Influence of community-based group exercise on fall risk on Parkinson's disease

NCT05940077

February 16, 2021

Participant's Initials: _____

Date: _____

Idaho State University

INFORMATION SHEET FOR HUMAN SUBJECTS RESEARCH

You are invited to participate in a research study conducted by Dr. Evan Papa, from the Department of Physical and Occupational Therapy, Idaho State University Health Science Center. Your participation is voluntary. Please take as much time as you need to read the information sheet. You may also decide to discuss it with your family or friends. You will be given a copy of this form.

PURPOSE OF THE STUDY

The purpose of this study is to determine the effect of a community-based exercise program on mobility and falls in persons with Parkinson's disease (PD). Overall, this investigation will inform clinicians regarding the effects of an exercise intervention focused on function, balance, and non-contact boxing activities to improve balance and reduce falls for persons with PD. In addition, this study attempts to investigate if men and women with PD respond differently to exercise. You are being asked to voluntarily participate in the study. This study does not provide any medical treatments.

STUDY OVERVIEW

You are invited to participate in this study if you have Parkinson's disease, and are 30 years or older. Additional inclusion and exclusion criteria can be seen below. You will be asked to commit to 12 weeks of exercise that is administered at the Caldwell YMCA twice per week, for approximately 90 minutes each session. You may want to participate if you want to improve your balance, or if you wish to help researchers discover more about how exercise influences men and women with PD. You may not want to participate if you do not enjoy exercise. This study does not guarantee any results, including that your balance will improve, though we anticipate you will see at least mild improvements in your mobility.

Participation in this study is independent from any therapies or medical care you may be receiving from other doctors, or health care professionals. If you decide to participate, or not participate, it will have no impact on your relationships with other clinicians or providers.

Individuals may choose to participate in the exercise program without being part of the study.

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CONSENT FORM
TO PARTICIPATE IN A RESEARCH PROJECT AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION FOR RESEARCH

Institution: Idaho State University Health Science Center

Principal Investigator: Evan Papa, PT, DPT, PhD

Subject's Name (please print): _____

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. It describes the procedures, benefits, risks, and discomforts of the study. It also describes your right to withdraw from the study at any time.

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You CANNOT participate in this study if you meet any of the following criteria:

- You are below the age of 30 years old
- You have an advanced stage of Parkinson's disease (Hoehn & Yahr stage 4.0 or 5.0)
- You have atypical Parkinsonian syndromes due to drugs, metabolic disorders, encephalitis, or degenerative diseases
- You have central or peripheral nervous disorders other than PD
- You have myopathic disease that effects skeletal muscle structure/function
- You have cardiovascular conditions that restrict exercise (Coronary artery disease, or a heart attack less than 1 year ago)
- You receive a score of less than 21 on the Montreal Cognitive Assessment indicating the presence of dementia
- You are unable to walk independently with or without an assistive device

Please let the researchers know if you have any of the above listed conditions.
You CAN participate in this study if:

- You are 30 years of age of older
- You have a diagnosis of Parkinson's disease from a physician
- You have mild to moderate idiopathic Parkinson's disease (Hoehn & Yahr stages 1.0-3.0)
- You are willing to commit to 2 exercise training sessions per week for 12 weeks

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PROCEDURES RELATED ONLY TO THE RESEARCH

This study requires you to participate in a total of 3 lab visits for about 1-2 hours each and a 12 week exercise program at the Caldwell YMCA that occurs twice per week for approximately 1.5 hours per session. Three months after the exercise training classes are completed you'll be expected to fill out and return a prepaid postcard to the researcher, indicating the number of times you've fallen since the last day of balance testing.

The lab visits will be used to evaluate your balance and mobility. These will take place at Idaho State University Health Science 1311 E. Central Dr. Meridian, ID 83642 Suite 695.

The exercise training sessions will take place at the Caldwell YMCA, located at 3720 S Indiana Ave, Caldwell, ID 83605.

Upon arriving at the laboratory at ISU, you will be given the opportunity to ask questions and receive answers regarding the experimental protocol and give informed consent.

Before we begin the clinical balance testing, we will collect data including your name, contact information, ethnicity, age, gender, weight, height, and the number of times you've fallen over the past 3 months.

Once we have finished gathering your information you will be asked to take the Montreal Cognitive Assessment, which is a brief screening tool to provide a quantitative assessment of cognitive status. If you pass this screening assessment you will undergo an assessment of your baseline motor function using the Unified Parkinson's Disease Rating Scale (UPDRS) and Hoehn and Yahr disease stage scale. You will then be asked to fill out a short 16-item questionnaire called the Activities-Specific Balance Confidence (ABC) scale, which assesses your degree of fear relative to falling. After filling out these forms, you'll perform six clinical balance tests: the miniBEST test (miniBEST), the Berg Balance Scale (BBS), Timed-Up and Go (TUG), Modified Clinical Test of Sensory Integration in Balance (mCTSIB), 5x Sit-to-Stand (5xS-S), and Functional Reach Test (FRT) described in detail below. We will also analyze your gait while you are walking in a straight line for approximately 25 feet.

1. miniBEST: This clinical balance assessment tool is a shortened version of the Balance Evaluation Systems Test (BESTest). It aims to target and identify 4 different balance control systems so that specific rehabilitation approaches can be designed for different balance deficits.

2. BBS: The Berg Balance Scale (BBS) is a 14-item objective measure that assesses balance and fall risk in adults. The BBS is a qualitative measure that assesses balance via performing functional activities such as reaching, bending, transferring, and standing that incorporates most components of postural control: sitting and transferring safely between chairs; standing with feet apart, feet together, in single-leg stance, and feet in the tandem Romberg position with eyes open or closed; reaching and stooping down to pick something off the floor.

3. TUG: The Timed-Up and Go (TUG) is a dynamic test designed to assess mobility, balance, walking ability, and fall risk in older adults. For this test you'll be seated on a standard armchair, placing your back against the chair and resting your arms on the chair's arms. When the researcher says "Go", you should walk to a line that is 3 m (9.8 feet) away, turn

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around at the line, walk back to the chair, and sit down. The test ends when your buttocks touch the seat.

4. FRT: The Functional Reach Test (FRT) is a single item test developed as a quick screen for balance problems. For this test you will stand with feet shoulder distance apart then make a fist and raise the arm up so that it's parallel to the floor. At this time the examiner takes an initial reading on the yard stick, usually spotting the knuckle of the hand. You will then reach forward along the yardstick without moving your feet. Any reaching strategy is allowed but the hand should remain in a fist. The examiner takes a reading on the yardstick of the farthest reach attained without taking a step. The initial reading is subtracted from the final to obtain the functional reach score.

5. mCTSIB: The modified Clinical Test of Sensory Integration in Balance is designed to assess how well an individual is using sensory inputs when one or more sensory systems are compromised. In condition one, all sensory systems (ie. vision, somatosensory, and vestibular) are available for maintaining balance. In condition two, vision has been removed through blind folding, and the individual must rely on the somatosensory and vestibular systems to balance. In condition three, the somatosensory system has been compromised by having the individual stand on a soft foam pad, and the individual must use vision and the vestibular system to balance. In condition four, vision has been removed (blind fold) and the somatosensory system has been compromised (foam pad). The individual must not rely primarily on the vestibular inputs to balance.

6. 5x Sit-to-Stand (5xS-S): The Five Times Sit to Stand Test measures one aspect of transfer skill. The test provides a method to quantify functional lower extremity strength and/or identify movement strategies a patient uses to complete transitional movements. The score is the amount of time (to the nearest decimal in seconds) it takes a patient to transfer from a seated to a standing position and back to sitting five times.

Following baseline balance testing you will be enrolled in a 12-week exercise training intervention designed to help persons with PD reduce improve functional mobility and reduce falls. The exercise intervention will take place at the Caldwell YMCA (see location above) and will be guided by certified personal trainers who are trained to work with individuals with neurologic conditions such as PD. Each session will begin with a 20-minute warm-up of breathing and stretching exercises for major muscle groups in the trunk and extremities. This will be followed by a 45- to 60-minute circuit training regimen of function, balance, and boxing activities that alternate between 3-minute training bouts and 1-minute rest breaks. The functional training will incorporate activities for whole-body fitness and calisthenics, such as push-ups, skipping, and jumping rope, along with boxing ring work, which focuses on footwork and agility drills. The balance training activities will be tailored to each individual's baseline mini BEST test evaluation, which provides a unique indication of which areas of balance dysfunction are prominent for individual participants. The training will focus on balance activities in the following areas: quiet stance, anticipatory postural adjustments, reactive postural adjustments, and dynamic postural control. The boxing activities will include punching heavy bags (heavily padded, cylindrical bags suspended from the ceiling for the practice of large punches), speed bags (small, air-filled bags suspended from an overhead platform for the practice of rhythmic, rapid punches), and focus mitts (padded mitts worn by a trainer to prompt the practice of various combinations of punches toward moving targets). Participants will not make contact with each other while boxing. You can pace yourself during the training sessions

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and take rest breaks as needed. The exercise sessions will end with a 15- to 20-minute cool-down that will emphasize core stretching and breathing exercises.

During the 6th week of exercise, the Principal Investigator will schedule a time for you to complete the ABC questionnaire and the balance tests described above (miniBEST, BBS, TUG, FRT, mCTSIB, 5xS-S). These tests will need to be completed at the Idaho State University Health Science Center in Meridian.

Approximately 1 week after your final exercise training session you will come back to the Idaho State University Health Science Center to take the ABC questionnaire and perform the same balance tests described above (miniBEST, BBS, TUG, FRT, mCTSIB, 5xS-S). Also during that visit you will be given a prepaid postcard, which you will be asked to return to the researchers 3 months after the study. After 3 months have passed you should write a single number on the postcard indicating the number of occasions that you have fallen since the final day of exercise training. You will be encouraged to include anything that might constitute a fall, including slips, trips, and stumbles. A positive number recorded on a card will be followed up by telephone to outline the exact circumstances of the fall event. If cards are not returned one week after expected, we will contact you by telephone to inquire about the number of falls over the past three months in question.

CONFIDENTIALITY

Confidential research data will be maintained in a secure manner. However, the Office for the Protection of Human Subjects, possibly other federal regulatory agencies, and the University's Institutional Review Board may examine your records. In the case that the final results of this study should be published, no individual results will be reported, and your name will not appear in any published material.

RISKS OF PARTICIPATION

There is a risk of falling while performing the balance testing. However, you will be supervised at all times by a licensed physical therapist or a student physical therapist, who are trained in fall prevention.

There is a risk that you might get tired during the exercise training. At any time if you get tired, you can ask to stop and take a break.

There is a risk that while you are exercising you may experience discomfort in your muscles and it is possible that 24-72 hours after exercise you may experience post-exercise muscle soreness in your arms and legs. The soreness can be perceived as a dull, aching pain in the affected muscle, often combined with tenderness and stiffness. The pain is typically felt only when the muscle is stretched, contracted or put under pressure, not when it is at rest. Permanent muscle damage does not occur. Previous studies involving this form of exercise training have been demonstrated to be both safe and feasible in persons with PD.

Finally, there is a risk of injury that is associated with any exercise program. Injuries could occur due to falling, or punching the heavy bags, or various other methods. All exercise sessions will be

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conducted by exercise specialists who are trained in this program. Additionally, you should consult your doctor if you are concerned about whether you are healthy enough for physical activity.

NUMBER OF SUBJECTS PARTICIPATING AND THE DURATION OF YOUR PARTICIPATION

The anticipated number of subjects involved in the study will be approximately 20.

This study requires your participation over a period of approximately 6 months. The length of time for your participation is estimated as follows:

Balance Testing: 3 lab visits at about 1-2 hours each scheduled at the beginning, middle, and end of the study

Exercise Training Phase: 12 week class that occurs twice a week for approximately 90 minutes per session. Dates and times of the exercise class are to be determined.

Fall History Record: Keep track of the number of times you have fallen over a 3 month period since the end of the last exercise training session, and return the pre-paid postcard.

CONTACTS

If a study-related problem should occur or if you have questions at any time about the study, you may contact Dr. Evan Papa at (208) 373-1914. If you have any questions about your rights as a participant in this study, you may contact the Idaho State University Research Outreach and Compliance office, phone (208) 282-2618.

BENEFITS

You may not directly benefit from your participation in the research project. However, we do expect that the exercise training sessions will improve your mobility and help reduce your risk of falling. The information we get from this study may also help us treat future patients.

PAYMENT

You be compensated for $50 for each balance testing session you attend. There are three sessions: one at the beginning of the study, one in the middle, and one at the end. If you attend all three you will earn $150.

COSTS OF PARTICIPATION

There is a cost associated with the use of the YMCA for the exercise training. If you are a member of the YMCA, the cost is $30 per month. The cost for non-members is $55 per month. Financial assistance is available for those who qualify. All balance tests are provided free of charge.

LEAVING THE STUDY

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You can choose not to be in the study or leave it (discontinue your participation) at any time without penalty or loss of benefits that you are otherwise entitled. If you are a student or employee of Idaho State University, your participation (or non-participation) will in no way effect your academic standing or employment status. If you are receiving therapy or other medical care your participation (or non-participation) will have no effect on your relationships with clinicians or other providers.

COMPENSATION FOR INJURY

We at Idaho State University have not set aside any funds for financial compensation or for costs of medical treatment should you be injured as a result of your participation in this research. If required, medical care will be made available to you in the case of such injury, but you (or your private insurer, Medicare, Medicaid or other government health care program) will be responsible for the expense of any medical care, including hospitalization, that is needed.

You should know that by signing this form you are neither waiving any of your legal rights against nor releasing the principal investigator, the University, or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are injured and feel that your injury justifies pursuing a legal remedy, you have the right to do so.

PARTICIPATING IN FUTURE RESEARCH STUDIES

We would like to contact you in the future to see if you would be interested in participating in another research study. Please indicate by **signing your initials** below if you are willing to be contacted about any future research studies.

_____ Yes, I agree to be contacted about future research studies

_____ No, I do not want to be contacted about future research studies

CONSENT

I voluntarily agree to participate in this study. I have had the chance to ask the study investigators any questions I have regarding this study.

YOU WILL RECEIVE A COPY OF THIS SIGNED INFORMED CONSENT AGREEMENT.

Signature of Subject	Date
Signature of Authorized Representative (if applicable)	Date

Participant's Initials: _____

Date: _____

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject and/or his/her authorized representatives.

Printed Name of Person Obtaining Consent	Date
Signature of Person Obtaining Consent	Date

Participant's Initials: _____

Date: _____