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Effects of a Whole Body Vibration (WBV) Exercise Intervention for Institutionalized Older People: A Randomized, Multicentre, Parallel, Clinical Trial

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Abstract

Objectives: To assess the efficacy of an exercise program on a whole-body vibration platform (WBV) in improving body balance and muscle performance and preventing falls in institutionalized elderly people. *Design/Setting/Participants:* A multicentre randomized parallel assessor-blinded clinical trial was conducted in elderly persons living in nursing homes.

Interventions: Participants were randomized to an exercise program performed either on a whole body vibratory platform (WBV plus exercise group) or on a stationary surface (exercise group). The exercise program for both groups consisted of static and dynamic exercises (balance and strength training over a 6-week training period of 3 sessions per week). The frequency applied on the vibratory platform was 30 to 35 Hz and amplitude was 2 to 4 mm.

Measurements: The primary outcome measurement was static/dynamic body balance. Secondary outcomes were muscle strength and number of falls. Efficacy was analyzed on an intention-to-treat basis and per protocol. The effects of the intervention were evaluated using the *t* test, Mann-Whitney test, or chi-square test, depending on the type of outcome. Follow-up measurements were collected 6 weeks and 6 months after randomization.

Results: A total of 159 participants from 10 centers were included: 81 in the WBV plus exercise group and 78 in the control group. Mean age was 82 years, and 67.29% were women. The Tinetti test score showed a significant overall improvement in both groups ($P < .001$). No significant differences were found between groups at week 6 ($P = .890$) or month 6 ($P = .718$). The Timed Up and Go test did not improve ($P = .599$) in either group over time, and no significant differences were found between groups at week 6 ($P = .757$) or month 6 ($P = .959$). Muscle performance results from the 5 Sit-To-Stand tests improved significantly across time ($P = .001$), but no statistically significant differences were found between groups at week 6 ($P = .709$) or month 6 ($P = .841$). A total of 57 falls (35.8%) were recorded during the follow-up period, with no differences between groups ($P = .406$).

Conclusion: Exercise program on a vibratory platform provides benefits similar to those with exercise program on a stationary surface in relation to body balance, gait, functional mobility, and muscle strength in institutionalized elderly people. Longer studies in larger samples are needed to assess falls.

Keywords: Institutionalized older people balance, muscle performance falls, whole-body vibration

Institutionalized older people have limitations in performing exercise because of greater osteoarticular deterioration and greater fatigue than noninstitutionalized persons (1).

Progressive aging of the population has increased the incidence of chronic diseases (2) and frailty in elderly people (3). Such frailty principally consists of cognitive impairment and social withdrawal, weight loss, weakness, and slowed motor processing and performance (1,4-6). Furthermore, frailty increases the risk of falls (7,8) in the elderly (9-11). Research from the United Kingdom (12), the United States (7), and Australia (8) has shown that falls are a tremendous burden to social and health services. It has been estimated that the total health costs attributable to fall-related injuries will practically triple in the next 50 years.

Strategies to prevent the negative consequences of falls are needed. One such strategy is to promote exercise (13,14). Increasing physical activity with an adequate exercise program could enhance the autonomy of elderly people and help prevent falls (2,15-20). These programs are based on exercise alone or multifactorial strategies (13,14). Exercise alone improves balance and gait, muscle strength in the legs, and cardiovascular resistance training, which are closely related to the risk of falling (15,21-27).

Whole body vibration (WBV) training is a type of physical exercise in which people perform various exercises in a squat position on a platform device. Several studies have shown promising results with the use of this intervention in walking ability, speed of gait, body balance, and muscle strength in older adults (28-35) compared with a nonintervention control group (36-39). However, there is little evidence about the efficacy of WBV compared with other active interventions. Furthermore, the effect of WBV on preventing falls in nursing home residents is unknown (40,41). The aim of the present study was to evaluate whether exercise on a vibration platform could improve body balance and muscle performance and prevent falls in institutionalized elderly people compared with that same exercise without a vibration platform.

Methods

Design

This study was an open randomized multicenter parallel assessor- blinded clinical trial in GERIAtric participants to assess the efficacy of vibration PLATforms (GERIAPLAT). The trial was registered at www. clinicaltrials.gov (NCT01375790) and the protocol was published42 following the CONSORT Statement (43).

Selection and Assignment of Subjects

Participants were recruited from 10 nursing homes in the metropolitan area of Barcelona, Spain, between November 2010 and November 2011. The study protocol was approved by the reference Clinical Research Ethics Committee of each center involved. All participants were informed about the purpose of the study and the potential risks associated with the interventions before informed written consent was obtained.

Clinicians (medical doctor and physiotherapist) at each nursing home screened eligible people for the study according to the inclusion and exclusion criteria (42). The inclusion criteria were volunteers of either sex aged older than 65 years, resident in a nursing home, and able to adopt a squat position on a vibrating platform (44). Exclusion criteria were acute illness (not resolved within 10 days), epilepsy, severe heart disease, and use of a pacemaker. We also excluded people who had a high risk of thromboembolism, a hip or knee replacement, or musculoskeletal disorders, and also those who had cognitive or physical disorders that could interfere with training methods.

Treatment

Participants were randomized to the WBV plus exercise group or to the exercise group.

Both groups of participants performed the same static/dynamic exercises (balance and strength training): 30-minute/session x 3 sessions per week over 6 weeks. The only difference was that the WBV plus exercise group performed these exercises individually on a vibratory platform (Pro5 Airdaptive Model; PowerPlate, Amsterdam, The Netherlands). The frequency of the vibration was 30 to 35 Hz and the amplitude was 2 to 4 mm. At each session, both groups performed warm-up and cool-down exercises that consisted of walking around the room for 3 to 5 minutes. Training volume and intensity were increased progressively over the 6 weeks of the exercise program (see online supplement Table 1 for the whole-body vibration training protocol). To prevent learning problems at the beginning of the WBV training period, participants in this group received an introductory practice session to familiarize them with positioning on the vibration platform before the first session (45).

Participants in the exercise group performed the exercises in groups, usually from 2 to 8 people. Participants were considered compliant if they performed 70% or more of the total number of training sessions (18 sessions). During the follow-up period, all participants were invited to perform a physical exercise (group class, 2 sessions per week) with other institutionalized elderly people.

Outcome Measurements

Measurements were performed at baseline, at the end of the intervention at 6 weeks, and 6 months after the study (46). Outcome was assessed by 2 external physiotherapists who were blinded to the interventions. Outcomes for the first 10 participants were evaluated to confirm concordance between the 2 physiotherapists. The intraclass correlation coefficient was 0.99 ($P < .001$).

All participants had a physical examination at baseline. We recorded clinical history, anthropometric parameters (height, weight, and body mass index), resting blood pressure, heart rate, and level of pain using the Visual Analogue Scale.

Primary outcome:

- Balance, gait and functional mobility at 6 weeks

Balance and gait outcome was assessed using the Tinetti test (46). The Tinetti test has 16 items and a lower score indicates poorer physical ability. The overall score is 28: the maximum score for body balance is 16 and the maximum score for gait is 12.

The Timed Up & Go (TUG) (47) test assesses functional mobility. Participants stand up from a chair (with armrest), walk 3 m as quickly and safely as possible, cross a marked line on the floor, turn around, and then walk back and sit down on the chair (47) The time taken to complete the task was recorded by chronometer.

Secondary outcomes:

- Balance, gait, and functional mobility at 6 weeks and 6 months
- Muscle performance at 6 weeks and 6 months

Muscle performance was evaluated using 5 repetitions of the Sit- to-Stand (STS) test (48,49). Participants were seated on a chair that was fixed to the wall and individually adjusted to 900 of knee height. They were instructed to stand up and sit down 5 times, as quickly as possible, with their arms folded across the chest. The time taken to complete the task was recorded using a digital stopwatch.

- The maximum speed (Vmax) at 6 weeks

The Vmax for each of the 5 repetitions was recorded using the SmartCoach encoder (Stockholm, Sweden) (50,51).

- Number of falls at 6 months

Data concerning falls were regularly collected from each nursing home or from relatives if a participant had moved to a different address. All falls during the study were recorded on a prospective report calendar developed specifically for the study (52).

- Adverse effects at 6 weeks and 6 months

The type of event observed, its duration, severity, and possible relation with the intervention were recorded. All adverse effects were evaluated by the physician and the physiotherapist at the corresponding residence.

Sample Size

The sample size was calculated assuming a difference of 5 points (SD 10) between the groups in the Tinetti test at the end of intervention. We considered a 2-sided alpha level of 0.05, a statistical power of 80%, and 20% of losses.28,53 The total number of estimated cases was 160 (80 in each group).

Randomization

A computer-generated randomization list was generated for participants at each nursing home using the statistical software SPSS17 (IBM SPSS Statistics, IBM Corporation, Chicago, IL). Allocation to treatment was centralized by telephone. All the researchers were blinded to the randomization sequence list.

Statistical Methods

Participants' baseline characteristics, percentage of falls, and adverse events were compared between groups by using the chi-square test. Continuous outcomes were compared using the t test. Outcomes in body balance and muscle performance were analyzed using a 2-way analysis of variance (ANOVA). Factors included in this analysis were the group (WBV plus exercise group, or exercise group), the time of evaluation (at baseline, after 6 weeks and after 6 months of intervention), and the interaction of the group and time of evaluation. The ANOVA was performed following the Generalized Linear Model procedure.

Efficacy was analyzed applying the intention-to-treat (ITT) principle. Missing values were adjusted to the last observation carried forward. A per protocol (PP) analysis was also performed. The statistical package SPSS17 was used for all analyses.

Results

The study included 159 participants, 107 women (67.29%) and 52 men (32.71%), with a mean age of 82 years. All participants were residents at 1 of 10 nursing homes in Spain (42). A total of 81 participants were randomized to the WBV plus exercise group and 78 to the exercise group. No differences were found between the 2 groups concerning baseline characteristics (see online supplement Table 2).

Cardiovascular, bone, and joint diseases were the most frequent illnesses. We noted that 46% of participants needed walking aids (see online supplement Table 3) and 81% were taking multiple medications. The most commonly prescribed drugs were antihypertensive agents (see online supplement Table 3).

Figure 1 shows a flow chart of participants in the study. Twenty-eight participants withdrew from the clinical trial. The main causes of dropout were concurrent pathologies, changes of nursing home, and personal reasons (usually related to difficulty in committing to exercise).

Balance, Gait, and Functional Mobility

The Tinetti static test showed a significant improvement over time in both groups at 6 weeks ($P < .001$) and at 6 months ($P = .012$), but no significant differences between groups at either 6 weeks ($P = .881$) or at 6 months ($P = .782$).

The Tinetti dynamic test showed no significant improvement over time ($P = .065$ at 6 weeks, $P = .220$ at 6 months) or between groups ($P = .681$ at 6 weeks, $P = .690$ at 6 months).

The Tinetti total score showed a significant overall improvement over time in both group at 6 weeks ($P < .001$) and at 6 months ($P = .012$), with no significant differences between groups ($P = .890$ at 6 weeks and $P = .718$ at 6 months,). Figure 2 shows the results of the Tinetti Test at 6 weeks, and Table 1 shows body balance and muscle performance scores at 6 weeks and at 6 months.

The results of the TUG test showed no significant improvement over time in either group at 6 weeks ($P = .599$) or at 6 months ($P = .368$). There were no differences between groups at 6 weeks ($P = .757$) or at 6 months ($P = .959$) (Table 1).

With the exception of the Tinetti dynamic test and TUG, all PP results for balance variables improved over time (Table 2).

Muscle Performance and Maxima Speed (Vmax)

Muscle performance results from 5 STS tests showed a significant improvement in both groups at 6 weeks ($P < .001$) or at 6 months ($P = .031$), but there no were differences between groups at either 6 weeks (P = .709) or 6 months (P = .841) (Table 1).

The PP analysis for the STS test showed similar results (Table 2).

The Vmax showed significant improvement of 0.05 m/s (from 0.59 to 0.64 m/s) in the exercise group and a worsening of 0.03 m/s (from 0.60 to 0.57 m/s) in the WBV plus exercise group (P = .038) (Table 1). In the PP analysis, the Vmax showed an improvement of 0.05 m/s (from 0.62 to 0.67 m/s) in the exercise group and a worsening of 0.01 m/s (from 0.61 to 0.60 m/s) in the WBV plus exercise group (P = .059) (Table 2).

Falls

Only 2 falls were recorded during the 6-week intervention period and neither was directly related to the intervention. The first fall occurred during sleep and the second occurred on the weekend before the first session of vibration began. This second participant was hospitalized for a collarbone fracture, the only fracture recorded throughout the study.

A total of 57 falls (35.8%) were recorded during the 6-month study period, corresponding to 35 participants. Twelve participants had multiple falls. No differences were observed between groups (P = .406) or between genders (P = .415). Most falls occurred in the participants' rooms (17 fallers) and were not directly associated with an object (29 fallers). No serious consequences were associated with the fall, but fallers presented contusions, wounds, and pain. There was only 1 fracture.

Adverse Effects

No severe adverse effects were observed in relation to the intervention, and statistical results showed no differences between groups (P = .430). Pain was the most common event during the intervention (18.25%). It was predominantly localized in the knees and lumbar spine. Soreness was also recorded in 12.6% of participants, and it appeared mainly in the quadricipital and gastrocnemius muscles. Itching, erythema, and edema of the legs were transient and mild affects that occurred in 0.6%, 1.2%, and 0.6% of participants, respectively. Most of these adverse effects occurred during the first and second week of the interventions (68.4%) and disappeared by the third or fourth week (61.4%).

Ten percent of participants in the exercise group and 16.3% in the WBV plus exercise group presented a possible or probable relation of causality with the intervention, but this difference was not statistically significant (P = .450).

Discussion

Our results suggest that the efficacy of WBV training in improving balance and muscle strength in institutionalized elderly people is equivalent to an exercise program without vibration. These results are in line with a study performed in patients with Parkinson disease and severely impaired balance (54), but differ from 2 previous studies in nursing homes (40,41). Results from these 2 studies (41,42) favored the use of WBV in institutionalized elderly people following an intervention performed over a period similar to that in our study. However, the number of patients, the type of platform, and the WBV protocol training differed, possibly explaining the divergence in results (40,41). Baseline Tinetti score concerning balance and gait were higher in our participants and this also could account for the variability in findings. In our study, the mean baseline score in the Tinetti test was 22.5 in the WBV plus exercise group and 22.7 in the exercise group, whereas in Bruyère et al's (40) and Bautmans et al's (41) studies, the mean baseline score was below 19. A cutoff value that predicts falls (short form Tinetti test) is greater than 18 points (46).

Concerning functional mobility, the cutoff value of greater than 30 seconds is stated to predict functional dependence (47) in the TUG test. This value was established for frail elderly people with a wide range of neurological pathologies, like our participants, although they were institutionalized. In our study, time to perform this test was similar to Bruyère et al's study (40) although our study does not show significant improvements of an intervention compared with the other, as Bruyère et al's study does. Findings from a recent clinical trial in an older population suggested that people with poor balance benefited most from WBV exercise (34) but our results do not follow this direction. In our study, one inclusion criterion was that participants had to at least tolerate standing. This could influence the population included, which were the fittest nursing home residents, and it could be an explanation for our results.

Standing up from a sitting position is a frequent everyday action and a prerequisite for upright mobility and independent living (47,55). This maneuver requires muscle strength in lower limbs. In our clinical trial, the sit-to-stand test improved similarly in both groups at 6 weeks and 6 months. An explanation of the large effect of both interventions was that all participants were invited to a physical exercise group class during the 6-month follow-up period.

These results do not corroborate a previous study (56) that found significant improvements in the sit-to-stand test favoring WBV with respect to the control group. One factor that could explain the differences in results in this study is the intervention in the control group. In our study, the control group followed the same exercise program (but on a stationary surface) as the WBV plus exercise group, whereas in Furness et al’s study (56), the control group did not perform any activity. Another factor that could influence the results in our study is the higher comorbidity (57) and greater limitations in participants’ autonomy. Nearly half (46%) of our participants needed walking aids and most (85%) had a risk of falling.

The maximal speed measurement showed a significant improvement of 10% in the exercise group and a worsening of 5% in the WBV plus exercise group (ITT). In the PP analysis, the results were in the same direction as the ITT analysis, but they were not significant. These results in maximal speed could be due to a misbalance in morbidities between groups. Although it was not significant at baseline, the WBV plus exercise group included participants with higher cognitive impairment, history of falls in the past year, and as a consequence post-fall syndrome, and the Downton fall scale has a higher risk index of falls. This could be a justification of the results.

The main strengths of this article are the relatively large sample size and the robustness of the study design. It is the first study to assess the efficacy of WBV in preventing falls in institutionalized older people. Furthermore, it includes a longer follow-up than previous studies in this setting. Another strong point is that compliance was more than 75%, indicating that an exercise program both with or without vibration was appropriate and enjoyable for the participants.

The main limitation in this study is that it did not have sufficient power to clinically detect relevant results in fall prevention, which was an objective of the study. Our sample size was calculated assuming improvements in the Tinetti test only. Longer studies in larger samples are needed to assess this intervention in institutionalized geriatric populations and to measure the incidence of falls.

Conclusion

Our results indicate that WBV together with an exercise program is a safe intervention, but that its benefits in body balance, gait, functional mobility, and muscle strength are similar to those of exercise alone in institutionalized elderly individuals.

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Appendix

Advisory Committee

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Tables

	Basal Mean (SD)		6 wk Mean (SD)		6 mo Mean (SD)	
	WBV Plus Exercise	Exercise	WBV Plus Exercise	Exercise	WBV Plus Exercise	Exercise
Tinetti total test, score	22.52 (4.38)	22.71 (4.24)	23.44 (3.60)	23.42 (3.73)	23.12 (4.17)	23.38 (4.02)
Tinetti static test, score	12.41 (2.41)	12.36 (2.47)	13.02 (1.98)	12.97 (2.16)	12.75 (2.22)	12.98 (2.24)
Tinetti dynamic test, score	10.11 (2.38)	10.35 (2.10)	10.42 (2.04)	10.45 (1.99)	10.37 (2.22)	10.39 (2.14)
Timed Up and Go test, s	20.04 (11.24)	21.09 (13.58)	21.14 (29.14)	18.52 (11.66)	20.34 (11.79)	19.47 (11.56)
5 Sit-to-Stand test, s	30.38 (27.22)	31.60 (28.20)	26.68 (24.91)	28.56 (27.42)	17.13 (9.30)	18.89 (11.11)
Vmax, m/s	0.60 (0.24)	0.59 (0.19)	0.57 (0.19)	0.64 (0.24)	—	—

Vmax, average value of each maximum speed during 5 chair uprisings; WBV, whole body vibration group.

Table 1 Body Balance and Muscle Performance (ITT Analysis)

	Basal Mean (SD)		6 wk Mean (SD)		6 mo Mean (SD)	
	WBV Plus Exercise	Exercise	WBV Plus Exercise	Exercise	WBV Plus Exercise	Exercise
Tinetti total test, score	n = 59 22.25 (4.50)	n = 63 22.67 (4.36)	n = 59 23.41 (3.60)	n = 63 23.65 (3.72)	n = 54 23.17 (2.86)	n = 58 23.24 (4.35)
Tinetti static test, score	n = 59 12.36 (2.36)	n = 63 12.43 (2.48)	n = 59 13.03 (1.92)	n = 63 13.11 (2.15)	n = 54 12.83 (1.89)	n = 55 12.82 (2.28)
Tinetti dynamic test, score	n = 59 9.90 (2.58)	n = 63 10.24 (2.16)	n = 59 10.37 (2.07)	n = 63 10.54 (1.91)	n = 54 10.33 (2.26)	n = 55 10.42 (2.83)
Timed Up and Go test, s	n = 59 19.98 (11.22)	n = 63 20.73 (12.76)	n = 59 17.73 (10.38)	n = 63 17.97 (10.73)	n = 54 19.83 (11.25)	n = 55 19.55 (12.31)
5 Sit-to-Stand test, s	n = 59 17.26 (7.20)	n = 58 17.22 (8.29)	n = 59 15.71 (7.49)	n = 58 15.34 (7.63)	n = 36 14.69 (5.65)	n = 39 14.34 (6.02)
Vmax, m/s	n = 60 0.61 (0.17)	n = 58 0.62 (0.23)	n = 60 0.60 (0.18)	n = 58 0.67 (10.22)	—	—

Vmax, average value of each maximum speed during 5 chair uprisings; WBV, whole body vibration group.

Table 2 Body Balance and Muscle Performance (PP Analysis)

Figures

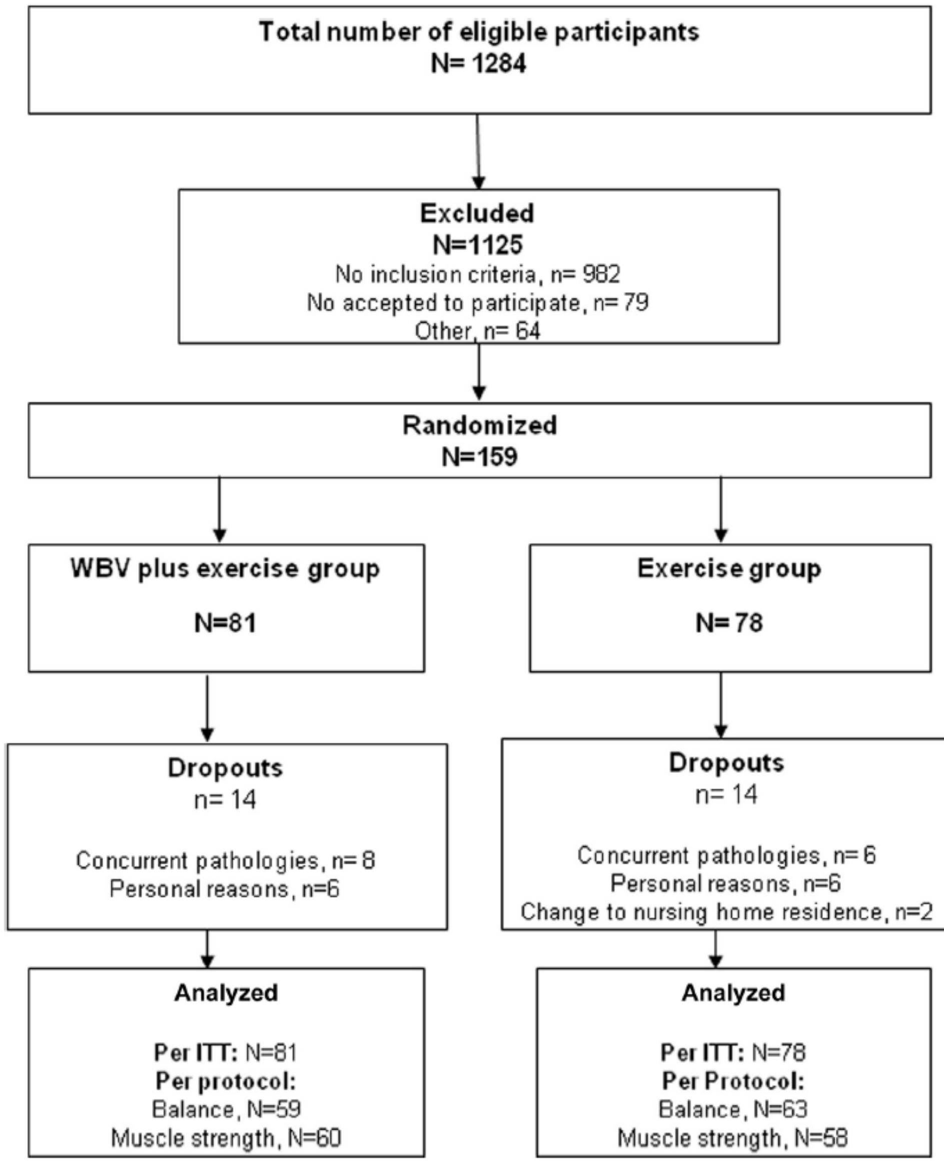

Fig. 1. Flow of participants through the study

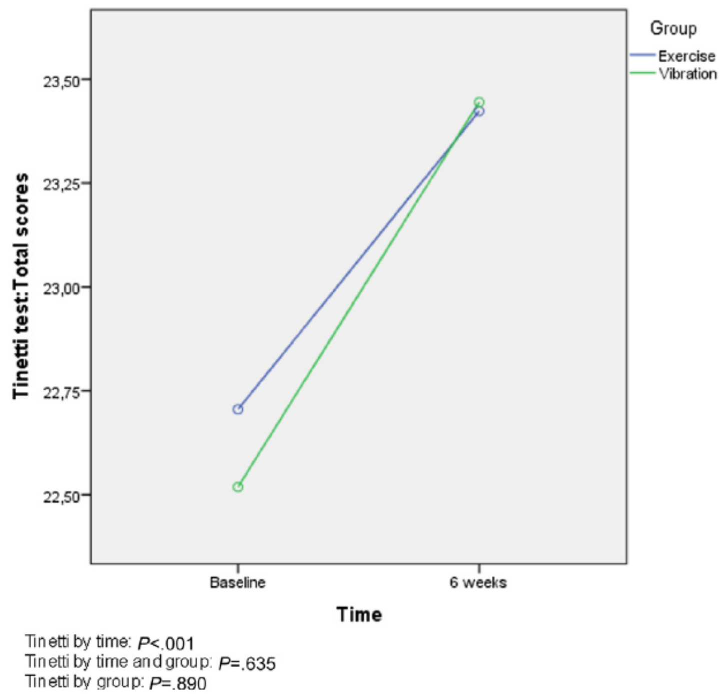

Fig. 2. Tinetti test at 6 weeks of treatment, multifactor ANOVA