

Intrinsic foot strengthening and electrostimulation in older adults - Randomized clinical trial

Fortalecimento intrínseco do pé e eletroestimulação em idosos - Ensaio clínico randomizado

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Abstract

Introduction: Aging reduces functional capacity related to reduced toe plantar flexion strength. The exercise for strengthening the foot's intrinsic muscles can be optimized using electrostimulation. Due to the scarcity of data in the literature on these methods, further studies are necessary. **Objective:** To evaluate and compare the effects of training to strengthen the foot's intrinsic muscles on the risk of falls in older adults. **Methods:** This is a randomized clinical trial with 19 older patients allocated into three groups: control (CG; n = 7), exercise (EG; n = 6), and exercise+electrostimulation (EEG; n = 6). The EG received an exercise protocol for the foot's intrinsic muscles, the EEG received the same protocol with Neuromuscular electrical stimulation (NMES), and the CG received guidance regarding preventing falls. The individuals were evaluated before and after the intervention using the Single-Limb balance test (SLBT), Functional Reach Test (FRT), Timed Up and Go (TUG), and Paper Grip Test (PGT) tests. One and two-way ANOVA was used for the statistical analysis. Statistical significance was set at $p < 0.05$. **Results:** There was a significant improvement in the TUG test (9.64 ± 1.78 vs. 8.20 ± 1.94) in relation to the EG. With the EEG, there was an improvement both in the TUG (12.68 ± 4.01 vs. 10.61 ± 3.70) and in the FRT (26.37 ± 7.66 vs. 33.14 ± 9.73) with $p < 0.05$. **Conclusion:** An exercise protocol associated with electrostimulation improves performance in functional and dynamic balance tests in older adults.

Keywords: Aged. Electric stimulation therapy. Exercise therapy. Muscle strength.

Resumo

Introdução: O envelhecimento reduz a capacidade funcional, que está relacionada com a redução de força muscular de flexão plantar dos dedos dos pés. O exercício de fortalecimento da musculatura intrínseca do pé pode ser otimizado com o uso da eletroestimulação eletro (EENM). Devido à escassez de dados na literatura sobre a utilização desses métodos, torna-se necessário realizar novos estudos. **Objetivo:** Avaliar e comparar os efeitos do treino de fortalecimento da musculatura intrínseca do pé no risco de queda em idosos. **Métodos:** Trata-se de um ensaio clínico randomizado, no qual 19 idosos foram alocados em três grupos: controle (GC; $n = 7$), exercício (GE; $n = 6$) e exercício+eletroestimulação (GEE; $n = 6$). O GE recebeu um protocolo de exercícios para a musculatura intrínseca do pé, o GEE recebeu o mesmo protocolo seguido de EENM e o GC recebeu orientações quanto à prevenção de quedas. Os indivíduos foram avaliados antes e após a intervenção através dos testes de Apoio Unipodal (AU), Teste de Alcance Funcional (TAF), Timed Up and Go (TUG) e Paper Grip Test (PGT). Para a análise estatística, utilizou-se ANOVA 1 e 2 vias. Considerou-se estatisticamente significativa um valor de $p < 0,05$. **Resultados:** Observou-se melhora significativa no teste TUG ($9,64 \pm 1,78$ vs $8,20 \pm 1,94$) em relação ao GE. Em relação ao GEE, houve melhora tanto no TUG ($12,68 \pm 4,01$ vs $10,61 \pm 3,70$) quanto no TAF ($26,37 \pm 7,66$ vs $33,14 \pm 9,73$). **Conclusão:** Conclui-se que um protocolo de exercício associado à eletroestimulação melhora o desempenho nos testes de equilíbrio funcional e equilíbrio dinâmico em indivíduos idosos.

Palavras-chave: Idoso. Terapia por estimulação elétrica. Terapia por exercício. Força muscular.

Introduction

Aging is a process marked by functional, morphological, biochemical, and psychological changes, resulting in a loss of adaptability and favoring a higher incidence of pathological processes in older adults. The same brings a reduction in functional capacity, determined by physical limitations, which can generate dependence in the execution of tasks related to daily life.¹ This process has a greater risk of accidents and reduces muscle mass and strength, which makes older adults more vulnerable.²

The foot is considered a structure of the human body that maintains posture by receiving and distributing the body's weight and supporting this weight both in the orthostatic position and during walking.³ Aging reduces the limb's muscle strength, reducing the muscle strength of the toes' plantar flexion. The muscle strength of the flexors is essential to control changes in body weight bearing and helps the body during gait.⁴

Neuromuscular electrical stimulation (NMES) is a viable option for preventing muscle strength. It consists of applying an electric current, depolarizing the motor nerves through electrodes on the muscles attached to the skin to promote muscle contractions, favoring increased muscle strength, resistance, and re-education.⁵ The effects of NMES in the abductor hallucis muscle in patients with hallux valgus significantly produce muscle strength and functionality during exercise.⁶ Interventions with NMES protocols in older adults have proven to be an effective alternative to preserve and recover muscle function since they directly stimulate the synthesis of skeletal muscle proteins, thus enabling a lower risk of falls for this population. However, authors are yet to reach a consensus regarding the parameters and intervention time.⁷

Exercise programs to strengthen the foot's intrinsic muscles effectively reduce falls, as older adults can significantly increase the strength of the hallux muscles and toe flexors.^{8,9} Physical exercise brings benefits, helps improve global mobility, and reduces the risk of falls, improving muscle strength, balance, and flexibility.¹⁰

Due to the scarcity of data in the literature on using these methods to reduce the risk of falls in older adults, it is necessary to carry out further studies and analyze the findings. Given the severity of the problems faced by this population, this study aimed to evaluate and compare the effects of training to strengthen the foot's intrinsic muscles and electrostimulation on the risk of falls in older adults.

Methods

This randomized clinical trial with a control group and two experimental groups was blinded to the evaluator. This study followed the recommendations of the Consolidated Standards of Reporting Trials (CONSORT).¹¹ The Lutheran University of Brazil - ULBRA

Ethics Committee approved this project (CAAE 5161 9221.6.0000.5349), and all participants signed the Free and Informed Consent Form (TCLE).

Inclusion and exclusion criteria

The sample was recruited in Cachoeira do Sul, in Rio Grande do Sul. Individuals of both sexes, aged ≥ 60 years, without physical limitations (not bedridden or using a wheelchair), who did not use prosthetic lower limbs (amputee), free of neurological disorders, who could understand (being responsive to verbal commands) and who duly signed the TCLE. The exclusion criteria included using a pacemaker, skin lesions on the feet, uncontrolled systemic arterial hypertension, uncorrected visual impairment, cognitive impairment, and performing another type of specific balance training.

Sample size

The sample size was calculated using the G*Power software version 3.1.9.2 for Windows (Franz Faul, Universitat Kiel, Germany). Twenty-one individuals would be required as the study sample to detect a 0.77 correlation coefficient for the foot strengthening intervention in the risk of falls, adopting $\alpha = 5\%$ and test power $(1-\beta)$ equal to 80%.

Randomization and allocation

The study was conducted between April and June 2022 at ULBRA, Campus Cachoeira do Sul. Individuals were recruited through a verbal request, in which they were instructed about the research's objectives, methodology, and application. Then, for those who accepted, the signature of the TCLE was requested, and personal data were collected. The initial assessment was performed by completing the sociodemographic questionnaire. Furthermore, the individuals were randomized into three groups: control (CG), exercise (EG), and exercise+electrostimulation (EEG).

The randomization procedure was performed using papers with the names of the groups placed in a container. Randomization and allocation were performed by the same researcher responsible for applying the intervention and control. Another researcher was responsible for conducting the initial assessment. A third was for carrying out the pre-and post-intervention tests

in the Timed Up and Go (TUG), Functional Reach Test (FRT), Paper Grip Test (PGT), and Single-limb balance test (SLBT), who was unaware of the groups' allocation order.

Study design

The participants were evaluated before and after the intervention; the intervention period was 4 weeks, twice a week, totaling eight sessions. The EG received an exercise protocol to strengthen the foot's intrinsic muscles. The EEG received the same exercise protocol but with an additional 20 min of electrostimulation, with the electrodes attached to the motor point of the abductor hallucis muscle. The CG received guidance regarding prevention and care regarding falls.

TUG assessed functional balance. The participant started the test sitting comfortably in a chair, with the back resting on the backrest and arms relaxed on the thighs. Before performing the test, the examiner demonstrated how it was performed. When the test started, the participant covered a distance of 3 m, turned around a marking cone, and sat in the chair again, recording the time from the start signal until returning to the chair. The cut-off point for the risk of falling was < 12.47 seconds.¹²⁻¹³

Dynamic balance was assessed using the FRT. To start the test, a measuring tape fixed to the wall was placed at the height of the participant's acromion, and the initial position from the end of the middle finger was marked on the wall. The subject remained standing, with the lower limbs shoulder-width apart. The shoulder was flexed at 90° , the elbow extended, the wrist in a neutral position, and the fingers flexed. The participant was asked to lean forward as much as possible, keeping the arm extended, without taking the heels off the floor and losing balance. Then, the measure reached was verified, considering three attempts, and the result was obtained as the average of the difference between the measure of the initial and final position.¹⁴⁻¹⁵

Muscle strength was assessed with the PGT. The participant was instructed to sit on a chair with the knees and hips flexed and the ankle in a neutral position close to the floor. A piece of unlaminated cardboard (85 × 55 mm) was placed under the hallux and subsequently under the toes. The individual was asked to push with his feet to prevent the evaluator from trying to pull the cardboard away from the toes. The test was performed thrice for the hallux and the other toes together, respectively. The

duration of each trial was approximately 3 to 4 seconds. The test is considered positive when the participant can execute and negative when he cannot apply enough resistance to the paper.¹⁶

Static balance was assessed using the TAU. The subject stood with his arms at his sides. The subject was asked to remove the foot from the ground, flex the knee, and balance on one leg for 30 s. The time count started, and the test was interrupted if the individual put his foot on the floor or reached the maximum time of 30 seconds. Three attempts were made, and the longest time was considered.¹⁷⁻¹⁸

Exercise protocol

The exercise protocol (Figure 1) followed that proposed by Mickle et al.,⁹ which consists of a brief warm-up, followed by strengthening exercises for the foot's intrinsic muscles. The protocol started with a warm-up, which consisted of walking with the tips of the toes and performing ankle rotations (3 to 5 min). After warming up, muscle strengthening exercises were started, which included elevating the plantar arch, plantar flexion, ankle inversion, ankle eversion, toe flexion, hallux flexion, ankle

dorsiflexion, foot and stretching of the plantar fascia associated with a brief massage. The protocol continued for approximately 45 min, using an elastic band or the individual's body weight. Progression was performed with increased repetitions and changes in the degree of resistance of the elastic band (one to three series; 10-15 repetitions).

Exercise protocol associated with electrostimulation

However, the same protocol as the EG was performed with electrostimulation, as Shimoura et al.⁶ proposed. The participants remained seated. After cleaning the skin with gel and alcohol, the electrodes were attached to the motor point of the abductor muscle hallux, more specifically posterior and inferior to the navicular tuberosity and 2 cm in front of the first electrode. The electrostimulation protocol (Figure 2), performed with the Ibramed® device, consisted of 20 min of electrical stimulation using low frequency, with a frequency of 20 Hz, pulse width of 300 ms, rise time of 1 second, stimulus time (ON) of 5 seconds, fall time of 1 second and relaxation time (OFF) of 10 seconds. The intensity was adjusted according to the participant's tolerance.



Figure 1 - Exercise protocol.

Note: A = heating; B = elevation of the plantar arch; C = plantiflexion; D = inversion; E = eversion; F = toe flexion; G = hallux flexion; H = dorsiflexion; I = spread of the toes; J = massaEG and stretching of the fascia.



Figure 2 - Eletrostimulation protocol

Statistical analysis

For quantitative variables, data were expressed as mean \pm standard deviation (SD) for each variable and group. Each variable and group's data were expressed in relative and absolute frequencies for qualitative variables. The Shapiro-Wilk test was performed to assess the normality of all variables. One-way ANOVA was used to compare groups of sociodemographic variables and baseline characteristics of the study groups. Two-way ANOVA with repeated measures was used to compare the effects of exercises with or without electrical stimulation and control on TUG (s), FRT (cm), and SLBT (s) values. The chi-square or Fisher's exact test was used to investigate sociodemographic, baseline, and PGT quantitative variables. Statistical significance was set at a p-value < 0.05 . SigmaPlot 11.0 (Systat Software Inc., San Jose, CA, USA) for Windows was used as a computational tool for data analysis. GraphPad Prism 5 (Graph-Pad Software, San Diego, CA, USA) for Windows was used as a computational tool for building the graphs.

Results

The study started with 27 volunteers, but two did not meet the eligibility criteria, as one individual had skin lesions on the feet and the other had uncorrected visual impairment. Six individuals withdrew from the study (Figure 3). Therefore, the final sample size was 19 individuals: CG (n = 7), EG (n = 6), and EEG (n = 6).

Table 1 expresses the sociodemographic data and baseline characteristics of the study groups. As prevalent comorbidities, systemic arterial hypertension (SAH) (63.15%) and diabetes mellitus (DM) (26.31%) stood out. Notably, all participants denied alcoholism (100%), and most denied smoking (78.94%). Similarly, some participants reported having had a recent episode of falls (42.10%), most reported not being physically active (73.69%), and others reported walking two to three times weekly.

Table 1 - Description of sociodemographic data and baseline characteristics of the study groups

Variable	CG (n = 7)	EG (n = 6)	EEG (n = 6)	ANOVA
Age*	68.6 \pm 5.91	68.7 \pm 7.73	72.3 \pm 6.18	0.5360
Sex (M/F)	1 (14.3)/ 6 (85.7)	1 (16.7)/ 5 (83.3)	3(50.0)/ 3(50.0)	-
SAH	5 (71.4)	3 (50.0)	4 (66.7)	0.7104
DM	1 (14.3)	2 (33.3)	2 (33.3)	0.6613
Smoker	3 (42.8)	1 (16.7)	0	0.1595
Alcoholic	0	0	0	-
RFE	2 (28.6)	3 (50.0)	3 (50.0)	0.6594
PA	1 (14.3)	3 (50.0)	1 (16.7)	0.2800

Note: CG = control group; EG = exercise group; EEG = exercise+ electrostimulation group; M = male; F = female; SAH = controlled systemic arterial hypertension; DM = diabetes mellitus; RFE = recent falling episode; PA = physical activity. *Data presented as mean \pm standard deviation; for the other variables: n (%). Statistical analysis = One-way ANOVA ($p < 0.05$).

Effects of interventions on participants

In the EG, for the analysis of the functional tests of participants' pre and post-intervention, there was a statistically significant increase in the TUG (9.64 \pm 1.78 vs. 8.20 \pm 1.94 (Figure 4A). In the FRT (30 .04 \pm 7.22 vs. 35.10 \pm 12.05; Figure 4B) and in the UA (15.91 \pm 15.48 vs.

20.16 ± 10.93; Figure 4C), no significant difference was observed. It was found that the exercise for the intrinsic musculature of the foot increases the performance in the TUG, that is, in the functional balance.

In the EEG, there was a statistically significant increase with TUG (12.68 ± 4.01 vs. 10.61 ± 3.70; Figure 4A) and with FRT (26.37 ± 7.66 vs. 33.14 ± 9.73; Figure 4B). There was no significant improvement in SLBT (11.97 ± 10.18 vs. 13.51 ± 13.01; Figure 4C). It is suggested that exercise associated with electrostimulation for the foot's intrinsic

muscles increases performance in TUG and FRT, that is, in functional and dynamic balance.

In the CG, no significant difference was observed in the TUG (13.29 ± 7.05 vs. 14.00 ± 6.45; Figure 4A), in the FRT (27.04 ± 7.74 vs. 25.03 ± 9.34; Figure 4B) and the SLBT (10.43 ± 9.67 vs. 8.94 ± 9.22; Figure 4C). The alterations provoked in the muscular strength of the foot's intrinsic musculature resulting from the intervention, evaluated through the PGT, did not present a significant difference.

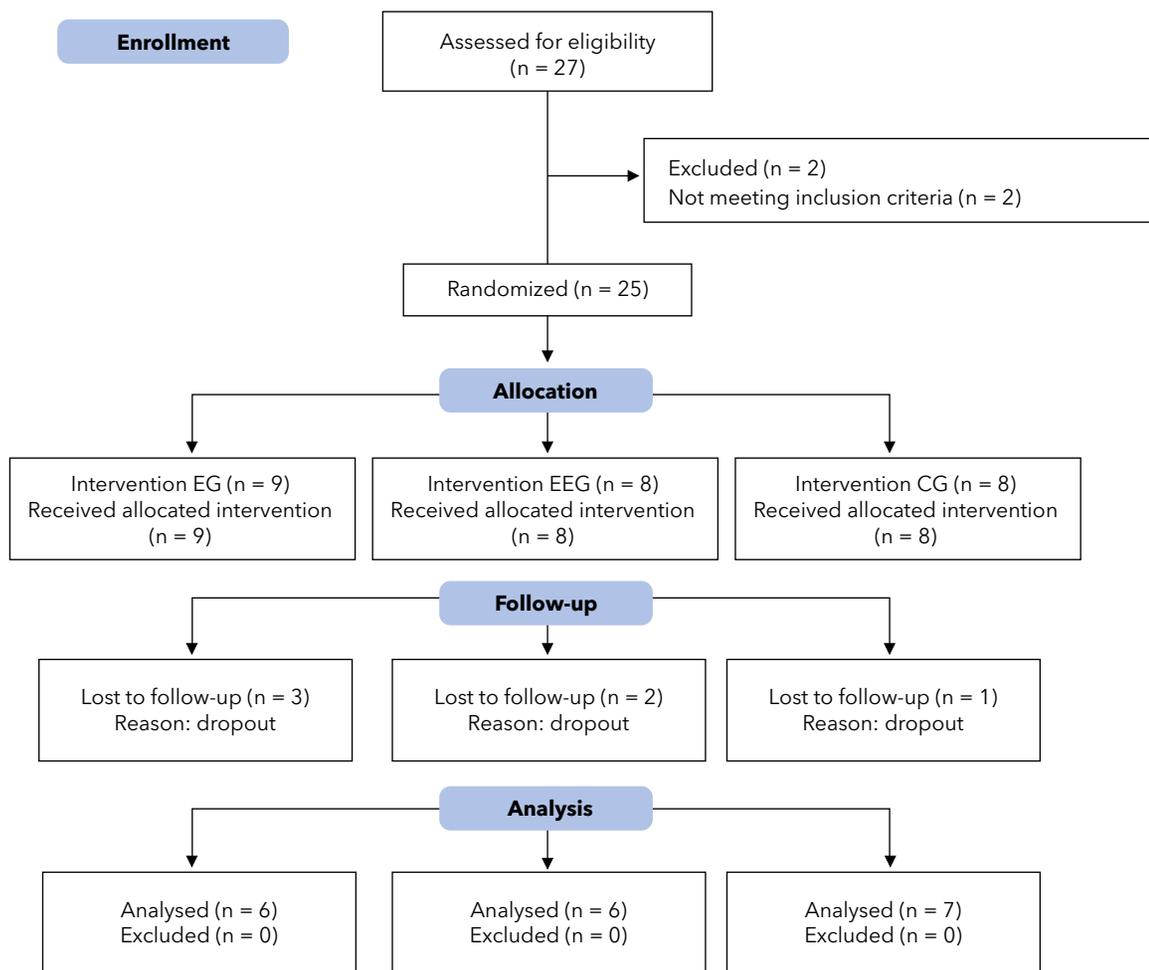


Figure 3 - Flow of participants according to the CONSORT 2010 diagram.

Note: EG = exercise group; EEG = exercise group with electrostimulation; CG = control group.

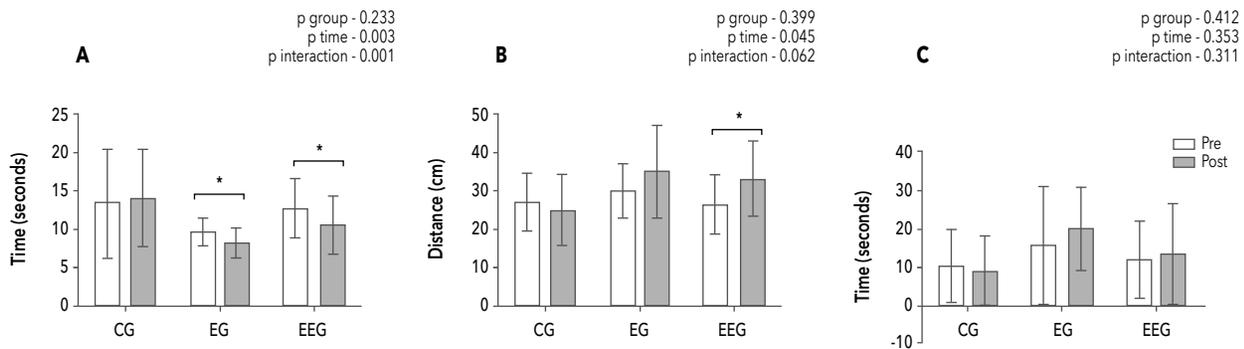


Figure 4 - Results of the Timed Up And Go tests (A), Functional Reach Test (B) and Single-limb balance test (C).

Note: CG = control group; EG = exercise group; EEG = exercise group with electrostimulation. Values are expressed as mean \pm standard deviation. Statistical analysis = two-way ANOVA. Symbols represent comparison between groups (* $p < 0.05$).

Discussion

This randomized controlled clinical trial showed that an exercise protocol associated with electrostimulation positively affects functional capacity compared with a routine without exercise in elderly individuals. This population's performance in functional and dynamic balance tests shows this result.

Notably, several studies have demonstrated the benefits of physical exercise in EGral, emphasizing training to gain strength in the lower limbs, as regards improving the quality of life in older adults compared with sedentary older adults.^{9,10,19} However, few studies evaluate the effects of training predominantly on muscle strength and balance with a focus on preventing falls, and those that use interventions employ different protocols in this population. The present study verified whether a protocol of therapeutic exercises for the foot's intrinsic muscles associated with electrostimulation in the abductor hallucis muscle would have positive effects in older adults, such as increased muscle strength and balance, to obtain functional gains and reduce the risk of falls, which is highly present in this population.²⁰ Regarding the benefit of physical exercise, which is essential for reducing the risk of falls in these individuals, a study by Mei et al.,²¹ where 40 older adults were selected to perform a sequence of exercises, including warm-up, aerobic exercise (running, brisk walking, group dancing, among other activities) and final cool-down, showed an improvement in several factors, such

as the quality of life and activities of daily living. Liu-Ambrose et al.²² applied an exercise program to older adults who suffered falls in the last 12 months, in which the intervention group received exercises to strengthen the lower limbs and balance with training in changes of direction and reduction of the support base, and the other group received usual care. At the end of the study, it was noted that the group that received the exercise program significantly reduced the rate of falls compared with the other group.

The TUG, described by Podsiadlo and Richardson,¹² is a simple and practical way of testing the measure of functional mobility, in addition to being used to assess the risk of falls in older adults.¹³ In the present study, an improvement was noted as significant in relation to TUG after an exercise program for the intrinsic muscles of the foot, providing better musculoskeletal performance and functional capacity to older adults, indicating a possible predictor for the risk of falls. Tomick et al.²³ carried out a study in which the participants were allocated into two groups, one in which they did not undergo any intervention and the other in which a physical exercise program was performed consisting of a brief warm-up period (walking), the main part with functional exercises of aerobic endurance, muscular strength and endurance, flexibility, static and dynamic balance, agility and motor coordination and the closing with stretching exercises for the main muscle groups and

breathing exercises. The authors observed a significant improvement in both the TUG and the Berg Balance Scale (BE) when comparing the exercise program and control groups.²³

The FRT, developed by Duncan et al.,¹⁴ is considered an assessment with an indicative index for the risk of falling, in which it analyzes the capacity for static balance and is related to activities of daily living. In that study, the FRT significantly improved when the exercise was associated with electrostimulation and significantly improved the TUG performance. This fact demonstrates that when exercise was associated with electrostimulation, there was an improvement in both dynamic and functional balance. In the literature, electrostimulation is yet to be investigated in this muscle group for a common purpose. However, Reidel et al.,²⁴ evaluated the effects of NMES on the quadriceps on the functionality of hospitalized frail and pre-frail older adults, divided into control and intervention groups, where both received passive stretching, strengthening of upper and lower limbs, and lower limbs kinesiotherapy, but only the intervention group received the NMES protocol. The same showed significant effects for perimeter of the right thigh, number of repetitions in the sit and stand test, and quadriceps muscle strength compared with the control group. This demonstrates that exercise, when associated with electrostimulation, can present significant results regarding preventing falls in older adults.

The PGT was chosen to measure the strength of the foot's intrinsic muscles due to its easy applicability, being correlated with the muscle strength of the foot and ankle muscle groups and the ability to maintain balance, ensuring a better assessment of the risk of falls. However, as it is a qualitative test and varies according to the evaluator, it demonstrates low reliability for research purposes. Given this, the improved PGT originated as a quantitative test in which a dynamometer is used next to the paper to measure muscle strength; however, its cost is more expensive.¹⁶ In the present study, the PGT did not show alterations caused between the groups on the strength of the foot's intrinsic musculature. Notably, this study had limitations regarding the PGT because the qualitative test was used since the cost for the improved PGT test would be high.

Gonçalves et al.²⁵ carried out a physical balance program related to falls in older adults, which included warm-up, adjustment control exercises, muscle strength

exercises with an emphasis on lower limb muscles, and stretching and relaxation exercises. The study involved 17 older adults, and tests were performed on SLBT, TUG, muscle strength, and flexibility of the lower limbs, in addition to the Falls Efficacy Scale-International (FES-I) questionnaire. There was a significant statistical change between the pre and post-training period in the variables SLBT, TUG, and flexibility, with improved balance.²⁵ In the present study concerning SLBT, there was no difference between the groups. According to these findings, a larger-scale study is recommended to reach more relevant conclusions for the theme.

In the present study, it was possible to apply a safe and efficient protocol of exercises for the foot's intrinsic muscles in older adults, providing an improvement in the functional balance and the dynamic balance when the exercise is associated with electrostimulation, bringing benefits and serving as a complementary phys-iotherapeutic tool, since this population requires special attention due to the factors exposed in this work. From a practical and clinical point of view, the results presented are related to improving the functional balance of elderly patients. Measurement through specific tests validated by the literature is essential for the results to make physical exercise combined with electrotherapy a vital tool for reducing the risk of falls in this population.

Conclusion

A strengthening exercise protocol for the foot's intrinsic muscles significantly improved performance in the TUG. Only in the EEG did we also obtain performance improvement in the FRT. Therefore, an exercise protocol associated with electrostimulation improves functional and dynamic balance in older adults.

Authors' contributions

MMR, DCBJ, and VSH were responsible for the conception and design of the study, analysis, and interpretation of data, and writing and revising the manuscript. LVO, MTC, and MFS, for data collection and critical manuscript review; and VSH, by statistical analysis. All authors approved the final version of the article.

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