

"Poised for Parkinson's"

Study Protocol for Participation in a Study of Online Alexander Technique Classes
for People Living with Parkinson's Disease and their Care Partners

Contact information for this study:

Monika Gross, Executive Director of the Poise Project
828-254-3102 monika.gross@thepoiseproject.org

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Principal Investigator: Rajal G. Cohen, rcohen@uidaho.edu

4. Research Strategy

4.1 Significance

Parkinson's disease (PD) is the second-most common neurodegenerative disease globally, with a prevalence expected to double in the next 20 years to over 12 million cases¹. It is thought to disproportionately affect rural populations, in part because of demographics and also because of its association with chemicals used in farming and found in well water²⁻⁴. PD symptoms, including gait impairment, falls, depression, anxiety, and chronic pain, are only partially ameliorated by current treatments. These symptoms cause tremendous disability and suffering for individuals with PD and their care-partners^{5,6}.

The care dyad is particularly important in the context of interventions for neurodegenerative disorders such as PD. A care partnership involves a bond between the person receiving care and the person providing it. This partnership takes place in a psychosocial context built on pillars of trust, equality and shared experience. Care provision helps the person with the condition achieve their optimal level of function. The progressive and complex nature of Parkinson's-related syndromes involving motor, psychiatric and cognitive symptoms diminishes an individual's ability to conduct everyday activities and manage self-care. This increases the need for a care partner, without whom the rate of admissions to institutional care, as well as the cost of care, would increase significantly. However, the impact of a neurodegenerative condition on spousal and other family care partner relationships is multifaceted and progressive and includes social, financial, physical, emotional, mental and cognitive aspects^{7,8}.

Rigor of prior research that serves as key support for proposed project. A randomized controlled trial found that Alexander technique, a somatic education practice targeting distribution and regulation of postural tone, can help PWP manage their motor symptoms. Stallibrass et al. compared Alexander technique to massage and found substantial benefits to motor symptoms, depression, and attitudes to self only in the Alexander group; benefits were retained at 6 months^{9,10}. These are promising results; however, the traditional way of delivering Alexander technique, via one-to-one in-person sessions with a trained Alexander specialist, is neither available nor affordable for a large percentage of PWP in the rural Western US. It was previously thought that the benefits of Alexander technique depended mostly on manual guidance. However, I have shown that even without manual contact, simple Alexander-based instructions can lead to improved balance, posture, and mobility, both in PWP and in healthy older adults^{11,12}. Therefore, online group delivery of Alexander training may be a way for PWP who do not live in a major urban center to gain greater agency and independence in their symptom management.

We have designed and begun testing an in-person Alexander-based group course for PWP and their care partners. In a small controlled study, our Alexander-based group intervention led to objective improvement relative to controls in balance (brief BESTest) and coordination (Physical Performance Test). In addition, 75-100% of care partners reported improvement in their care recipient's fatigue, anxiety, posture, rigidity, rolling over, bradykinesia, vocal volume, self-awareness, balance, and overall confidence in ability to manage living with Parkinson's disease. PWP reported reduced shuffling, freezing, and anxiety; increased upright posture; and improved ability to roll over. They also indicated that they learned practical tools for self-management, encountered new ideas that they are likely to use in daily life, and would recommend this class to a friend. At 6 months post-course, most participants reported that they continued to experience benefits from the class and to use the things they had learned in their daily life¹³.

Transitioning to online instruction is both a logical extension of our long-term research goal of removing barriers to access for as many people as possible and a sensible way to proceed during this time of major uncertainty about the safety of person-to-person contact.

How the proposed project will improve scientific knowledge and clinical practice. The proposed project will lead to larger, controlled studies, and eventually to the widespread adoption of this unique intervention, alongside other PD-specific programs such as Rock Steady Boxing, Dance for PD, and the Parkinson Voice Project. From a scientific perspective, evidence that a program targeting postural tone can have widespread benefits for the motor system and anxiety would lend support to the continuation of basic research on the relation of postural tone to the motor system¹⁴⁻¹⁸. From a clinical practice perspective, having this online

Lighten Up! Synchronous online delivery of a dyad-based program to improve motor symptoms in rural adults with PD

intervention could have potential for reducing the health risks of social isolation for rural PWP and their care partners^{19,20}.

4.2 Innovation

Our course is an innovative biopsychosocial approach that bridges the gap between exercise approaches like dance or fitness classes, psycho-social approaches like support groups and psychotherapy, and informational approaches like educational symposiums and meditation classes. It is based on Alexander technique, a non-exercise somatic education process that accesses the motor system via postural tone, body schema, and executive function^{12,21-25}. Once learned, the skills can be applied during any activity. Thus, Alexander principles can be applied during PT, OT, SLP, psychotherapy, or exercise sessions, facilitating greater gains through increased self-awareness and control of reactions. The skills can also be put into use during normal daily activities, without setting time aside to practice or requiring a particular set of movements. This is especially beneficial for individuals who can't (or won't) exercise. Self-efficacy is not limited by physical fitness. There can be personal growth as a human being no matter what physical limitations are imposed by chronic conditions. While PD may be out of a person's control, how PWP choose to respond to moment-to-moment stimuli is within their control. It follows that with greater agency and control of physical and emotional responses, overall confidence and self-esteem will increase, especially for PWP who may be experiencing high levels of despair or helplessness.

The care dyad approach is also innovative. Inclusion of care partners means that if disease progression leads to cognitive decline, the care partner's reminders will help keep PWP active longer. Care partners also learn how to give physical assistance with less risk of injury to themselves, and they will gain self-care skills that can reduce tensions in what can be very challenging relationships.

4.3 Approach

Intervention. Our "Poised for Parkinson's" course is designed for PWP in early stages of PD and their care partners. The targeted impacts for our program are: 1) Practical education of PWP to promote more independent self-management of motor symptoms during activities of daily life, with additional non-motor symptom benefits; and 2) Practical education of care partners to enable them to facilitate care receivers' retention of skills and to help care partners manage their own physical and emotional stress.

Our study focuses on early stages of PD, when both partners are often experiencing a significant period of transition and changing roles that can include negative feelings, depression, diminished well-being, social isolation, and loss of autonomy. Our program aims to ease that transition through enhancing partnered communication and understanding of one another's experiences through the lens of group interactions with other care dyads.

The course meets twice per week, for two hours per class session, over 8 weeks, for a total of 32 "contact hours." Each class includes some time for participants to connect with each other to review what they learned last time, and to share how they have applied the knowledge and what problems they encountered. We have piloted using Zoom "breakout rooms" to simulate the smaller breakout groups used in an in-person class, and we found them to be effective.

Participants are taught principles and methods to allow them to attend to unproductive habits of muscle tension and to become aware of their ability to make different choices. These practices develop body awareness, intentionality, and inhibitory control, which are used to improve the accuracy of the body schema and the distribution and regulation of postural tone, leading to cascading benefits through the motor system.

Research Methods

Design: We will use a single-group design with a primary focus on course development and feasibility testing. We will include 5 dyads, each comprising a PWP and their care partner. Experience suggests that this is an ideal group size to create a feeling of cohesion and connection.

Inclusion criteria: To be included in the proposed study, the PWP needs to be: over 50 years of age; diagnosed with PD by neurologist; ambulatory without assistance from another person, a walker, or a

wheelchair; cognitively sound enough to follow instructions and retain information; and not at high risk for falls. They also need a willing care partner, a good Internet connection, and a decent computer monitor with speakers and microphone. Screening will include administration of the Montreal Cognitive Assessment²⁶. Participants will be excluded if they score below nineteen, which is the standard cutoff for dementia for white non-Hispanic Americans²⁷. Information regarding fall history of the PWP will be collected from the PWP and their care partner. If the PWP had any falls in the past 6 months, we will administer the ABC-6 survey and also ask the PWP to stand on one leg unassisted. If they cannot stand on one leg for at least five seconds (best of three tries)²⁸ AND if they score less than 55 on the ABC-6 (a brief survey of balance confidence that has been validated for PWP)²⁹, we will exclude them from the study.

Recruitment: There are support groups both in Moscow (where the University of Idaho is located) and Pullman (8 miles away). We have previously reached out to local PD support groups and found members willing to participate in studies. Depending on the status of the pandemic, we can do support group presentations either in person or online. Other recruitment strategies we've employed include: announcements in regional Parkinson's organizations' monthly email newsletters and social media platforms; announcements on The Poise Project website, Facebook page, and Twitter account; emails to the larger PD community from email lists; referrals from medical and allied health professionals and fitness trainers; distribution of flyers to local community sites, including retirement communities, community organizations, and places of worship; and distributing press releases to regional news sources.

Retention: Our previous courses have had very high retention. In our in-person courses, average course attendance was 89% for those who completed the course, and course participants reported they had learned practical self-management tools, enjoyed the social interaction of the group setting, and were likely to remember and use what they had learned in their daily lives. Retention strategies include: enhancing participant engagement in the research process and in the meaning and purpose of study outcomes for the larger PD community; specialized training for instructors in group dynamics and bonding; individualized instructor attention within the group setting; incremental learning and capacity building through carefully designed curriculum; field notes from instructor and follow up supervision and mentoring; access to review handouts and videos; and establishing a buddy system to keep participants updated if they miss a class.

Outcome measures: Our primary outcome measures are class attendance and study retention. Our secondary measures include self-reports of symptom management, anonymous course evaluations, and objective assessments of balance and motor performance. For our in-person classes, we used the Brief BESTest to assess balance³⁰ and the 7-point Physical Performance Test to assess motor performance³¹. If it is safe to travel, we will invite participants to our lab to complete these tests, as well as an instrumented Timed Up and Go³². This is a variation on the standard Timed Up and Go that involves standing up from a chair, walking 10 meters, turning around, walking back to the starting location, and sitting back down. The instrumented version includes wearable inertial sensors (APDM) and automatically computed metrics such as step cadence, arm swing, and gait asymmetry. If it is not safe to travel, we will choose a subset of these objective measures that can be administered online, with the assistance of the care partner.

Protocol: Consent. Participants will be sent a copy of the informed consent to read in advance. At the screening session, a researcher will go over it with them, answer any questions, and observe them signing the form. The form will be returned, either by mail or electronically, before the first testing session. All surveys and testing will take place at the same time of day, in the morning when PWP are typically at their best.

Analysis and interpretation: Class attendance will be compared to attendance at our in-person group courses, as well as to other PD-focused courses described in the literature. Study retention will provide information about how many participants we will need to recruit in our next study. Qualitative course evaluations will be used along with instructor notes and video to improve the course. We will also look at balance and motor symptoms, but these will not be subject to inferential statistics due to the small sample size and absence of a control group

Potential pitfalls: Recruitment: If we don't find enough willing volunteers who qualify for the study in Moscow or Pullman, we will expand our recruitment efforts to other towns within an hour's drive. Scheduling: we will

have three different possible times of day that we could offer the class, to maximize our ability to find participants who can do it. This flexibility is made possible by the absence of a need to reserve a teaching space. Technical problems: If the Internet connection is not as good as anticipated for some of the participants, they can switch to using telephone for audio and only streaming video live. PD is a neurodegenerative disease, so balance and motor symptoms may not improve even if the course is successful. Sometimes slower disease progression and decline is the best one can hope for. However, this will not affect our primary outcomes.

4.3.1 Intent to yield key preliminary data to facilitate an extramural grant application. The knowledge gained from this study will facilitate the subsequent generation of a large-scale grant submission. The PI recently had a conversation with an NIH program officer who suggested that we consider following this study with an R34 and then an R01. The R34 is a three-year medium-sized planning grant that would allow us to establish a full research team and develop the data management tools necessary to be fully prepared to submit a competitive R01. NIH has a keen interest in and has announced funding opportunities for studies to identify best practices to deliver remote symptom-management courses. For instance, PAR-20-154 solicits investigator-initiated clinical trials (R01) of complementary and integrative interventions delivered remotely.

4.3.2 Interim milestones. The Poise Project (TPP) will take the lead on content development and revision, using the PI's expertise and background as needed. TPP will develop the course manual and training materials, train the instructor, and supervise the delivery of the course. TPP has previously done all these steps for several different in-person courses according to specified timelines. The PI will be responsible for recruiting, screening and testing participants, analyzing data, disseminating the results, and writing subsequent grant(s).

4.3.3 Project timeline (**The Poise Project in red, Mind in Movement Lab in blue; TPP & MML in purple**)

	Sept-Oct	Nov-Dec	Jan-Feb	Mar-Apr	May-Jun
Aim 1					
Develop Content					
Develop Training Materials					
Train Instructor					
Aim 2					
Recruit, Screen, & Pretest					
Deliver Course					
Posttest					
Aim 3					
Analyze Data					
Create & Present Poster					
Revise Course					

During the course of this project, we plan to submit for publication the results of our recent study testing in-person Alexander courses for PWP/care partner dyads. We will also continue conversation with our NCCIH program officer contact and initiate conversations with NCMRR and NIA program officers to discuss next steps, such as whether it would be wise to apply for an R01 next or to apply for an intermediate mechanism such as R34 (described above in 4.3.2). Such an application could potentially be generated in summer 2021, depending on the results of the proposed work. For this extramural proposal, we will work with MW CTR-IN's appointed biostatistician at the U of I on the project's study design and analysis strategy.

Impact. "Poised for Parkinson's" has great potential as an impactful, scalable, sustainable, and measurable program. This innovative, dyad-centered, Alexander technique-based approach to the care of individuals with Parkinson's disease has the capacity to significantly improve management of several refractory PD symptoms.