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Research Protocol

The effectiveness of mental imagery on motor, cognitive and emotional status of older people with early-stage dementia: A study protocol

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Abstract

Dementia involves the loss of cognitive abilities and represents a decline from the prior level of function which impairs functional abilities in day-to-day life. No previous experimental research has been done to assess mental imagery (MI) effectiveness in the motor, cognitive and emotional status of individuals with early-stage dementia. One hundred and forty older individuals with early-stage dementia from the Day Care Centre of the Alzheimer Association in Athens will take part in this study. The sample will be randomly divided into three groups: MI and physical exercise (intervention group), only physical exercise (1st control group), and neither MI nor physical exercise (2nd control group). Assessment will be obtained one week prior to the program, in the middle of the program (6th week of the intervention program) and after the end of the program (13th week of the intervention program). Participants of the intervention group will perform a 30-minute MI programme after the end of every physiotherapy session. Reliable and valid instruments will be used to assess the primary outcomes, i.e., balance and functional status as well as the secondary outcomes i.e., cognitive ability, emotional state and quality of life. The two-way Mixed ANOVA with factors 'intervention' (between groups) and 'time' (within group) will be used as a statistical analysis. Approvals of clinical trial protocol: a) UNIWA Research Committee study protocol approval: 93292 - 26/10/2021. b) ClinicalTrials.gov: ID NCT05232526.

Keywords: Balance, Cognitive status, Dementia, Mental Imagery, Physiotherapy

Introduction

Dementia is a health problem and is most commonly attributed to Alzheimer's disease (AD). It is defined as chronic, acquired loss of two or more cognitive abilities caused by brain disease or injury. There are three stages of dementia: (a) early or mild stage, (b) moderate and (c) severe. Early-stage dementia is characterized by loss of cognitive abilities (i.e., forgetting appointments, being repetitive, misplacement of items), functional impairment in everyday life activities and emotional symptoms (anxiety, lack of motivation)[1,2].

It has been proven that physical exercise, both aerobic and non-aerobic, improves the cardiovascular system and reduces the risk of stroke. Randomized trials report that such interventions may positively affect cognitive and motor function in dementia[3,4]. Also, a randomized clinical trial found that diet, exercise, cognitive training and vascular risk monitoring intervention improved cognition in people at risk of cognitive decline in dementia[5]. There are also randomized trials showing that there are no clear

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benefits from exercise regarding cognition[6,7].

Mental imagery (MI) is a technique that has been defined as a cognitive procedure in which motor activities are mentally rehearsed without any overt body movements[8]. MI and motor execution have similar neural networks[9]. During MI, brain regions that are related to movement preparation and execution are consciously activated, while overt movement is inhibited[10]. The latter is considered an effective tool in neurological rehabilitation, i.e., in stroke[11,12], in Parkinson's disease[13] and in Multiple Sclerosis[14] to improve gait speed and cognitive function. In AD this technique has been used to improve memory[15].

To our knowledge, early-stage dementia is a condition that has not been benefited from services arising from the development of MI, such as its integration into early diagnosis, prevention and rehabilitation programs. Geriatric rehabilitation should promote the health of older adults in a broad and holistic way. From our investigation of the literature there have been no studies to examine the role of MI on motor, cognitive and emotional status in early-stage dementia. No research studies have confirmed the psychophysiological processes of MI in dementia. The theoretical base and the clinical relevance of these processes in relation to dementia should be investigated. This knowledge will allow scientists involved in the rehabilitation of older people with early-stage dementia to benefit in the areas revealed, so that aging with functional autonomy and a quality of life can be achieved for the longest possible time. Indeed, this knowledge might help physiotherapists incorporate MI into their rehabilitation program contributing more to the individuals' mobility and cognitive status.

As MI is an approach that complements other rehabilitation approaches, especially exercise, the focus of our research group is to discover its best application in the rehabilitation program, in order to achieve the alleviation of cognitive and age-related mobility deficits. More specifically, the purpose of the present protocol is to initially assess the effects of MI on the motor, cognitive and emotional status of older people with early-stage dementia.

Materials and Methods

Study design

The present intervention study will examine the efficacy of adding MI to exercise as a therapeutic strategy for older people with early-stage dementia. A randomized control clinical trial of a 3-month intervention program will be conducted. Participants will be allocated to experimental or to either one of the two control groups, using randomization via the method of drawing lots. The intervention study will be held in a private clinical setting in Athens, by a team of physiotherapists. The recruitment of participants has begun in September 2021 and will end in May 2023. It is anticipated that the trial will be completed by the end of June 2023.

Recruitment and consent

Study participants will be recruited from the Day Care Centre of the Alzheimer Association in Athens. They will be asked to complete an information sheet with the number of falls during the last year, their lifestyle and exercise habits. Demographic variables, including age, gender, occupation, and level of education will also be considered. Their smoking and drinking status, medical problems and medication will also be obtained from the information sheet. A consent form will be provided to all participants.

Inclusion criteria

Older individuals with early-stage dementia will take part. The inclusion criteria of the sample are: (a) diagnosed early-stage dementia, (b) community-dwelling participants, (c) age 65 to 95 years, (d) men and women, (e) good verbal, written communication and ability to follow instructions, (f) ability to walk, (g) no other health problems in the last month (i.e., heart or respiratory failure, stroke) and (i) willingness to take part in the study.

Exclusion criteria

The exclusion criteria of the sample are: (a) moderate and severe stage dementia, (b) psychiatric problems, (c) serious health issues (i.e., medically significant cardiac or respiratory disease) and (d) inability to walk.

Randomization and allocation

A signed form will be completed by all participants after being informed about the procedure of the study with their consent to take part. A code will be given to each participant. After registering, they will be randomly divided into the following three groups by the method of drawing lots:

1. Intervention group (MI and exercise program),
2. 1st control group (exercise program),
3. 2nd control group (no MI or exercise program).

The enrollment and the assignment of participants to the allocation group will be done by one of the researchers. The experimental group will follow the 3-month intervention program in addition to their physiotherapy program, the 1st control group will continue receiving their regular exercise program while the 2nd control group will not undergo MI or any exercise program.

Intervention

The suggested protocol includes the use of a combined MI and exercise program. In particular:

(a) MI program

MI will start immediately when the sample starts the exercise program. The experimental group will undergo 24 sessions of imagery for 3 months (2 sessions per week), starting simultaneously with the 1st exercise program session. The approximate time of day that the MI will be

performed is from 09:00 in the morning to 14:00 in the afternoon. Participants will undergo a 30-minute imagery session after the end of each exercise program session. The content of each imagery session will be similar to the content of the usual exercise program session, i.e., each session including imagery of the same exercises of the exercise program performed earlier by the participant. An effort will be made so that all participants of the MI group receive the same number and content of sessions.

Physiotherapy exercise program

The participants will carry out the exercise program by the same experienced physiotherapist at the Day Care Centre of the Alzheimer Association in Athens. They will receive 24 physiotherapy sessions of exercise, lasting 45 minutes each, twice a week. The duration of the physiotherapy program will be three months (12 weeks). The physiotherapy exercise program will include exercises selected from the Otago Exercise Program (OEP) which was developed and tested by the New Zealand Falls Prevention Research Group in New Zealand to reduce falls in older persons. Yet little research has investigated the use of OEP in people with dementia[17,18]. In particular, OEP consists of a warm-up stage promoting circulation and preparing the body for the rest of the program. Participants will mobilize their joints and stretch their muscles. Strength exercises programs i.e. resistance training protocols with the use of weights, can improve muscle strength, physical performance and endurance in elders[19]. Balance is essential to improve posture and perform everyday activities. Dynamic and static balance exercises may also increase confidence and reduce the possibility of a fall. Finally, stretching exercises develop flexibility and promote relaxation. They reduce the likelihood of fatigue and revitalize the body at the end of an exercise session[20]. The exercise program may include the following: (1) easy marching, (2) head movements, (3) back extensions, (4) ankle movements, (5) front and back knee strengthening, (6) slide hip strengthening, (7) calf and toe raises hold, (8) toe and heel walking, (9) one leg stances, (10) sideways walking, (11) sit to stand, (12) back of thigh and calf stretches. All participants will perform identical exercises during their program. They will be able advance to the next level of exercises, according to the Otago protocol instructions[20].

All participants will be screened for their imagery ability. The experimental group will complete the Vividness of Movement Imagery Questionnaire (VMIQ) which examines movement imagery[21]. This instrument consists of 24 items related to movement imagery, including visual imagery of the movement itself and imagery of kinesthetic sensations. Participants are required to visualize movements and also to imagine someone else performing the same movements. The items fall into six groups of four items each relating to: (a) basic movements; (b) basic movement with more precision; (c) movement with control but with some unplanned risk; (d) movement controlling object; (e) movements which cause imbalance and recovery; and (f) movements requiring control in aerial situations. The VMIQ score is from 1, i.e., perfectly clear and as vivid as normal vision, to 5, i.e., no image at all, you only "know" that you are thinking of the skill. In the first four sessions of the intervention phase, participants will be informed about MI and get a brief report on its influence on clinical and healthy populations. They will follow exercises and instructions designed to develop their skills of MI in terms of self-perception, vividness and control during the first four sessions. A training period of MI is necessary to enable participants to see, control and vividly construct an image in their mind. During this training participants see images of themselves performing movements from everyday life i.e., single leg stance, walking, jogging, climbing stairs, going downstairs, going uphill, going downhill, swimming, etc.[22,23]. A relaxation technique will be performed before starting each imagery training session to facilitate clarity and vividness of imagery representations[24]. Participants will complete a manipulation check with a Likert scale ranging from 1 (not at all) to 5 (very much) at the end of every session to confirm whether they are imagining the content of the representation vividly and truthfully.

The same physiotherapist experienced in managing individuals with dementia will perform the assessments. The assessor that will perform the data collection is trained in the procedure and in using the study instruments. A blinded assessor will be involved in motor, cognitive and emotional assessment of participants.

Outcome Measures

Personal data will only be collected in the baseline assessment. Primary and secondary outcome measures will be measured three times over a period of approximately 3 months: A first baseline assessment prior to the 3-month intervention period (pre), in the middle of the intervention program (6th week of the intervention program) and at the end of the 3-month post-intervention assessment (post).

The primary outcome measures are:

1. Balance

(a) The Berg Balance Scale (BBS) is used to objectively examine participants' ability to safely balance during a series of predetermined tasks. It has 14 items with each item consisting of a 5-point ordinal scale, ranging from 0 to 4. 0 indicates the lowest level of function and 4 is the highest level of function. It takes approximately 20 minutes to complete. Research has confirmed its reliability in older adults with mild to moderate AD[25,26].

(b) The Multidirectional Reach Test (Reach in Four Directions Test) is a tool used to assess participants' balance limits in 4 directions: forward, backward, leftward and rightward. Participants perform maximal outstretched arm reach in each direction with their feet flat on the floor. Reach is measured by the participants' total hand extension using a measuring tape[27,28].

(c) The Five Times Sit-to-Stand Test (FTSST) is considered a useful, consistent and low-cost tool for examining sit-to-stand ability. The FTSST examines the time taken to stand five times from a seated position, as quickly as possible. It measures lower limb strength, balance control and exercise capacity[29].

2. Functional status

(a) The Timed Up and Go test (TUG) is a test used to examine a person's mobility. It assesses the time it takes a participant to rise from a chair, walk three meters, turn around 180 degrees, walk back to the chair and sit down while turning 180 degrees[30,31].

(b) The Functional Gait Assessment (FGA) is used to measure a participant's ability to perform multiple motor tasks while walking. It includes 10 items: gait on level surface, changing gait speed, gait with horizontal and vertical head turns, gait with 180° pivot turn, stepping over obstacles, gait with narrow base of support, gait with eyes closed, backward gait and ascending stairs. The test is scored on a 4-point ordinal scale ranging from 0-3, with 0 indicating severe impairment and 3 indicating normal ambulation with a total score of 30. All items are summed to calculate[32].

The secondary outcome measures are:

1. Cognitive ability

(a) The Mini-Mental State Exam (MMSE) is a 30-point test of cognitive function among the older adults; it includes testing of attention, memory, language and visual-spatial skills. A short administration period is required. MMSE has several advantages, i.e., no specialized equipment or training for administration is required and has validity and reliability for the diagnosis and longitudinal assessment of AD. Early, moderate and severe dementias have scores of 20 to 24, 13 to 20 and less than 12 respectively[33]. The sample chosen will only have early-stage dementia.

(b) The Walking While Talking Test (WWITT) is a dual-task measure to assess cognitive-motor interactions. Participants are asked to walk at self-paced speed for 6 meters before turning and walking back to the starting point. They recite 12 Greek alphabet letters (each letter in each step) starting with "A" (ΑΒΓΔ, ΚΛΜΝ, ΠΡΣΤ) until the starting point. Time and errors in the alphabet will be recorded[34].

2. Depression

The Short-Form of Geriatric Depression Scale (SF-GDS) is a 15-question scale for measuring depression in older adults ("Yes/No" response). It takes 5 to 7 minutes to complete[35].

3. Quality of life

The Euro-Qol 5 Dimensions 5 Level of severity scale (Euro-Qol 5D-5L scale) is a preference-based Health Related Quality of Life measure and includes 5 domains, i.e., mobility, self-care, usual activities, pain/discomfort, anxiety/depression. The score ranges from 1 (best score) to 5 (worse score). It also includes a Visual Analog Scale (VAS), by which respondents can report their perceived health status on a scale ranging from 0 (worst possible health status) to 100 (best possible health status)[36].

Statistical analysis

At this point the design and analysis of the study have insufficient reference to accurately determine the sample size estimate. Firstly, a pilot study will be conducted to investigate the feasibility of the protocol, the acceptability of the intervention, the selection of the most appropriate primary outcome measure and to calculate the exact sample size. Regarding our dependent variables, it has been calculated that a sample size of 40 participants per group is required to have an 80% probability of demonstrating a between-group difference of >3% in % change with a significance of 5%. Sample size estimation was performed using G*Power 3.1.9.4 program. A total of 120 participants are required for the clinical trial (matched pair design with a 1:1 allocation ratio). With an expected drop-out rate of 20%, the number of participants to be included is estimated at 140.

Data will be expressed as mean ± standard deviation (SD) or median (interquartile range), in case of violation of normality, for continuous variables and as frequencies or percentages for categorical variables. The Kolmogorov-Smirnov test will be utilized for normality analysis of the parameters. Independent samples t-test and Fisher's exact test Homogeneity between groups will be performed. The interaction between the "intervention" and "time" factors will be assessed by the two-way ANOVA model. The comparison of raw data variables at each time point between groups will be performed using the above model. The variation of change in time measurements in each group will be investigated by the one-factor Repeated Measures ANOVA model for the comparison of different time measurements of variables for each group. Bonferroni test will be used to examine multiple pairwise comparisons. In case of violation of normality, Friedman and Wilcoxon test will be used. The effectiveness of the intervention will be assessed by calculating the mean percentage changes from baseline and at one and a half months (6th week of the intervention program) and at 3 months. Independent samples t-test or Mann-Whitney in case of violation of normality will be used to compare the percentage change from baseline at each time point of parameters between interventions. The ANCOVA model will be used for the analysis of variables using as covariates the above characteristics which differentiate the compared group if there is no homogeneity between interventions in relation to demographic or clinical characteristics. Potential missing values from non-adherence will be discussed and analyzed through intention-to-treat analysis. Multiple imputations will be used for missing value analysis[37]. Statistical significance will be set at $p<0.05$ using SPSS v28 (28.0.0) (IBM Corporation, Somers, NY, USA).

Ethics approval

Official Institutional approvals have been obtained by the Ethics Committee of the University of West Attica (study protocol: 93292 - 26/10/2021) and the scientific committee of the Day Care Centre of the Alzheimer Association in Athens. The study will be conducted in compliance with this protocol, the Declaration of Helsinki and Good Clinical Practice (GCP). The study has been reported on ClinicalTrials.gov: ID NCT05232526[16].

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