have been harmed from being in this study call: [redacted]

If you want to speak to someone, who is not a member of the study, to discuss problems, ask questions or voice concerns, you can call:

The Research Compliance Officer at ([redacted] or the Clinical Studies Center Manager at ([redacted].

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at ([redacted] or toll free at 1[redacted].

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
The study doctors have the right to end your participation in this study for any of the following reasons: If it would be dangerous for you to continue, if you do not follow study procedures as directed by the study doctors, or if the sponsor decides to end the study.

Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. For your safety, however, you should consider the study doctor's advice about how to go off the study treatment**.** 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, Medical, Physical and Cognitive testing, Questionnaires

The investigator may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions.

We will give you a copy of this consent form to keep. If you are willing to volunteer for this research, please sign below.

RESEARCH PARTICIPANT'S SIGNATURE AND DATE:

_____
Research Participant's name

_____ _____
Research Participant's Signature Date