



Consent Form

Principal/Overall Investigator: Derek Liuzzo PT, DPT, PhD

Research Personnel: Zachary Levin SPT, Rachel McLellan SPT, Melissa Patrick SPT, Jason Trinh SPT

INVITATION

You are invited to take part in a research study. "Research" is a way to find out more about something. A "participant" is a person who is studied by researchers. Research sometimes promises treatment or help to the participants, but not always.

This form will tell you all you need to know about this research study so that you can decide whether or not you would like to participate. You should make a decision that you are comfortable with. You need to take into account all the risks and benefits to make up your mind. Any questions can be directed to the following study contact:

STUDY CONTACT:

Derek Liuzzo PT, DPT, PhD

Principal Investigator

Office S331A

O: 617-521-2334

Derek.liuzzo@simmons.edu

PURPOSE

The purpose of this study is to assess the effect of yoga on balance and dual-task performance in those affected by Parkinson's disease (PD). Dual-tasking will consist of a timed speaking activity while standing on a force plate. We are investigating how yoga, which has been shown to improve stability, can influence balance during dual-tasking for individuals with PD. We expect participants may have reduced rigidity and improved dual-task function after engagement in yoga exercises. Results of the yoga intervention may vary between participants.

PROCEDURES

If you consent to participate in the study, you will only need to commit to two offsite sessions which will take place at Simmons University. The first session will happen before the first yoga class and the second session will happen after the final yoga class. During the sessions, you will be asked to perform a dual-task where you name as many words as you can that start with a given letter in 30 seconds while standing on a force plate. The force plate will measure postural sway. In addition, immediately after yoga classes 1, 4, and 6, researchers will meet you onsite to collect data, using the Romberg test with dual-tasking, the functional reach test, and the Activities-specific Balance Scale (ABC). Data collection will last between 20-30 minutes. For each activity, you will be given two trials with a minute to rest between each trial. Additional breaks will be given as frequently as you wish. Results will be stored at Simmons University in a locked office. Upon completion of data collection each participant will be debriefed by the researchers.

CONFIDENTIALITY

Information will be stored at Simmons University in S331-A. Access to this information will be limited to research personnel only. The information will be kept in a safe and locked location when not in use by the researchers. All electronically stored data will be stored with password protection, only known by the researchers. As the researchers, we will make all efforts in order to provide confidentiality of the recorded data related to the study.

We will store and use your data for the duration of the study. We will continue to use the confidential code labels to protect your privacy. If your data is used for any further study analysis related to this study, all the information that could link it back to you would be removed. You have the right to have your data excluded at any time. The investigators have the right to remove your data at any time.

COMPENSATION

There will be no charge or compensation, including parking or transportation, for your participation in this study.

RISK AND DISCOMFORTS

There are minimal to no risks associated with participation in this study including fatigue and minimal fall risk. There are no anticipated psychological or social risks. There are no anticipated legal or financial risks.

PROTECTION AGAINST RISKS AND DISCOMFORTS

There may be anticipated fatigue and muscle soreness related to increased physical activity. Participants may rest at any time during the yoga and testing sessions. There are minimal fall risks associated with this study. Precautions will be taken by Doctor of Physical Therapy students and a physical therapist with 7 years of experience. Your participation is completely voluntary and you may withdraw at any point from the study for any reason. This will not affect your relationship with the Simmons University community or the research investigators.

BENEFITS

There are no direct benefits for participants in this study. We hope to contribute to the body of literature on yoga in the PD population.

YOUR FREE CHOICE

You are free to decide to not join this study. If you choose to participate, you are free to quit the study at any time. No one will be mad at you and you will not suffer any penalty or lose any benefits you would otherwise have. Dropping out and refusal to participate in the study will not affect your relationship with TriYoga.

IF YOU HAVE ANY QUESTIONS

If you have any questions regarding the research study, contact Dr. Derek Liuzzo at: (617) 521-2334. You may also email the research staff at: Derek.liuzzo@simmons.edu. If you have any questions regarding your rights as a research participant, or you experience any research related injury, contact the Human Protections Administrator in the Office of Sponsored Programs at Simmons University at: (617) 521-2414.

SIGNATURE

The purpose of this research, the study procedures, the potential benefits, and the possible risks and discomforts that I may experience has been explained to me. All of my questions have been answered and I have read this entire consent form. My signature below indicated my willingness to participate in this study.

Participant name PLEASE PRINT

Date

Participant's SIGNATURE

Date

I have explained the purpose of the research, the study procedures, the possible risks and discomforts, benefits, and have answered any questions regarding this study to the best of my ability.

Study Representative's SIGNATURE

Date

APPROVED February 18, 2019 Simmons University IRB