

Research Study Title: Remote online administration of balance training / fall prevention exercises for individuals with dementia and their care partners: A feasibility study

Researchers: This research is being carried out by principal investigator Julie Ries PT PhD, a physical therapist and faculty member of the Physical Therapy (PT) Department and Senior Research Fellow in the Center for Optimal Aging at Marymount University.

Research Purpose: Improving balance and decreasing fall risk is an important consideration for older adults with dementia, as falls are more frequent and more problematic for individuals with dementia (IwD) than for those without. Our previous research, bringing balance training to Adult Day Health Centers, has shown that balance training programs are effective in improving balance; however, sustaining the training programs has proven to be difficult. The Purpose of this Study is to assess the feasibility of a remotely administered web-based Otago Exercise Program (OEP, balance/fall prevention program) for IwD supervised by their care partners, using select components of an established framework for feasibility (RE-AIM [Reach, Effectiveness, Adoption, Implementation, and Maintenance]).

The Otago Exercise Program (OEP) is an established fall prevention program, demonstrated effective in decreasing falls for older adults. It has been used in research and clinical activities with IwD, but not administered remotely, as within this study. It consists of a 3x/wk balance & strength program (~30 minute sessions). Given that the COVID pandemic has given many people a new comfort with remote technology, we will use remote (Zoom) technology to provide oversight and opportunity for interaction among exercise participants.

We are recruiting participant "dyads" of IwD and their care partners to engage in this study. Both the partner with dementia and care partner will participate in data collection activities. There will be three (3) testing sessions (in the home), 8-weeks of OEP with sessions involving some remote supervision and support, and 8-weeks with waning oversight by the research staff. Care partners will receive instruction related to safely and effectively supervising the OEP exercise program at home, and there will be opportunity for regular Zoom interaction among small groups of dyads over the course of the study.

Study Expectations / Procedures: We are inviting dyads to participate in this research study—You are responsible for reading and signing this consent form as the person who makes decisions for someone with dementia. You are agreeing to work with your partner with dementia over the course of this study, participating in all activities outlined below. Both members of the dyad who participate must be able to walk without help while at home (no use of cane, walker, furniture, or another person). Here are the procedures that will be followed:

1. A researcher who is an experienced Physical Therapist (PT) will come to your home for the Enrollment Visit (during which you will sign this form)
 - a. You will be screened to assure you can safely supervise the IwD during exercise. This entails demonstrating safe and stable mobility in the home (and possibly a formal screen using the Timed Up and Go test) and discussing your understanding of the study (and possibly a formal cognitive screen using the Montreal Cognitive Assessment).
 - b. We will ask the IwD if they agree to participate in the study. Their assent is necessary to continue.
 - c. You will be asked about medical information and medications taken by the IwD, (which is important for safety) and about any balance issues or falls in the past.
 - d. You will be given a survey with questions about your sense of burden as a care provider.
 - e. We will ask the IwD about their confidence in their balance and whether they are concerned about falls.

This consent form will be kept by the researcher for at least three (3) years beyond the end of the study.

This study was approved by the Marymount IRB on 24 August 2022.

2. A researcher who is an experienced Physical Therapist (PT) will come to your home for the 1st of 3 Home Visits that will take place over the course of the 16-week study. This visit will take ~60 minutes and will include the following:
 - a. We will have the lwD perform a brief cognitive screen (Montreal Cognitive Assessment).
 - b. We will have the lwD perform three (3) functional/balance tests:
 - i. 30 Second Chair Stand Test: The participant will repeat the movement from sit to stand and back to sitting for 30 seconds; the score is the number of full stands.
 - ii. Four Stage Balance Test: The participant will stand with feet in four different positions and be timed for up to 10 seconds in each position. The positions are: (1) feet side by side, (2) staggered stance with feet next to each other, (3) one foot in front of the other, and (4) standing on one foot.
 - iii. Timed Up and Go- The participant will be asked to sit in a chair and upon an instruction to “Go,” will stand, walk 3 meters, go around a cone, walk back, and sit down. The participant will be asked to go as fast as they comfortably can. They will do this activity twice after a practice trial, and the researcher will time the performance.
 - c. We will confirm access from your computer / tablet to the technology (Zoom and Canvas [the learning management system that will house the exercise videos and Zoom access]).
 - d. We will work with you to find the best / safest place in the home for participating in the balance program and make recommendations about optimal guarding and safety.
3. For 8 weeks after the first home visit, you will work with your partner with dementia, supervising the exercise program (~30 minutes per day) by accessing the online program. One time per week, the program will be run with research team members attending/supervising online using Zoom technology, and there will be up to 3 other dyads connected to the Zoom “room.” The other two times per week, you and your partner with dementia will independently access a video online and do the exercises with the video (without oversight by the research team). A research team member will also check in with you every week (by phone, email, video conference, depending upon your preference) to see how things are going, ask specifically about balance and falls, and answer any questions.
4. After 8 weeks of carrying out the exercises in the manner above, there will be a 2nd Home Visit, lasting ~60 minutes. The function and balance tests for the lwD will be re-assessed, as will confidence in balance. Additionally, we will ask you to repeat the caregiver burden questionnaire, and we will ask questions of both members of the dyad related to how easy/hard you have found the technology to be, and your level of enjoyment of the program (these measures help us understand if this program is feasible to implement for others).
5. For the next 8-weeks, after the 2nd home visit, the exercise program will continue, but with fading oversight by the research staff. The staff will no longer be online during exercise and dyads will exercise independently 3x/week; staff will begin to fade regular check-ins from weekly to, by the end of the 8-weeks, just once per month. The dyads WILL have the ability to continue to interact on Zoom with the other dyads they have shared screen time with over the first 8-weeks.
6. After the final weeks of carrying out the exercises in the manner above (16-weeks after the start of the study), there will be a 3rd (and final) Home Visit, lasting ~60 minutes. The function, balance, and confidence measures for the lwD will be re-assessed, as will the feasibility measures (usability, burden, enjoyment) assessed at the 2nd Home Visit.

Risks: The potential risks associated with this project are minimal for lwD, but include the risk of falling during exercise and/or testing activities and risk of frustration and/or embarrassment associated with difficulty performing clinical tests. These risks are no greater than participating in a physical therapy session or community-based exercise program and researchers will do the following to minimize risk:

1. Throughout all testing sessions, participants will be closely supervised to protect against falls. Physical Therapists (PTs) have an excellent understanding of protection and safety measures to minimize the risk of falls. PT Researchers will position themselves for optimal safety during all testing activities. Additionally, PTs will spend time during the Enrollment Visit and Home Visit 1 educating care partners about optimal location and set-up for safety during exercise sessions. Strategies for optimal safety include: always prioritizing safety during exercises, positioning IwD near stable surface for support, positioning care partner strategically to “sandwich” IwD between stable surface and care partner during standing/walking exercises.
2. There is the risk of frustration or embarrassment associated with inability to understand directions for activities, or the inability to perform activities during testing or exercise sessions due to cognitive or physical limitations. PTs working with this study have extensive experience in working with IwD and will work to minimize any feelings of frustration or embarrassment by using short, goal driven cues and providing a progression prompts to facilitate success with tasks. Researchers will be sensitive to participants’ comments, behaviors, and non-verbal language and will modify activities appropriately as needed.

There are no greater risks than those present in everyday life for you as care partner in this study.

Benefits: Participating in this study will have the potential benefit of improving functional balance and decreasing the risk of falls for the IwD. Another potential benefit for both dyad members is the enjoyment of the online interaction with other dyads through the course of the study.

This research study has a potential benefit to the clinical and research community. If this protocol is deemed feasible, this could lead to further research, and potentially be a way to substantially improve accessibility to this type of fall prevention programming by bringing it to people in their homes. Currently, accessibility to this type of programming is limited and successful programs are hard to sustain.

Compensation: To thank you for your participation in this study, we are offering a \$50 Amazon gift card following Home Visit #2 (at 8 weeks, after the second data collection session) and another \$50 Amazon gift card following Home Visit #3 (at 16 weeks, after the third data collection session).

Privacy and Confidentiality: If you agree to participate in this research as a dyad, we will protect the privacy of both partners (no one outside of the research team will know that either of you participated in this study) and the confidentiality of the data (when we share study findings we will present the data in such a way that no one will be able to associate specific individuals with their data). We will store all digital information collected for this study in password protected database. Data will only be viewed and analyzed by the research team.

Sharing Study Findings: The results of this study may be published in a medical or academic journal or presented at professional / educational conferences. In publications or presentations, all identifiers of individual participants will be removed and no one will be able to identify either member of the dyad.

Voluntary Participation: Participation in this study is entirely voluntary and either member of the dyad may refuse to participate or may withdraw consent and discontinue participation in the study at any time and for any reason. Withdrawal from the study will not impact any future relationship with the researchers or with Marymount University. If the dyad withdraws participation, you may request that any of the data which has been collected be destroyed at the time of withdrawal. There will be no penalty or consequences to you or your family member for the termination of participation in the study. The principal investigator, Julie Ries, may terminate the dyad’s participation in this study at any time.

**Participation in Research
Guardian Informed Consent**



Injury Statement: In the unlikely event of injury to your family member resulting directly from their participation in this study, no compensation or medical care will be provided by the researchers or the university with which they are affiliated.

Questions: Please ask any questions you have before signing the consent form. If you have questions later, you may contact Julie Ries at 703-284-5983 or jries@marymount.edu. If you have any questions or concerns regarding rights as participants in this research, you may contact Marymount University's Institutional Review Board (IRB) via email, irb@marymount.edu, or phone, (703) 526-6898.

By agreeing to participate in this study, you are not waiving any of your legal rights.

Statement of Consent: I have read the consent form and I fully understand the content of this form. All of my questions concerning the research have been answered.

- I hereby consent to my own and my family member's participation in this research study as a dyad.
- If I have any questions in the future about this study, I will contact Julie Ries (703-284-5983, jries@marymount.edu).
- A copy of this form has been given to me.

Printed Name of Signing Individual: _____

Your Signature _____ Date _____

Your email contact _____

Your phone contact _____

Printed Name of lwd for whom you are providing consent: _____

Signature of lwd (or verbal indication of assent): _____