ABSTRACT

Background and Purpose: Because of its high prevalence and association with negative health-related outcomes, frailty is considered one of the geriatric giants and its mitigation is among the essential public health goals for the 21st century. However, very few studies have focused on institutionalised older adults, despite the knowledge that frailty can be reversible when identified and treated from its earliest stages. Therefore, the objective of this study was to evaluate the effects of a supervised group-based multicomponent exercise program intervention (with or without oral nutritional supplementation) on functional performance in frail institutionalised older adults.

Methods: We conducted a multi-centre, randomised controlled trial with a 6-month intervention. A total of 111 frail institutionalised older adults (aged 75 years or more) who met at least 3 of the 5 Fried frailty criteria were randomly allocated to the control group (CG; n = 34, mean age = 87.3 ± 5.3 years), supervised group-based multicomponent Otago Exercise Program group (OEP; n = 39, mean age = 86 ± 5.9 years), or a supervised group-based multicomponent exercise program intervention with oral nutritional supplementation (OEP+N; n = 38, mean age = 84.9 ± 6 years). Measurements included the timed up-and-go test (TUG), Berg balance scale (BBS), short physical performance battery (SPPB), repeated chair stand test (STS-5), hand grip strength (HGS), 10-meter walking test (10MWT), and 6-minute walking test (6MWT), both at baseline and after the 6-month intervention period.

Results and Discussion: The between-group analysis by two-way mixed ANCOVA showed significant improvement in the TUG [{OEP vs. CG: −8.2 s, 95% CI [−13.3 to −2.9]; $p < 0.001$}; {OEP vs. OEP+N: −7.3 s, 95% CI [−12.4 to −2.2]; $p = 0.002$}], BBS [{OEP vs. CG; 8.2 points, 95% CI [5.2 to 11.2]; $p < 0.001$}; {(OEP+N vs. CG; 4.6 points, 95% CI [1.6 to 7.6]; $p < 0.001$}; {OEP vs. OEP+N; 3.5 points, 95% CI [0.6 to 6.5]; $p = 0.011$}], and HGS [{OEP vs. CG; 3.4 kg, 95% CI [1.5 to 5.3]; $p < 0.001$}; {OEP+N vs. CG; 3.6 kg, 95% CI {1.7 to 5.5}; $p < 0.001$}]. Additionally, the within-group analysis showed a significant improvement in the TUG (−6.9 s, 95% CI [−9.8 to −4.0]; $p < 0.001$) and BBS (4.3 points, 95% CI [2.6 to 5.9]; $p < 0.001$) in the OEP group. A significant decrease in the BBS and HGS was shown in the CG.

Conclusions: A 6-month supervised group-based multicomponent exercise intervention improved the levels of mobility, functional balance, and hand-grip strength in frail institutionalised older adults. Further research will be required to evaluate the nutritional supplementation effects on functional performance to better determine its clinical applicability for tackling frailty.

Keywords: physical exercise; functional performance; Otago Exercise Program; frail older adults; nutritional supplementation.

INTRODUCTION

Functional reserve capacity is reduced in frail older adults, leading to a decrease in functional performance.[1] Because of the high prevalence of frailty[2] and its association with negative health-related outcomes,[1] it is considered a true modern giant of geriatrics and so its reduction is among the essential public health goals for the 21st century.[3] In Western European countries, the prevalence of frailty can reach up to 9.9% of the population[2] and more profoundly affects adults aged over 75 years.[4] The prevalence of frailty in institutionalised older adults is even higher at up to 68.8%,[5] meaning that frailty is a common characteristic of the populations residing in long-term care facilities. Frailty has also been associated with higher levels of disability in terms of the basic activities of daily living in the occupants of residential care settings.[6] Despite its high prevalence and association with negative health-related outcomes, very few studies have focused on institutionalized older adults, even though frailty can be reversed when identified and treated from an early stage.[7,8]

Exercise and nutritional supplementation are widely supported interventions for the management and prevention of frailty.[9,10] Recently published clinical guidelines strongly recommend that frail older adults be referred to supervised progressive multicomponent exercise programs comprising resistance, balance, and aerobic training components.[11,12] Multicomponent exercise programs also effectively decreased and delayed the development of frailty in an institutionalised setting, improving the functional capacity and health-related quality of life of the participants.[13,14] The Otago Exercise Program (OEP) is an evidence-based exercise program that has been broadly documented in different geriatric populations and clinical settings[15] The OEP consists of progressive resistance strength training exercises, balance exercises related to everyday activities, and aerobic exercises supplemented with periods of walking.[16] Improvements in muscle strength, functional balance, functional performance and fall prevention have been reported in healthy and impaired adults who followed this program,[17–19] and when conducted in a group-based modality, the intervention provides the opportunity for social interaction during the training sessions,[20] thereby promoting physical activity between participants.[21]

Oral nutritional supplementation is also recommended to prevent the development of frailty. Previous studies have highlighted the association between the intake of low amounts of energy and inadequate levels of proteins and vitamin D, and an increased risk of developing frailty.[11,22] The European Society for Clinical Nutrition and Metabolism recently reported a strong consensus recommendation for the use of nutritional supplementation to improve and maintain nutritional status in frail older adults in residential care settings.[23] Furthermore, interventions combining nutritional supplementation and exercise were highly beneficial in terms of decreasing frailty[24] and improving physical performance and muscle mass.[25]

However, despite this existing evidence, very few studies have examined multicomponent exercise programs combined with nutritional supplementation interventions in frail institutionalised older adults.[13] To the best of our knowledge, no study has analysed the effects, in terms of functional performance, of a combined intervention applying the OEP and a nutritional supplementation in frail institutionalised older adults. Therefore, the main purpose of this present study was to evaluate the effects of the OEP on the functional performance in a sample of frail institutionalised older adults aged 75 years or more; our secondary aim was to evaluate the effects of nutritional supplementation on functional performance. We hypothesised that functional performance would significantly improve in both intervention groups and that the combination of OEP plus nutritional supplementation would show the largest improvements.

METHODS

Study Design

This was a multi-centre randomised controlled trial study with a 6-month intervention period (ClinicalTrials.gov ID: NCT03958318) that was designed to adhere to the recommendations of the Consolidated Standards of Reporting Trials statements.[26] The study design, protocol, and informed-consent procedure was approved by the Bioethics and Clinical Research Committee of University CEU Cardenal Herrera. The written informed-consent statement was signed by all the participants after we confirmed that they had fully understood the procedures. The assessments were conducted at baseline and at the end of the 6-month intervention period. The study was conducted from May 2019 and January 2020 in 7 long-term care facilities belonging to the Ballesol Residential Group in Valencia (5) and Alicante (2), Spain and followed the ethical guidelines set out in the Declaration of Helsinki.

Study Participants and Selection Criteria

We recruited 145 potential volunteer participants between March 2019 and May 2019. The participants met the following inclusion criteria: age ≥ 75 years, able to independently ambulate (with or without the assistance of a walking aid), no severe medical contraindication for performing physical exercise or completing the testing procedures (as determined by the attending physician), sufficient self-reported visual and auditory capacity to be able to follow the exercises and communicate, willingness to stay in the same facility during the length of the study, provision of a signed informed-consent statement, and a positive score for at least 3 of the 5 Fried frailty criteria.[27] Candidates who presented (1) a Mini-Mental State Examination score ≤ 17 points[28], corresponding to severe dementia or cognitive impairment that would prevent them from performing the exercise program; (2) a Barthel Index score < 60 points;[29] (3) unwillingness to comply with the study requirements; (4) an upper- or lower-extremity fracture in the year prior; (5) myocardial infarction in the year prior; (6) unstable cardiovascular disease or a neurological disorder that could prevent them from exercising; (7) or who were participating in any other activities involving a physical exercise routine, were excluded. A total of 111 individuals met the inclusion criteria and completed a baseline assessment; figure 1 shows the flow of the participants through the trial.

Randomisation and Blinding

The participants were randomly allocated into one of two intervention groups, the supervised group-based multicomponent OEP (OEP, *n* = 39) or OEP intervention with oral nutritional supplementation (OEP+N, *n* = 38), or to the control group (CG, *n* = 34). To do this, before starting the trial, researcher 1, who was not involved in the recruitment or inclusion of the participants, generated a random sequence using a computerised random number generator; this was concealed from all the other researchers throughout the entire study period. The assessors who collected the data were blinded to the group allocation, main study design, and hypothesised study outcomes, although it was impossible to conceal the group assignment from the co-investigators involved in the nutritional and exercise training procedures. Finally, the researcher responsible for conducting the data analysis was also blinded to the group allocations and treatments.

Outcome Measurements

Seven assessors administered the baseline and post-intervention measurements; all these staff had 10–25 years of clinical experience in physiotherapy (PT), had previously participated in physical exercise program studies designed for older adults, and had extensive experience in assessing participants using the functional tests employed in this work. Prior to starting the data collection, all the assessors attended a briefing seminar which described the assessment protocol and test implementation. Each assessor conducted the same tests at baseline and post-intervention at the end of the 6-month intervention, and there were no changes in the tests assigned to the assessors. Both the baseline and post-intervention measurements were conducted in 2 consecutive assessment sessions over 2 days. To minimise bias, the researchers collecting the data were not the same as those involved in the group allocation or data analysis.

All the test stations at each of the 7 facilities were set up in large indoor rooms, except for the 6-minute walking test (6MWT) and 10-metre walking test (10MWT) sites which were completed in large, wide corridors. All the measurements administered have been confirmed as valid and reliable in the scientific literature for assessing mobility, balance, aerobic endurance, gait speed,[30,31] lower-limb function, and upper-body strength in older adults.[32] Functional performance, such as the ability to safely and effectively perform the functional tasks necessary for daily living, is influenced by ambulation, postural stability, functional mobility, functional lower extremity strength, dynamic balance, and endurance.[33] Therefore, in this study, functional performance was considered the sum of mobility measured with the timed up-and-go test (TUG);[34] balance with the Berg balance scale (BBS)[35] and standing balance; aerobic endurance (6MWT);[39] usual gait speed (10MWT);[38] lower-limb function with the short physical performance battery (SPPB);[36] and lower body strength with the repeated chair stand test (STS-5).[36]

Primary outcome

The TUG[34] measures the time required for the participant to rise from a standard chair with armrests, walk 3 meters at a comfortable and safe pace to reach a plastic cone, go around the cone (in either direction), return to the chair, and sit down again. Participants were instructed to start the test seated in the chair with both arms resting on the armrests and their feet flat on the floor; they were allowed to use their walking aids if needed during the test. Before the participants performed the 2 test trials, 1 practice trial was conducted to ensure they had correctly understood how to complete the test. The time (in seconds) was recorded from the command "go" until the participant's back was placed against the back of the chair after sitting down. We recorded the quickest time after completing the 2 trials, with faster times indicating better performance.

Secondary outcomes

Functional balance was evaluated using the BBS,[35] a battery of 14 different tasks that are common in everyday life, with varying levels of balance difficulty (e.g., transfers, retrieving an object from the floor, tandem standing, reaching, 360° turns, standing with their eyes closed, or placing a foot on a stool). Each task was scored on a 5-point scale from 0 ('unable to perform' or 'needs assistance') to 4 ('able to perform independently'), according to the participant's performance or the time taken to complete the task. The sum of the individual task scores was recorded (the potential maximum score was 56 points), with higher scores representing better performance.

The SPPB[36] is a 3-component test that includes an assessment of standing balance, usual gait speed, and lower extremity strength on a 12-point scale ranging from 0 ('severe limitation') to 12 points ('absence or minimal limitation'); the overall score is the sum of the scores from each component, with higher scores representing better performance. Standing balance was evaluated using 3 independent tests: a side-by-side (feet together), semi-tandem (heel of one foot against and touching the side of the big toe of the other foot), and tandem (heel of one foot in front of and touching the other foot) standing positions. The participants were instructed to keep their feet in these positions; the highest score (4 points each) was given for balancing for 10 seconds in each test. Usual gait speed was evaluated by instructing participants to walk at their usual pace past the end of an 8-metre walking course. The assessor recorded the time required to cover the 4 central metres of the course (delimited by two tape lines). The test was repeated twice, and the fastest time (in seconds) was recorded, with higher scores given for faster times.

The STS-5,[36] which measures the time needed to rise from a chair and sit down again 5 consecutive times without the participant using their arms, was used to assess lower-limb strength. Participants were instructed to perform this test as quickly as possible while keeping their arms folded across their chest and their feet flat on the floor. The time (in seconds) was recorded from the command "go" with the participant seated, until the participant stood up for the fifth time. Higher scores corresponded to faster performance times.

Hand-grip strength (HGS) in the dominant hand (defined as the preferred hand used for daily activities) was evaluated using a hydraulic hand dynamometer (Jamar, Sammons Preston Rolyan, Chicago, Illinois, USA). The participants were instructed to remain seated with their shoulder adducted and neutrally rotated, elbows flexed at 90°, and forearm and wrist unsupported and in a neutral position during the measurement, and were told to squeeze the dynamometer handle as hard as possible after the command "go" while the assessor used strong verbal encouragement.[37] The second handle position on the dynamometer (at a fixed value of 5.5 cm) was set during the measurements. The test was repeated 3 times with at least 2 minutes of resting period between attempts, and the highest value (in kg) was recorded.

The 10MWT[38] was performed over a 6-metre walking course delimited by 2 tape lines. The participants were instructed to stand with their feet next to the starting point, which was designated by a plastic cone placed 2 meters behind the first tape line. After the command "go", the participants walked past the end of the course to reach a second cone placed 2 meters behind the second tape line; the assessor recorded the time (in seconds) required to cover the 6 central meters of the course starting when the participant's foot first crossed the first tape line and stopping when the same foot completely crossed the second tape line. For the usual speed evaluation, the assessor asked the participant to walk at their usual pace and not to walk at a fast speed or run, to reach the plastic cone; the mean time from the three trials were recorded and converted to meters per second (m/s).

Finally, the 6MWT[39] measured the maximum distance covered along a 30-metre corridor during a 6-minute period. Two plastic cones delimited the corridor, and 2-meter distance intervals were indicated with tape. The participants were instructed to walk the maximum distance they could (without running) from one end of the walkway to the other, stopping when needed. The assessor walked alongside the participants to ensure their safety and provided them with standardised verbal encouragement at 1, 3, and 5 minutes (e.g., "you're doing well" and "keep up the good work"). The test finished after 6-minutes and was stopped immediately if chest pain, dizziness, or dyspnoea was reported by the participant. The total distance covered (in metres) was recorded.

In addition to the functional performance evaluation, the following parameters were also measured: age, sex, height (cm), weight (kg), waist circumference (cm), body mass index (BMI; kg/m^2), and Barthel Index and Mini-Mental State Examination scores. Finally, exercise session attendance rates (compliance) was calculated in both intervention groups (OEP, OEP+N).

Intervention

Otago exercise program

The participants assigned to the OEP group enrolled in 3 non-consecutive sessions per week (Monday–Wednesday–Friday) of the multicomponent Otago Exercise Program[16] conducted at each centre. Thus, a total of 72 sessions were performed over a 24-week (6-month) intervention period; with 6 weeks spent on each of the 4 levels comprising the program. All the exercises were undertaken in a large indoor room with a level and non-slippery floor. Each participant was provided with a standard chair with a height of 45 cm, and 4 elastic bands (Thera-Band®, Hygenic Corp. Akron, USA), to provide resistance during the strength exercises.

The OEP[16] exercise routine performed in each session included balance, strength, and aerobic exercises, supplemented with walking periods at the end. The progression of the exercises, intensity (repetitions and resistance), and difficulty (support and performance) of the program was structured according to the guidelines for the practical implementation of the OEP.[16] A PT conducted and supervised the implementation of the OEP during the sessions to help the participants understand the session and program structure, assist them with the use of the elastic bands, and ensure confident, safe, and correct performance of the exercises. The PT also provided safety information, verbal instructions, and accurate visual guidance on how to perform the exercises. The chairs were set out in a semi-circle in front of the PT to favour participant eye contact with the PT and fluid transmission of the instructions.

The participants used elastic bands as an external source of resistance for the strengthening exercises. As recommended, they started with the yellow band at level 1, which provided 1–2 kg of resistance, and increased the resistance by 1–1.5 kg[40] at levels 2, 3 and 4 (every 6 weeks).[16] Any participants who perceived the elastic band change to be too intense were allowed a few sessions to accommodate to the new level using the band from the previous level. Each exercise session lasted 45–60 minutes, according to the program level. Because the OEP is progressive, each level included different exercises with varying degrees of difficulty and repetitions per exercise, with the difficulty increasing over the 4 levels. Therefore, level 1 sessions were shorter (45 min) compared to level 3–4 sessions (60 min).

Intensity was monitored by noting the resistance band used during the exercises as well as perceived effort. The participants were instructed to perform the strengthening and aerobic exercises at a "somewhat hard" (5–6/10) intensity according to the OMNI-Resistance Exercise Scale of perceived exertion with elastic bands in the elderly,[41] and the Modified-Rating of Perceived Exertion RPE.[42] The PT also reminded the participants of these intensity instructions during the walking sessions. An exercise booklet to illustrate and provide instructions about the OEP was provided to each participant or their carer/family. Participants in the OEP and OEP+N groups did not participate in any other activities involving a physical exercise routine that could have compromised the effects of the intervention in this work.

Otago exercise program plus nutritional supplementation

Participants assigned to the OEP+N group followed the same exercise protocol as the OEP group but also received an oral nutritional supplementation with 2 daily doses of 35g of ENSURE®, a formula designed to preserve muscle mass in older adults (Abbott Laboratories, Indianapolis, IN). Each dose contains 233kcal, 8.65g protein, 7.61g fat (polyunsaturated fatty acids 0.85g), 30.64g carbohydrates, 1.68g fibre (fructooligosaccharides), 500 IU vitamin D, ß-hydroxy-β-methylbutyrate, and 321mg calcium (a more detailed composition can be found here: https://www.ensure.abbott/uk/products/nutrivigor/). The nursing staff at each facility supplied the doses and encouraged the participants to continue the consumption of their regular meals. Participants who were unable to tolerate the full amount of the nutritional supplement doses were initially allowed to consume the overall dose (70g) fractionally throughout the day until full tolerance was achieved.

Control group

The participants in the CG did not receive any interventions and were asked to continue their ordinary daily living activities.

Data Analysis

In order to detect a reduction in TUG by 1.8 (standard deviation [*SD*] = 1.5), as found in a previous study,[18] with a two-sided 5% significance level and a power of 80%, and also accounting for an anticipated dropout rate of 20%, we calculated that a sample size of 35 participants per group would be required.

Intention-to-treat statistical analyses were performed. To compare the success of the randomisation, one-way ANOVA and chi-squared tests were used to determine the differences between the groups at baseline. Compliance with the assumption of normality was checked for each dependent variable and each study group by using Kolmogorov–Smirnov tests. Two-way mixed ANCOVA tests were employed to compare the intervention effects on TUG, BBS, SPPB, STS-5, HGS, 10MWT, and 6MWT between the groups, with time (baseline vs. 6 months) serving as the within-group factor and groups (CG vs. OEP vs. OEP+N) as the between-group factor. Baseline data were used as a covariable to control for pre-intervention differences between the groups.

To further explore the effects of the interaction between the factors (time and group), post-hoc paired Student *t*-tests with a Bonferroni adjustment for alpha inflation were carried out. Effect sizes were estimated using the partial eta squared (η^2_p) and were interpreted following the Cohen guidelines[43] for small effect sizes (η^2_p = 0.01), moderate effect sizes (η^2_p = 0.06), and large effect sizes (η^2_p = 0.14). The data are presented as the mean ± the *SD*. The statistical analyses were conducted using SPSS 21.0 for Windows (IBM Corp., Armonk, NY). To avoid increasing type I error by repeating the univariate tests for each of the 7 dependent variables, a Bonferroni adjustment was applied to the level of significance. Thus, the alpha level for these 7 comparisons was 0.05/7, that is, $p = 0.007$.

RESULTS

We screened 145 candidates in this randomised controlled trial; 34 were not allocated for randomisation because they declined to participate ($n = 7$) or did not meet the inclusion criteria ($n = 27$) as follows: not frail (7), unable to ambulate independently (8), severe psychiatric disorder (3), Barthel index score < 60 points (4), unstable cardiovascular disease or neurological disorder (3), or other (2). The baseline descriptive characteristics of the 111 participants are presented in table 1; although there were no significant differences at baseline between groups for age, sex, weight, height, BMI, waist circumference, use of an assistive device for walking, TUG, BBS, STS-5, HGS, or 6MWT scores, there was a significant difference ($p = 0.002$) for the 10MWT (table 1). In addition, the OEP group showed poorer performance in the TUG (27.6 s) compared to the OEP+N and CG groups (20.6 s and 21.0 s, respectively), although these differences did not reach significance. Thus, the baseline data were used as a covariable.

Adherence

The dropout rate (percentage of participants who abandoned the exercise program without follow-up) was 23.1% and 44.7% for the OEP and OEP+N groups, respectively during the 6-month intervention. A training session was considered completed when 100% of the exercises had been performed. Reasons for missing sessions were illness, hospitalisation, participant choice, or other reasons (e.g., family visit, medical examination, or chiropodist visit). The adherence rate (percentage of sessions attended from the total number of planned sessions) in the OEP and OEP+N after the 6 months of the intervention was 71% and 63%, respectively. No significant adverse effects were reported during the intervention period by the participants involved in the exercise groups.

Intervention effects

The interaction between time and group was significant for the TUG ($F[2,106] = 9.083$, $p < 0.001$, $\eta^2_p = 0.146$), BBS ($F[2,107] = 21.911$, $p < 0.001$, $\eta^2_p = 0.291$), and HGS ($F[2,107] = 13.329$, $p < 0.001$, $\eta^2_p = 0.199$). The between-group post-hoc analysis of the two-way mixed ANCOVA showed significant differences in the TUG in the OEP group compared to the CG group (OEP vs. CG; −8.2 s, 95% CI [−13.3 to −2.9]; $p < 0.001$) and OEP+N group (OEP vs. OEP+N; −7.3 s, 95% CI [−12.4 to −2.2]; $p = 0.002$) after the 6-month intervention period (table 2).

The post-hoc analysis of the secondary outcomes showed a significant difference in the BBS (OEP vs. CG; 8.2 points, 95% CI [5.2 to 11.2]; $p < 0.001$) and HGS (OEP vs. CG; 3.4 kg, 95% CI [1.5 to 5.3]; $p < 0.001$) in the OEP group compared to the CG. There was also a significant difference in the OEP+N group for the BBS (OEP+N vs. CG; 4.6 points, 95% CI [1.6 to 7.6]; $p < 0.001$) and HGS (OEP+N vs. CG; 3.6 kg, 95% CI [1.7 to 5.5]; $p < 0.001$) compared to the CG. The OEP group showed significant differences in the BBS (OEP vs. OEP+N; 3.5 points, 95% CI [0.6 to 6.5]; $p = 0.011$) compared to the OEP+N group.

Additionally, the within-group post-hoc analysis showed a significant improvement in the TUG (−6.9 s, 95% CI [−9.8 to −4.0]; $p < 0.001$) and BBS (4.3 points, 95% CI [2.6 to 5.9]; $p < 0.001$) in the OEP group, with moderate to large effect sizes ($\eta^2_p > 0.09$) for the TUG and BBS (table 3). In contrast, there was a significant decrease in the BBS and HGS in the CG group, but no significant improvements in the OEP+N group after the 6-month intervention period.

DISCUSION

The main result of this current study was that completing the 6-month, supervised, multicomponent group-based OEP significantly improved functional performance in frail institutionalised older adults, with a large effect size for the TUG test and BBS. Thus, this exercise program was safe and no adverse effects were reported by the participants during the assessments or the exercise sessions. Moreover, the reported attendance rate (75%) was considerably higher than that for other facility-based individual exercise programs.[44] The improvements in functional performance showed by the OEP group were consistent with previous OEP group-based interventions lasting 8,[45,46] 12, or 24 weeks,[18,20,47] demonstrating that its implementation in this manner could help to reduce fragility in older adults living in long-term care facilities and could partially mitigate the age-related decline in their physical condition. Improvements in mobility by −2.4 to −0.9 seconds after group-based interventions have been previously reported.[18,20,45,47] Although our findings in this current study were in line with these studies, the improvements we saw in the OEP group were considerably higher at a mean −6.9-second reduction in the time needed to perform the TUG.

Given that our study lasted 24 weeks while previous interventions lasted 8 to 16 weeks, this variance could perhaps be explained by the length of the program. Thus, longer interventions may contribute to producing greater benefits in variables such as mobility, balance, and lower limb strength compared to shorter interventions.[45,47] Additionally, the sample characteristics may also impact on the effectiveness of the exercise program; our study cohort comprised institutionalised frail older adults, while previous studies analysed healthy community-dwelling[18,20,45,46] or independent institutionalised[47] older adults with less advanced ages and higher functional statuses. As reported by Rejesky et al., baseline values intrinsically affect changes in functional performance, with higher gains obtained in participants with the poorest baseline performance.[48] This is encouraging, given that in our work, the intervention in the OEP group resulted in an improvement that reached the performance level considered as 'independently mobile', despite their low levels of baseline mobility.[34]

Previous studies revealed that an 8-week OEP intervention in a group-based setting significantly improved functional balance[45] assessed with the BBS. Our results showed an improvement in functional balance similar to that reported by longer OEP interventions (by 3.2 to 5.3 points) lasting 4–6 months.[18,20,47] In agreement with these results, the OEP group showed an improvement by > 4 points, indicating that these individuals achieved a clinically meaningful change in their functional balance.[49] Additionally, the intervention in the OEP group improved the performance status of the participants to the degree that they were considered 'independent'.[50] Finally, we also found a significant improvement in the HGS in both the OEP and OEP+N groups compared to the CG, while a significant decrease was observed in the CG during the same period.

The improvements in functional capacity shown in our study are consistent with previous group-based OEP interventions, providing further evidence to support the benefit of delivering the OEP in a group setting. Furthermore, in this current work, improvement or maintenance of the values of these functional variables contributed to reducing or minimising frailty in older adults living in long-term care facilities. Nonetheless, no significant changes were found in the usual gait speed (10MWT) or aerobic endurance (6MWT) in OEP or OEP+N groups compared to the CG. The lack of improvement in these gait speed-related measures may have been influenced by the use of walking aids by the participants, given that previous studies have shown that these moderate the effects of exercise on gait speed in populations of older adults, thereby potentially concealing the positive effects achieved by these exercises.[51]

Despite the enhancement in physical performance reported by previous interventions that combined nutritional supplementation and exercise,[24,25] and the recent recommendations in the guidelines for nutritional supplementation in frail institutionalised older adults,[11,22] our results for the OEP+N group falsified our original study hypothesis. In our setting, adding a nutritional supplementation to the OEP improved functional balance and HGS compared to the CG but did not produce better results in the functional outcomes compared to the OEP. The high dropout rate seen for the

OPE+N group (44.7%), in addition to the lower adherence rate to exercise sessions (63%) for this group were likely the main reasons for the absence of functional performance improvements seen in these participants.

Some individuals in the OPE+N group decided to leave the study after reporting intolerance to the nutritional supplement which included nausea, vomiting, diarrhoea, and abdominal pain, which may have contributed to the absence of significant improvements in the functional performance variables for this group. In this context, daily dose, protein quality, timing of ingestion, and tolerance, in addition to metabolic factors,[52] may have all contributed to causing this high percentage of dropouts. Indeed, we must consider all these specific aspects of supplementation, as well as individual preferences and palatability, in order to improve participant tolerance to these supplements.[53] Furthermore, anabolic resistance mechanisms at work in older muscle tissues can limit additional responses to exercise when the upstream signal of amino acids or proteins are increased.[14] This factor may have also contributed to the non-significant improvement in functional performance we observed in the OEP+N group.

Of note, although the SPPB, STS-5, HGS, gait speed, 10MWT, and 6MWT in the OEP group and TUG, BBS, SPPB, STS-5, HGS, 10MWT, and 6MWT in the OEP+N group did not significantly improve, these factors did not worsen. In comparison, there was significant worsening in the BBS and HGS after 6-month period in the CG. As also recently reported elsewhere, functional decline and an increase fragility-related adverse outcomes can occur very quickly[7] thus, reinforcing the need for the implementation of long-term, interrupted exercise programs in frail institutionalised older adults.

A major strength of this study was the effectiveness of the PT-supervised multicomponent OEP which helped manage frailty in institutionalised individuals. The OEP was a defined, progressive, and simple program which can easily be transferred to clinical practice, favoured social interaction, and had a low economic cost. However, we also noted some limitations; first, the study sample size for the OEP+N group was small. Even though we based our sample size calculations on previous work, there were 17 drop-outs (45%) over the 6-month intervention period, meaning that our statistical analysis was underpowered. Thus, the ability to detect significant effects of the intervention in the OEP+N group data may have been compromised. Second, we did not perform a follow-up to determine the long-term effects of the intervention. Third, we did not monitor the diet of the participants during the study. Finally, varying degrees of frailty and other geriatric syndromes are common in institutionalised older adults; our study participants were volunteers who were frail and therefore, were not representative of all older adults living in long-term geriatric care facilities. Therefore, volunteer bias may threaten the generalisability, transferability, and utility of our findings and detract from their clinical value.

When sample cohorts comprise only those willing to participate, systematic differences may arise between those who volunteer and those who decline the invitation to participate. Consequently, we must be mindful of the need to adapt the application of exercise programs to a heterogeneous population and consider individual characteristics and preferences (person-centred care) to guarantee the safety of the participants with greater limitations, as well as the effectiveness of the intervention. Thus, caution should be used when directly applying these findings to all frail institutionalised older adults.

CONCLUSION

In conclusion, the findings of this current study showed that a 6-month supervised group-based progressive multicomponent exercise intervention which included strength, balance, and aerobic exercises improved the levels of mobility, functional balance, and hand-grip strength in frail institutionalised older adults. Further research will be required to evaluate the effects of nutritional supplementation on functional performance and to better determine its administration and clinical applicability in the treatment of frailty.

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