RESEARCH PAPER



Effects of a modified Otago exercise program delivered through outpatient physical therapy to community-dwelling older adult fallers in Greece during the COVID-19 pandemic: a controlled, randomized, multicenter trial

Dimitrios Lytras¹ · Evaggelos Sykaras¹ · Paris Iakovidis² · Christos Komisopoulos³ · Georgios Chasapis² · Charikleia Mouratidou¹

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Key Summary Points

Aim To investigate the effectiveness of a video-supported OTAGO exercise program (OEP) in balance, functional ability, fear of falls and number of falls in Greek older adults with a history of falls.

Findings A 6-month OEP helped older adults to improve their balance and functional ability test scores as well as reduce fear and number of falls, both after the intervention and at the 12-month follow-up. However, the adherence to the program remained unaffected.

Message The OEP contributes to the well-being of older adults with a history of falls by improving all their relevant skills and scores. More long-term research under less adverse conditions is required to solidify these findings.

Abstract

Background The pandemic has led to the isolation and social exclusion of older adults and cut them off from any exercise activity. Thus, it is more than ever necessary to implement organized interventions to prevent falls in older people as they remain a global health problem associated with serious injuries, chronic disability, and high costs for the healthcare system. Otago exercise program (OEP) can effectively reduce the number of falls.

Aim To study the effect of a 6 months modified video supported OEP in balance, functional ability, fear of falls and number of falls in Greek older people who have fallen.

Method 150 fallers aged 65–80 years [Median age 70 (67–74), 88.7% women] were divided into two groups (intervention and control). Primary outcomes included changes in Short FES-I, CONFbal scale, 4-Stage Balance test, BBS, TUG test and number of falls, while the secondary outcome consists of the monthly adherence to exercise after the intervention. Analysis of variance with repeated measures was applied.

Results There were statistically significant between groups differences after 6 months with the OEP group to shows improved values in TUG time score (17.8 vs 3.9%, p < 0.001, 95% CI), 4-Stage Balance Test (6.85 vs 1.09%, p < 0.05 95% CI), 30-Second Chair Stand Test 7.35 vs 2.93%, p < 0.001, BBS score (13.27 vs 3.89%, p < 0.001, 95% CI), Short FES-I (35.78 vs

Dimitrios Lytras lytrasde@gmail.com

- ¹ Department of Physical Education and Sports Sciences, Aristotle University of Thessaloniki, Thermi, 57001 Thessaloniki, Greece
- ² Department of Physiotherapy, Faculty of Health Sciences, International Hellenic University-Alexander Campus, 57 400 Sindos, P.O. Box 141, Thessaloniki, Greece
- ³ Department of Physiotherapy, Faculty of Health Sciences, University of Brunel, Kingston Lane Middlesex, Uxbridge UB8 3PH, UK

13.01%, p < 0.001, 95% CI) and number of falls (69.12 vs 18.70%, p < 0.001, 95% CI). All the above differences remained statistically significant in the 12 months follow-up (p < 0.05), when differences in the CONFbal score were also observed (p < 0.001, 95% CI). No differences were found in adherence to OEP (p > 0.05).

Conclusions A modified OEP decreases the number of falls, improves the balance and functional ability of older adults and reduces the fear of falling. However, it did not contribute to satisfactory adherence to exercise.

Trial registration number/date of registration NCT04330053/April 1, 2020.

Keywords Aging · Fall prevention · Otago exercise program · Physiotherapy

Introduction

Falls in old age and their related injuries are a major problem for older adults. It is reported that 30% of people over the age of 65 experience a fall annually, while the percentage is 50% for adults over 80 [1, 2]. Injurious falls in older people are responsible for 70,000 hip fractures per year and are the leading cause of mortality of traumatic etiology in older adults in the United Kingdom [3]. Furthermore, falls are accompanied by psychological side effects, as they negatively impact the confidence of older adults, increase the tendency for isolation and reduce older adults' ability to engage in self-care [4, 5].

The economic impact of falls on the health care systems worldwide is enormous [6-8]. In the UK, the amount reaches $\pounds 2.3$ billion a year [7]. In the United States, for the year 2015, the economic impact of falls in older adults was estimated at \$31 billion [9]. In Greece, the only available data regarding falls refer to the period 1996-2003. According to the Accident Research and Prevention Center of the University of Athens, during this period approximately 30,694 falls were recorded in older adults, with 72% of these involving women. An older adult stumbling or slipping accounted for 70% of falls. These accidents occurred mainly in the home or in nursing homes, and in 50% of cases a fracture was caused. Furthermore, the percentage of older adults who were hospitalized ranged from 16% for ages 65-74 years (9 days of hospitalization) to 44% for ages over 85 years (up to 14 days of hospitalization); 90 deaths were recorded [10].

The Otago exercise program (OEP) was developed by the University of Otago in New Zealand and is a personalized resistance and balance exercise program originally designed as a home treatment to reduce falls in older adults [11–15]. It consists of 6 warm-up exercises, 5 exercises for strengthening the muscles of the lower limbs, 12 balance exercises of gradually increasing difficulty and 2 recovery exercises [16, 17]. This protocol has been shown to effectively reduce the number of falls as well as the risk of death in older adults [18].

Although falls seem to be a major health problem in Greece, few comprehensive interventions for their prevention have been implemented to date [19–22]. Additionally, the beginning of this study coincided with the beginning

of the pandemic in Greece (and also around the world) and was applied in a particularly impacted area of Greece (Central Macedonia), where the older adult population was cut off from all social and sports activities. The aim of this trial was to study the effect of a modified, supervised and video-supported OEP on physiological and psychological factors related to falls in the older adults of Central Macedonia during the COVID-19 pandemic. The pandemic has led to the isolation and social exclusion of older adults [23]. Their inability to participate in an exercise program makes it more necessary than ever to spread and implement organized interventions to prevent falls [24]. The results of this research can provide useful data and conclusions regarding the effect of interventions to prevent falls in older adults.

Method

Study design

This was an assessor-blind, two-arm multicenter randomized controlled trial (clinicaltrials.gov number: NCT02802189), conducted under the supervision of the Department of Physical Education and Sports Sciences of the Aristotle University of Thessaloniki following the Consolidated Standards of Reporting Trials (CONSORT) extension for pragmatic clinical trials. Ethical approval was granted by the Ethics Committee of the Aristotle University of Thessaloniki (No.44338/2020). None of the care providers or participants could be blinded to the study aims.

Procedure, randomization and blinding

The recruitment of participants took place during the period December 2019–February 2020 and was conducted after a telephone invitation of all registered members from a total of 15 open care centers for the elderly (KAPI) from a total of five different cities in Central Macedonia in northern Greece. The boards of directors of KAPI in each municipality gave their approval for the conduct of this research and the employed physical therapists of KAPI, in collaboration with the administrative committee (presidents and board of directors of KAPI), undertook to inform their registered members about the conduct of the research. The invitation was made through telephone, display of printed information material (information posters), distribution of printed invitations and publication in a press release in the local municipalities. The members of KAPI were invited to attend an open informative speech held at the KAPI site in each municipality implementing the research, during which physical therapists specializing in geriatric physiotherapy informed the older adults about issues related to falls and the intention of the study while attendees were asked if they wished to participate in it.

The members of the research team then met with each candidate participant during scheduled appointments held at the KAPI site, where information about the purposes of the research was provided. The individuals were evaluated on whether they met the research inclusion criteria; also, printed information material was given and, upon agreement, the consent form was signed. During the recruitment quarter, 150 people were recruited. Recruitment stopped at this number because the research team would have difficulty managing more participants. Each person recruited to participate in the study was represented by a number to achieve the consulted allocation. When the recruitment process was completed, an independent researcher used the Research Randomizer Computer software (version 4) randomization program [25] to divide the participants into two groups. The distribution was done by randomization in blocks (in groups of four people) following a ratio of 1:1 in each of the 15 KAPI from which the participants were recruited.

Moreover, because we knew that the operation of the KAPI would be suspended due to the pandemic, although we had originally planned to conduct the exercise program within the physiotherapy facilities of the KAPI, we ultimately chose to use five outpatient clinics, one in each of the cities where the research was conducted. This was done to ensure that the program would not be interrupted due to the special circumstances of the pandemic (outpatient clinics in Greece remained open throughout the pandemic).

Participants

To be eligible, each individual had to: (1) be a man or woman aged 65–80, (2) have a history of at least one fall in the last 12 months, (3) be ambulatory and (4) have a score on the Timed Up-and-Go (TUG) test of less than 15 s. Criteria for excluding study participants were: (1) neurodegenerative disease diagnosis (e.g., Parkinson's disease), (2) recent stroke (less than 12 months prior) and (3) cognitive impairment (Mini-Mental State Exam score less than 24).

Therapists

Three physical therapists implemented the OEP in this trial. Each of them had an average of 10.2 years of clinical experience working with older adults and had completed a specialization seminar on the OEP.

Outcomes

Prior to randomization, the following sociodemographic characteristics were collected through a measurement sheet with questions about age, gender and social background (lives alone or takes care of another person of the same age). Additionally, in the context of the assessment for the suitability of the participants regarding the exclusion criterion of cognitive deficits, the Greek version of the "Mini-Mental State Exam" (MMSE) was used according to the instructions of Fountoulakis [26] for evaluating cognitive deficits; a score of less than 24 was considered a valid cut-off level for the diagnosis of cognitive impairment. The MMSE is a 30-item questionnaire widely used for the evaluation of cognitive impairment in older adults [23, 27, 28]. It was originally introduced by Folstein et al. in 1975 [29] and is a widely used test of cognitive function among older adults, including tests of orientation, attention, memory, language and visual-spatial skills [30]. Any score of 24 or more (out of 30) indicates normal cognition. Below this, scores can indicate severe (<9 points), moderate (10–18 points) or mild (19–23 points) cognitive impairment [31]).

Primary outcome measures

The following outcomes were measured by the same blind assessor at baseline, after 6 months and on the 6 months follow-up after the intervention (12 months after baseline).

Timed up-and-go (TUG) test

The TUG test is a performance-based measure of functional mobility that was initially developed to identify mobility and dynamic balance impairments in older adults [32–35]. It has demonstrated moderate to high interrater and intrarater reliability when used to examine older adults [36, 37]. The score of the test is the time it takes for the participant to perform the following sequence: get up from a chair, walk to a specific point (a floor marking is used to define this point), redirect themselves 180°, return to the chair at a walking pace and, finally, sit down [38]. Given the goal that participants be at a similar functional level, the TUG score was among the inclusion criteria for the study. More specifically, the bar was set at a score of less than 15 s. Generally, a score of 20 s or less indicates independent mobility and that the individuals who achieve such a score are capable of

outside walking and going up and down stairs (34). Finally, Bohannon et al. [39] present population mean values categorized by age group: 60–69 years old at 8.1 (7.1–9.0 CI) seconds, 70–79 years old at 9.2 (8.2–10.2 CI) seconds and 80–99 years old at 11.3 (10.0–12.7 CI) seconds.

4-stage balance test

This test is used to assess the static balance of an individual through their ability to hold four progressively more challenging positions for 10 s each: (1) standing with feet closed side-by-side, (2) placing the instep of one foot in touch with the big toe of the other foot, (3) placing one foot in front of the other (heel touching toe) and (4) single leg stance. Each of the four positions is evaluated with the eyes open and closed except for the single leg stance, which is scored only with the eyes open (i.e., the examinee is evaluated in a total of seven tests) and from four to zero (corresponding to "able to stand for 10 s safely" and "needs help to keep from falling," respectively). The examinee's final score is formed by the sum of the scores from the seven tests from zero to 28 [40]. The score of this test has been associated with the risk of falling in older adults [41]. According to the National Center for Injury Prevention and Control [42], an older adult who cannot hold the tandem stance for at least 10 s is at increased risk of falling. Rossiter-Fornoff et al. [43] infer moderate interclass (Pearson) correlations (0.66), with time between test and re-test of 3-4 months on 187 older adults from the community.

30 s chair stand test

The 30 s chair stand test assesses leg strength and endurance in older adults. It is part of the stop elderly accidents, deaths, and injuries (STEADI) tool kit, which was created by the Centers for Disease Control and Prevention as a screening tool for seniors belonging to the high fall risk group [41]. The test measures the number of times an older adult can get up from a chair with their arms crossed in front of their trunk (on the opposite shoulder crossed at the wrists) in 30 s. This test was developed to overcome the floor effect of the five or ten repetition sit-to-stand test in older adults and has been characterized by excellent test–retest reliability in a total number of participants: r=0.89 (95% confidence interval 0.79–0.93) [44].

Berg balance scale (BBS)

The BBS is a tool suggested by Berg [45, 46] for evaluating balance in older adults. The test involves the execution of 14 tests of gradually increasing difficulty. In each one, the subject is asked to maintain a given position for a specific time or to conduct specific tasks. Each of the 14 tests on

the list is graded according to the balancing ability of the examinee from zero to four points (with zero indicating low balance ability and four high). According to Berg et al. [45], a score of 56 indicates functional balance, whereas a score lower than 45 indicates notable balance deficits that have been associated with high fall risk. Studies have shown high intrarater and interrater reliability in older adult populations with intraclass correlation (ICC) ranging from 0.98 to 0.88. [45, 47].

CONFbal-GREEK questionnaire

The CONFbal scale is a 10-item questionnaire used to assess balance confidence in the geriatric population during specific daily tasks [48]. The examinee is asked to indicate how confident they feel about their balance when performing ten different daily skills related to self-care and performing movement skills. Each answer (given in the form of a Likert scale) is scored from one (sure) to three (not at all sure); for this reason, the higher the score, the lower the confidence of the examinee in terms of their balance. According to Simpson et al., [48] the questionnaire demonstrates excellent internal consistency (Cronbach's alpha 0.91, with an intra-class correlation coefficient of 0.95) and excellent test–retest reliability. The Greek version of the questionnaire CONFbal–GREEK [49] was used in this study.

Short falls efficacy scale international (short FES-I) score questionnaire

Short FES-I is a measure of "fear of falling" or, more properly, "concerns about falling," which is suitable for use in research and clinical practice. It is the short version of the Falls Efficacy Scale International (FES-I), comprised of seven questions and more applicable in clinical practice [50]. The score ranges from 7 to 28. Each answer (given in the form of a Likert scale) is scored from one (does not concern me at all) to four (it concerns me a lot); for this reason, a higher score indicates a greater fear of falling. The Greek version of the questionnaire [49] was used in this study. The test has shown excellent internal and 4 weeks test–retest reliability (Cronbach's alpha 0.92, intra-class coefficient 0.83) according to Kempet et al. [50].

Number of falls

Changes in the number of falls have been evaluated at baseline and at the 12 months mark to determine whether there were differences between the groups in reducing the total number of falls during the study period compared to 12 months before the start of the intervention. Therefore, in this particular variable, we used only two measurement times (in contrast to all other primary outcomes, which had three measurement times): that of the baseline measurements (number of falls in the last 12 months) and that of the 12 months measurement (for the entire period of research). The falls were recorded throughout the intervention through a Falls Diary. The Falls Diary was kept on a weekly basis and the assessor collected the data by telephone 2–3 times a month.

Secondary outcomes measures

Adherence to exercise After the 6 months intervention period, the participants of both groups were asked to continue performing the exercise program they followed three times per week for another 6 months. Between groups differences in adherence to exercise during this period were assessed through a monthly diary. For the measurement, the total number of times that each participant performed the program per month was calculated and the differences between the averages on a monthly basis throughout the 7th to 12th months of the intervention were compared. Each participant recorded, in a weekly diary, the times they performed the exercise program while the assessor collected the data by phone 2–3 times a month.

Interventions

Both groups received consulting and training on fall prevention issues such as: awareness of injurious falls and identification of risk factors, environmental security, identifying hazards that can lead to a fall, standing techniques for getting up from a fall and calling for help. Consulting and training of the participants took place through oral information and demonstration by the physical therapist as well as through the distribution of printed educational material.

Intervention group

The intervention team followed a fall prevention exercise program based on the OEP [12, 13]. The program was performed individually or in groups of two people three times per week for the first 3 weeks and once a week thereafter for a total period of 6 months. The participants were instructed to repeat the exercises at least twice a week at home. The exercise session lasted 45 min. The weekly session took place in one of the five outpatient clinics under the supervision of a specialized OEP trainer. The exercise program included five exercise groups: general warm-up exercises, lower limb muscle resistance exercises, exercises to improve dynamic and static balance, range of motion exercises and recovery exercises. All of the aforementioned exercises were performed according to the recommendations of the American College of Sports Medicine [51] and according to the standard levels of exercise progress for beginners,

intermediate and advanced. We matched the program in terms of intensity and degree of difficulty to the competence level of each individual so that trainees could make relevant adjustments. We used the four levels of difficulty incorporated in the original Otago program, assigning each participant to their corresponding level. From the beginning of the program and every time the content of the program changed, we recorded the live session and provided it to the participant so that they could play it on their TV or computer at home for feedback when performing the program alone.

Control group

The individuals in the control group did not receive any special exercise intervention to prevent falls but were given a leaflet with general gentle home exercises (not fall prevention specific). This leaflet included some breathing exercises for relaxation and gentle upper limb exercises in combination with breathing and gentle self-stretching exercises. The duration of these exercises was estimated at 45 min. The participants of the control group were instructed to perform this exercise regime three times a week during both the intervention period and the follow-up period.

Treatment side effects

Participants of both groups were asked to report any adverse events during the intervention period, especially during the first 3 weeks of the exercise program's implementation. Adverse effects were considered to be any discomfort, dizziness or sensation of weakness (especially those in the intervention group) after the exercise program at home that could lead them to consult a doctor or take a painkiller.

Sample size calculation

A total sample size of at least 100 subjects was recruited based on an a priori power analysis (G*Power 3.0.10). As a basic prerequisite for this calculation, the power $(1-\beta)$ was set at 95%, and the detection of a difference in the order of f=0.3 (Cohen's f) [52]. The alpha was set at 0.05 for all tests. At the same time, an additional 20% was added to the calculated sample size for the 6 months follow-up measurement performed after the intervention. Based on the above sample size calculation, the minimum number of participants who should be recruited for this study was 120 participants.

Statistical analysis

Data were analyzed using SPSS Statistics for Windows, Version 25.0 (SPSS Inc., Chicago, IL, USA) and the software R, version 4.0.3. Normal distribution was checked with the

Shapiro–Wilk test as well as with the appropriate graphs (Q–Q plots and P–P plots). Normally distributed variables were presented with mean value and standard deviation or with median value and interquartile range in the case of abnormally distributed variables. Respectively, the quality variables were presented with frequencies and percentages.

To compare the quantitative variables between dichotomous quality variables, the *t* test for independent samples or the non-parametric Mann–Whitney test was used if the normality condition was not met. For the comparison of quality variables, the χ^2 independence test or Fisher's exact test were used in case of expected frequencies less than five.

A two-way analysis of variance (ANOVA) was applied to examine the interaction effect of "group" (Intervention Group and Control Group) and "time of measurement" (baseline, 6 months and 12 months) on each dependent measure. The 12-month measurement was included in the model. The overall comparisons between groups were made using the "group" × "time" interaction effects. If the interaction was statistically significant, the simple main effects were reported using the Tukey post hoc test (HSD). The 95% confidence intervals of the group differences at each time point were also calculated. The intention-to-treat (ITT) analysis methodology was used to avoid the effect of dropouts so that the study's randomized group assignment would not be disrupted. All participants were included in the analysis and were analyzed in the original group assigned. For each dropout during the intervention period, the missing values were replaced with the value of each variable from the previous time point. An exception to this was the ITT analysis for the values of the variable "adherence to exercise" during the monthly measurement (7th, 8th, 9th, 10th, 11th and 12th months). The specific measurements were carried out only during the 6 months follow-up (when the participants had left from the 1st month) so, for the replacement of their values, the average of all the other participants at the same time was chosen. Statistical significance was accepted at a level of 0.05. All measures were bilateral. An effect size [d=(post-test mean-pre-test mean)/pre-test standard deviation] using estimates of changes from the linear mixed models was computed for each continuous outcome variable. Effect sizes of f=0.2 were considered small; f=0.5 medium; and f=0.8 large [53].

Results

Between December 2019 and February 2020, 224 older adult persons from 15 KAPI were screened for eligibility. In total, 150 of them (67%) met the inclusion criteria and were randomly allocated to the intervention group or the control group (n=75 each) (Table 1). During the treatment phase, some exercise sessions were missed due mainly to the COVID-19 pandemic. It was deemed necessary for 2 women from the intervention group who came into close contact with COVID-19 patients to be quarantined for 14 days during the treatment period. Neither of them contracted the disease and the weekly sessions were held for these 2 weeks via video conference using Skype from a computer or Viber from a mobile phone, depending on the equipment available to the participant. No other participants missed treatment or evaluation sessions throughout the study.

All of the 150 participants completed the 6 months exercise program. Four people from the intervention group and two people from the control group left the study after 6 months (between the 6th and 7th months) and did not attend the 12 months measurement. Concerning the intervention group, two became seriously ill, while the other two left for personal reasons. As for the control group, one became seriously ill, while the other moved out of the study

Demographics Intervention group (n = 75)Control group (n = 75)p value Age (years) 70 (67-74) 70 (67-74) 0.86 Sex (female) 90.7% (n=68)86.7% (n=65)0.44 Number of single (vs. recurrent) fallers 37.3% (n=28)34.7% (n=26)0.73 Using assistive devices to walk 5.3% (n=4) 4.0% (n=3)1 Living alone? (Yes or No) 16.0% (n = 12) Yes 26.7% (n = 20) Yes 0.11 Are you taking care of your spouse or 17.3% (n = 13) Yes 21.3% (n = 16) Yes 0.53 any other relative at home? (Yes or No) Vision impairments (Yes or No) 28.6% (n=22) Yes 29.9% (n=23) Yes 0.85 Osteoarthritis (Yes or No) 18.7% (n = 14) Yes 21.3% (n = 16) Yes 0.68 Diabetes (Yes or No) 16.0% (n = 12) Yes 10.7% (n = 8) Yes 0.33 23.4% (n=18) Yes Osteoporosis (Yes or No) 20.8% (n = 16) Yes 0.69 Mini-mental state exam score^a 28 (26-29) 28 (25-29) 0.67

A higher score indicates a lower risk of dementia

^aScore range 24–30 (indicates a normal cognition)

Table 1 Demographic

assignment

characteristics by treatment

area. The dropouts of the study for each group at each stage are shown in Fig. 1. Furthermore, none of the participants reported any deterioration of their symptoms nor did they experience any adverse reactions during both the treatment period and the follow-up period.

The demographic features of both groups are summarized in Table 1. There were no significant differences between the two groups in terms of demographic variables (p < 0.05) from the results of the independent samples t tests and χ^2 tests that were performed.

Outcome measures

Timed up-and-go (TUG) test

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the TUG score, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) post-hoc test displayed a significant difference between groups in the TUG score from the 6th month until the 12th month (p < 0.001, 95% CI). The above analysis shows that the TUG score was significantly reduced in both groups. However, this reduction was greater in the intervention group, 17.8% by the 6th month (-2.06 s) versus 3.9% (-0.44 s) in the control group (relative to baseline). The difference in the





Fig. 1 CONSORT flow diagram of participants' recruitment

Table 2 Outcomes measure scores mean (SD) values of the intervention group (IG) and control group (CG) for each time point with p values presentation

	Baseline	6th month	12th month
TUG sec (SD))		
IG	11.5 (1.31)	$9.5(0.74)^{a}$	$9.9(0.78)^{a}$
CG	11.3 (1.49)	10.9 (1.24)	11.3 (1.22)
p value	0.153	< 0.001	< 0.001
95% CI	(-0.10, 0.65)	(-1.72, -0.92)	(-1.76, -1.01)
Cohen's f	0.71		
4-stage balan	ce test sec (SD)		
IG	21.1 (3.71)	22.5 (3.14) ^a	22.2 (3.02)*
CG	21.0 (4.23)	20.9 (3.34)	20.5 (2.62)
p value	0.904	0.003	0.001
95% CI	(- 1.02,1.15)	(0.59,2.77)	(0.70,2.87)
Cohen's f	0.31		
30 s chair sta	nd test times (SD)	1	
IG	9.8 (2.63)	12.5 (2.56) ^a	11.5 (2.11) ^a
CG	10.2 (2.42)	10.5 (2.18)	10.4 (2.22)
p value	0.242	< 0.001	0.007
95% CI	(-1.21, 0.31)	(1.16,2.68)	(0.29,1.81)
Cohen's f	0.28		
BBS			
IG	45.2 (5.67)	51.2 (2.62) ^a	49.5 (3.10) ^a
CG	46.0 (4.46)	47.7 (3.02)	46.2 (3.08)
p value	0.257	< 0.001	< 0.001
95% CI	(- 1.93,0.52)	(2.28,4.73)	(1.96,4.41)
Cohen's f	0.54		
CONFbal-Gl	REEK score (SD)		
IG	13.5 (2.71)	11.5 (2.82) ^a	12.1 (2.44) ^a
CG	13.7 (2.70)	12.5 (3.51)	13.6 (3.83)
p value	0.688	0.051	0.003
95% CI	(-0.18, 0.78)	(- 1.95, 0,01)	(- 2.47, - 0.51)
Cohen's F	0.23		
Short FES-I s	score (SD)		
IG	12.5 (3.13)	$8.0(0.95)^{a}$	8.5 (1.26)*
CG	12.6 (3.49)	11.0 (2.33)	11.8 (2.66)
p value	0.844	< 0.001	< 0.001
95% CI	(-0.88, 0.72)	(- 3.72, - 2.12)	(-4.04, -2.44)
Cohen's f	0.74		
Number of fa	lls times (SD)		
IG	2.0 (1.02)	-	0.6 (0.75) ^a
CG	2.1 (1.07)	-	1.7 (1.16)
p value	0.629	-	< 0.001
95% CI	(-0.41,0.25)	-	(- 1.39,- 0.74)
Cohen's f	0.48		

^aBetween groups significant comparisons in the post hoc testing

intervention group was observed in the 6th month, while the reduced values remained statistically significant until the 12th month.

4-stage balance test

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the 4-Stage Balance Test time score, while a main effect on the "Time" factor was observed (p < 0.05) (Table 2). Tukey's (HSD) post hoc test displayed a significant difference between groups in the 4-Stage Balance Test time score from the 6th month until the 12th month (p < 0.05, 95% CI). The above analysis shows that the 4-Stage Balance Test time score increased after the intervention in the intervention group, while it was slightly reduced in the control group. In the intervention group, it increased by 6.85% (+1.45 points) in the 6th month, while, on the contrary, in the control group it was reduced by 1.09% (-0.22 points).

30 s chair stand test

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the 30 s chair stand test score, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) posthoc test displayed a significant difference between groups in the 30 s chair stand test score from the 6th month until the 12th month (p < 0.05, 95% CI). The above analysis shows that the 30 s chair stand test score increased more after the intervention in the intervention group than in the control group. In the intervention group, it increased by 27.35% (+2.67 lifts) in the 6th month, while in the control group, it increased by 2.93% (+0.3 lifts).

Berg balance scale (BBS)

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the BBS test score, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) posthoc test displayed a significant difference between groups in the BBS test score from the 6th month until the 12th month (p < 0.001, 95% CI). The above analysis shows that the BBS test score increased more after the intervention in the intervention group than in the control group. In the intervention group, it increased by 13.27% (+6.00 points) in the 6th month, while in the control group it increased by 3.89% (+1.79 points).

CONFbal–GREEK questionnaire

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.05) for the CONFbal–GREEK questionnaire score, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) post hoc test displayed a non-significant

difference between groups in the CONFbal–GREEK questionnaire score on the 6 months measurement (p > 0.05, 95% CI), whereas it displayed a significant difference between groups on the 12 month measurement (p < 0.001, 95% CI). The above analysis shows that the CONFbal–GREEK questionnaire score decreased more after the intervention in the intervention group than in the control group. This difference was not statistically significant in the 6th month but was statistically significant in the 12th month. In the intervention group it decreased by 14.47% (-1.95 points) in the 6th month, while in the control group it decreased by 8.63% (-1.18 points).

Short falls efficacy scale international questionnaire

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the Short FES-I questionnaire score, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) post hoc test displayed a significant difference between groups in the Short FES-I questionnaire score from the 6th month until the 12th month (p < 0.001, 95% CI). The above analysis shows that the Short FES-I questionnaire score decreased more after the intervention in the intervention group than in the control group. In the intervention group, it decreased by 35.78% (-4.48 points) in the 6th month, while in the control group, it decreased by 13.01% (-1.64 points).

Number of falls

The two-way ANOVA analysis displayed a significant "Group" × "Time" interaction effect (p < 0.001) for the number of falls, while a main effect on the "Time" factor was observed (p < 0.001) (Table 2). Tukey's (HSD) post hoc test displayed a significant difference between groups in the number of falls on the 12 months measurement (p < 0.001, 95% CI). The above analysis shows that the number of falls decreased more after 1 year in the intervention group than in the control group. The total number of falls in the 12 months measurement in the intervention group decreased from 149 (in the baseline measurement) to 46, a reduction of 69.12%, while in the control group it decreased from 155 to 126, a reduction of 18.70%.

Secondary outcomes

Adherence to exercise program

The two-way ANOVA analysis displayed no significant "Group" × "Time" interaction effect (p > 0.05) for adherence to the exercise program, while a main effect on the "Time"

factor was observed (p < 0.001). The progress of adhering to the program during the 6 months period is shown in Fig. 2.

Discussion

This study aimed to investigate the effects of a 6-month OEP on older adults who have fallen. The TUG test score results revealed that the intervention group improved more than the control group (Table 2). The improvement can be attributed to the application of the OEP, which benefited the functional ability of the participants. We employed the TUG test cut-off values proposed by Bohannon [39] to ensure our sample homogeneity and produce safer conclusions. Indeed, the TUG test mean values in baseline measurement in both groups corresponded to older adults with a moderate risk of falling (Table 2) [38]. In contrast, the final values of the participants of the intervention group after 6 months of application of the OEP were close to the normal values corresponding to the specific age group (9.2 s in the age group 70–79) [39].

The TUG test results of this study are in line with the results of Dadgari et al. [54]. Additionally, in terms of program conduction (live sessions and video supported), it is in line with the results of Benavent-Caballer et al., [55] who found positive effects on the TUG score after 6 months of implementation of a video-supported OEP. Our findings, however, contradict the findings of Liu-Ambrose et al. [56] and Binns & Taylor, [57] in whose studies the TUG time after application of an OEP did not improve significantly. It is also important to note that the TUG time changes were maintained in the follow-up after the completion of the OEP. The clinical significance of the TUG test score reduction is based on Cohen's f, which was found to be moderate to high (f=0.71, Table 2) [53].

Regarding the score of the 4-Stage Balance Test, also known as Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT-4) [58], it improved more in the intervention group compared to the control group (Table 2). This can be attributed to the implementation of the OEP, which can be assumed to significantly benefit the static balance of older adults. According to the American Physical Therapy Geriatrics Association (APTA Geriatrics), no study to date has individually evaluated this test [59]. According to the STEADI toolkit proposed by the Centers for Disease Control and Prevention (CDC) to assess the risk of falls in older adults, [38] an older adult who cannot hold a 10 s tandem stance is at increased risk of falling. Some studies evaluate the tandem stance or the single limb stance in seconds, [12, 55] while in one study the FICSIT-4 [60] was not scored using the 28-point scale suggested by APTA Geriatrics [40]. The use and scoring of this test are a novelty for our research. However, we cannot compare our findings to



Fig. 2 Mean values for the times the exercise program was performed by each group per month of follow-up. *IG* Intervention Group, *CG* Control Group

those of other studies due to a lack of comparable data. We consider our findings to be clinically significant, despite a low to moderate Cohen's f (f=0.31, Table 2). Cohen [53] states that the commonly used interpretation of effect sizes as small (f=0.2), medium (f=0.5), and large (f=0.8) may not be strictly valid in reference to novel findings and cannot be compared to related findings in the literature [61]. The use and application of this test in future research will provide additional information about the more accurate interpretation of this test.

Furthermore, the BBS test score improved significantly in the intervention group (Table 2). This can be attributed to the OEP, which presumably improved the balance of the participants. Based on the findings of Donoghue et al., [62] true change (95% confidence) in individuals with original BBS scores in the range of 45–56 is defined as a minimal clinical difference of four points. The BBS score of the intervention group at the end of the 6 months OEP implementation period improved by six points (compared to baseline), while the difference between the groups was 3.5 points. The results of this study are in line with those of Benavent-Caballer et al., [55] who also found a difference of 3.5 points in the BBS score after the implementation of a 4 months video-supported OEP. In addition, we found a 3.2-point difference between the groups at the 12 months follow-up (Table 2), unlike the previous researchers, who did not conduct a follow-up measurement. The results of our study are also in line with those of Dadgari et al., [54] who identified positive effects on the BBS score by applying an OEP to older adult women. Cohen's f was found to be moderate (f=0.54, Table 2), [53] making the improvement in the BBS score in our research clinically significant.

The 30 s chair stand test values were also significantly improved in the intervention group (Table 2). This test evaluates functional lower limb strength [63]. Therefore, this performance improvement can be attributed to adjustments in lower limb muscle strength due to the OEP resistance exercise components. The mean test performance values in both groups in baseline measurements were low compared to the normal values (12-13 lifts) proposed by Jones et al.; [63] eventually, the participants in the intervention group approached the mean normal values corresponding to the specific age group (70-79). Our research agreed with the findings of other researchers, [54, 64] who also identified positive effects of an OEP on the 30-Second Chair Stand Test score. However, they are in contrast to those of Binns & Taylor, [57] who did not find any significant effects on the test score after the application of an OEP in older adults.

Cohen's f was found to be low to moderate [53] (f=0.28, Table 2), which makes our findings clinically insignificant.

The CONFbal score was improved in the intervention group (Table 2). This difference was marginally statistically insignificant in the 6th month but increased further in the 12th month. The intervention group participants exhibited higher balance confidence after completion of the study. This can be attributed to the positive effects that the application of OEP had on the balance of the participants, which was also confirmed by the results of the BBS and 4-Stage Balance Test scores. The CONFbal score difference in the 6th month (1.95 points, Table 2) was not only statistically insignificant but also not true as, according to Simpson et al., [48] the minimal detectable change in score indicating a true difference following treatment is three points. Cohen's f was found to be low (f=0.23, Table 2) [53]. It is worth noting that a significant percentage of participants from each group before the intervention were primitive fallers (Table 1), so they had no sense of insecurity, having experienced no recurring falls. Moreover, their low average age compared to those in other, similar studies may have played a role. The results of this study are in agreement with those of Gawler et al., [65] who found positive effects from the application of the OEP after 12 months of exercise.

The score of the Short FES-I improved significantly in the intervention group (Table 2). Baseline measurement mean values in both groups were indicative of moderate concern for fall (score range 9-13), according to the FES-I established cut-points for low, moderate and high concern about falling [66]. However, the intervention group values during the 6 months measurements approached the levels corresponding to low fear of falls, [49] while these improved values were maintained during the 12 months measurement. This indicates that the participants in the intervention group experienced lower levels of fear after the end of the program, which were maintained for 6 months after. In our opinion, this is due to the balance, strength, and functional ability adjustments of the OEP (Table 2). These findings are consistent with the results of Mat et al., [67] who also found positive effects on the Short FES-I score after the application of a 6 months modified OEP for older adults with knee osteoarthritis. Cohen's f was found to be moderate to high (f=0.74, Table 2), making the improvement clinically significant [53].

The number of falls was one of the main variables in our research because various studies have shown that the improvement of balance, strength and functional ability does not always lead to fewer falls. [65, 67] However, the participants of the intervention group experienced fewer falls 1 year after the start of the research (Table 2). This could be attributed to the implementation of the OEP and its benefits on the above-mentioned physical characteristics. Our findings in this area are in line with those of other studies that also found a decrease after the implementation of an OEP [54, 56, 68]. In addition, the 12 month decrease in the mean value of the intervention group number of falls compared to the baseline (decrease by 1.38 points, Table 2) was much greater than that of Dadgari et al. [54] (reduction by 0.3) after their application of a 6 month OEP in individuals with a similar mean age (approximately 70 years). This large decrease may be due to the way our program was administered. Probably, the fact that throughout the program there was a weekly individual supervised session which we recorded, and the participant repeated watching it at home, contributed to the optimal implementation of the OEP and more effective adjustments of the exercise. This fact is further confirmed by the participants' great improvement in strength, functional ability and balance. The reduction in the number of falls is clinically significant, as Cohen's f was found to be moderate (f=0.48, Table 2) [53].

Finally, some difference was observed between the mean values of the two groups regarding how many times they conducted the program per month (Fig. 2), although this difference was not statistically significant. Despite the successful implementation and application of our program during the intervention period and the consulting and training of all participants at the beginning of the intervention on how important it is to adopt lifelong exercise, we ultimately failed to persuade them to continue implementing the program after its completion. However, we cannot ignore the special conditions that prevailed during the period of this study, when, due to continued guarantine and restrictive measures, older adults were tired and had limited exercise options. The individual conducting of the OEP, given the general situation and social exclusion, may have had a negative effect on its long-term adoption.

This study had several limitations, related mostly to the COVID-19 pandemic. We had to modify the research design to account for the restrictive measures implemented in Greece for the protection of older adults. Despite that, the research was eventually completed without any particular problems for the benefit of the participants, as we covered, in a difficult period for them, their basic needs for communication, exercise and maintaining good health. A second limitation concerns the characteristics of the participants such as their unequal gender distribution, as well as a high functional level along with a relatively low average age. The fact that the majority were women and that the participants were in good physical condition (based on the TUG score < 15 s as an inclusion criterion) may have affected the sample representation in relation to the general population. Another limitation was the lack of control over how the OEP was implemented at home, as we did not have oversight regarding whether the program was implemented properly when the research team members were not present. By recording the sessions, we tried to provide each participant, individually, with the maximum feedback to properly perform the program at home. The data collection period was also limited. Despite the original OEP design (12 months duration with long follow-ups), due to the condition of the pandemic on one hand, and the accumulated fatigue of the participants on the other, we chose to conduct a 12 months follow-up instead of an 18 months follow-up (12 months after the end of the intervention).

The results of our study suggest that the application of a 6 months OEP performed under the supervision of a specialist physical therapist once a week and twice more individually at home with the help of the videotaped session significantly improved functional ability, balance and lower limb strength while reducing fear of falling and improving the balance confidence of older adults. In addition, the OEP managed to significantly reduce the number of falls a year after the start of the intervention. Most of these effects were statistically and clinically significant. However, adherence to the OEP was not found to be statistically significant. This confirms that individualized programs may better meet the needs of older adults but do not provide the socialization they require, especially during the COVID-19 pandemic. Because we were limited to a 6 months follow-up, we cannot provide a clear picture of the long-term effects of the OEP. More relevant research with longer follow-ups is needed in the future to determine the long-term effects of similar programs.

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Declarations

Conflict of interest The authors report no conflicts of interest.

Ethical approval Ethical approval was granted by the Ethics Committee of the Aristotle University of Thessaloniki (No. 44338/2020).

Informed consent The individuals were evaluated on whether they met the research inclusion criteria; also, printed information material was given and, upon agreement, the consent form was signed. The authors state that all participants signed an informed consent form.

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