EFFECTS OF ADAPTED TANGO ON AFRICAN-AMERICAN WOMEN CAREGIVERS OF ALZHEIMER'S DISEASE PATIENTS

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ATLANTA VA HEALTH CARE SYSTEM
Consent to be a Research Subject

TITLE: Effects of Adapted Tango on African-American Women Caregivers of Alzheimer's Disease Patients

PRINCIPAL INVESTIGATOR: [redacted]

SPONSOR'S NAME: Department of Veterans Affairs, Center for Visual and Neurocognitive Rehabilitation

INTRODUCTION/PURPOSE: You are being asked to participate in this study because you are an African-American woman and caregiver for a parent who has been diagnosed with Alzheimer Disease. The goal of the study is to look at the influence of a partnered, dance-based intervention versus a control condition on blood biomarkers, cognition, and mood in those at high risk for Alzheimer's disease (AD). You will be randomized to one of two treatments: Tango Dance, or Education Classes. Your involvement with this study will take place over about four months. About 60 people will be enrolled in this study.

This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in 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.

PROCEDURES: Please read this consent form. Before you decide to take part, discuss any questions or concerns with the research team. If you agree to be in this study, you will need to sign this consent form and a HIPAA form before starting in the study.

Overview of Study Activities:

Visit	Activity	Location	Time
Baseline	Testing & Randomization	[redacted]	2 hours
Intervention (12 weeks)	Tango/ Education		90 minutes, 2 times/week
Final	Testing		2 hours

Baseline and Final Visit:
You will go to the Emory Brain Health Center at Executive Park and/or Wesley Woods Health Center. At your baseline and final visits, 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
- Take a blood sample (2-3 tablespoons)
- 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.

Each visit will take approximately 2 hours. You may take rest breaks between tasks or stop at any time. At your baseline visit, we will randomly assign you (like flipping a coin) to 12 weeks of participation in either Tango Classes or Education Classes. Walking and balance assessments may be videotaped in order to be evaluated later by another researcher who does not know what group you have been assigned to.

Intervention:
If you are in the Tango Class, you will go to the Atlanta VA 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. 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.

If you are in the Education Class, you will go to Wesley Woods Health Center on the Emory University campus two times a week for about 90 minutes each time. Those randomized to Education will attend twenty, 1.5-hour interactive seminars about health education presented by experts covering a variety of topics. You will participate in small group and partnered discussion about the topics to enhance your learning. If you miss a class, a research team member will call you to see why and will encourage you to return to class.

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

RISKS:

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.

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.

Blood Draw: We will collect a blood sample at the baseline visit and final visit. Blood draws can cause mild pain in the arm and may cause bruising, infection, and occasional fainting.

Cognitive Evaluations: During the cognitive evaluations you may become bored, fatigued, or frustrated by their difficulty. To avoid this, you will have rest breaks when needed. There are no physical risks to these tests.

Mobility and Balance Tests: These tests may cause you to become tired or dizzy. To avoid this, you will have rest breaks as needed.

Tango Dancing: 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.

Education Class: No known risks associated with the Education Class.

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

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

CONFIDENTIALITY: 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:

- Department of Veterans Affairs
- The Office for Human Research Protections (OHRP)

- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General (IG)
- The Emory University Institutional Review Board and other offices in Emory University that help run and/or oversee studies
- The Atlanta VA Research Compliance Officer
- VA research staff within the VA Hospital or at Emory University (when data is stored at Emory)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

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.

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

COMPENSATION: You will be compensated a total of $50 for your participation, $25 after completion of each testing visit. Compensation will be given in the form of gift cards.

There are no costs, research or standard of care related, associated with the study. 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.

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 emergency medical care if you get injured from being in this study. Under Federal Law, you will qualify for follow-up treatment if the injury was related to the research

study. You may or may not get further compensation if you are injured in this study. This rule would not apply if you do not follow study procedures. If you believe you have been injured by this research, you should contact [redacted]

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]

[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:

[redacted]

Or

[redacted]

If you have any questions about your rights as a participant in this research study, call the [redacted]

NEW FINDINGS: We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

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. The study

doctor, investigator, or sponsor 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 Time
(to be entered by participant)

_____
Name of Approved Individual Obtaining Consent

_____ _____ _____
Signature of Approved Individual Obtaining Consent Date Time
(to be entered by Approved Individual)

An Approved individual is one who has completed HRPP training and is officially approved to consent subjects for this specific study. The signature and date of this individual certifies that this is the most current approved consent document for this study.