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ATLANTA VA HEALTH CARE SYSTEM
Consent to be a Research Subject

TITLE: Optimizing Motor Training in Parkinson Disease through Neural Mechanisms

PRINCIPAL INVESTIGATOR: Madeleine E. Hackney, Ph.D.

SPONSOR'S NAME: Department of Veterans Affairs

INTRODUCTION/PURPOSE:

You are being asked to be in this research study because you are either an adult age 40 and older or an adult with Parkinson disease. 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.
The purpose of this research study is to:
1) learn more about brain activity when individuals with and without Parkinson disease (PD) move their lower limbs
2) see if and how two different types of partnered dance affect brain activity in individuals with and without PD.

All procedures will be videotaped for data analysis purposes. Testing will take place at the Atlanta VA Health Care System and at Emory University. We expect to enroll about 140 people for this study over a five-year period.

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.

For All Participants

- You will first complete questionnaires about your medical history, physical and cognitive functioning.
- Next, you will participate in evaluations of function, including:
    - cognitive (brain function) evaluations. These evaluations are designed to examine your memory, processing speed and attention. Some will be pencil and paper type tests, some will require you to verbally respond to a question and some will be conducted on a computer, (Total time: about 1 hour).
    - tests of mobility (your ability to get around) and balance. These evaluations will examine your walking and balancing ability (Total time: 45 minutes)
    - a research assistant will be with you at all times. You may take rest breaks between each task or stop at any time.

- You will have a Magnetic Resonance Imaging (MRI) scan. MRI is used to create pictures of the inside of the human body. You will lie on a table that slides in the MRI or 'magnet.' You will be asked to lie very still during the scan. The space within the magnet is small. If you feel claustrophobic (uncomfortably confined), you can stop the scan at any time. The magnet makes loud repetitive tapping noises. You will be required to wear earplugs and protective ear coverings for hearing protection. An MRI imaging coil made of plastic will be placed around your head.

Foam pads will be placed around your head to limit movement during the scan. You may be fitted for a bite bar in order to keep your head from moving during the scans. You will be in the magnet for about 60 minutes. While you are in the magnet, you will be asked to do a foot-tapping task. You will be given specific instructions about the task. The technologist will be constantly monitoring you. You can stop the scan and take a few minutes break at any time.
For your safety, you may not have a MRI scan if you have:

- head or eye injury involving metal fragments,
- worked in a metal shop,
- some type of implanted electrical device (such as a cardiac pacemaker),
- severe heart disease (including susceptibility to arrhythmias),
- metal braces on teeth,
- pregnancy.

You will complete an MRI screening evaluation prior to undergoing the MRI.

This test will take place at Emory CSI located on the Wesley Woods Campus.

For those without PD (noPD). You will be asked to take part in one testing session only. These will include all the above tests and occur at Emory CSI located on the Wesley Woods Campus. Those without PD will not attend any training sessions.

For those with PD (PD). You will undergo all testing at both: 12 h after you have stopped taking your anti-PD medications (OFF meds) AND when you feel your anti-PD medications are working best (ON meds).

Each occasion will involve testing while OFF meds and then while ON meds. Testing while OFF meds will take about 2-3 hours, after which you will have a long break, then when you feel ready you will be tested while ON meds for another hour.
So, in summary:

OFF (evaluation 3 hours) -> REST (45 minutes) -> ON (1 hour evaluation)

During testing, we will ask you to perform balance, walking and memory tasks, and to answer standardized questionnaires. Brain activity will be measured while performing a foot-tapping task, with functional magnetic resonance imaging (fMRI) in a scanner. We will ask to videotape the balance and walking testing and the dance classes.

Training:
After your first visit, you will be randomly assigned (much like flipping a coin) to one of three groups**:** **Tango Leaders, Tango Followers**, or **Education**. You must attend 20 lessons of your assigned group to complete all testing. We will offer a total of 48 classes so you will have plenty of opportunity to make up missed lessons.

Adapted Tango: Those randomized to the Leader or Follower groups will attend adapted tango dance classes. These dance classes consist of warm-up, new steps and rhythms, and putting steps together in patterns. You will always dance your assigned role (**Leader** or **Follower**) in your class. The Participants with PD will always dance with a partner without PD, such as a research assistant, a volunteer, a spouse, friend, loved one that you bring with you, or a caregiver. You will change partners every 15 minutes. 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.

Education: 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.

Dr. Madeleine Hackney and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact Dr. Hackney at the number in the Contact Persons section of this form. The intended dosage is 30 hours. You will be invited to participate in post-intervention evaluations only if you achieve this dosage.

RISKS:

The most common risks and discomforts expected minimal and are:

- memory and attention tests. These tests may cause you to become tired or frustrated. To avoid this, you will have rest breaks when needed.
- mobility and balance tests. These tests may cause you to become tired or dizzy. To avoid this, you will have rest breaks. There is a risk that you may fall. To prevent falls or balance loss we will walk beside you monitoring your balance and/or you will wear a safety belt.
- Tango classes. 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.

The risks associated with imaging of brain activity done with MRI are:

- You may be bothered by the beeping and hammering sounds made by the scanner as it collects measurements. Disposable earplugs will be provided to diminish the noise.
- You may also experience mild numbness or tingling in your fingers and toes. This feeling is similar to the feeling you get when your arm has fallen “asleep” – not the painful “needling” feeling, but the numb tingling you feel afterward. Again, you are free to quit the experiment at any time you choose.
- You may experience a claustrophobic reaction in the scanner. If you are experiencing claustrophobia you will be removed from the scanner immediately.
- You should stay away from loud noise environments for 24 hours after you have been scanned. Examples of a loud noise environment include mowing the lawn, riding on a motorcycle, and attending a music concert or sporting event. If you must be in a loud noise environment you should use hearing protection. We will provide you with foam earplugs for this purpose and we will show you how to use them.
- Women of childbearing potential should especially note that the risks to fetuses of exposure to MRI are unknown.

Imaging in the scanner is done for research purposes only. Scanning is designed to answer research questions, not to medically examine your brain. This MRI scan is not a substitute for one a physician would order. It may not show problems that would be picked up by a medical MRI scan. None of the researchers are medically qualified radiologists. However, if we see something unusual in your scan,

we will inform you so that you can obtain a follow-up evaluation by your physician. Any follow-up evaluation or treatment that you seek will be at your own expense.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform Dr. Hackney, Principal Investigator, or the person reviewing this consent with you before enrolling in this or any other research study or project.

There may also be risks or discomforts that are not yet known.

BENEFITS:

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

For adults without PD: this is a pilot study designed to learn more about brain activity when moving the lower limbs. The information we gain from this study may help us to help others.

For those with PD:
Adapted-tango classes may improve physical function and quality of life in persons with PD. This may decrease fall risk and reduce associated injury and mortality. These benefits are not guaranteed. Your condition may improve while you are in this study but it may not, and it may get worse. The information we gather from your participation in this study will be important because we will know more about how the brain works before and after mobility or education training in people with PD. The study results may be used to help others in the future.

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:

- The sponsor of the study: Department of Veterans Affairs, Rehab R&D Service
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- 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 with 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.

- Tango Rio

We will keep your records private to the extent required by law. However, we may be required to release your record if we receive a subpoena or a court order. 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.

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:

There will be no cost to you to participate in this study. The Department of Veterans Affairs Rehabilitation Research and Development Service are funding all costs of this project.

For those without PD: You will be compensated $25 for participation in one assessment.

For those with PD: You will be compensated $25.00 following each of the 3 testing visits: pre-test, post-test, and 1 month follow-up.

A check will be mailed to you about 6 weeks after each visit as listed above.

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 **Dr. Madeleine Hackney, the Principal Investigator, at 404-321-6111, ext. 205006.**

CONFLICT OF INTEREST: None.

CONTACT PERSONS:

If you have any questions, concerns, or complaints about this study or if you have been harmed from being in this study you can call Dr. Madeleine Hackney, the Principal Investigator, at 404-321-6111, ext. 205006.

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 Emory Institutional Review Board (404) 712-0720 or toll free at 1(877) 503-9797
- The VA Research Compliance Officer at (404) 321-6111 ext. 206964
- The VA Clinical Studies Center Director at (404) 321-6111 ext. 206933

If you have any questions about your rights as a participant in this research study, call the Emory University Institutional Review Board at (404) 712-0720 or toll free at 1(877) 503-9797.

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:

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 investigator and/or sponsor may stop you from taking part in this study at any time if they decide it is in your best interests 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.