Northwestern University

Consent Form and HIPAA Authorization for Research

PROTOCOL TITLE: Yoga Versus Resistance Training in Parkinson’s Disease: A Randomized, Controlled Pilot Study of Feasibility & Efficacy

PRINCIPAL INVESTIGATOR: Tanya Simuni, MD

SUPPORTED BY: The Northwestern Parkinson’s Disease & Movement Disorders Advisory Council

Introduction
You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health.

Conflict of Interest Disclosure
The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

If your doctor is also the person responsible for this research study, please note that he/she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

What is the reason for doing this study?
You are being asked to participate in a research study of a yoga intervention as a form of physical activity for Parkinson’s disease (PD). The purpose of the study is to determine if people with PD can safely and reliably participate in a specially designed yoga class, and whether participation in this class leads to improvement in measures of motor function and quality of life, as compared to resistance exercise classes.

How many people will take part in this study?
The study will enroll up to 24 subjects at Northwestern Medicine.

What will you do if you choose to be in this study?
This study will involve up to 26 visits over 4-5 months.

Visit 1: Screening/Baseline Visit
You will be screened to determine if you meet inclusion and exclusion criteria for this study. Screening will include having a physical and neurological examination performed by a Movement Disorders specialist here at Northwestern. The assessment will take place at the Northwestern Parkinson’s Disease and Movement Disorders Center (675 N St Clair St, Suite 20-100) and will take approximately 20 minutes. During this visit you will also fill out other questionnaires assessing mental function and emotional state to further determine your eligibility that will take an additional 15 minutes to complete.

If you meet the inclusion and exclusion criteria for this study, you will also undergo additional questionnaires and assessments during this same visit to measure your pre-intervention (baseline) motor and non-motor function prior to the intervention. This will include having an additional neurological assessment performed by a Movement Disorders specialist and filling out several questionnaires related to various symptoms that may be associated with PD, such as surveys measuring quality of life and walking ability, along with other motor and non-motor functions (if you have access to a computer and feel comfortable using one, then these forms can be filled out electronically at home through a secured website). These forms will take approximately 45 minutes to complete.

Randomization
Between this visit and the start of the intervention, you will be randomly assigned to participate in a yoga class or a resistance training exercise class with other people who have PD. Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. You do not need to have any experience with either of these interventions.

Visits 2-25: Exercise Classes
The intervention classes will meet for 60 minutes twice a week for 12 weeks. This intervention will begin within eight weeks of your original screening/baseline visit. Both classes will be taught by licensed instructors hired through the Northwestern Integrative Medicine center, and will be tailored to the level of your ability. They will take place at the Prentice Women’s Hospital Building (250 E Superior St, Chicago IL, 3rd Floor room R).

If you are randomized to the yoga group, at each class you will perform yoga breathing techniques, warm up stretches, yoga poses, and a cool down phase, which involves meditation and resting.

If you are randomized to the resistance group, at each class you will perform breathing exercises, core exercises (strengthening of the back, abdominal and pelvic muscles), arm and leg exercises with weights or resistance bands, and a cool down with stretching.

Visit 26: Post-exercise Evaluation Visit
Within two weeks of the last therapy session, you will repeat the neurological assessments and questionnaires that were performed prior to the intervention at the Northwestern Parkinson’s Disease and Movement Disorders Center.
You will also have three 5-10 minute phone interviews with a study coordinator (at weeks 3, 6, and 9), simply to report on how the classes are going and how you are doing.

**What are some of the possible risks and discomforts?**

Your participation in this study may involve risk of fatigue, muscle soreness, muscle strain or falls, although there is no evidence of any particular harm associated with these interventions and close supervision from a licensed instructor will help to prevent any injuries. Your participation may make you feel emotionally uncomfortable due to some of the questions asked in the questionnaires. You may withdraw from the study at any time.

**What are the Possible Benefits for Me or Others?**

The possible benefits to you from this study include improved physical fitness, decreased fatigue, improvement in mobility and other motor symptoms of PD, and improvement in non-motor symptoms such as mood, quality of life, and sleep. Taking part in this study may help scientists to better understand if and how yoga may impact any or all of these motor and non-motor manifestations of Parkinson’s disease.

**What other procedures or courses of treatment might be available to me?**

You do not have to take part in this research study.

**Are there any financial costs to being in this study?**

Participation in this study will involve no cost to you.

**Will I receive payment for participation in this study?**

You will not be paid for your participation in this study. However, you will be given parking vouchers redeemable at any designated Northwestern parking garage at the end of each clinic visit and therapy session.

**If I have questions or concerns about this research study, whom can I call?**

You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. Tanya Simuni, MD is the person in charge of this research study. You can call her at anytime at 1-888-350-1334. You can also call the study coordinator at 312-503-2593 Monday through Friday from 8am to 5pm, with any questions about this research study.

**What are my rights as a research subject?**
If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Northwestern University Institutional Review Board (IRB) Office. You can call them at 312-503-9338.

At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information/specimens/materials already collected from you can be used.

**What about my confidentiality and privacy rights?**

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Certain health information indicating or relating to a particular condition, as well as assessments and questionnaires
- Mobility test (“Timed Up and Go”)
- Records about study medication, drugs, or devices

During this study you may be coming to the Northwestern Medical Faculty Foundation (NMFF) clinical offices for research appointments. When that happens, you will be scheduled for these services through the NMFF computer system. When a clinical exam or lab is done by NMFF or one of its employees for the purpose of this research study, that information will be kept in both NMFF’s clinical records and in the study records.

**The following groups of people may give the researchers information about you:**

- All current and previous health care providers, including but not limited to the Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), and Northwestern Memorial Hospital (NMH).
Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates) will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),

- Clinical affiliates, including Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), and Northwestern Memorial Hospital (NMH). Your participation in this clinical trial will be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Clinical affiliates, including but not limited to Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Physicians Group (NMPG), and Northwestern Memorial Hospital (NMH), for purposes including, but not limited to, the affiliate’s provision of care to you and/or the affiliate’s scheduling of appointments and/or billing activities.

- Other University research centers and University contractors who are also working on the study,

- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or presentation at scientific meetings.

**Please note that:**

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.

- You may change your mind and “take back” (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this
study. To revoke your consent for the use of your health information, you must do so in writing to:

PI’s Name: Tanya Simuni, MD
Institution: Northwestern University Feinberg School of Medicine
Department: Neurology
Address: 710 N Lake Shore Drive, Abbott Hall 11th Floor, Chicago IL 60611

• Unless you revoke your consent, it will not expire.

Consent Summary:
I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above. A copy of the consent form will be provided to me after I sign it.

A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

______________________________________________________
Subject’s Name (printed) and Signature                  Date

______________________________________________________
Name (printed) and Signature of Person Obtaining Consent  Date