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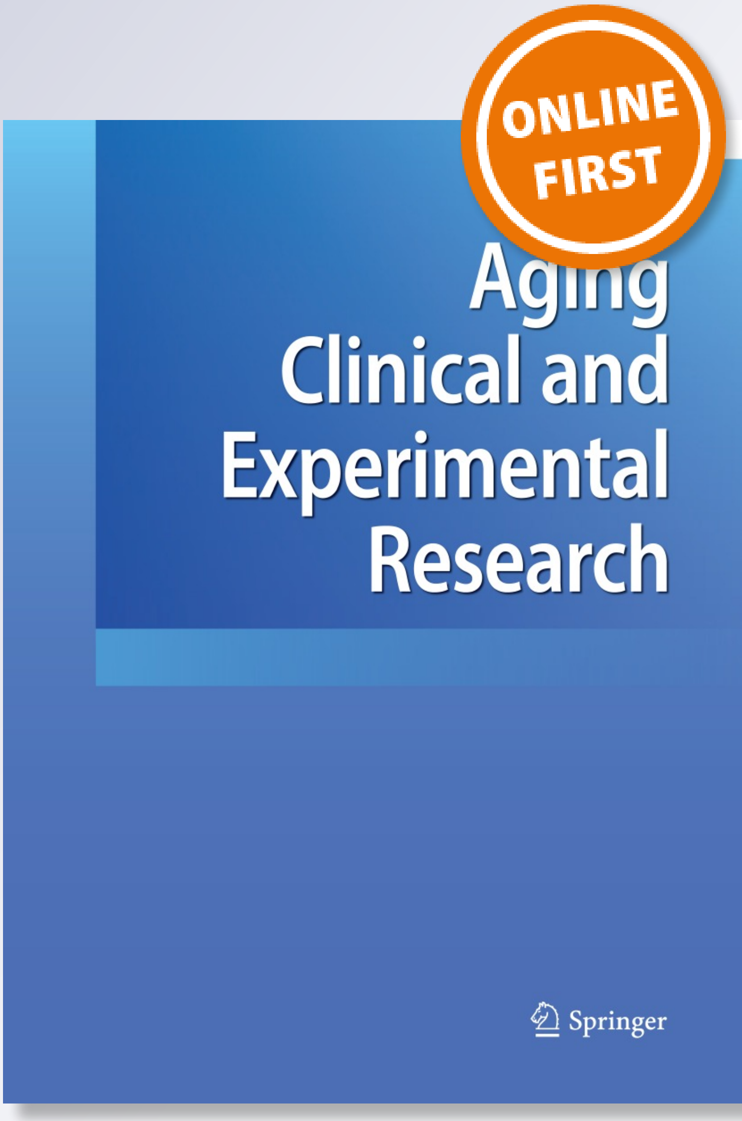

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ORIGINAL ARTICLE

Evaluation of the impact of 6-month training by whole body vibration on the risk of falls among nursing home residents, observed over a 12-month period: a single blind, randomized controlled trial

F. Buckinx · C. Beaudart · D. Maquet · M. Demonceau · J. M. Crielaard · J. Y. Reginster · O. Bruyère

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Abstract
Background We have previously shown that short sessions of whole body vibration (WBV) were not able to significantly improve fall risk among nursing home residents but some trends towards an improvement of motor capacity were observed.
Objective The objective of the present study was to evaluate the impact of 6-month training by WBV on functional and motor abilities among nursing home residents observed over a 12-month period.
Methods Patients were randomized into two groups: the WBV group which received three training sessions every week composed of five series of 15 s of vibration at 30 Hz intensity for a period of 6 months and a control group with normal daily life. The impact of this training on the risk of falls was assessed blindly after 6 and 12 months by the Tinetti Test, the "Timed Up and Go" test and a quantitative evaluation of a 10-s walk performed with a tri-axial accelerometer. The occurrence of falls was also observed.
Results 62 elderly healthy volunteers, (47 women and 15 men, mean age 83.2 ± 7.9 years) were included in this study. There was no significant difference between the two groups regarding the Tinetti test ($p = 0.75$), the "Timed Up and Go" test ($p = 0.19$) and the Locométrix® test, except for the step length, measured by dual task ($p < 0.01$). No significant inter-group difference in the frequency of falls was observed during the 12 months of research. A total of 42 falls were recorded during the first 6 months of experimentation: 24 falls in the treated group and 18 in the control group ($p = 0.60$). During the next 6 months, 19 falls occurred: 8 falls in the treated group and 11 in the control group ($p = 0.52$).
Conclusion This study failed to establish the effectiveness of low doses of WBV, under the conditions used in our study, on functional and motor abilities of institutionalized elderly patients. However, given the positive results of other studies, further investigations, with modified therapeutic protocols, seem necessary to clarify the effects of WBV in the elderly.

Keywords Whole body vibration · Elderly · Nursing home · Falls · Functional and motor abilities

Introduction

According to the World Health Organization the proportion of older people is increasing and in 2060, one-third of the population will be over 65 years old. Gait disorders are common among the elderly. Abnormalities are present in 14 % of individuals aged between 65 and 75 years and this figure increases with advancing age [1]. These abnormalities are in part responsible for falls among elderly people. Falls are one of the main causes of disability, injury and death among older adults and, therefore, constitute an important public health issue [2].

Physical activity appears to have a beneficial effect on falls. Indeed, the meta-analysis of Sherrington et al. [3],

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including 54 randomized controlled trials, shows that exercise as a single intervention can prevent the risk of falling ($R = 0.84$ with 95 % CI = 0.77–0.91). The meta-regression shows that programs involving balance exercises, including a higher frequency of exercise and excluding gait training, have the greatest impact on reducing falls. However, fatigue and lack of motivation are sometimes observed in the elderly [4].

Recently, whole body vibration (WBV) exercise has been developed as a new modality in the field of physiotherapy to avoid injuries and low compliance. The WBV is a vibration system that involves involuntary contractions of whole muscle groups and enables isometric exercises. Recently, WBV has gained popularity in rehabilitation of various populations, especially among elderly. It has been suggested that WBV exercise increases muscle power and strength and improves muscular performance and body balance [5]. Thus, WBV training may be an efficient intervention. A recent meta-analysis has showed a beneficial effect of WBV on the risk of falls in the elderly, but optimal conditions of use still need to be defined [6].

We have previously shown that short sessions of WBV for 3 months were not able to significantly improve fall risk among nursing home residents but some trends towards an improvement of motor capacity were observed [7]. This study was originally scheduled for a period of 6 months completed by 6 months of follow-up. Because of the very slight improvement in motor skills observed after 3 months, we stuck to the originally schedule of 6 months to see if the improvement would continue.

The main objective of the present study was to evaluate the impact of 6-month training by WBV on functional and motor abilities among nursing home residents observed over a 12-month period. The impact of this training on the risk of falls was also observed.

Methods

Participants

The design and methodology of the study have previously been described in a former report [7].

Briefly, residents of two nursing homes in the area of Liège, Belgium ("Seigneurie Michelange", Beaufays and "Notre dame", Huy) were eligible for the study if they were able to remain standing and to move with or without technical assistance. Exclusion criteria were mainly based on contra-indications for WBV: (1) weighing more than 150 kg, (2) having electronic implants (e.g. pacemaker, brain stimulators), (3) having knees or hips prosthesis, (4) suffering from epilepsy or bleeding disorders, (5) suffering from inflammatory abdominal disorders or being at high risk of thromboembolism, (6) being diagnosed with a malignant tumour, (7) having an unconsolidated fracture, (8) refusal of doctor and (9) refusal of family.

As requested by the two collaborating nursing homes, the attending physician was asked to verify the exclusion criteria to WBV and to give his consent for the inclusion of each resident in our study.

The protocol was approved by the "Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège". Informed consent was obtained from each of the subjects prior to their participation in the study.

Study design

The patients enrolled in this study were randomized into two groups: the WBV group and the control group. We performed the randomization by blocks of four with a computer-generated randomization procedure. The outcomes were blindly assessed. Thanks to the two locations, the investigators who conducted the assessments in one nursing home supervised patients from the other nursing home so that they would not know to which group the patient, they were assessing, belonged.

Training programme

WBV group

The participants assigned to the WBV group performed a 6-month exercises programme on a vibration platform (Vibrosphère®), which was installed for the study purpose in the rehabilitation room of the nursing homes. This device provides a sinusoidal vibration with a frequency of 30 Hz and an excursion of 2 mm. Exercises were performed three times per week for 6 months (with a minimum of 1-day rest in between) and consisted of 5 series of 15 s of stimulation, alternating with 30 s of rest. Per session, the total time of exposure to vibration was 1 min 15 s. During the activity, the subject was standing on two feet, shoeless and knees flexed. A cushion was placed under the vibrosphere® during the sessions to minimize ground vibrations. All training sessions were supervised by a physiotherapist or a researcher.

Control group

The control group subjects did not participate in any training programme and were requested not to change their lifestyle or to engage in any new type of physical activity, during the study.

Data collection

For each patient, functional and motor skills, as well as risk of falls, were assessed blindly by means of different tests at baseline, 6 and 12 months.

Tinetti test

The Tinetti test or "Performance-Oriented Mobility Assessment" (POMA) was used to assess balance and gait abnormalities. It is one of the most widely used tests in this field [8]. This test consists of 16 items: 9 for body balance and 7 for gait. The maximum score is 16 for body balance, 12 for gait and thus 28 for the global score (balance + gait). A total score of less than 20 points indicates severe risk of falls, a score between 20 and 23 points indicates moderate risk of falls, a score between 24 and 27 indicates low risk of falls and a score of 28 points indicates no risk of falls [9].

"Timed up & go" test

We assessed functional mobility using the "Timed Up & Go" test, which is a modified version of the "Get Up & Go" test [10]. This test measures basic mobility and capabilities of dynamic equilibrium in a complex task in the elderly [11]. From a sitting position, the subject has to stand up, walk 3 m, turn over, walk back and sit down again. The time needed to complete the task is recorded and used for analyses [12]. A time of more than 30 s indicates a high level of dependence. A time of between 20 and 30 s indicates uncertain mobility and risk of falling. A time of less than 20 s indicates independence of the subject [13].

Quantitative walking analysis (Locometrix®)

This test consists of a quantitative evaluation of a 10-s walk performed with the Locometrix®. It enables to quantify the locomotion disorders in the elderly [14]. The method is based on the recording of tri-axial accelerations of the body at a point near the centre of gravity, the median lumbar region. The recording is done using a sensor composed of 3 accelerometers arranged perpendicularly, according to three orthogonal axes. The axes of the sensors are cranio–caudal, anterior–posterior and medio–lateral [14]. The system is applied on the lumbar region, at L3–L4 disc space high, using a semi-elastic belt. It is then connected to a computer which calculates the dynamic gait parameters: frequency, symmetry, stability, regularity of gait cycles, cranio caudal power, medio-lateral power, antero-posterior power. These data can then be interpreted to detect any gait deterioration of the elderly. The patient walks 3 times 20 m. The first run is a preliminary test, the second is a simple task analysis and the third is a dual task analysis. In the dual task, the patient counts down out loud from 70 while walking. The number of digits said out loud and the number of errors in the countdown are recorded by the experimenter.

Assessment of falls

Falls were defined as "unintentionally coming to rest on the ground, floor, or other lower level." During the 12-month study, falls were recorded in the two groups, by the nurses in the nursing homes. The date, circumstances and consequences of falls were recorded.

Statistical analysis

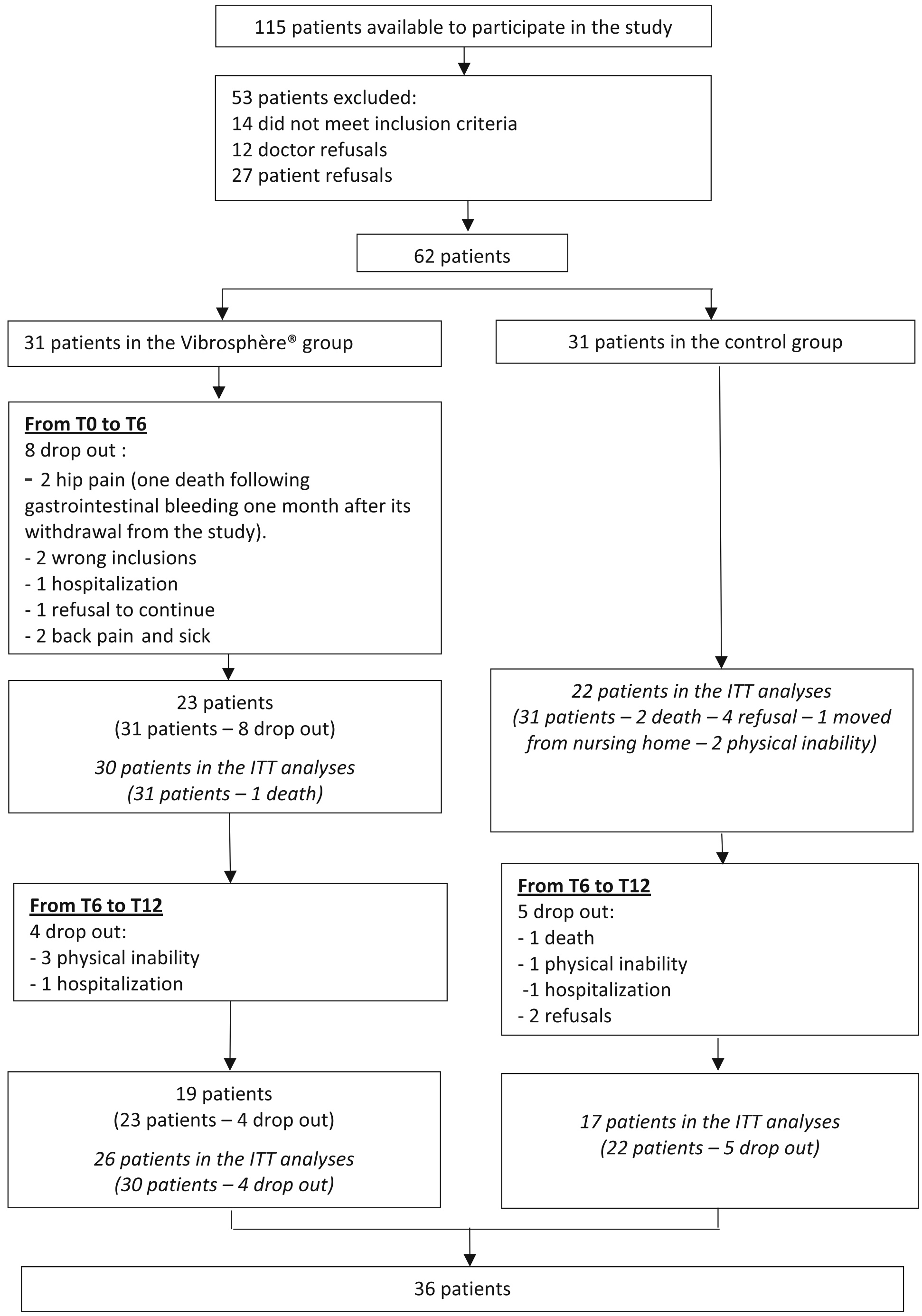
Quantitative variables that were normally distributed were expressed as mean ± standard deviation (SD), and quantitative variables that were not normally distributed were reported as absolute or relative frequencies. A Shapiro–Wilk test verified the normal distribution for all parameters. Differences between groups were assessed using the "Student *t* test", "Mann–Whitney *U* test" or "Pearson Chi square test" when appropriate. The results were adjusted using a multiple regression on the variables that differ significantly between the treatment group and the control group at "baseline." Falls were analysed by "Kaplan–Meier survival" and pairwise method. Intention-to-treat analyses were performed. We used the last available data for the analysis. Data of dropouts who returned for follow-up measurements were also included in the analysis. All analyses were performed with the Statistica 10 software. Results were considered statistically significant when 2-tailed p values were less than 0.05.

Results

Descriptive analysis

A total of 62 healthy volunteer institutionalized patients were enrolled and randomized into two groups. Thus, 31 participants were included in the WBV group and 31 in the control group (Fig. 1). Baseline and demographics data showed that 64.5 % of the patients were females in the WBV group while there were 87 % women in the control group ($p = 0.04$). Also, subjects' mean age was 82 years in the treated group and 84 years in the control group ($p = 0.31$). Table 1 shows the baseline characteristics of the subjects.

Fig. 1 Flow Chart



Principle of the study

Patients were followed for 12 months, 6 months during which patients received treatment followed by 6 months without treatment for the WBV group and two periods of 6 months each, without treatment, for the control group.

Dropout and compliance

Out of the 31 patients in the WBV group, 8 have stopped intervention prematurely (Fig. 1) and 23 completed the 6-month exercise programme and attended 90.9 % of the exercise sessions. Their baseline characteristics do not differ statistically from those of patients who have

Table 1 Baseline patients' characteristics

Parameter	*n*	WBV	*n*	Control	*p* value
Sex					
Women	31	20 (64.5)	31	27 (87.1)	0.04
Age (years)	31	82.2 ± 9.02	31	84.2 ± 6.83	0.31
BMI (kg/m^2)	31	25.2 ± 4.13	31	22.5 ± 3.91	
Glasses					
Yes	31	24 (77.4)	31	26 (83.9)	0.52
Walking assistance					
Yes	31	17 (54.8)	31	12 (38.7)	0.20
Physiotherapy					
Yes	31	13 (41.9)	31	8 (25.8)	0.18
Medication (number)	31	8.58 ± 3.41	31	8.90 ± 4.01	0.74
Medication					
>4	31	30 (96.8)	30	27 (90.0)	0.29
Comorbidities (number)	31	3.00 (2.00–5.00)	31	3.00 (2.00–4.00)	0.42
MMSE (points)	30	26.0 (19.0–28.0)	29	23.0 (15.0–27.0)	0.04
History of fall within 6 months					
Yes	31	11 (35.5)	31	10 (32.3)	0.79
History of fractures					
Yes	31	7 (22.6)	31	6 (19.4)	0.75

WBV whole body vibration, *MMSE* Mini Mental state Examination

completed 6 months of training by Vibrosphère®, except the stride regularity measured in simple task, assessed by the test Locometrix®. This average stride regularity coefficient was significantly higher ($p = 0.03$) in the group that completed the study (198.7 ± 42.4) than in the group that discontinued the study prematurely (146.3 ± 85.7). Compliance is defined as the act of taking the prescribed treatment [15]. In our study it was calculated by dividing the number of vibrotherapy sessions actually carried out by the number of prescribed sessions. We obtained 90.9 % of compliance.

Outcomes

Tinetti test

In the WVB group, we observed a balance increase of +0.08 ± 2.28 points and a gait decrease of −0.71 ± 1.92 points after 6 months which represents a total Tinetti decrease of −0.63 ± 2.91 points. In the control group, the scores for balance, walking and total Tinetti were reduced of −0.36 ± 2.84, −1.09 ± 2.69 and −1.45 ± 4.79 points respectively. No significant inter group differences were observed, after adjustment for age, sex and BMI. Figure 2 below shows the evolution of the Tinetti test (total score, gait score and balance score), during the 12-month study, in the WBV group and in the control group. The solid line represents 6 months of training by body vibration while the dashed line is used to symbolize a period without treatment.

Timed Up and go test

After 6 months of training, the TUG execution time decreased in the treatment group (median: −0.15; P25–P75: −5.08 to 2.16 s) as opposed to the control group (median: +0.89 s; P25–P75: 2.00–4.02 s). This difference is not significant ($p = 0.19$). Figure 3 shows the evolution of the TUG in both groups (control and Vibrosphère®) from T0 to T12. The median time required to perform this test appears to decrease in the first group while it seems to increase in the second.

Locométrix® test

No significant inter group difference, for the parameters recorded by the Locometrix®, was observed, except for the step length, measured by dual task between T0 and T12. Step length decreased in both groups after 12 months of study, more in the control group (−0.12 ± 0.20 m) than in the experimental group (−0.04 ± 0.29 m) ($p < 0.01$).

Falls

A total of 42 falls were observed during the 6 months of experimentation: 24 falls occurred in the treated group (mean of 0.77 falls per patient) and 18 in the control group (mean of 0.58 falls per patient). During the 6 months post experimentation, 19 falls occurred: 8 falls in the Vibrosphère® group (mean of 0.33 falls per patient) and 11 in the control group (mean of 0.48 falls per patient). No significant inter group differences in the frequency of falls was observed during the 12 months of research (Table 2).

There is no inter-group difference in the probability of survival, corresponding to the probability of not falling (p value obtained by Cox regression = 0.96) (Fig. 4).

According to Poisson regression model, neither randomization (intervention group or control group) nor the period (T0–T3, T3–T6, T6–T12) has an effect on the number of falls observed (Table 3).

Discussion

This 12-month study investigated the effects of 6-month training by Vibrosphère® on functional and motor abilities and occurrence of falls in elderly living in nursing homes. The results do not show any significant improvement on

Fig. 2 Evolution of the Tinetti test for both groups (t12)

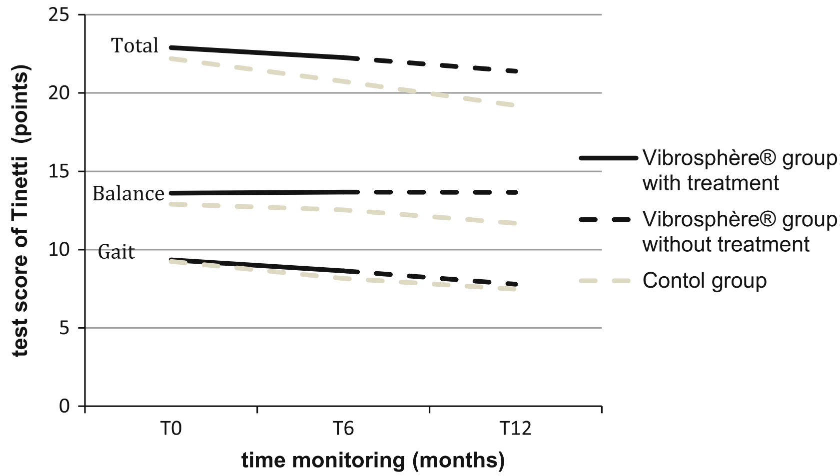


Fig. 3 Evolution of the timed Up and Go test for both groups

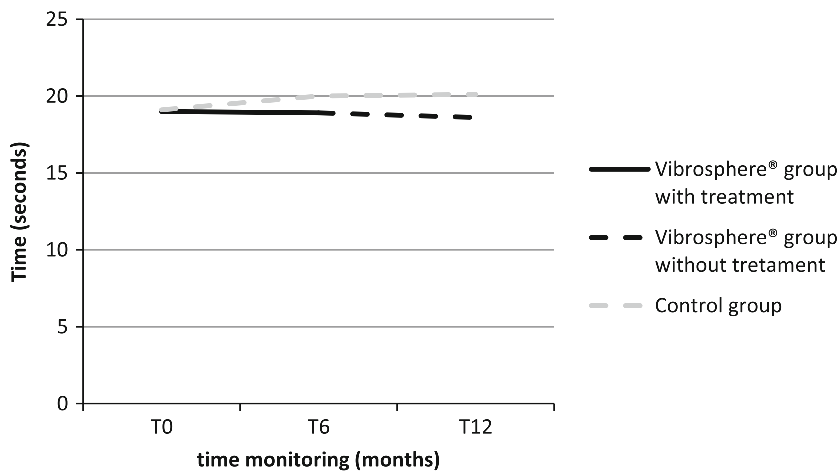


Table 2 Number of falls recorded for the two groups during the 12-month follow-up

Parameter	*n*	WBV	*n*	Control	*p* value
Number of falls recorded during the study (number per patient)		0.77 ± 1.69		0.58 ± 1.12	0.60
Patients who fell (number)	31	9 (29.0)	31	9 (29.0)	1
History of falls	31	4 (12.9)	31	5 (16.1)	0.53
No history of falls	31	5 (16.1)	31	4 (12.9)	0.65
Number of falls recorded during the study (number per patient)		0.33 ± 0.64		0.48 ± 0.90	0.52
Patients who fell (number)	18	6 (25.0)	17	8 (34.8)	0.46
History of falls	18	1 (16.7)	17	3 (37.5)	0.31
No history of falls	18	5 (83.3)	17	5 (62.5)	0.56

WBV whole body vibration group

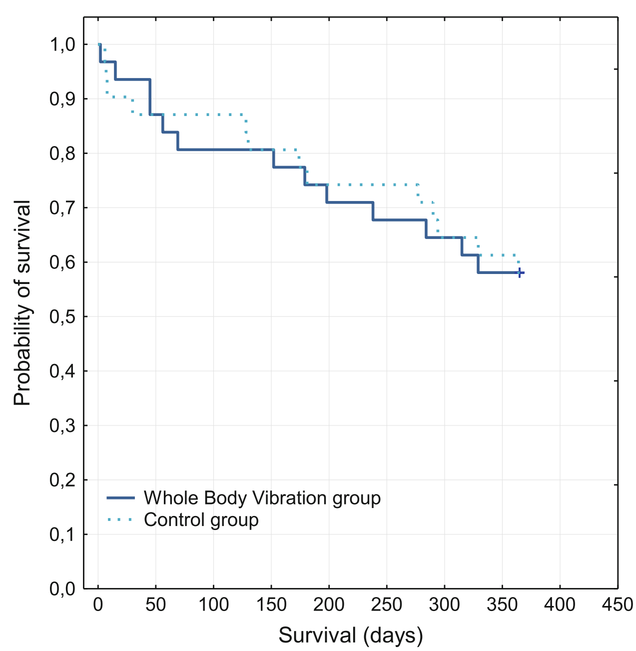


Fig. 4 Kaplan-Meier Curve

Table 3 Analysis of GEE parameter estimates (Poisson regression Model)

Parameter	Estimate	Standard error	$|Pr > Z|$
Intercept	−0.9127	0.3050	0.0028
Period			
T0–T3	0.1985	0.4343	0.6476
Period			
T3–T6	−0.5994	0.4307	0.1640
Period			
T6–T12	Reference		
Randomization			
Control	−0.0235	0.3920	0.9521
Randomization			
WBV	Reference		

WBV whole body vibration

the various studied parameters, except for the step length, measured in dual task. However, some aspects of the study that may have affected the results should be discussed.

62 volunteer patients were randomized into two groups (Vibrosphère® and control) of 31 subjects. The two groups were similar for the majority of the characteristics except for sex, BMI and MMSE score. According to different studies and meta-analyses, women are more likely to fall than men (OR = 1.52, 95 % CI = 1.45–1.59), a low BMI (<22) as well as the presence of cognitive impairment (MMSE score < 24) increases the risk of falling (OR = 1.80, 95 % CI = 1.2–2.5 and OR = 2.2, 95 % CI = 1.5–3.2) [16–18]. Due to differences in sex, BMI and MMSE score observed in the two groups, the results should be interpreted with caution and were, therefore, adjusted for these three variables.

A recent meta-analysis has revealed that WBV is effective in improving functional mobility in older adults [6]. Its effects on falls, however, remain uncertain. Further research is required to identify the optimal protocol of WBV to reduce falls risk among elderly. Indeed, methodology varies from one study to another and the effects of WBV may vary depending on the exposure parameters such as frequency, amplitude of vibration, exposure time and rest intervals [19]. Our study differs from others by its shorter duration of exposure (5X15s instead of 5X30s more frequently observed), which was expected to improve compliance, and by the equipment used. Indeed, the Vibrosphere® because of its unstable equilibrium tray improves proprioception and balance. One study compared muscle performance and mobility between a WBV group and a physical activity group and showed no significant inter group difference [20]. Moreover, WBV shows good tolerance among elderly [21].

Our study shows a high methodological quality. First, it is a randomized study, controlled by a group of patients who did not change their lifestyle. Second, this study used a single-blind method to assess the patient's risk of falls. Third, analyses were performed by intention to treat. We can also add that a calculation of statistical power was done for the functional and motor abilities. Finally training has been rigorously monitored.

The major limitation of this study is the introduction of a novel type of intervention (short bouts of vibration) together with a novel device, which might have reduced the efficacy of the intervention and, as a consequence, reduced the statistical power to demonstrate a beneficial effect of the intervention. This could be the reason for the inconsistency of the present results with those of previous reports from other authors on the same topic.

Another limitation of this study is the lack of statistical power for the frequency of falls. Indeed, it had been calculated prior to the beginning of the research, based on the results of Bruyere et al. [12] who had obtained a much higher improvement in the Tinetti score between treated and untreated patients of 5.9 points versus 2.25 points in our study. Based on our results, and considering a study discontinuation rate of approximately 25 % [22], 256 patients in total (128 in each group) would have been necessary to ensure sufficient statistical power. Therefore, the statistical power of our study is too low to demonstrate any statistically significant difference in the frequency of falls between the two groups. Indeed, the study had not been designed to assess the frequency of falls, as main objective, and the results are hence only indicative. Moreover, falls are multifactorial events and, therefore, a single intervention would have to be very effective to be able to exert a robust influence on such an outcome. The WBV intervention proposed in our study could be tested in simpler outcomes than falls in a new study.

Some aspects of the therapeutic protocol have introduced some limitations to the study. Although the protocol seemed suitable for institutionalized elderly people, due to too short periods of stimulation and a too thick cushion under the device, the balance and proprioception was not optimally worked out. Moreover, patients in the treatment group had to walk all the way up to the physiotherapy room three times a week which may have influenced the results obtained because of an additional effect on the risk of falling. The benefit of physical activity on falls was shown in a meta-analysis on 54 randomised controlled trials [3]. To overcome this limit we could have walked with the subjects from the control group, three times a week up to the physiotherapy room.

Considering the population enrolled in the study, it would have been interesting to evaluate muscle parameters, such as muscle strength of the lower extremities. Indeed, these parameters are known for their beneficial effects on functional and motor skills as well as on the risk of falling [23].

Conclusion

According to the results of our study, WBVs do not seem appropriate for improving the functional and motor abilities among nursing homes residents. Our results do not agree with previous results found in the same domain. The treatment protocol should be amended to ensure adequate proprioceptive work: it would be interesting to extend the duration of the vibration sessions, according to a progressive protocol to avoid treatment addiction. A limited exposure time does not seem appropriate because our results are generally not significant. However, as they seem in favour of the treatment group, they are an incentive for further research.

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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