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Published in:
Archives of Physical Medicine and Rehabilitation

DOI:
10.1016/j.apmr.2011.09.005

2012

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Running head: Whole-body vibration training in chronic stroke

2867 words

ACKNOWLEDGEMENTS

The study was prepared within the context of the Centre for Ageing and Supportive Environments (CASE) at Lund University, and funded by grants from Skane University Hospital, the Swedish Stroke Association, the Norrbacka-Eugenia foundation, Magn. Bergvall foundation, Gun and Bertil Stohnes foundation and the Swedish Association of Registered Physiotherapists.

No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.

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ABSTRACT

Objective: To evaluate the effects of whole-body vibration (WBV) training in individuals after stroke.

Design: A double-blind randomized controlled study with assessments pre and post training**.**

Setting: A university hospital rehabilitation department.

Participants: Thirty-one participants (mean age 62 ± 7 years; 6-101 months post-stroke) were randomized to an intervention group or a control group.

Interventions: Supervised WBV training (two sessions per week for 6 weeks; 12 repetitions of 40 to 60 seconds WBV per session). The intervention group trained on a vibrating platform with a conventional amplitude (3.75 mm) and the control group on a “placebo” vibrating platform (0.2 mm amplitude); frequency 25 Hz on both platforms. All participants and examiners were blinded to the amplitudes of the two platforms.

Outcome Measures: Primary outcome measures were isokinetic and isometric knee muscle strength (dynamometer). Secondary outcome measures were balance (Berg Balance Scale), muscle tone (Modified Ashworth Scale), gait performance (Timed “Up & Go”, Comfortable Gait Speed, Fast Gait Speed and 6-Minute Walk tests) and perceived participation (Stroke Impact Scale).

Results: There were no significant differences between the two groups after the WBV training. Significant but small improvements ($p<0.05$) in body function and gait performance were found within both groups, but the magnitude of the changes was in the range of normal variation.

Conclusions: Six weeks of WBV training on a vibration platform with conventional amplitude was not more efficient than a “placebo” vibrating platform. Therefore, the use of WBV training in individuals with chronic stroke and mild to moderate disability is not supported.

Abstract 252 words

Keywords: Gait; Muscle, skeletal; Outcome Assessment; Rehabilitation; Stroke; Vibration

LIST OF ABBREVIATIONS

CGS = Comfortable Gait Speed

FGS = Fast Gait Speed

ICC = Intraclass Correlation Coefficient

MVC = Maximal Voluntary Contraction

Nm = Newton Meter

RCT = Randomized Controlled Trial

SEM = Standard Error of Measurement

SIS = Stroke Impact Scale

TUG = Timed "Up & Go" test

WBV = Whole-body Vibration

6MWT = 6-Minute Walk test

A common impairment after stroke is muscle weakness. The reduced muscle strength is strongly related to limitations in daily activities, such as gait performance, and restrictions in perceived participation.[1,2] Different training methods are used to improve lower extremity function after stroke[3] and whole-body vibration (WBV) training is promoted as an alternative to other forms of training. WBV training is performed by standing on a vibrating platform in a static position or by doing dynamic movements at the same time. The vibrations are believed to initiate muscle contractions by stimulating the muscle spindles and the alpha motor neurons and thereby to have an effect similar to that of conventional training, such as resistance training.[4] Despite being on the market for over a decade there are no clear recommendations on how WBV training should be performed with regard to length of training, intensity, frequency or amplitude-setting.

The effect of several weeks of WBV training varies. In healthy individuals, some positive effects are reported, for example increased muscle strength in untrained females,[4] improved balance, muscle strength or gait performance in the elderly[5, 6] whereas other studies have found no or insufficient effects of WBV training.[7, 8] In individuals with stroke or other neurological diseases, few studies have evaluated the effects of WBV training and the results differ also in those studies. In randomized controlled studies (RCTs), improvements in balance, muscle strength or gait performance are reported in individuals with stroke and other neurological diseases,[9-12] but the effects of WBV training are generally small and within the measurement errors of the outcome measures used. Furthermore, in one uncontrolled study after stroke, short-term effects on postural control were reported,[13] whereas another uncontrolled study in persons with post-polio found no effects on muscle strength and gait performance.[14]

The very limited evidence of its efficacy means that we cannot provide recommendations about the training, either to patients or clinicians, and therefore further RCTs are needed. The purpose of this study was to evaluate the effects of WBV training in individuals with chronic stroke. We performed an RCT with one group training on a vibrating platform with a conventional amplitude of 3.75 mm and the other group training on a "placebo" platform with an amplitude of 0.2 mm (control group), twice weekly for 6 weeks. The hypothesis was that WBV training on the vibrating platform with the conventional amplitude would lead to improvements in i) muscle function, ii) balance, iii) gait performance and iv) perceived participation.

METHODS

Participants

Fifty-six potential individuals with chronic stroke, who previously had been treated at a University Hospital in Sweden, were contacted by telephone and were informed about the study. The telephone interview consisted of questions regarding demographics, medical health, current medication, side of paresis, walking ability, physical training, self-perceived knee muscle strength and self-perceived gait performance (rating scales 0-100; where 100 indicated full recovery). The inclusion criteria were: ability to walk at least 300 m, at least 10% self-perceived muscle weakness in the knee extensors or knee flexors in the paretic lower limb and not engaged in any heavy resistance or high-intensity training. Exclusion criteria were: epilepsy, cardiac disease or cardiac pace-maker, osteoarthritis in the lower limbs, knee or hip joint replacement or thrombosis in the lower limbs in the past six months. If there were any concerns about the subjects' self-perceived knee muscle strength based on the telephone interview a pre-test was performed prior to inclusion.

Of the 56 contacted individuals, 15 did not meet the study criteria, and 10 declined to participate. Thus, 31 men and women (mean age 62 ± 7 years) were enrolled in the study (Figure 1). All participants were medically checked by the responsible physician (last author). To characterize the group regarding dependency in daily activities, each subject was interviewed and scored with the Functional Independence Measure (FIM). The baseline characteristics are presented in Table 1.

Assessments and outcome measures

All assessments were performed in a hospital setting by two experienced physiotherapists (first and second authors). Isokinetic and isometric knee muscle strength (primary outcome measures), muscle tone, balance, gait performance and perceived participation (secondary outcome measures) were assessed during two hours before and after the WBV training. Both assessors were blinded to the participants' assignment to the intervention group or control group (see below).

Isokinetic concentric knee extension and knee flexion muscle strength and isometric knee extension muscle strength was measured with a Biodex® Multi-Joint System 3 PRO dynamometer[a] using a standard protocol, previously applied in our research group.[15] The participants were seated in the adjustable chair of the dynamometer, without shoes or orthotic device, and were stabilised with straps across the shoulders, waist and thigh throughout the test. Before each measurement the full range of motion (ROM) was set and the Biodex®

software applied the gravity correction. After a structured warm-up the participants performed three maximal isokinetic extensor and flexor contractions at 60°/s with the non-paretic limb and the highest peak torques were recorded (Newton meter; Nm). Following a 2-minutes rest, they performed two maximal isometric knee extensor muscle contractions with a knee flexion angle at 90º, and the highest maximal voluntary contraction (MVC) was recorded (Nm). Consistent verbal encouragement was given throughout. The same procedure was thereafter repeated with the paretic lower limb.This protocol has been shown to be reliable after stroke[15] and the $ICC_{2,1}$ for knee muscle strength measurements at 60°/s ranged from 0.89 to 0.94. The standard error of measurement (SEM%) was 9% to 17% for the concentric knee extension and flexion, respectively.

The occurrence of increased muscle tone in the more affected leg was assessed with the modified Ashworth scale.[16] The following muscles were assessed: hip adductors, hip extensors and flexors, knee extensors and flexors and ankle dorsiflexors and plantarflexors. The score ranges from 0 to 5 with a maximum of 35 points.

Balance was assessed with the Berg balance scale. The test consists of 14 items ranging from 0 to 4 points with a maximum of 56 points and has been shown to be reliable after stroke.[17]

Gait performance was assessed with the Timed “Up & Go” test (TUG),[18] the 10 metres Comfortable and Fast Gait Speed tests (CGS and FGS)[19] and the 6-Minute Walk test (6MWT).[20] These gait performance tests are also reliable after stroke,[21] with $ICC_{2,1}$ between 0.94 and 0.99 and SEM% between 5% and 8%. The TUG was carried out twice, with a one-minute rest between each trial, and the CGS and FGS were performed three times with 30 sec between each trial. For the TUG, CGS and FGS, the mean value (sec) of the trials was calculated. The 6MWT was performed once and the distance (metres) was recorded.

The participants also rated their perceived participation, using the Stroke Impact Scale (SIS 3.0, Swedish version).[22] The SIS is a self-reported questionnaire that assesses eight aspects of the impact of a stroke on a person’s self-perceived health. The items are scored from 5 (limited none of the time) to 1 (limited all of the time). In this study, only the SIS participation domain was used. The SIS participation addresses the impact of stroke on work, social activities, quiet recreations, active recreations, role as a family member, religious activities, life control, and ability to help others. For each participant, the mean score of these eight items was calculated and converted into a percentage value (0-100), using the following equation: 100 x (the mean value of the eight items -1)/(5-1).[22] High values represent no or few restrictions in participation and low values indicate more restricted participation.

Ethics

Prior to inclusion, each participant gave their written informed consent to participate in the study. The principles of the Declaration of Helsinki were followed and the study was approved by the Regional Ethic Review Board, Lund, Sweden (Dnr 2009/5).

Randomization procedure and blinding

When the initial assessments were completed, the 31 individuals who fulfilled the criteria were randomized into an intervention group or a control group. Randomization was performed using sealed envelopes; prepared in advance and marked inside with “X” or “Y”, indicating the two WBV training platforms. An independent person, not involved in the project, labelled the platforms with” X” and “Y”. Thus, both the participants and the assessors were blinded to the amplitude of the two platforms. When the study was completed and all assessments had been performed, the key to the randomization was disclosed.

Whole-body vibration training

All participants underwent 12 sessions of WBV training (twice weekly during six weeks) on a vibrating platform (Xrsize[b], Sweden; vertical vibrations). The intervention group (X; n=16) trained on a vibrating platform with an amplitude of 3.75 mm, which is the conventional amplitude-setting of the Xrsize[b] machine and also a common amplitude in other WBV studies.[23] The control group (Y; n=15) trained on a vibrating platform with an amplitude of 0.2 mm, which was specifically manufactured for the present study. This amplitude was considered to have no or limited effects and was therefore referred to as the “placebo” platform. The frequency on both platforms was set to 25 Hz.

All participants were standing barefoot on the platforms in a static position with the knees flexed 45-60 degrees and with handhold support, if needed. During the six weeks the WBV training increased from 40 to 60 seconds per repetition and the number of repetitions from 4 to 12 (with a one-minute rest between each repetition). Each session lasted no more than 45 minutes and was supervised by a physiotherapist.

Statistics

Our research group has previously performed a reliability study on knee muscle strength after stroke[15] and shown that the measurement errors are generally small. Based on these results, we performed a power calculation; a total of 30 participants would yield an 80% chance of detecting a 20% difference in strength between the intervention group and the control group, with a significance level of $p<0.05$.

Differences between the two groups were assessed before and after the intervention using the independent sample *t*-test for continuous variables and the Mann-Whitney U test for ordered variables (muscle tone). To correct for any between-group differences at baseline, a linear regression analysis was used. Differences within each group were tested with the paired sample *t*-test, except for muscle tone, where the Wilcoxon Sign Rank test was applied. For each group and measurement, the percentage differences between before and after intervention were calculated from the means of the group values. SPSS[c] version 18.0 was used for all statistical analyses and the criterion for statistical significance was set at $p<0.05$.

RESULTS

All outcome measures on balance, knee muscle strength, and muscle tone are presented in Table 2 and gait performance and perceived participation are presented in Table 3. All participants completed the 6 weeks of WBV training with no discernible discomfort; fifteen participants reported transient mild muscle soreness or muscle fatigue, regardless of which platform they trained on.

At baseline, significant between-groups differences were found in three outcome measures: balance ($p<0.01$), TUG ($p<0.05$) and 6MWT ($p<0.01$). After the intervention, significant between-group differences were still found in TUG ($p<0.05$) and 6MWT ($p<0.05$). Following adjustments for the between-group differences at baseline, using the linear regression analysis, the differences in all outcome measures after the training were non-significant (Table 2 and 3).

Significant but small improvements were found within both groups after the WBV training. The intervention group (X; n=16) improved significantly in balance (+4%; $p<0.05$) and in gait performance (TUG +8%, CGS and 6MWT +5%; $p<0.05$). The control group (Y; n=15) improved significantly in isometric knee extension strength in the paretic limb (+12%; $p<0.05$) and in gait performance (TUG and 6MWT +6%; $p<0.05$).

DISCUSSION

This is to our knowledge the first RCT that has evaluated WBV training with two different amplitudes in patients with neurological diseases, such as stroke. No significant differences were found in any outcome measures between the intervention group and the control group after 6 weeks of WBV training. Thus, our hypothesis that the vibrating platform with a conventional amplitude-setting would improve muscle function, balance, gait performance and perceived participation could therefore be rejected.

There are several possible explanations for the lack of significant differences between the groups. One is that WBV training overall has a limited effect in post-stroke individuals. Another explanation is that the training was not intense or long enough. However, the training protocol used in this study was similar to that of other WBV studies[14, 24, 25] and decided after literature search and discussions with a person with experience of WBV training in rehabilitation. Training twice weekly is also a common frequency at private gyms and in public health care facilities. Moreover, it is not known which is the optimal amplitude or frequency. The amplitude of 3.75 mm and a frequency of 25 Hz used in this study can be considered as conventional settings. Tihanyi et al.[25] have reported that low vibration frequency (20 Hz) can increase strength in the weak muscles after stroke as compared to the controls. We did not specifically evaluate that parameter and the participants in their study were in the acute phase after stroke, which could have influenced the result.

We found significant but small improvements after the WBV training within both groups. Balance improved in the intervention group, whereas isometric knee muscle strength in the paretic limb improved in the control group. Gait performance, as assessed by the TUG and 6MWT tests, increased to a similar extent in both groups. No improvements in knee muscle strength in the non-paretic limb, changes in muscle tone in the paretic limb or changes in perceived participation were found in any of the groups. However, the magnitude of the changes after WBV training was within or very close to the limits of measurement errors, which indicates no real clinical improvement.[15, 21]

WBV training has been promoted to be an alternative to resistance training.[4] Ten weeks of progressive resistance training (PRT; 80% of 1 Repetition Maximum) after stroke significantly improved knee muscle strength (+14% to +73%) as well as gait performance (+10% to +19%), without any negative effects on muscle tone.[26] When comparing these two interventions, the magnitude of the improvements was much larger after PRT than after WBV training in individuals with chronic stroke.

In this study, we used commonly applied and reliable outcome measures that reflect different aspects of function, activity and participation according to International Classification of Functioning, Disability and Health (ICF).[27] From a rehabilitation perspective, an intervention is considered to be effective when it reduces not only impairments, but also impacts on activity limitations and participation restrictions. Our findings of no or only small changes on body function, activity and participation post treatment indicate that WBV training is not an efficient training method after stroke. Our results are in agreement with other RCTs in patients with neurological diseases.[9-12] Those that have used a structured design often report no or small effects. In persons with stroke, WBV training has not been found to be more effective than conventional training regarding balance and activities of daily living.[9] The effects of WBV training on gait performance in persons with Parkinson's disease and adults with cerebral palsy are also reported to be small and not more efficient than conventional training.[10, 12] In persons with Multiple Sclerosis, 20 weeks of WBV training did not have any effects on leg muscle performance and functional capacity[28] as compared to controls maintaining their usual lifestyle. Thus, studies so far have not been able to show that WBV training is a viable treatment for patients with stroke or other neurological disorders.

Study Limitations

The post-stroke individuals included in the present study were all ambulatory and mildly to moderately affected in their lower limbs. None of the participants was engaged in any high-intensity training and could therefore, theoretically, have responded to conventional training. It was a bit unexpected that isometric knee muscle strength in the paretic limb increased significantly in the control group after the WBV training. It cannot be excluded that just standing in a static position with the knees bent for several minutes, activates the thigh muscles to such an extent that it can result in increased isometric muscle strength. Therefore, it would have been interesting to include a third group that was standing on a platform without any vibrations, as pure controls. However, it was not possible with a double-blinded design, as the group assignment and the standing on a platform without any vibrations would have been obvious to the participants and the physiotherapists. Instead, we chose a study design with two different amplitudes, one with a "conventional" amplitude-setting and one amplitude-setting near zero, i.e. a "placebo" amplitude, to be able to imitate a placebo-controlled study as much as possible. Although the sample size in this study could be considered small, it was based on a power calculation and therefore a type II error is unlikely.

CONCLUSION

Six weeks of WBV training on a vibration platform with conventional amplitude had small effects on balance and gait performance in chronic post-stroke individuals, but was not more efficient than a "placebo" vibrating platform. The use of WBV training in individuals with mild to moderate disability after stroke is therefore not supported. With the very limited evidence for the effectiveness of WBV training after stroke, it can be questioned if further randomized controlled trials for this patient group are needed.

Suppliers

[a]Biodex Medical Systems Inc, 20 Ramsey Rd, Shirley, NY 11967-0702.

[b]Xrsize, Askims Verkstadsväg 5A, 436 34 Askim, Sweden

[c]SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606

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LEGEND

Figure 1: Flow chart of the participants included in the study.

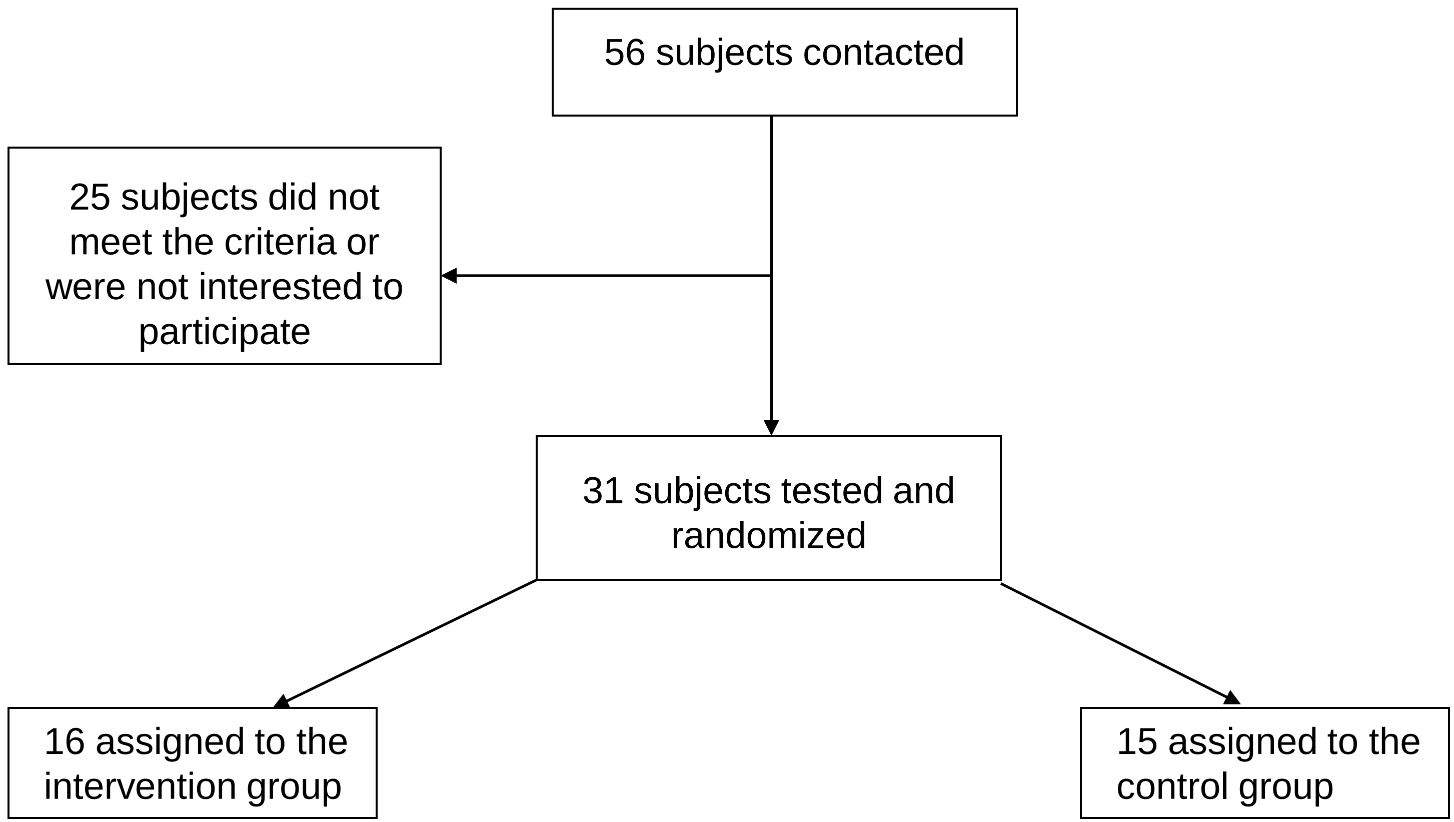
56 subjects contacted
25 subjects did not meet the criteria or were not interested to participate
31 subjects tested and randomized
16 assigned to the intervention group
15 assigned to the control group

Figure 1

Table 1. Characteristics of the 31 post-stroke participants, randomized to the intervention group (n=16) or the control group (n=15).

	Intervention group	Control group
Gender; men/women (n)	13/3	12/3
Mean age (SD); years	61.3 (8.5)	63.9 (5.8)
Mean time post-stroke (SD); months	37.4 (31.8)	33.1 (29.2)
Affected side; right/ left (n)	7/9	8/7
Type of stroke; infarction/haemorrhage (n)	14/2	13/2
Mean FIM score (SD); points	83.1 (3.1)	83.5 (3.2)

Table 2. Muscle tone, balance and knee muscle strength before and after whole-body vibration (WBV) training for the intervention group (n=16) or the control group (n=15).

	Before WBV		After WBV		Differences between groups	
	Intervention group	Control group	Intervention group	Control group	Difference before WBV	Difference after WBV
Muscle tone (Ashworth scale; points)	1.5 (0-7)	1.0 (0-9)	1.0 (0-7)	2.0 (0-14)	0.5	1.0
Balance (Berg balance test; points)	50.0 (2.8)	52.6 (1.6)	52.1 (2.0)	52.3 (2.3)	-2.7 (1.0 to 4.4) **	-0.3 (-1.9 to 1.3)
Muscle strength measurements						
Isokinetic knee extension (60º/s; Nm)						
Non paretic lower limb	132.8 (24.1)	124.5 (31.7)	133.4 (25.7)	126.0 (36.3)	8.2 (-12.4 to 28.8)	7.4 (-15.5 to 30.4)
Paretic lower limb	83.9 (32.9)	72.7 (28.9)	80.6 (39.0)	87.7 (29.8)	11.1 (-11.7 to 34.0)	-7.1 (-32.6 to 18.3)
Isokinetic knee flexion (60º/s; Nm)						
Non paretic lower limb	70.9 (15.2)	65.2 (18.1)	71.4 (15.1)	65.2 (20.2)	5.7 (-6.6 to 17.9)	6.1 (-7.1 to 19.4)
Paretic lower limb	29.6 (24.5)	42.3 (27.4)	29.4 (25.6)	43.2 (23.0)	-12.7 (-31.8 to 6.3)	-13.7 (-31.6 to 4.1)
Isometric knee extension (MVC; Nm)						
Non paretic lower limb	152.4 (30.4)	136.7 (41.5)	147.5 (31.8)	138.9 (39.3)	15.7 (-10.9 to 42.3)	8.6 (-17.8 to 35.0)
Paretic lower limb	102.0 (36.1)	94.1 (30.8)	102.1 (36.4)	105.6 (27.6)	7.8 (-16.9 to 32.5)	-3.5 (-27.2 to 20.2)

NOTE: Nm=Newton metres; MVC=Maximal voluntary contraction. Data are presented as mean (SD) except for muscle tone which is presented as median (min-max). Differences between groups are presented as mean differences (CI) for all outcome measures except for muscle tone. **= $p<0.01$

Table 3. Gait performance and perceived participation before and after whole-body vibration (WBV) training for the intervention group (n=16) or the control group (n=15).

	Before WBV		After WBV		Differences between groups		
Outcome measures	Intervention group	Control group	Intervention group	Control group	Difference before	Difference after	Difference after adjustment
Gait performance; mean (SD)							
TUG (sec)	17.1 (4.5)	12.6 (3.7)	15.7 (4.5)	11.9 (4.4)	4.5 (1.5 to 7.5) †	3.8 (0.6 to 7.1) *	0.8 (-0.3 to 1.8)
CGS (sec)	13.8 (4.5)	10.6 (5.0)	13.0 (4.7)	10.2 (4.1)	3.1 (-0.4 to 6.6)	2.8 (-0.4 to 6.1)	
FGS (sec)	9.9 (2.9)	8.2 (3.6)	9.6 (3.2)	8.1 (3.4)	1.8 (-0.6 to 4.2)	1.6 (-0.9 to 4.0)	
6MWT (m)	305 (108)	393 (115)	322 (110)	416 (116)	-88 (5 to 170) *	-94 (11 to 177) *	8.0 (-13 to 29)
Participation %							
SIS; mean (SD)	62.5 (22.8)	69.8 (12.1)	67.6 (18.4)	66.2 (11.1)	-7.3 (-6 to 21)	1.3 (-5 to 18)	

NOTE: TUG=Timed “Up & Go”; CGS=Comfortable Gait Speed (10 m); FGS=Fast Gait Speed (10 m); 6MW=6-Minute Walk. SIS=Stroke Impact Scale. Differences between groups are presented as mean differences (CI). Difference after adjustment’ refers to the corrections for baseline differences between the groups. *= *p*<.05, †= *p*<.01