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The effect of proprioceptive neuromuscular facilitation techniques compared to general aerobic exercise on balance, fear of falling, and quality of life in older adults living in nursing homes: a randomized controlled trial

Mehrnaz Kajbafvala^{1*} , Mina Ansari Eshlaghi¹, Shabnam ShahAli¹, Fateme Pourkazem¹ and Anahita Hejazi²

Abstract

Background With aging, changes occur in various body systems, such as cardiovascular, respiratory, neuromusculoskeletal, and vestibular, leading to a decreased quality of life (QOL) and an increased fear of falling (FOF). Exercise and physical activity reduce the progression of aging complications. Therefore, we examined the effect of proprioceptive neuromuscular facilitation techniques compared to aerobic exercise on balance, fear of falling, and quality of life in older adults living in nursing homes.

Methods Fifty-two older adults aged over 60 (31 males, 21 females) living in nursing homes were included. After initial evaluation, individuals were randomly assigned to two treatment groups (PNF techniques and aerobic exercise). Both treatment groups received 12 treatment sessions over 4 weeks. Balance, fear of falling, and quality of life were assessed at baseline and after a 4-week intervention. Analysis of covariance (ANCOVA) and paired samples t-test were utilized to between and within-group changes of variables.

Results The results showed no significant differences in balance, fear of falling, and quality of life between groups after the intervention ($P > 0.05$). In the within-group comparison, only the PNF techniques group showed significant improvement in the Berg Balance Scale (BBS) after the intervention ($P < 0.05$).

Conclusion The findings suggest that PNF techniques compared with aerobic exercise could not contribute to improved balance, fear of falling, and quality of life. Therefore, more clinical trial studies with a control group are needed to determine the exact effects of these techniques.

Trial registration number (TRN) and date of registration The trial was registered at the (<https://www.irct.ir>), (IRCT20210505051181N4) on 9/2/2023.

*Correspondence:
Mehrnaz Kajbafvala
mehrnaz.kajbafvala@gmail.com

Full list of author information is available at the end of the article



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Keywords Proprioceptive neuromuscular facilitation, Aerobic exercise, Balance, Fear of falling, Quality of life, Aging

Introduction

Aging is a continuous and irreversible process with a growing trend worldwide [1]. Over the last decade, human lifespans have increased significantly, and by 2050, the population over 65 years old will reach from 550 million to 1.4 billion people [2, 3]. With aging, changes occur in various body systems, such as cardiovascular, respiratory, neuromusculoskeletal, and vestibular, leading to a decreased quality of life (QOL) and an increased fear of falling (FOF) [4, 5].

Low levels of physical activity are associated with poor postural control and impaired balance [5]. Exercise and physical activity could reduce the progression of aging complications [5, 6]. Aerobic exercise is a common physical activity. The benefits of aerobic exercise for older adults extend beyond cardiovascular changes. This type of exercise could reduce the inactivity-induced loss of strength, mobility, balance, and endurance that are necessary for the safe performance of an activity of daily living (ADL) in older adults [7].

Several studies have investigated the effect of aerobic exercises on improving physical function [7–9]. According to a systematic review and meta-analysis, exercises including an aerobic component could be effective for balance improvement and fall prevention in older adults [5]. The results of the study by Mei and Chang showed that aerobic exercise could effectively improve the body performance of older adults in ADL [9]. Walking, as a general aerobic exercise could improve postural balance in older adults by increasing muscle strength and proprioception [10]. In addition, walking has positive effects on coordination, reaction time, falling reduction, and mobility [10].

The proprioceptive neuromuscular facilitation (PNF) technique is a therapeutic approach for improving balance through proprioception [4, 11]. Proprioceptive exercises are specifically designed to stimulate mechanoreceptors which are embedded in the skin, joint capsule, and surrounding connective tissue, and all of them lead to improvement in proprioception [12]. Areeudomwong et al. in a randomized controlled trial study, assessed the effects of PNF training and general trunk exercises on pain intensity, disability, and static balance in working-age patients with chronic low back pain. The results demonstrated more improvement in static balance provided by PNF techniques compared to the general trunk exercises [13]. Rhythmic stabilization (RS) and stabilizing reversal (SR) as PNF techniques could improve balance through increasing stability, muscle strength, and coordination between agonist/ antagonist muscles [14]. In

addition, they could play an important role in decreasing FOF and increasing QOL in older adults [6, 15, 16].

The high prevalence of proprioceptive deficits as the main basis of physical function and balance disorders, as well as the relationship between balance disorders and FOF and consequently decrement in QOL in older adults, make it necessary to plan an effective treatment approach [6, 17, 18]. The underlying assumption of this study was that neuromuscular stimulation using proprioception could provide an effective treatment strategy for balance disorders and its consequences in older adults [11, 19]. Because of the importance of the role of trunk muscles in balance and postural control, applying PNF techniques in the lower trunk was chosen [20].

To the best of the authors' knowledge, a study on the effect of PNF techniques on balance, fear of falling, and quality of life in older adults has not yet been investigated. Findings of this specific protocol are needed to provide scientific knowledge for the appropriate treatment strategies in the clinical setting of this population. Therefore, the main aim of this study is to compare the effect of proprioceptive neuromuscular facilitation techniques to aerobic exercise on balance, fear of falling, and quality of life in older adults living in nursing homes.

Methods

Trial design

The current study is an assessor-blind 1:1 randomized clinical trial with a parallel group of 52 patients designed to investigate the effect of PNF techniques compared to aerobic exercise on balance, fear of falling, and quality of life in older adults living in nursing homes. This study followed the CONSORT guidelines. The study protocol was registered in the Iranian Registry of Clinical Trials (IRCT20210505051181N4).

Participants

Fifty-two older adults were recruited through nursing homes. Figure 1 shows a flowchart of participant recruitment. Demographic variables, including age, gender, weight, height, body mass index (BMI), were recorded. BMI was captured from height and weight measurements (weight divided by height squared). Data was collected from several nursing homes in Tehran, Iran, from March 2023 to November 2023. Participants were included if they met the inclusion and exclusion criteria. Table 1 summarizes the eligibility criteria of the study. Ethical approval for the study (IR.IUMS.REC.1401.914) was obtained from the Iran University of Medical Sciences. All eligible participants were informed about the interventions before signing the consent form.

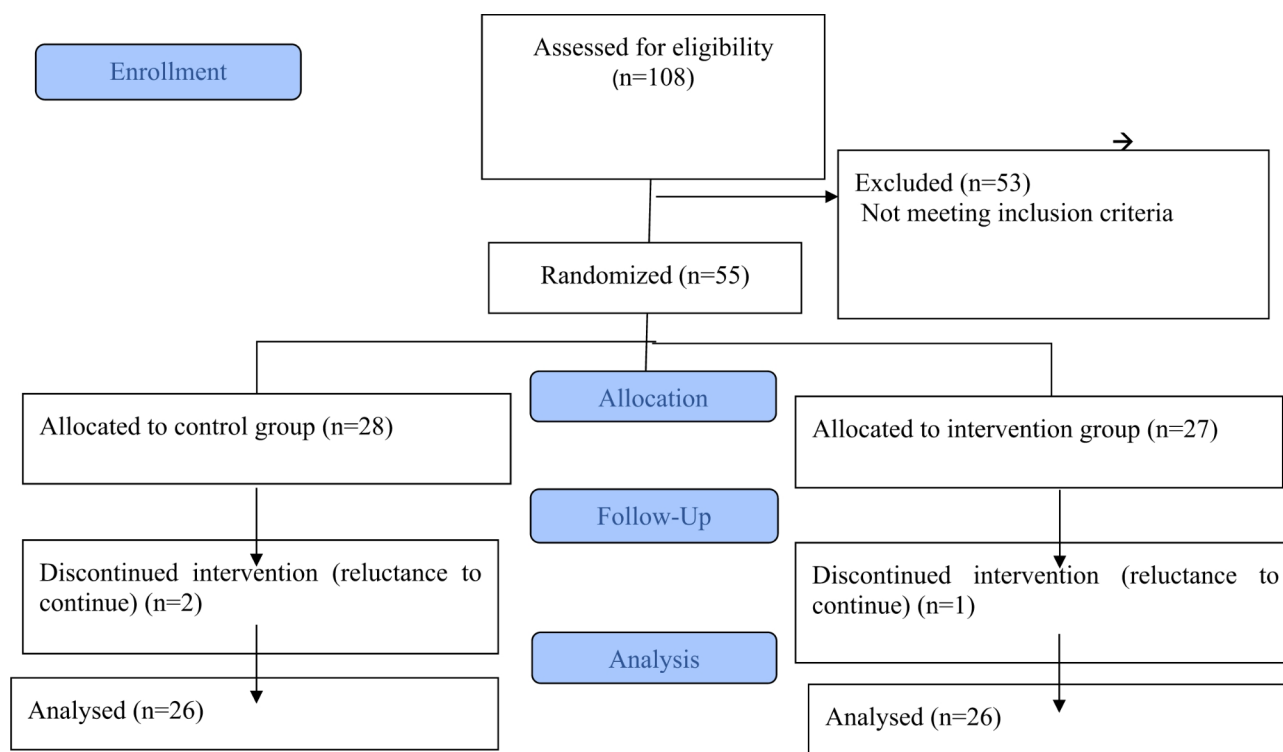


Fig. 1 The CONSORT flow chart of participants

Table 1 Inclusion and exclusion criteria of the study

Inclusion criteria	Exclusion criteria
1-Age over 60 years old	1-Inability to stand without assistive device
2- BBS score between 21 to 48	2- Use assistive devices during walking
	3- Inability to walk 30 m or more without assistance
	4- Any physical and movement restrictions in pelvic, hip and knee joints
	5- Inability to exercise for 30 min
	6- Having neuromusculoskeletal, neurological, neuropathy, psychological and mental diseases
	7- Vestibular disease
	8- unstable or ongoing cardiovascular/respiratory disorders
	9- History of hearing and visual impairment
	10- Cognitive impairments diagnosed by a physician

BBS: Berg Balance Scale

Initial assessment

The initial assessment consisted of evaluating balance disorders in older adults. To check the presence of balance disorders, the Berg Balance score (BBS) test was taken, if the acquired score was between 21 and 48, they were included in the study. The assessor examined all outcome measures before and after treatment sessions.

Randomization

Before beginning the intervention, a clinic secretary, outside the research team, performed the randomization process. All participants were randomly assigned to two

treatment groups (PNF techniques and aerobic exercise) with an allocation ratio of 1;1, using a block-balanced randomization method [13].

Blinding

The study followed an assessor-blind design. The examiner was unaware of the specific allocation and treatment group assignments, and participants were not blinded to the intervention groups.

Interventions

One of the two treatment groups received PNF techniques ($n = 26$) and the other received aerobic exercise ($n = 26$). The trial was conducted over 4 weeks, 3 sessions a week, with a total of 12 sessions intervention period [21–23]. Each treatment session included a 5 to 7-minute warm-up followed by 40 min of exercise protocol and concluded with a 6-minute cool-down. The entire session lasted approximately 50 min. The interventions were supervised by a physiotherapist with more than 3 years of clinical experience with older adults.

Warm-up and cool-down exercises

Active warm-up exercises for both groups included lunge, whole body stretch, upper trapezius, wrist extensors, and wrist flexors muscle stretch (Fig. 2). All these warm-up exercises were done 3 times with a hold time duration of 15 Sect. [24]. Cool-down exercises for both



Fig. 2 Warm up (A) Whole body stretch, (B) Upper trapezius muscle stretch, (C) Wrist flexor stretch, (D) Wrist extensor stretch, (E) Lunge

groups included (A) knee to chest in the supine position (2 repetitions, 20–30 s hold time) [25] (B) shavasana relaxation; subjects were asked to lie in the supine position with eyes closed and relax the body for 5 min [24] (Fig. 3).

Aerobic exercise group

Participants in the aerobic exercise group engaged in supervised outdoor walking sessions led by a therapist, each lasting 40 min [26]. The initial walking distance for each participant was established based on their capacity to ambulate before exhibiting signs of fatigue, shortness of breath, pain, or expressing a need to sit or rest. Throughout the 4-week walking program, the advised walking intensity was set at a cadence of 100–115 steps per minute, which is considered optimal for achieving moderate-intensity walking. Accupedo Pedometer software was utilized to monitor the participants' step counts during the walking sessions. Participants were

encouraged to increase their step counts by 10–15% in each subsequent session compared to the previous one [26–28]. Achieving a daily step count of 3,000 steps corresponded to approximately 30 min of moderate physical activity.

PNF techniques group

Participants in the PNF techniques group received PNF techniques including rhythmic stabilization (RS) and stabilizing reversal (SR) that were conducted on the lower trunk (flexor and extensor muscles) (Figs. 4 and 5). At first, the RS technique was performed on the lower trunk, and after 2 min rest the SR technique was executed [29]. Each technique consisted of 3 sets [21, 23] and 10 repetitions with a duration time of 10 s in each set [21, 23, 29]. Among the sets, 1 min was given for rest and 30 s between repetitions. The RS technique comprised of isometric contraction of antagonist muscles with emphasis on co-contraction of agonists and antagonist muscles. No



Fig. 3 Cool down (A) Knees bending toward the body, (B) Shavasana relaxation

movement was allowed. Verbal cues included “Don’t let me move you, hold” [17, 30]. This technique was applied to the trunk flexor and extensor muscles in a sitting position [16, 31]. The SR technique consisted of alternating isotonic contraction of the first agonist and then the antagonist’s muscle without rest [14, 32]. Specific details of the PNF techniques are provided in Supplementary 1.

Outcomes

All outcomes were measured by a blind assessor on two measurement time points: 24 h before the commencement of the first treatment session and 24 h after the end of the twelfth session [33].

Primary outcome measures

Balance

In the current study, balance was the primary outcome. Berg Balance Scale (BBS), Functional Reach test (FRT), and Timed Up and Go test (TUG) were used to evaluate balance. The test order was randomized for each

participant [34]. Before testing, a familiarization trial of all tests was performed [31]. The BBS assesses both dynamic and static balance [35]. The BBS is a sensitive tool for measuring functional balance in older adults. the test contains 14 self-report items describing functional activities of daily living such as sitting to stand, standing with eyes opened, sitting, stand to sit, standing with eyes closed, standing without support with paired feet, forward reach, etc. Higher scores indicate better functional balance [26]. The BBS is a reliable and valid assessment tool [36]. The TUG test is a single-item test for rapid screening of functional mobility. TUG has demonstrated acceptable reliability and validity in older adults [26]. To perform the test, participants were instructed to stand up from a chair without the support of hands, walk 3 m at their comfortable speed, turn, walk back toward the chair, and sit down without the support of hands. The duration of the test was measured in seconds using a chronometer [37]. The participant performs 3 trials of the test with a 1 min rest between trials. The average is



Fig. 4 Rhythmic stabilization technique

considered for analysis [26, 27]. The FRT is a reliable and valid test for balance assessment [26]. Participants were asked to stand next to the wall while keeping their arms straight at shoulder level and reach forward as far as possible, without stepping. The distance between the length of the arm and a maximal forward reach was recorded in the standing position. Longer reaching distances indicate better dynamic balance [28]. The difference between the

first and second measurements is obtained and the average of 3 trials of the test is used for analysis [26, 38].

Secondary outcome measures

Fear of falling and quality of life

In the current study fear of falling and quality of life were the secondary outcomes. The FES-I and WHOQOL-OLD questionnaires were used to assess FOF and QOL, consequently. The FES-I questionnaire measures FOF, in which 16 items exist, 10 items are related to basic activities, and 6 items are related to more difficult social and physical activities. A higher score indicates more concern about falling [30]. The WHOQOL-OLD questionnaire evaluates QOL. It consists of 24 items in 6 domains. Higher scores indicate better QOL [39]. The Persian version of both questionnaires is reliable and valid [30, 39].

Sample size

This study is the first to investigate the comparative effects of PNF techniques and aerobic exercise in older adults residing in nursing homes. Given the scarcity of prior research in this area, the Cohen standardized effect size was utilized to calculate the sample size for comparing the means of two independent groups. The sample size was calculated with G*Power, version 3.1.9.2. Considering a statistical power of 0.80, an alpha level of 0.05, and a Cohen's *d* of 0.8, the analysis determined that a total sample size of 52 participants is necessary, with 26 individuals assigned to each group [40].

Statistical analysis

All data were analyzed using SPSS, version 24. The Shapiro–Wilk test was used to evaluate the normality of the variables. Demographic information was compared by independent *t*-test between two groups. Levene's test was

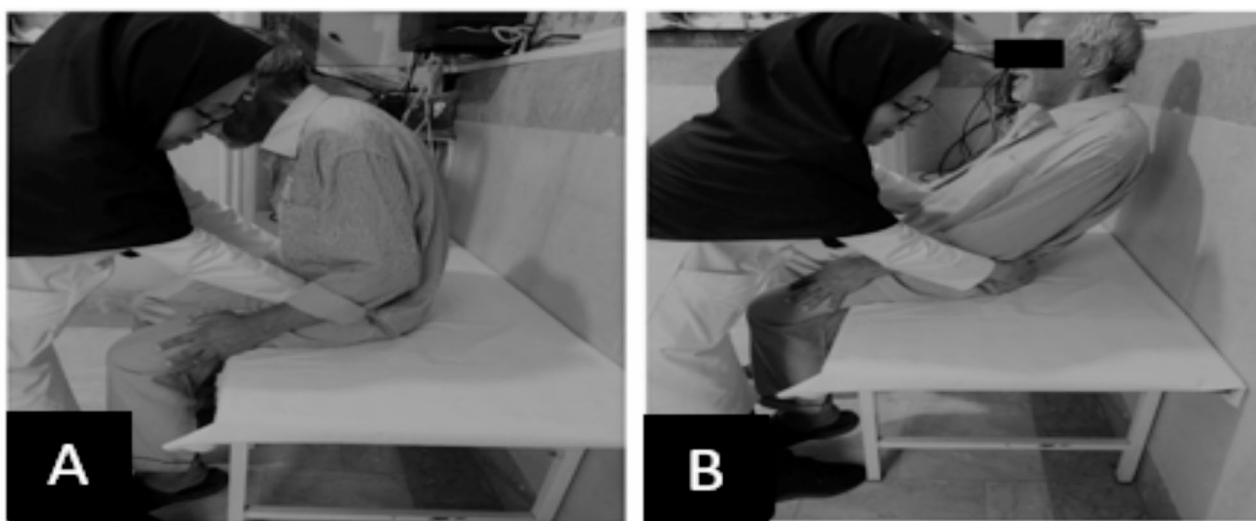


Fig. 5 Stabilizing reversal technique (A) Agonist isotonic contraction, (B) Antagonist isotonic contraction

Table 2 Demographic characteristics of the subjects

Variable (Unit)	Aerobic exercise group (n = 26)	PNF techniques group (n = 26)
Age (y)	70.12 (1.49)	68.31 (1.18)
Sex		
Male	19 (73.08%)	12 (46.16%)
Female	7 (26.92%)	14 (53.84%)
Weight (kg)	68.92 (1.77)	64.29 (2.25)
Height (cm)	165.80 (1.80)	162.70 (1.83)
BMI (kg/m ²)	25.17 (0.68)	24.32 (0.82)

BMI: Body Mass Index

Table 3 Comparison of post intervention values between groups, using baseline values as covariates (ANCOVA)

Outcomes	Aerobic exercise group (n = 26)	PNF techniques group (n = 26)	Levene's Test	Between-Group Differences	
	Mean (SD)	Mean (SD)	P-value	P-Value	Effect Size
BBS Score	44.57 (6.10)	45.00 (6.03)	0.527	0.506	0.009
FRT Score (cm)	19.54 (7.35)	17.30 (7.33)	0.578	0.649	0.004
TUG Time (sec)	13.95 (3.59)	13.96 (3.19)	0.914	0.279	0.024
FES-I Score	26.96 (12.14)	30.30 (12.38)	0.343	0.479	0.010
WHOQOL-OLD Score	87.80 (16.20)	89.73 (19.26)	0.142	0.832	0.001

BBS: Berg Balance Scale; FRT: Functional Reach Test; TUG: Timed Up and Go; FES-1: Falls Efficacy Scale- International; WHOQOL-OLD: World Health Organization Quality of Life-Old module

performed to determine variance homogeneity. Analysis of covariance (ANCOVA) was utilized to compare post-intervention values between groups, using baseline values as covariates. After checking all assumptions of ANCOVA, separate ANCOVA was conducted for each dependent variable (BBS, FRT, TUG, FES-1, WHOQOL-OLD scores). Within-group changes of variables with normal and non-normal distributions were analyzed with paired samples t-test and Wilcoxon test, respectively.

Mean, SD, and effect sizes were calculated for each variable and 0.05 was considered the significance level.

Results

The baseline demographic characteristics of the participants are demonstrated in Table 2. All data were disturbed normally ($P > 0.05$). Age, BMI, and number of men were higher in the aerobic exercise group. The number of women were higher in the PNF techniques group. There were no significant differences in baseline demographic characteristics and outcome measures between the two groups ($P > 0.05$) at baseline. All assumptions of ANCOVA were confirmed. As shown in Table 3, the main effect of intervention type (aerobic and PNF) is not significant in any of the tests and there were no differences in test scores between groups for each dependent variable (BBS, FRT, TUG, FES-I, WHOQOL-OLD score) ($P > 0.05$).

In the PNF techniques group, within-group analyses showed no significant differences for FRT, TUG, FES-I, WHOQOL-OLD pre- and post-intervention ($P > 0.05$), but the BBS significantly increased post-intervention versus pre-intervention (Mean difference = 2.26, 95% CI = (-13.37 - -1.54), $P < 0.05$). However, in the aerobic exercise group, within-group differences were not achieved for all outcome measures ($p > 0.05$) (Table 4).

Discussion

This study was a randomized clinical trial designed to evaluate the effect of PNF techniques compared to general aerobic exercise on balance, FOF, and QOL in older adults living in nursing homes. The findings showed non-significant between groups differences in balance, FOF, and QOL.

This study found no significant differences between the groups in the balance outcomes post-intervention. It was hypothesized that PNF techniques would enhance balance through several underlying physiological mechanisms. The PNF techniques stimulate mechanoreceptors in the skin, joint capsules, and connective tissues, contributing to enhanced proprioception [12]. Consequently, PNF techniques may enhance proprioceptive loading,

Table 4 Within-Group differences for the outcomes of balance, fear of falling and quality of life

Outcomes	Measurement time	Aerobic exercise group (n = 26)			PNF techniques group (n = 26)		
		Mean difference	P-Value	Effect Size (95% CI)	Mean difference	P-Value	Effect Size (95% CI)
BBS	After intervention vs. Before intervention	1.26	0.214	0.248 (-0.78–3.32)	2.26	0.021	0.478 (0.36–4.17)
FRT	After intervention vs. Before intervention	-1.66	0.285	-0.214 (-4.79–1.47)	-1.58	0.200	-0.178 (-3.78–1.45)
TUG	After intervention vs. Before intervention	0.49	0.350	0.186 (-0.57–1.56)	-0.60	0.256	-0.226 (-1.67–0.46)
FES-1	After intervention vs. Before intervention	0.00	0.259	0.308 (-1.08–8.16)	0.50	0.938	-0.004 (-3.29–3.21)
WHOQOL-OLD	After intervention vs. Before intervention	-1.57	0.332	-0.193 (-4.86–1.70)	-1.00	0.746	-0.064 (-7.30–5.30)

BBS: Berg Balance Scale; FRT: Functional Reach Test; TUG: Timed Up and Go; FES-1: Falls Efficacy Scale- International; WHOQOL-OLD: World Health Organization Quality of Life-Old module

and improve balance through proprioceptive mechanisms. This enhancement can lead to increased stability and strength of muscles, improved inter- and intra-muscular coordination, better coordination between agonist and antagonist muscles, and the effective engagement of sensorimotor components crucial for balance [14]. However, this hypothesis was only confirmed for the within-group comparison of BBS in the PNF techniques group. The BBS is a multidimensional assessment tool designed to evaluate balance in individuals with various disabilities [41] examining both static and dynamic balance components [31]. In the present study, the beneficial effects of PNF techniques on the BBS were observed; however, due to the absence of significant differences between groups, these findings should be interpreted with caution.

Studies have shown that muscle strength, ankle and upper limb range of motion, trunk flexibility, and trunk coordination have effects on FRT and TUG results [42–45]. There is a possible interpretation that due to the application of PNF techniques only in the lower trunk, this intervention could not affect the results of the FRT and TUG outcomes.

According to the results of Mesquita et al., using PNF techniques and patterns together led to the BBS, TUG, and FRT improvement in healthy women [28]. This inconsistency could be explained by the PNF pattern's characteristics in which spiral and diagonal movements of the limbs activate deep abdominal muscles and increase trunk stability [4]. Consequently, balance improvement could occur due to the importance of the role of trunk control in balance [20]. Kim et al. showed balance improvement by using trunk PNF in people with stroke [46]. In this study, the techniques were performed in both standing and sitting positions, but in the current study, only the sitting position was applied. In the standing compared to the sitting position, the activity of lower limb muscles is higher, that considered necessary to perform the FRT [46, 47]. In addition, different studies' samples can lead to apparently different results.

Additionally, it was expected that walking as an aerobic exercise would improve balance variables [10], but this within-group hypothesis was not confirmed. In the present study, 4 weeks of walking was considered a therapeutic intervention, which seems to be not enough to improve balance. Within 4 weeks, only neural adaptation occurs [48]. Studies that designed at least 6 and 8 weeks of exercise, showed improvement in balance because of muscular adaptation and increased strength of lower limb muscles [10, 48]. Regarding Rezola et al. balance exercises should be specially included in the exercise program to improve balance, and walking does not improve balance alone [49]. Based on the evidence, aerobic exercises such as a treadmill, and a stationary bicycle because of the improvement of motor re-learning, activation of

sensory afferents, and locomotor patterns could have positive effects on the balance of older adults [50, 51].

The authors hypothesized that the lack of difference in FES-I score as an outcome measure of FOF between and within groups could be related to the type of intervention. Considering the positive effect of physical exercises on the FOF [52], it was expected that PNF techniques would reduce FOF, but this hypothesis was not confirmed. The FOF depends on lower limb muscle strength and walking speed [6, 53]. There is also a strong correlation between the TUG and the FES-I outcome measures [30]. In addition, studies have shown that FOF is affected by physical and cognitive problems, therefore, to improve FOF, there should be a cognitive component in the interventions [54]. The results of the present study are inconsistent with the study of Song et al. in which using the proprioceptive neuromuscular facilitation integration pattern (PIP) reduced the FOF in older adults [55]. In Song's study, the recovery of the FOF can be followed by the improvement of walking speed, while in the current study, the walking speed was not increased. In addition, it was expected that due to the positive effect of physical exercises on FOF [52], walking as a physical exercise can improve FES-I score, but this hypothesis was not confirmed, too. There is a relationship between lower limb muscle strength and FOF [6]. The results of the present study are inconsistent with the study of Sitthiracha et al., which showed that progressive step marching exercises reduce the FOF [56]. In this study, an increase in the strength of the lower limb muscles was seen, which reduces the FOF [6], while in the current study, due to the short duration of walking as a general exercise (4 weeks), muscle strength improvement was not likely.

According to the results, the QOL did not significantly improve between and within groups. In general, exercise causes the release of serotonin, dopamine, and norepinephrine neurotransmitters and the regulation of endorphins, which increase the sense of vitality, well-being, and self-esteem, and finally could improve QOL [57–60]. In the present study, it was expected that PNF techniques and walking as physical exercises would improve QOL, but this hypothesis was not confirmed. The reason could be the short time of the study. The QOL is reduced due to long-term problems and therefore improves only over time, and 4 weeks is a relatively short time to observe a definitive change in the QOL [24]. Before this study, no study had investigated the effect of PNF techniques on older adults' QOL. The result of the present study in the aerobic exercise group is inconsistent with studies by Jan-yacharoen et al. [61] and Sitthiracha et al. [56]. In these studies, modified stepping and progressive step marching exercises improved the QOL in older adults. The reason for this discrepancy in the results could be the longer duration of the study (8 weeks) in these studies.

Limitations

The present study can be criticized for some limitations. First, this study was conducted on healthy older adults and the sampling method was improbably simple, so the study's results cannot be generalized to all older adults. Second, in the current research, PNF techniques were performed only in the lower trunk and not in other areas. Third, most nursing homes did not have the necessary cooperation to enter the present study due to their low morale. Future studies should investigate the effect of other PNF techniques on older adults' balance.

Conclusion

The results of this study indicated that older adults living in nursing homes had no improvement in balance, FOF, and QOL by receiving the PNF techniques compared to aerobic exercise. According to the study findings, only the BBS as an outcome measure of balance was improved in the PNF techniques group after intervention.

Abbreviations

BBS	Berg balance scale
BMI	Body mass index
FES-I	Fall Efficacy Scale-International form
FRT	Functional reach test
FOF	Fear of falling
PIP	Proprioceptive neuromuscular facilitation integration pattern
PNF	Proprioceptive neuromuscular facilitation
QOL	Quality of life
ROM	Range of motion
RS	Rhythmic stabilization
SR	Stabilizing reversal
TUG	Timed up and go test
WHOQOL-OLD	World health organization quality of life-old module

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12877-025-05822-y>.

Supplementary Material 1: Supplementary 1: DOXS, PNF techniques, Specific details of the PNF techniques

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Author contributions

Concept and Design: MKV and SSA, Data collection: MA and FP. Data analysis and interpretation: AH and MKV. Manuscript preparation: MA and MKV. All authors read and approved the final manuscript.

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Data availability

The data presented in this study are available on reasonable request from the corresponding author.

Declarations

Ethics approval and consent to participate

The study was conducted in agreement with the Declaration of Helsinki and was approved by the Human Research Ethics Committee of the Iran

University of Medical Sciences (IR.IUMS.REC.1401.914). All participants signed an informed consent form.

Consent for publication

All the participants were informed of the protocol and the consent was then obtained. They give their consent for the publication of identifiable details, which can include photograph(s) and/or videos and/or case history and/or details within the text ("Material") to be published in the above Journal and Article.

Competing interests

The authors declare no competing interests.

Author details

¹Iranian Center of Excellence in Physiotherapy, Rehabilitation Research Center, Department of Physiotherapy, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran, Iran

²Department of Physiology, School of Medicine, Iran University of Medical Sciences, Tehran, Iran

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