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Original Research

The effectiveness of progressions of difficulty during an exercise program to improve balance and gait in older individuals: A randomized clinical trial

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ABSTRACT

Background: Little is discussed about the effectiveness and systematization of progressions of difficulty during balance exercises. Exercise progression provides continuous stimulation and assists physical therapists in offering challenges to patients.
Objective: To investigate the effectiveness of an exercise program with systematic progression of difficulty for older individuals.
Methods: Randomized clinical trial, with 22 older individuals allocated to experimental (EG, $N = 12$) or control (CG, $N = 10$) group. In EG, individuals performed an exercise program with progressions of difficulty for 12-weeks (2 days/week, 1 h/session). In the control group the participants performed the same program without progressions of difficulty. The Berg Balance Scale (BBS), Timed up and Go (TUG), and modified Dynamic Gait Index (mDGI) were assessed after and before the 24 exercise sessions. An intention-to-treat approach and multiple imputation by chained equations were utilized. Raw data were transformed into standardized individual differences (SID) and analyzed using one-way ANCOVA to test group effects, with baseline and age as covariates. A one-sample *t*-test was used to compare SIDs against zero. Effect sizes were estimated using partial eta squared (ηp^2) and Cohen's d.
Results: ANCOVA revealed no significant group effect across any of the variables. Baseline values emerged as significant predictor of changes in BBS ($P = 0.038$, η_p^2=0.219), TUG ($P = 0.042$, η_p^2=0.210), and mDGI ($P <$ 0.001, η_p^2=0.545), suggesting a substantial differences among participants with lower baseline values. Age also emerged as a significant predictor of change for mDGI ($P = 0.002$, η_p^2=0.431). Comparison with zero-value produced significant differences for BBS and mDGI, indicating increases in post-intervention for both groups.
Conclusion: Applying progressions of difficulty to the exercises, did not lead to greater improvements than not applying them.
Clinical trias: https://ensaiosclinicos.gov.br/rg/RBR-8dpxgcf

Introduction

The aging process can lead to the deterioration of various functions, including muscle strength, mobility, and postural stability.[1,2] These changes render individuals more susceptible to experiencing falls,[1,2] which can result in fractures, hospitalization costs, disability, social isolation, and mortality.[3–5] A study identified 135,209 deaths resulting from falls among individuals aged 60 and older, between 2000–2019.[4] Therefore, exercise programs for fall prevention are very important given the significance of balance training and muscle strengthening in enhancing both static and dynamic postural stability.[6–8] These interventions reduce the risk and frequency of falls and enhance functional capacity, muscle strength, and quality of life in older individuals.[6,8,9]

An interesting strategy that can be associated to different types of exercises to reduce the fall risk in the elderly is progressions of difficulty. This approach offers several potential benefits: facilitation of

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individualized training; consistent stimulation for ongoing development of strength, balance, and coordination; prevention of skill plateaus through continuous improvement; guidance to maintaining an appropriate challenge level; and boosts motivation and adherence to the exercise program, thereby potentially enhancing the clinical effectiveness of exercises.[10,11] While some studies made progressions in difficulty like dual-tasks or sensory modifications, none systematically examined their impact on postural control. Moreover, some studies lacked treatment for control groups and provided limited information on when and how difficulty progressions were added during treatment.[12–19]

Hence, the objective of this study is to assess the efficacy of an exercise program incorporating systematic progression in stability demands, aimed at decreasing the risk of falls in elderly. We hypothesized that the progressions of difficulty in postural stability training would have a positive impact on the effectiveness of the exercises, reducing the risk of falls.

Methods

This study consists in a two-arm, assessor-blinded, randomized clinical trial (ReBEC RBR-8dpxgcf), and was approved by the CEP-UNISUAM, Rio de Janeiro, Brazil (protocol-number 40,095,420.4.0000.5235). The findings were reported according to the CONSORT statement.[20]

Between April-September 2022, older individuals of a local university exercise center, and residents from the program's neighborhood were invited to participate. Also, invitations were made through social media. After being informed about the study, they were invited to attend the research center where they underwent an interview. If the eligible individuals agreed to participate, they had to read and sign the consent form.

Inclusion criteria were the following: individuals of both sexes, aged 60 years or older, with ability to walk 10 m with or without the use of an aid device; exclusion criteria were: individuals scoring ≤ 18[21] on the Brazilian version of the Mini-Mental State Examination,[22–24] individuals with neurological or orthopedic conditions that limit their daily activities, amputees and/or individuals with lower limb prostheses, and individuals who have any uncontrolled cardiovascular, pulmonary or metabolic diseases, or any other health condition that could potentially impact the safe execution of the exercise protocol.

Intervention

For randomization purposes, a computer-generated sequence was used to allocate participants in either experimental or control group, with allocation ratio 1:1. The allocation sequence was arranged using a stratified and block randomization model by an investigator not involved in the study. The stratification variable was the risk of falls measured by the Berg Balance Scale.

In the experimental group, participants engaged in an exercise program designed to improve balance both in static positions and during walking, with varying levels of difficulty. In the control group the participants performed the same program without progressions of difficulty. Both groups performed muscle strengthening. The program lasted 12 weeks with two one-hour sessions per week, individually administered under the supervision of two physical therapists. After each session, a physical therapist recorded patient progress, noting difficulties of complaints, as well as any complications, incidents, or potential falls.

Balance in static positions

In this part of the program, the patients were instructed to adopt the following postures: kneeling, semi-kneeling, standing with feet together, standing in semi-tandem position (feet together, with one of them slightly in front of the other), standing in a tandem position (one foot in front of the other), and standing in a one-foot posture. During each session, all postures were performed. They were required to maintain each posture for 30 s, repeating it four times for each lower limb, except for the one-foot support, which required a 20-second hold.[25] Using different postures leads the individuals to learn to control their balance under different degrees of freedom, different heights of the center of mass, and different support base sizes, these biomechanical constraints being important factors for postural orientation and stability[26]

In the experimental group, the levels of difficulty included:

[1] *External support*: the participant performed each posture using a different degree of external support (based on the instructions recommended by Otago Exercise Programme[27]), which changed every three sessions. This variable was included with the aim of exercising the ability to maintain the posture stability against gravity through the following degrees of support: support offered by the physical therapist (1st-3rd sessions), support on the parallel bar or wall (4th-6th sessions), without external support (7th-9th sessions), and with the physical therapist applying external resistance at the individual's scapula (Stabilizing Reversals from – Proprioceptive Neuromuscular Facilitation-PNF Approach[28] at the scapula - 10th-12th sessions).
[2] *Dual task*: individuals should maintain the postures while performing head or arms movements in one plane (neck flexion/extension, cervical rotation, shoulder flexion/extension, and shoulder adduction/abduction – 13th-15th sessions), and then in three planes, that is, diagonally (in each of the postures, while catching a ball in one side and giving it to the physical therapist on the opposite side – 16th-18th sessions); diagonal movements are a basic procedure from PNF concept, called patterns of PNF, which combines three-dimensional muscle contractions, meaning the movement occurs in the sagittal, transverse, and frontal planes. The aim of this part was to acquire the ability to perform movements in one or more planes while maintaining stability.[28]
[3] *Sensory information*: in the 19th-21st treatment sessions, participants performed the exercises blindfolded. In the last three sessions, they were challenged to execute the exercises on an unstable surface using a balance pad (Mormaii®, Garopaba, Brasil). Modifying sensory information during training is important to train the individual's ability to reweight sensory information (coming from the visual, vestibular, and somatosensory systems) to maintain stability in different contexts.[26]

Balance during walking

This part consisted of gait training under different conditions: forward and backward gait; lateral gait crossing the foot in front, and after crossing the foot behind; braiding gait; march in tandem forward and backward, ending with a mixing of the preceding gaits.

In the experimental group, the levels of difficulty included:

[1] *External support*: it varied as follows - during the 1st to 3rd sessions the participant performed the different gait exercises with the hands of the physical therapist on their shoulders; during the 4th to 6th sessions, with support of one hand on the wall; during the 7th to 9th sessions without any external support/aid; and during the 10th to 12th sessions with the physical therapist applying manual resistance to the patient's pelvis.
[2] *Dual task*: during the 13th to 15th sessions vertical and horizontal movements of the head were included; and during the 16th to 18th sessions the patient was asked to walk while catching and throwing a ball.
[3] *Sensory information*: during the 19th to 21st sessions, the exercises were performed blindfolded and during the 22nd to 24th sessions the program was executed using an unstable surface (mats).

Muscle strengthening

Strength training was performed all sessions and included exercises to strengthen lower limbs using weight shin guards: squat; climbing a step with weight shin guards (step) and plantar flexion. Training consisted of 1 series of 10–15 repetitions, with an interval of 2–3 min between each exercise, following the concept of an "intrinsic model, ,[29] in which the training program is guided by the participant's perceived effort.[30,31] The objective was to make the patient reach a specific number of repetitions and performing the movement correctly, at a controlled speed. The load was determined so that a "somewhat hard" effort, corresponding to scores 6–7 on the OMNI-Resistance Exercise Scale,[32] or OMNI-RES, reported after each exercise. Load adjustment was performed whenever there was a reduction in the effort perceived by the patient for a given exercise, maintaining scores of 6–7.

Outcome measures

The outcomes were assessed before the exercise program began (pre-intervention) and immediately after completing the 24 intervention sessions (post-intervention).

Modified dynamic gait index (mDGI)

The mDGI consists of 8 items that assess the ability for gait adaptation: gait pattern, level of assistance, and time to perform tasks. The total score ranges from 0 (severe gait impairment) to 64 (no gait impairment).[33,34] The Minimal Detectable Change (MDC) of this scale correspond to a difference of 4 points in the total score.[33]

Berg balance scale (BBS)

The BBS aims to assess functional balance in 14 tasks of daily living. Each item receives a score of 0–4, with a total score ranging from 0–56. The higher the score, better the individual's balance. The individual is at a high risk of falls if his score is equal to or <45.[35]

Timed up and go test (TUG)

It is a functional mobility test in which the risk of falling, gait, and transfers are evaluated. It measures the time it takes the individual to get up from a chair, walk three meters, return, and sit down.[36] A time greater than 13.5 s to perform the test indicates a high risk of falls in healthy older individuals.[37,38]

Four stages balance test (4Stage)

This test aims to assess static balance. Individuals are asked to stand in 4 progressively more challenging positions: feet together; semi-tandem; tandem; and single leg stance. If the individual can maintain a position for 10 s without moving their feet or needing support, the next position is performed.[37]

Blinding

Outcome assessors were blinded to group allocation. However, blinding of participants and treating physical therapists was not feasible.

Statistical analysis

The sample size calculation was performed using the G*Power program (version 3.1.9.2, Düsseldorf, Germany). Originally, it was considered a statistical design using a mixed ANOVA, with 2 intra-group factors (pre-test vs. post-test time) and 2 inter-group factors (control vs. experimental). The model used in this study assumes a moderate effect size ($\eta^2 = 0.14$), alpha of 5 %, and statistical power (1-beta) of 80 %. It considers a repeated measures correlation of 0.3 (lower limit of the moderate correlation range) and does not involve correction for sphericity. A sample loss of 10 % was considered. Thus, we obtained a total sample size of 22 participants. The post-hoc power analysis for ANCOVA was 82 %, based on the findings reported in the Results section.

Data registry and organization was performed in Microsoft Excel (Microsoft®, Redmond, Washington), while statistical analysis was run in JASP 0.17.2.0 (The JASP Team, Amsterdam, The Netherlands) and Python 3.11.5 environment. An intention-to-treat approach was used for data analysis. Missing data were handled using multiple imputation by chained equations (MICE), which iteratively impute missing values in a dataset using regression models[39] (Fig. 1). MICE was implemented in a Python 3.11.5 environment using the "statsmodels" package, version 0.14.0.

The raw data were transformed into standardized individual differences (SID), computed for each variable as the individual delta (post-pre) values divided by the standard deviation of the group delta.[40] A one-way ANCOVA, adjusted for the corresponding outcome's baseline value and age, was used to check for between-group differences. Additionally, a one-sample *t*-test was applied to compare the SID with zero-value reference, to check for significant changes in outcome values over time (where zero-value implies no change). The effect size was estimated by calculating the partial square of eta (η_p^2) and Cohen's *d*,[41,42] respectively. The η_p^2 scores were interpreted according to the following cut-off values: trivial effects for $\eta_p^2<0.01$, small effects for $0.01\leq\eta_p^2<0.06$, moderate effects for $0.06\leq\eta_p^2<0.14$, and large effects for $\eta_p^2\geq0.14$.[41] Cohen's d values were interpreted according to the following limits: trivial ($d = 0.20$), small ($0.20\leq d < 0.50$), moderate ($0.50\leq d < 0.80$), or large ($d \geq 0.80$).[42]

Finally, the scores of 4 STAGE were grouped according to changes in post-to-pre-intervention data (decreases in performance, increases in performance, or no change). Because only one individual from the control group exhibited a decrease in performance, their data were excluded and a 2 × 2 contingency table analysis was applied. The statistical threshold was defined as alpha equal to 5 %.

Results

The trial ended when the sample size was achieved, and the participants performed the intended 24 exercise sessions. Three individuals dropped out of the study during the intervention period (Fig. 1). Nevertheless, after imputation of missing data, the final sample used for analysis consisted of 22 individuals (Control group = 10, Experimental Group = 12; Fig. 1), of which 19 completed the 24 sessions without complications or falls. Table 1 shows clinical and demographic variables.

Outcome measures

Descriptive analysis for the pre- and post-intervention outcome data for both groups are shown in Tables 2 and 3 and Fig. 2.

Between-group differences

ANCOVA showed no significant effect for group for any of the variables (BBS, $P = 0.722$, $\eta_p^2=0.007$; TUG, $P = 0.755$, $\eta_p^2=0.006$; mDGI, $P = 0.644$, $\eta_p^2=0.012$; Table 2), indicating that the type of intervention did not have a discernible overall effect when controlling for baseline value and age. However, baseline values emerged as significant predictor of changes in all variables (BBS, $P = 0.038$, $\eta_p^2=0.219$; TUG, $P = 0.042$, $\eta_p^2=0.210$; mDGI, $P < 0.001$, $\eta_p^2=0.545$), suggesting a substantial difference in change in participants with lower baseline values. Additionally, age also emerged as a significant predictor of change for mDGI ($P = 0.002$, $\eta_p^2=0.431$), but not for BBS ($P = 0.329$, $\eta_p^2=0.053$) or TUG ($P = 0.632$, $\eta_p^2=0.013$), indicating large changes in those with lower ages.

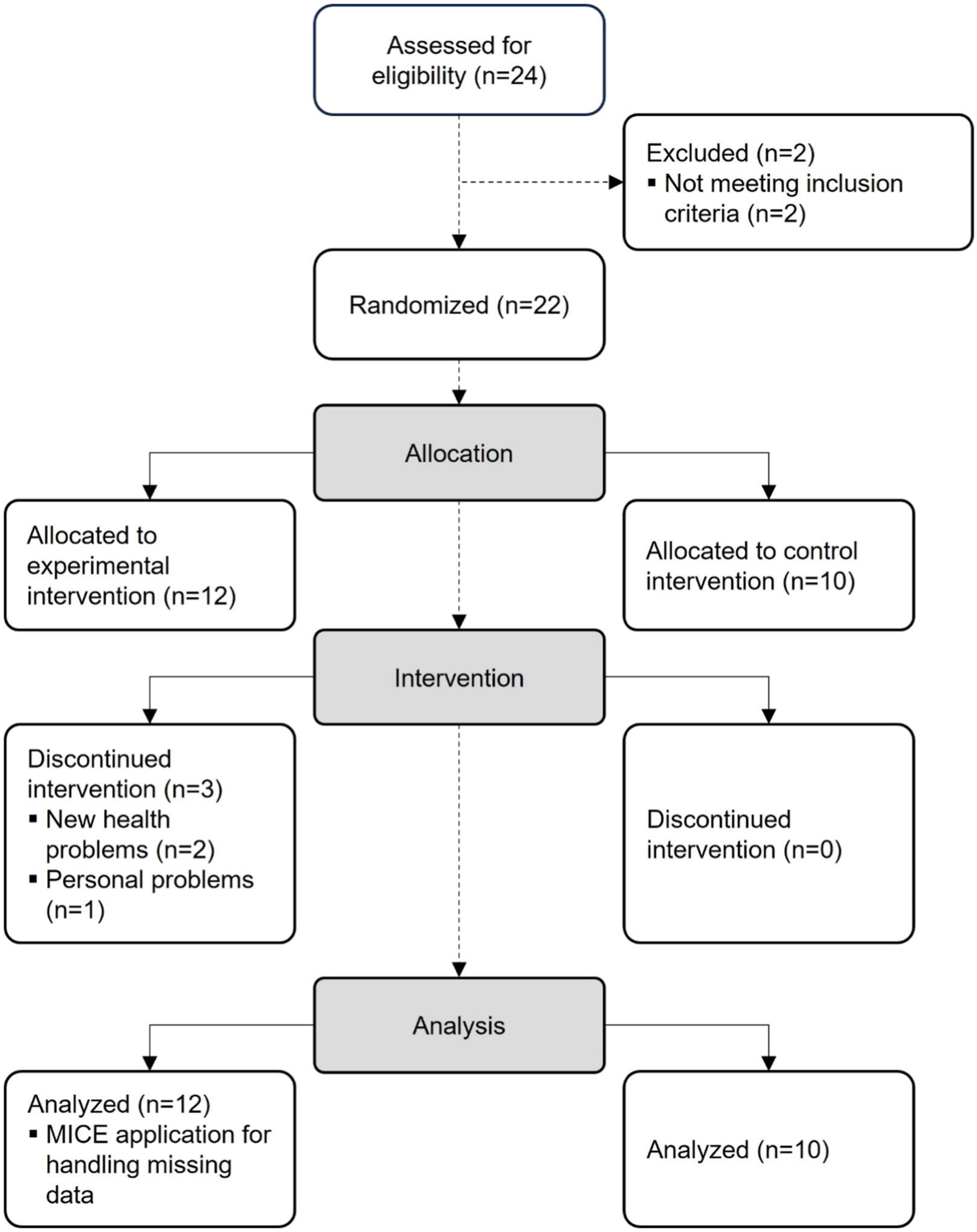

Fig. 1. CONSORT Flow Diagram. MICE, multiple imputation by chained equations.

Table 1
Clinical and demographic variables of patients (n = 22).

Variable	Groups	
	Control (n = 10)	Experimental (n = 12)
Sex (Male/Female)	5/5 (50/50)	3/9 (25/75)
Age (Years)	65 (60–73)	71 (61–83)
Weight (kg)	77 (52–118)	66 (49–92)
Height (cm)	163 (150–178)	159 (145–178)
Aid device (Yes/No)	0/10 (0/100)	2/10 (17/83)
Physical activity (Yes/No)	2/8 (20/80)	6/6 (50/50)

Data are showed as mean (range) or absolute (relative) frequency.

Comparison with zero-value

The computed SID values were compared between groups with a t-test for independent samples. Additionally, SID values were compared with zero-value (indicative of no change between pre and post intervention) with a one-sample t-test. Comparing the SIDs between the groups, we did not find differences for BBS (P = 0.378, d=−0.386), TUG (P = 0.316, d=−0.440), or mDGI (P = 0.679, d=−0.180).

However, significant differences were observed when comparing the SIDs to the zero-reference value. As shown in Fig. 2, there are differences in both groups for BBS (control group P = 0.001, d = 1.539; experimental group P = 0.002, d = 1.136), and mDGI (control group P = 0.022, d = 0.872; experimental group P = 0.014, d = 0.837), but not for TUG (control group P = 0.451, d = 0.249; experimental group P = 0.490, d = 0.206). Along with the raw scores, these results corroborate the significant changes (increases) in BBS and mDGI scores in the post-

Table 2
Pre- and post-intervention scores for both groups.

Variables	Groups						ANCOVA, effect of group	
	Control			Experimental				
	Pre	post	SID	pre	post	SID	P-value	η_p^2
BBS (scores)	54.4 ± 1.2 (53, 56)	55.9 ± 0.3 (55, 56)	1.0 ± 0.7 (0.0, 2.0)	52.1 ± 4.7 (41, 56)	54.2 ± 3.9 (43, 56)	1.4 ± 1.2 (0.0, 4.1)	0.722	0.007
TUG (s)	10.6 ± 1.4 (8.4, 13.2)	10.2 ± 1.6 (7.9, 12.3)	−0.2 ± 0.9 (−1.5, 1.4)	13.9 ± 10.4 (5.7, 45.9)	14.4 ± 12.1 (7.2, 52.0)	0.2 ± 1.1 (−1.3, 3.0)	0.755	0.006
mDGI (scores)	51.9 ± 4.8 (43, 60)	56.2 ± 3.6 (50, 61)	0.8 ± 0.9 (−0.4, 2.5)	44.0 ± 13.1 (7, 56)	49.3 ± 11.2 (18, 62)	1.0 ± 1.2 (−1.6, 2.2)	0.644	0.012

Data expressed as unadjusted mean ± SD (min., max.). BBS, Berg Balance Scale; mDGI, modified Dynamic Gait Index; SID, standardized individual difference; TUG, Timed Up and Go Test.

Table 3
Contingency table with the distribution of 4Stage' changes in performance.

	"no improvement"	"improvement"	total	statistics*
Control group	4 (44 %)	5 (56 %)	9 (100 %)	$P = 1.000$, φ=0.028
Experimental group	5 (42 %)	7 (58 %)	12 (100 %)	

*Results from Fisher's exact test. Data presented as groups' absolute (relative) frequency.

intervention period for both groups.

Analysis of the 4Stage

Table 3 presents the distribution of changes in performance of the 4 Stage for each group, along with the result of the Fisher's exact test and the effect size measure (phi coefficient, φ). Overall, nine participants showed no change, nine increased their performance by 1-point, and three increased it by 2-points. Only one participant in the control group exhibited a negative change, going from a score of 4 to 3 after the intervention (data excluded from analysis). As observed in the table, there is a strong correspondence in the distribution of performance change among the groups, with no differences between them.

Discussion

This study aimed to investigate the effectiveness of systematic progressions of difficulty during an exercise program to reduce risk of falls in elderly. The results showed improvements in performance on the balance (BBS), gait (mDGI), and 4Stage test, with no difference between groups.

The increase in BBS and mDGI scores in both groups demonstrates an improvement in functional and gait balance (or capacity to adapt gait[33]), respectively. Although the BBS showed a ceiling effect, baseline values significantly predicted changes in all variables, indicating important differences for participants with lower baseline scores. T-Test analysis also revealed significant differences in both groups compared to the zero-reference value, confirming substantial increases in BBS scores post-intervention for both groups. Similarly, the results of the 4Stage indicate an improvement in static balance. Altogether, these results suggest a potential reduction in the risk of falls among participants after the intervention.

At baseline, there was a difference between the TUG scores of the two groups, but the ANCOVA analysis showed that when adjusting for different pre-intervention values, there was no difference between groups. Interestingly, the average time to perform the TUG test increased for the experimental group after the intervention. This may be because those in this group had a higher average age than the control group, showing an apparent decline in their functional mobility despite the exercise intervention.

No difference was found between the groups in any outcomes, contrary to initial hypothesis. This result may be attributed to the fact that, in both the experimental and control group, participants were engaged in muscle-strengthening exercises with load progression. This would likely have promoted benefits for both groups. The hypothesis of this study posited that progressions in difficulty could result in increased challenges in the execution of various body functions, such as balance and strength. It is plausible that if the muscle strengthening, to which both groups were exposed, had not been implemented, the experimental group might have demonstrated more improvements than the control group. Also, the sample of control group had a relatively younger mean age than the experimental group, and therefore, they could have a major potential to benefit from the proposed exercises. This is corroborated by the ANCOVA result which showed that age (as a covariate) emerged as a significant predictor of change for mDGI scores ($P = 0.002$, $\eta p^2=0.431$), implying large changes in those with lower ages.

According to Shummway-Cook et al.,[33] MDC for the mDGI score is 4 points. Analyzing the present results, both groups exceeded this difference by comparing the pre- and post-intervention periods (Table 2). Furthermore, considering the 4Stage test, the inability to maintain the tandem posture for 10 s is a predictor of a fall.[43] It is interesting to note that after treatment, 11 % of the individuals in the experimental group and 10 % of the individuals in the control group were in stage 3 (tandem), and that 66.7 % of the individuals in the experimental group and 90 % of the control group were in stage 4 (single leg stand). Together, these results suggested that there was an important change in the ability of the participants to maintain postural balance.

Several recent clinical trials that investigated the effects of exercise on the risk of falls in older individuals did not offer a treatment to the control group, or offered an intervention not focused on balance or strengthening exercises (such as, for example, muscle stretching).[12,15,16,19,44,45] This makes it difficult to compare these results with the present study, or even to verify the effectiveness of the treatment offered. On the other hand, other trials offered treatment related to balance and/or strength exercises for both treatment groups.[13,14,18,46–49] Of these, five studies found an improvement for both groups in the post-treatment period,[18,46–49] as did the present study; one did not find improvement for either group,[13] and finally, one study did not compare the pre- and post-treatment periods.[14] Regarding the difference between groups, four studies found a difference in at least one outcome,[46–49] in the post-intervention period, different from the present study; and one study found no difference between groups for any of the parameters, with improvement for both.[18]

Some limitations of the study were that in the control group, the participants already started the study with higher scores than those in the intervention group (Table 2), combined with the fact that both groups were subjected to strengthening exercises with load progression. These factors may have masked the effects of progressions of difficulty in balance exercises.

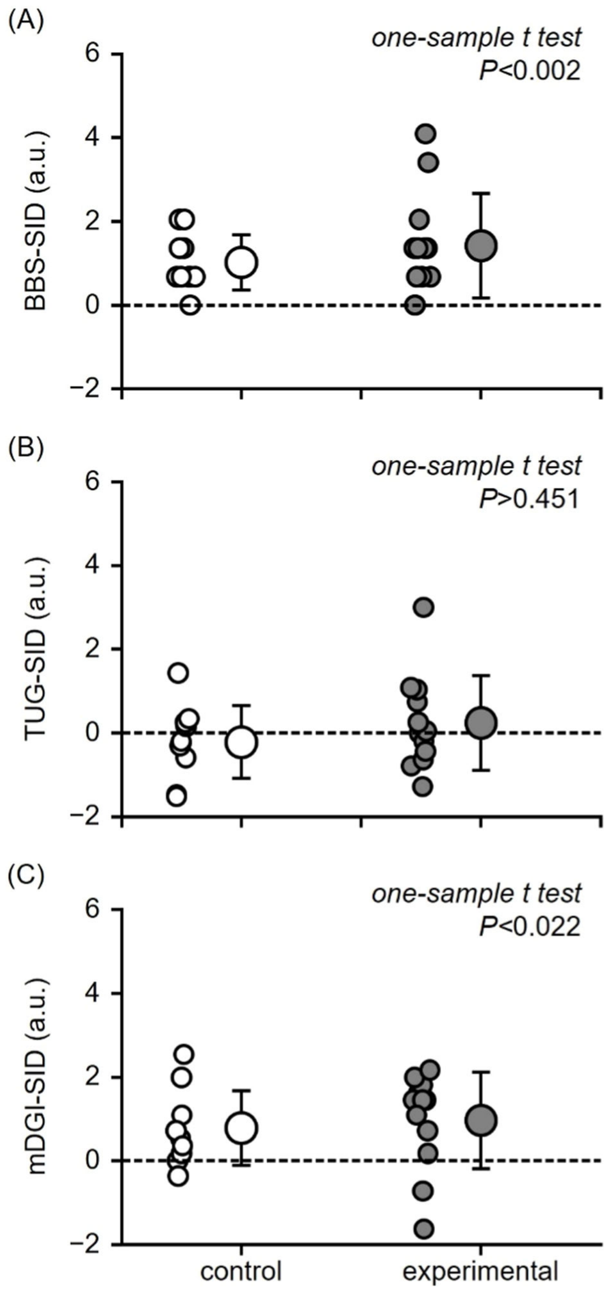

Fig. 2. SID values of control (white markers) and experimental (gray markers) groups, for Berg Balance Scale (A), Timed Up and Go (B), and modified-Dynamic Gait Index (C). Individual data (small circles) were showed along with groups' mean and SD (circles with whiskers). Results from one-sample t-test are showed as inset. a.u., arbitrary units.

Conclusion

This study showed that implementing variations in exercise difficulty did not result in greater performance enhancements. Both exercise programs proposed were effective to improve balance and gait in older individuals. In this study, a feasible and safe exercise protocol was provided, with details about progression of difficulties, series, repetitions, and duration, that can be useful as a guide for physical therapists in clinical practice.

Declaration of competing interest

The authors declare no competing interest.

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