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# Tilt vibratory exercise improves the dynamic balance in fibromyalgia: a randomized controlled trial

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**Abstract**

**Objective:** To evaluate the feasibility and efficacy of tilt whole-body vibration for improving dynamic balance in women with fibromyalgia (FM).

**Methods:** Forty-one women (aged 41 to 65) were randomly assigned to either a vibration (n=21) or control (n=20) group. The vibration intervention consisted of a 30-minute session of instruction plus 3 sessions of whole-body vibration per week over a period of 12 weeks. Each vibration session consisted of 6 repetitions of a 45-60 second 12.5 Hz vibration. The posture of patient was lateral. Dynamic balance was assessed with a balance platform, the level of stability could be controlled. We performed intent-to-treat analysis and efficacy analysis in participants who completed the study (vibration, n=18; control, n=18).

**Results:** Based on intent-to-treat analysis, the dynamic balance of the vibration group improved by 36%, as compared to baseline, whereas that of the control group was unchanged. Differences in the dynamic balance index were predicted (61%; P<0.001) by the following linear model: (0.027·BODY-WEIGHT) – (0.800·DYNAMIC BALANCE AT BASELINE) – (0.632·GROUP).

**Conclusions:** The vibration program was useful and feasible for improving dynamic balance in women with FM. These novel results support further research aimed at the development of physical therapy programs that utilize controlled vibration. [ISRCTN16950947]

**Keywords:** exercise, pain, rheumatology, therapy, stability

The prevalence of fibromyalgia (FM) is 2-3% in the general population, and women are disproportionately affected (90% individuals with FM are women) (1-3). FM is characterized by mainly persistent, widespread musculoskeletal pain and regions of localized tenderness (4). However, most patients with FM have multiple symptoms. Impaired balance is the 6$^{th}$ most frequent symptom, affecting 45% of patients, and 15$^{th}$ in terms of severity (5). Previous studies have shown that FM patients have significantly impaired balance as compared to healthy adults (6-8). Recent works have shown the benefits of aquatic training on static balance performance measured by the blind flamingo test which measures the number of trials required to achieve a total time of 30 seconds on one leg with eyes closed (9) and the ameliorations of on-land aerobics in improving static balance, as assessed by the flamingo balance test which measures time in seconds balanced in 1 leg stance with eyes open (10). However, most daily activities require dynamic balance (e.g. walking, climbing stairs, preventing falls, etc.). On-land exercise with moderate mechanical impact or aquatic training has been shown to be effective in preventing painful experiences in people with FM (11-13), but these individuals may also require complementary physical activities that provide osteogenic mechanical strain for preventing bone mass density loss.(14) .

Whole-body vibration (WBV) has recently emerged as an intervention that can have positive effects on the neural, muscular, and skeletal systems (15). In WBV a patient stands on a platform that oscillates at a particular frequency and amplitude, causing muscle contractions through stimulation of sensory receptors (16). Devices that are currently on the market deliver sinusoidal vibration to the whole body via two different types of vibrating plates (17): a) a vertical platform, in which the whole plate oscillates up and down; and b) a tilt platform, with reciprocal vertical displacement on the left and right side of a fulcrum, increasing lateral accelerations. Recent clinical studies of WBV have shown a positive effect of controlled WBV on balance, bone mass, and the motor capacity of post-menopausal women and nursing home residents (18-21). In fact, tilt WBV was more effective on balance than walking in postmenopausal women (20). A recent study reported that twice-weekly mixed WBV exercises on a vertical platform plus on-land exercise in individuals with FM lowers visual analogue scale (VAS) pain scores and fatigue ratings, whereas an on-land exercise only or a control treatment did not (22). In addition, WBV was shown to be well tolerated by participants (22). To date, there have been no reported randomized, controlled studies of the feasibility and efficacy of intensive (at least three sessions per week) WBV using a tilt platform in patients with FM. In the current study, we investigated whether tilt WBV is feasible and effective for improving the dynamic balance of women with FM.

**Material and methods**

**Recruitment**

Women who participated in a local FM association were recruited into the study. The women were eligible if FM had been diagnosed by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology (23). Exclusion criteria included: history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness, other diseases that prevent physical loading, pregnancy, participation in another psychological or physical therapy program, or participation in regular physical exercise more than once a week for 30 minutes (min) or longer during any 2-week period in the last 5 years.

Sixty potentially eligible participants requested additional information (Figure 1). Of these, 19 were excluded based on the following criteria: participation in other therapies (either manual therapy and/or psychological treatment) that could influence the current intervention (3 candidates); failure to meet the inclusion criteria (other severe diseases) (10 candidates); and excessive distance from the intervention setting (6 candidates). Following an explanation of the study protocol 41 female patients aged 41 to 65 gave written informed consent to participate, in accordance with the updated Declaration of Helsinki. The project protocol was approved by the Biomedical Ethical Committee of the University of Extremadura.

**Study design**

The study design was a randomized controlled trial [ISRCTN16950947] immediately after verification of inclusion/exclusion criteria participants were randomly and sequentially assigned to either the vibration group (n=21) or the control group (n=20) by a research assistant, according to a random number table, and assigned a code number. Participants were blinded to group assignment before baseline measurements, after which all participants were informed of their assignment. Research team members that were also blinded to the group assignments of the participants conducted the measurements of dynamic balance at baseline and 12 weeks. Different members of the research team administered the intervention and performed the statistical analysis.

**Intervention**

All participants received standard care that included medical attention through the public health system (hospital and outpatient clinic, including primary care) and social support through the local FM association. Patients in the vibration group also received WBV therapy using the Galileo Fitness Platform (Novotec Medical GmbH, Pforzheim, Germany), which, in contrast to other commercial platforms that move up and down, oscillates on the medial axis.

The vibration intervention included a 30-minute session of instruction on how to self-administer the 36 vibration sessions (3 times per week over a period of 12 weeks). Each session included a 10-min warm-up of slow walking and then 6 repetitions of vibration at 12.5 Hertz, with a rest interval of 60 seconds between repetitions. We set the frequency at 12.5 Hertz because it has been shown to improve body balance and bone mass density in women of a similar age using a tilt vibratory platform (20). The lower pain threshold of FM patients and the novelty of the exercise technique also prompted us to be cautious with the frequency setting. The vertical amplitude of the vibrations was set at 3 mm.

The duration of each repetition was 30 seconds during the first 4 weeks, 45 seconds during the second 4 weeks, and 60 seconds during the third 4 weeks. As the tilt vibratory platform mainly produces lateral mechanical forces (20), we set the stance of participants to align the mechanical stimulus with the action line or vector of the knee extensors and flexors, since they are involved in major daily activities such as walking and climbing stairs. The stance of the participants on the platform alternated between two stances, stance A and stance B, for each repetition to train both sides of the body; the soles of both feet were always in contact with the platform in both stances (Figure 2). A description of the stances is as follows:

- **Stance A:** Begin with the feet planted perpendicular to the midline axis of the platform with the right foot placed slightly ahead of the left foot. Lift the toes of the right foot and the heel of left foot 4mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

- **Stance B:** Begin with the feet planted perpendicular to the midline axis of the platform with the left foot placed slightly ahead of the right foot . Lift the toes of the left foot and the heel of the right foot 4mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

Each participant was required to sign a logbook, which included the date, after completing a vibration session. A research assistant spoke to each participant once a week in a 3-min phone conversation to monitor progression through the program, provide instruction, and give emotional support. During the 12-week study period, participants in the control group continued their daily activities, which did not include any form of physical exercise that resembled the exercises performed by participants in the vibration group, and did not receive a weekly phone call.

The vibration program was designed without reference to any explicit behavioral model or theory, and was intended as a pragmatic intervention that could easily be implemented within a population of patients with FM.

**Data collection**

Sample characteristics and number of reported falls in the last 6 months were obtained. The vibration program was implemented at the local FM association, and the dynamic balance measurements were performed at the Fitness and Quality of Life Laboratory at the University of Extremadura (Spain). The balance assessments were carried out using a Biodex Balance System (BBS) (Biodex, USA). In a recent report, the BBS was used to evaluate and train postural balance and postural stability (24). It is a multi-axial device that objectively measures and records an individual's ability to stabilize an involved joint under dynamic stress. It is a circular platform that moves freely along the anterior–posterior and medial–lateral axes simultaneously. The BBS allows up to 20° of foot platform tilt, which permits maximal stimulation of the ankle joint mechanoreceptors. The device measures, in degrees, the tilt about each axis during dynamic conditions and calculates a medial–lateral stability index (MLSI), anterior–posterior stability index (APSI), and an overall stability index (OSI) which is a composite of MLSI and APSI (25). These indices are standard deviations assessing fluctuations around a zero point established prior to testing when the platform is stable, rather than around the group mean. A high score indicates poor balance. Given that individuals with FM report widespread alterations, we selected OSI as the parameter for analysis because it reflects fluctuations in both axes, rather than a single direction. The dynamic tilting platform BBS differs from a static force plate system in that the center of pressure resulting from a vertical ground reaction force remains constant.

All participants were evaluated on the BBS at baseline and 12 weeks after the initiation of the study. The BBS could be set at 12 different levels of stability, with a setting of "1" being the least stable and a setting of "12" being the most stable. To obtain the dynamic balance index, we carried out a *fall risk test* (26), according to the manufacturer´s instructions, consisting of 3 trials performed on the BBS at level 8. There are many possible variations in the BBS stance protocol, including degree of instability of the platform (24); crossed (24) or free (27) arms; one or two-leg stances (28) and open or closed eye stances (29). In the current study, participants were instructed to maintain the vertical projection of their center of gravity in the center of the platform by observing a vertical screen placed 30 cm in front of their face. Each trial was 20 seconds long with 10-second rest periods between the trials. All tests were performed while the participants stood barefoot with both feet on the platform, at a constant instability setting (level 8), with open eyes. The posture of the arms was not regulated. The average of three trials was subjected to analysis.

We selected free arms during the BBS test for security (i.e., it is easier to rebalance using the arms), and because it more closely mimics imbalance in everyday life, where rebalancing is generally performed using the whole body, including arms, thereby increasing the ecological validity of the test. Allowing or not allowing the use of the arms during testing of postural stability affects the score (30), so it should be considered for comparison purposes.

The reliability of the test used in this paper was measured in our laboratory in 30 women with FM, (average age, 51 ±10) using a 7-day test-retest protocol. The intra-class correlation coefficient (ICC) was 0.77 (95% confidence interval from 0.52 to 0.89) and the coefficient of variation of method error (CVME) (31) was 33.90%.

**Statistical analysis**

We carried out an efficacy analysis that included data only from subjects who completed the intervention, and an intent-to-treat analysis for comparative purposes (e.g. meta-analys, economic studies, etc.). The intent-to-treat analysis is more useful for making decisions in health care settings while the efficacy analysis is more representative of the effects of individual treatment.

After verifying the parametric criteria for homogeneity and distribution of the data, we compared changes in the dynamic balance index of both groups using an analysis of variance adjusted for body weight (in kilograms) and performance on the BBS at baseline. In depth analysis of changes in dynamic balance index was done using a step-by-step regression test. A significance level of less than 0.05 was required in order to introduce a new variable into the prediction model.

**Results**

Table 1 summarizes the participant characteristics for this study. Twenty-five percent of the participants fell 2 or more times in the last 6 months, and 34.4% fell almost once in the last 6 months. These values were much higher than for healthy people in a similar age group, but similar to individuals with FM (8).

**Feasibility and safety**

There was a high level of feasibility for the proposed low-frequency vibration program in patients with FM. In the vibration group, 86% (18 of 21) completed the program. Of the 3 participants who quit the program, 2 did so because their work schedule was not compatible with the platform exercise schedule and one (5%) quit the program because of pain. Two participants were lost from the control group because of lack of interest. A detailed comparison of the baseline data (age, tender points, muscular strength, and balance index) between participants who dropped out and participants who completed the program did not reveal any relevant differences. There were no statistically significant differences (P>.05) between participants who completed the protocol, in the control or vibration group, and those who did not. There were no reports of secondary health discomforts related to the low-frequency vibration program. Overall, 95% of participants in the vibration group did not report health problems with the WBV program.

**Effects**

In intent-to-treat analysis, the dynamic balance index of participants in the vibration group improved by 36% as compared to baseline (43% of treated participants with a treatment effect of 46%), whereas in the control group it was unchanged (Table 2). This improvement was higher than the reported CVME (33.9%); thus, it could be considered a real change in magnitude from statistical perspective. The falls-related clinical relevance of these changes partly depends on baseline score of each person. Small improvements in persons with poor balance could be more relevant than these obtained in persons with better balance scores. The study of number of falls requires longer studies than the current research. Table 3 summarizes the efficacy analysis of participants who completed the program. We used two efficacy models, one that included weight as independent variable and one that did not, in order to explore the influence of weight, which is one of the major determinants of training load in WBV. Model 1 *(Differences in Dynamic Balance Index = 0.018·BODY-WEIGHT - 0.809·DYNAMIC BALANCE AT BASELINE - 0.689·GROUP)* predicted 61% of the observed variability in the dynamic balance index. Model 1 model quantified the positive effect of treatment (variable GROUP, P<0.001) in 69% of each unit gained in the dynamic balance index. Participants with the worst balance and heaviest weight at baseline improved more than the others (P<0.001). Model 2, in which the *BODY WEIGHT* variable was dropped, predicted 57% of each unit gained in the dynamic balance index. Table 4 shows similar results in the intent-to-treat analysis. The results suggested that the use of model 1 is more appropriate, because weight is easily measured and contributes to a better prediction..

## Discussion

### Main findings

We have demonstrated the efficacy, safety, and feasibility of a proposed low-frequency vibration program in women with FM. The program was reasonably safe: only 5% of the participants (n=1) dropped out of the program because of acute pain in the legs. The program was completed by 85% of the participants, without secondary adverse effects. Although the program was performed individually and self-administered, the retention rate was similar to other group-based exercise programs for patients with FM (70-90%) (32). The intervention included vibratory exercise plus phone call reinforcement as compared to a control group that received neither. The 12-week program was easily self-administered in a small room after a 30-minute instructional session and was maintained with one 3-min phone call per week. Thus, the current vibration program could serve as an additional resource for patients with FM that can easily be implemented in different settings (e.g., at the patient's FM association, in primary care settings, welfare institutions, clinics or gyms). This aspect of the program is particularly important for patients living in sociodemographic areas with few resources (e.g., warm-water pools or highly specialized technicians) (33-34). It is important to note, however, that the cost of a commercial system is approximately $11900, which is potentially cost-prohibitive for individuals and local FM associations with low-to-moderate income. Further studies analyzing cost-effectiveness of different commercial machines and/or health care settings (e.g., clinics, gyms, etc.) are warranted.

Previous studies have shown that WBV is effective for improving static and dynamic balance in the elderly, as measured by timed up-and-go, chair rise, and Tinetti tests (18, 35-36), as well as in patients with neuromuscular disorders such as Parkinson disease (37-38) or multiple sclerosis (39). It has also been reported that increased sway in the medio-lateral direction, one of the components of the overall index, is a sensitive biomarker for determining the functional capacity of elderly individuals.(40). Postural dynamic balance, measured using the BBS with arms crossed on the chest, is associated with functional disability (24). In a cross-sectional study in arthritis patients, postural dynamic balance dependent on body mass index, age and sex (24). We reported here the positive effects of tilt platform vibration on dynamic balance in patients with FM characterized by pain. This finding is novel and important because it raises the possibility of adding a new technology with potential health benefits to the usual exercise regimes recommended for patients with pain (e.g., on-land aerobics with moderate mechanical impact, aquatic training, tai chi, yoga) in order to help reduce bone mass loss (20) and improve strength and speed, which are critical for reacting and preventing stumbles and falls (41).

The equations could be used to predict the expected changes with this WBV protocol and to modulate the therapy. Persons with FM with poorer scores at baseline will improve more than patients with better scores. In addition, the load and efficacy of therapy could progress by adding weight to a back-bag carried by patients. This modulation of the program could promote the assessment by health professionals through conventional consults or on-line (e.g. web-based consultancies).

**Limitations**

Differences in the parameters of the BBS protocol (i.e., platform stability level, one or two-leg stance, arm position, open or closed eyes) in different studies limit comparisons of the magnitude of changes or norm-references. The balance improvements reported in the current study were influenced by the level of dynamic balance at baseline; therefore, greater improvements would be expected in patients with worse balance at baseline. We could not analyze the influence of previous training because one of our inclusion criteria was that the participant be physically untrained. the effects of WBV in a physically trained population remain unknown. On the other hand, the 10 min of easy walking prior to each WBV session could have influenced fitness in patients who were very deconditioned at baseline. Furthermore, we must caution against generalizing the current findings from a self-administered program performed at a local FM association to a home-based program; the high rate of participation in the present study could partially be explained by peer support from other members of the local FM association and by the weekly phone call from a research assistant. Therefore, additional studies are needed in order to evaluate whether the current program is effective in other settings, such as the home. The current findings suggest that WBV is feasible and effective for improving the dynamic balance of women with FM; however clinical implications of obtained balance improvements cannot be determinate in the present study. To explore it, longer duration studies (i.e., more than 6 months) are needed to explore whether balance improvements are associated with a lower number of falls., Additionally, a larger study population is required to fully understand the interactions between changes in dynamic balance and pain, as only one patient dropped out because of pain, and between dynamic balance and pain range (measured by pain thresholds at tender points). Further studies are also needed to assess different vibratory devices (i.e., those with tilt or up and down mechanisms) (42), different postures that induce different lines or vectors of vibration (e.g., lateral, vertical, etc.), and different levels of vibration for different durations of time.

**Conclusions**

The proposed WBV program, which utilized a tilt platform with low-frequency (12.5 Hz) anteroposterior vibration, is useful and applicable for improving the dynamic balance of women with FM. The current study supports the development of novel approaches to physical therapy programs that utilize vibration therapy.

**List of abbreviations**

BBS: Balance platform

FM: Fibromyalgia

WBV: Whole-body vibration

**Competing interests**

The authors declare that they have no competing interests.

**Authors' contributions**

NG was involved in the conception, planning and design of the study, as well as the analysis, and interpretation of data, and writing the manuscript. JAP, JCA and PRO were involved in the planning, analysis and writing of the manuscript. AL participated in the interpretation and review of the manuscript. All authors read and approved the final manuscript.

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## TABLES

Table 1. Characteristics of women with fibromyalgia who completed the protocol of the vibration-based exercise program and controls*

| Group | Control (n=18) | Exercise (n=18) | p |
|---|---|---|---|
| Age. (years) | 53.0 ± 12.0 | 52.4 ± 10.8 | .860 |
| Weight (kg) | 70.0 ± 10.56 | 73.7 ± 14.4 | .384 |
| Height (cm) | 156.0 ± 4.7 | 156.4 ± 5.0 | .782 |
| Number of tender points (1–18) | 15 ± 5 | 15 ± 4 | .943 |
| Duration of symptoms. (years) | 13.7 ± 6.2 | 12.7 ± 6.7 | .672 |
| FIQ[†] total score | 53.6 ±12.3 | 59.2 ± 9.7 | .681 |

*Values expressed as mean ± SD;
[†]FIQ total score, Fibromyalgia Impact Questionnaire total score

Table 2. Effects of 12 weeks of whole Body Vibration Training on Dynamic Balance in women with Fibromyalgia Syndrome*

| | Baseline | Change to 12 weeks | Treatment Effect | $p^{\dagger}$ |
|---|---|---|---|---|
| | Mean ±SD | Mean (95% CI) | Mean (95% CI) | |
| ***Efficacy*** | | | | |
| Exercise (18) | 1.49 ± 0.67 | -0.64 (-0.36 to -0.93) | -0.69 (-1.10 to -0.27) | <.001 |
| Control (18) | 1.47 ± 0.55 | 0.44 (-0.28 to 0.37) | | |
| ***Intent-to-treat*** | | | | |
| Exercise (21) | 1.59 ± 0.73 | -0.57 (-0.31to -0.82) | -0.60 (-0.97 to -0.23) | .002 |
| Control (20) | 1.40 ± 0.55 | 0.03 (-0.25 to 0.32) | | |

*Values expressed in degrees of displacement in mean, standard deviation and 95% of confidence interval;

$^{\dagger}$p values of ANOVA for repeated measures, adjusted by baseline data and weight to compare differences between groups at 12 weeks.

Table 3. Predicted models of changes in the dynamic balance after 12-weeks of vibratory exercise. Efficacy analysis of participants who completed the protocol in the exercise group (N=18) and control group (N=18).

| | MODEL 1 | | | MODEL 2 | | |
|---|---|---|---|---|---|---|
| | $R^2$= 0.611 | | | $R^2$= 0.569 | | |
| | BETA | SE | p | BETA | SE | p |
| Balance Index PRE | -0.809 | 0.137 | <.001 | -0.676 | 0.128 | <.001 |
| Group | -0.689 | 0.145 | <.001 | -0.670 | 0.152 | <.001 |
| Weight (kg) | 0.018 | 0.008 | .041 | ----- | ------ | ---- |
| Constant | -0.737 | 0.559 | .197 | 0.367 | 0.220 | .105 |

*Groups: Control=0, Vibratory Exercise= 1.

Table 4. Predicted models of changes in the dynamic balance after 12-weeks of vibratory exercise. Intent-to-treat analysis of participants who initialized the protocol in the exercise group (N=20) and control group (N=21).

| | MODEL 1 | | | MODEL 2 | | |
|---|---|---|---|---|---|---|
| | $R^2$= 0.607 | | | $R^2$= 0.449 | | |
| | BETA | SE | p | BETA | SE | p |
| Balance Index PRE | -0.800 | 0.132 | <.001 | -0.492 | 0.123 | <.001 |
| Group | -0.632 | 0.139 | <.001 | -0.515 | 0.159 | .002 |
| Weight (kg) | 0.027 | 0.007 | <.001 | ----- | ------ | ---- |
| Constant | -0.689 | 0.407 | .099 | 0.727 | 0.206 | .001 |

*Groups: Control=0, Vibratory Exercise= 1.

**FIGURES**

Figure 1. Flow of participants throughout trial

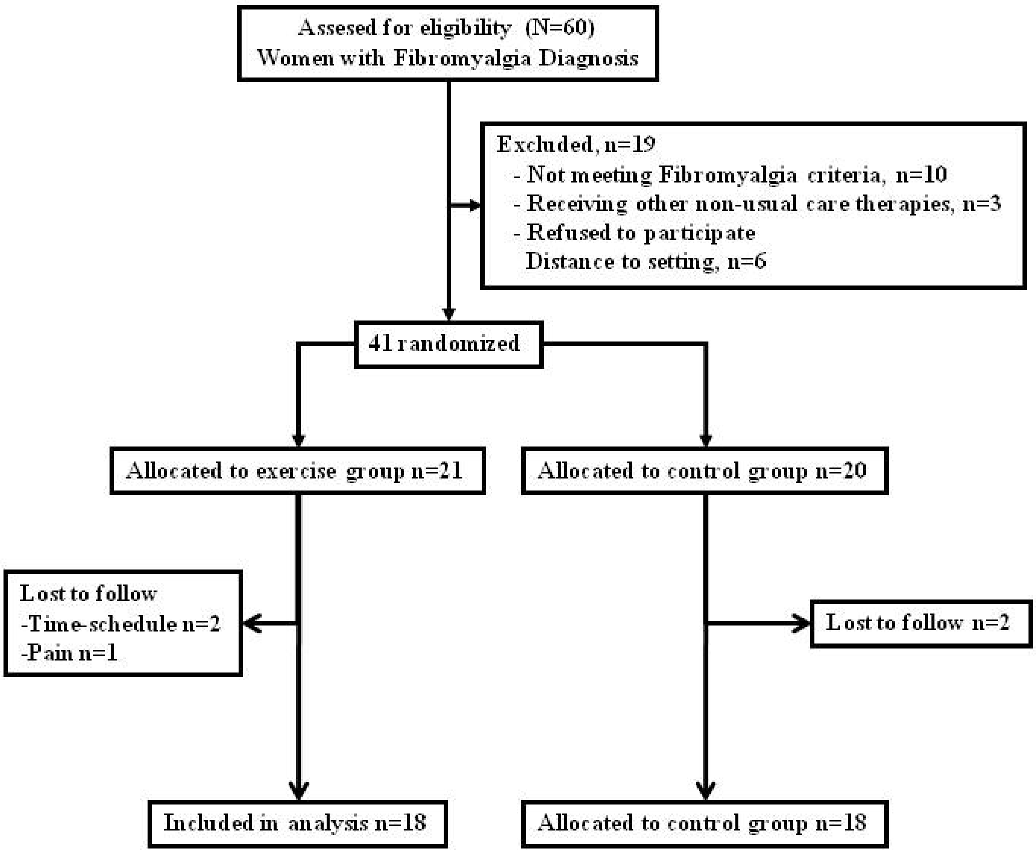

Figure 2. Posture of subjects on the vibratory platform