Research Study Protocol

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Study Title: Home-Based Dual-Task Training for Older Adults

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Study Protocol Title

Home-Based Dual Task Exercise for Older Adults

Investigative Team and Study Site

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Study site

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Research Synopsis

Title: Home-based Dual-Task Exercise for Older Adults

Clinical Phase: II

Study Population: Community-Dwelling adults, 65 years or older

Study Design: Two-group randomized controlled trial (RCT)

Sample Size: 30 participants are being sought for enrollment.

Study Duration: 12 months

Intervention Description: Home-based dual-task exercise training: combining aerobic exercise, balance training, strength, training, and simplified non-contact cardio kickboxing movements

Background and Significance:

Mild cognitive impairment (MCI) is an intermediate state between the cognitive decline expected with normal aging and more severe loss of cognition of Alzheimer's disease (AD) that effects more than 15% of older adults in the United States. MCI is associated with reduced attention, memory, physical functioning, as well as dualtask performance, and thus can be a significant burden to older adults.[1, 2] MCI also predicts AD with an annual conversion rate from MCI to AD equal to 15% in the United States.[3-5] Our rapidly aging society is ushering in a public health crisis for which we are not fully prepared. To better manage this approaching challenge and help preserve function and independence well into older age, we must develop and adopt innovative, evidence-based therapies that support cognitive and physical function in aging. Unfortunately, the COVID-19 pandemic has brought to the fore the need for effective and feasible therapies to help preserve function in the midst of the significant challenges posed by temporarily closed senior and recreation centers and the need for physical distancing that has isolated many older adults at home. Our team has demonstrated success in developing, implementing, and evaluating a community-based intervention to improve cognition and physical function in an older adult population.

The underlying neurophysiological mechanisms of improved cognition in response to dual-task exercise training have not been fully characterized. However, there is evidence that dual-task exercise stimulates essential, adaptive neurobiological processes eliciting a widespread response. Previous studies demonstrate that these adaptations correlate with better outcomes in older adults both with and without cognitive impairment.[9-16] Exercise and cognitive stimulation increase cerebral blood flow[9], improve brain plasticity, and preserve hippocampal volume. [10-12, 14- 17], all of which are important factors in maintaining cognitive and motor function as we age.

Study Objectives

Primary Objective

The main purpose of conducting this study is to assess the therapeutic benefits of a home-based dual-task exercise intervention on functional capacity in older adults, aged 65 years or older with mild cognitive impairment. To do so, a 12-week dual-task exercise program will be delivered via pre-recorded videos accessed by tablet computer. Baseline and endpoint assessment of physical function (balance, walking, and lower-body strength) will be conducted to compare changes in function between intervention and control participants.

Secondary Objectives

The secondary purpose of conducting this study is to assess the therapeutic benefits of a home-based dualtask exercise intervention on functional capacity in older adults, aged 65 years or older with mild cognitive impairment. To do so, a 12-week dual-task exercise program will be delivered via pre-recorded videos accessed by tablet computer. Baseline and endpoint assessment of cognitive function (task-switching, memory, interference inhibition, and attention) will be conducted to compare changes in function between intervention and control participants.

Study design/methodology

This is a randomized controlled pilot trial to investigate the therapeutic impacts of home-based dual-task exercise on physical and cognitive function among older adults, 65 years or older with mild cognitive impairment. Study arms include one intervention group receiving a 12-week exercise-based intervention and one control group receive no exercise intervention.

A total of 30 participants will be sought for enrollment, recruited from senior living communities, recreation centers, and other areas in which older adults congregate, via flyers and informational sessions. Once enrolled, participants will be randomly assigned to either control or intervention group. Baseline

measures will be completed among all participants prior to initiation of any intervention activities. At baseline physical function will be assessed using the Four-Stage Balance Test, the 30-Second Sit to Stand Test, and aerobic fitness will be assessed using the Six-Minute Walk Test. Cognitive function will be assessed using the Stroop Color-Word Test and Trail-Making Test A and B.

For participants in the intervention group, a 12-week home-based program will be delivered by computer tablet within each participant's home. Each participant will be loaned a tablet and stand and small exercise equipment (resistance bands, light dumbbells, and a body-bar). Two exercise sessions will be completed weekly on non-consecutive days for the duration of the program. To access videos, participants will log in to a password protected Vimeo site. For participants in the control group, no changes to current exercise habits will be made for the duration of the 12-week program. Upon completion of the 12 weeks, all participants will complete endpoint assessments that will be identical to the baseline assessments (physical and cognitive functions).

Study Participants

Inclusion Criteria: 1) male or female, 2) mild cognitive impairment with a score on the Montreal Cognitive Assessment 23 – 26 points, 3) > 65 years of age, 4) healthy enough for home-based physical activity as screened using the Physical Activity Readiness Scale for Older Adults.

Exclusion Criteria: 1) Having any condition that prevents safe participation in the physical activity component as screened using the Physical Activity Readiness Questionnaire for Older Adults; 2) likelihood of 4 withdrawing due to presence of severe illness; 4) having any amputation; 5) inability to provide informed consent, 6) Having a score of less than 15 points on the UBACC. Importantly, in reviewing and signing the consent form, the participant's score on the UBACC will be reviewed with the participant and ability to consent will be discussed to ensure the participant understands that they possess the ability to consent.

Informed Consent Process

Participants must provide written informed consent for data collection related to safety and outcomes assessments. Only data elements specific in this protocol will be collected. This study does not require a review of the medical record for data collection purposes. Consent procedures will be conducted in-person at the first measurement session prior to completion of any research-related activities. The research assistant on this project of the project director will conduct the consent process.

Each participant will be provided with a written consent form detailing the expectations for participation in the study. Each participant will be asked to read the consent form carefully and then the consenter and participant will review the consent form verbally together to ensure complete understanding of the research process. Questions or concerns will then be addressed by the consenter. If comfortable, the participant will sign and date the form, followed by the consenter.

Privacy and Confidentiality

Privacy and confidentiality: Data will be electronically stored on a University at Buffalo-owned, password protected desktop computer using a password protected Microsoft Access file, in the locked office of Dr. Satchidanand. Data for the proposed study will be stored, coded with randomly assigned identification numbers. Data for this project will be stored for three years. Only Dr. Nikhil Satchidanand, in the Department of Medicine, will have access to the key linking participant information to participant identification. This key will be stored in a separate electronic file folder for all study data using a password protected Microsoft Access File on a passwordprotected desktop computer in Dr. Satchidanand's locked office.

Intervention Description:

The intervention being tested consists of two days per week of dual-task exercise training delivered by prerecorded videos posted on a password protected Vimeo site. Participants in the intervention group will participate in an exercise program consisting of balance and strength training, non-contact cardio kickboxing movements, stepping and walking, combined with frequent changes to instructions to engage both mind and body, simultaneously.

Overall Study Duration: 12 weeks

Study Arms: Participants will be randomly assigned to either intervention, as described above, or control

Control: Participants receive no guided dual-task exercise; instructed to not make any changes to their physical activity and exercise habits for the 12-week study duration.

Intervention: Participants receive two non-consecutive days per week of guided dual-task exercise. Sessions are 40 minutes in length with warm-up and cool-down.

Outcomes Measurement

Primary Objective

The main purpose of conducting this study is to assess the therapeutic benefits of a home-based dual-task exercise intervention on functional capacity in older adults, aged 65 years or older with mild cognitive impairment. To do so, a 12-week dual-task exercise program will be delivered via pre-recorded videos accessed by tablet computer. Baseline and endpoint assessment of physical function (balance, walking, and lower-body strength) will be conducted to compare changes in function between intervention and control participants.

Functional Capacity Measures

- Change in performance on the Four-Stage Balance Test (baseline to end point)

  A Modified Four-Stage Balance Test is a literature-validated assessment of fall risk. It is based on the person's ability to hold four progressively more difficult stances for a duration of 10 seconds: side-by-side, tandem, left leg, and right leg. This test will be administered at baseline and end point.

- Change in performance on the Six-Minute Walk Test (baseline to end point)

  The Six-Minute Walk Test will be used to assess changes in walking speed from baseline to end point. This assessment is a literature-validated test of physical function in older adults. Scoring is based on distance covered in in six minutes. This test will be administered at baseline and end point.

Secondary Objectives

The secondary purpose of conducting this study is to assess the therapeutic benefits of a home-based dualtask exercise intervention on functional capacity in older adults, aged 65 years or older with mild cognitive impairment. To do so, a 12-week dual-task exercise program will be delivered via pre-recorded videos accessed by tablet computer. Baseline and endpoint assessment of cognitive function (task-switching, memory, interference inhibition, and attention) will be conducted to compare changes in function between intervention and control participants.

Cognitive Function Measures

- Change in performance on the Stroop Color-Word Test (baseline to endpoint)

  The Stroop Color Word Test will be administered at baseline and end point to assess interference inhibition, task-switching, and attention. This assessment is valid among older adults with mild cognitive impairment.

- Change in performance on the Trail-Making Test (baseline to end point)

  The Trail-Making Test parts A and B will be administered at baseline and end point to measure attention and working memory. It is a valid test for older adults with mild cognitive impairment.

Study Schedule

Projected Start Date: 12/15/2021.

Intervention Duration: 12 weeks

Study Duration: (planning, recruitment, intervention): 12 months

Study End Date: 12/31/2022

Study Timeline

1) Planning and Content Development: 09/01/2021 – 11/15/2021
2) Recruitment and Enrollment: 09/01/2021 – 05//21/2022
3) Baseline Assessment: 06/15/2022 – 07/05/2022
4) Intervention: 07/10/2022 – 10/10/2022
5) End Point Assessment: 10/05/2022 – 10/20/2022

Statistical Analysis Plan

Due to limited sample size and in response to a non-normal distribution, the key measure central tendency (Median) will be assessed along with interquartile range. Differences between intervention and control in median change scores will then be assessed quantitatively.

Change in physical and cognitive measures between intervention and control will be assessed first with calculation of a change score between baseline and endpoint for each group (intervention and control). These change scores will then be compared statistically using a separate Mann-Whitney U test (Median with interquartile range) for each outcome. Due to the small sample size, the ability to make deeper comparisons is very limited.

Risk/Benefit:

Limited risks to participants are associated with participation in non-physician supervised physical activity programming. These are: falls, musculoskeletal injury including strained muscles or joints that are frequently temporary and resolve on their own. Other minor risks include lightheadedness, exercise induced fatigue and diaphoresis, which will resolve on their own upon termination of the exercise challenge. Serious cardiovascular risks include sudden cardiac death, myocardial infarction, and stroke during exercise. These risks often significantly impact the health of the participant and the impacts of which are not fully reversible. However, serious adverse effects of exercise participation are very rare.

From the American College of Sports Medicine: “Contemporary estimates of major cardiovascular

complications in exercise-based cardiac rehabilitation programs range from 1/100,000 to 1/300,000 participant exercise hours. Thus, exercise rehabilitation has been shown to be safe with serious events being rare. Moreover, the overall risk of a cardiac event appears to be reduced in persons who are regular exercisers".

There are no known direct benefits to participants in this study.

Data Safety Monitoring

Data safety monitoring will be conducted throughout this investigation by the PI. Weekly review and interim analyses of both safety and outcomes data will be conducted to monitor participant safety throughout the intervention. This will include both an ongoing quantitative review of adverse events and a qualitative assessment of participant experience in the intervention.

Adverse Event Reporting

Case report forms will be used for review and reporting of safety data. Prior to engaging in intervention activities, participants will be screened for safe physical activity participation using the PAR-Q for Older Adults. These data will be collected on an intervention data sheet and reviewed by the PD. Adverse events during the physical activity sessions will be recorded on the intervention data sheet for each participant and compiled into an Access Database.

Adverse event data collection will be performed monthly by direct contact with participants. Management strategies will be primary in pre-screening of participant risk via the Physical Activity Readiness Questionnaire for Older Adults. Non-serious adverse events that might occur include musculoskeletal pain, joint sprains / strains, lightheadedness, fatigue, shortness of breath, and overexertion. Serious adverse events include falls, syncope, sudden cardiac death, myocardial infarction, and cerebrovascular accident. Occurrence of a serious adverse event including hospitalization, myocardial infarction, sudden cardiac death, cerebrovascular accident, fracture, or death, that the PI determines might be research-related, will trigger an immediate suspension. In addition, any changes to the risk / benefit profile of the study determined by the literature, interim results, or other findings that indicate unexpected changes to the risks and potential benefits of the study will trigger a suspension. The PI reserves the right to suspend the research if any previously unforeseen event or problem presents risks to the participants.

References:

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