

ORIGINAL RESEARCH

Tilt vibratory exercise improves pain, strength and somatosensory function in patients with fibromyalgia: A randomized controlled trial

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Abstract

The main objective of this study was to analyse the effects of 12 weeks of tilting whole body vibration therapy on pain, strength and somatosensory function in patients with fibromyalgia syndrome. This study was randomized controlled trial with assessor blinding. Thirty-six women with fibromyalgia were randomly allocated to exercise or control groups. The exercise group received a 12-week program of tilting whole body vibration therapy at 12.5-Hz frequency and 3 mm amplitude. The Muscle strength was assessed with an isokinetic dynamometer, pain with a digital algometer and the somatosensory system with a stabilometry platform.

The treatment induced a 23.5% improvement in widespread pain ($P < .05$) and 40% improvement in knee pain ($P < .05$).

The concentric knee extension and flexion strength improved by greater than 19% ($P < .05$), and balance with eyes closed showed a 25% improvement in the overall stability index ($P < .05$) and a 40% improvement in the antero-posterior stability index ($P < .05$) for all positions evaluated.

Twelve weeks of tilting whole body vibration therapy 3 times a week at a frequency of 12.5 Hz could be an effective therapy to improve strength, somatosensory function and pain in women with fibromyalgia.

This article presents new approaches for management of strength, somatosensory function and pain in patients with fibromyalgia. These measures and these results could potentially help clinicians, physiotherapists and rheumatologists who seek to improve these properties in these patients, this study aims provide a new type of disease management.

Key words

Vibration, Pain, Fibromyalgia, Strength, Balance

1 Introduction

Fibromyalgia (FM) is a rheumatological syndrome of unknown aetiology. FM is characterized by widespread non-inflammatory musculoskeletal pain present for at least 3 months and an acute response to digital palpation with 4 kg/cm² of pressure in at least 11 out of 18 tender points^[1]. It is generally accompanied by sleep disturbances, stiffness, fatigue, depression, and anxiety. For treatment of pain associated with FM, several therapies have been used including

pharmacologic interventions with antidepressants, non-steroidal anti-inflammatory drugs, sedatives, muscle relaxants and opiates [2] and non-pharmacologic therapies such as Tai Chi, yoga, low impact aerobics, walking, water aerobics and whole-body vibration (WBV) [3-6]. WBV is a mode of exercise that has recently been utilized for its positive effects on pain, balance, and neural, muscular and skeletal systems in different patient populations [7-9].

WBV has been used to reduce chronic pain in several patient [10, 11], including FM [12]. It is not clear how vibration therapies lead to reductions in pain. One possible explanation is that vibrations activate skin somatic sensory receptors, thereby masking pressure and touch processes. According to the gate control hypothesis [13], subsequently modified by Kerr [14], the vibrations can mask pain in a fashion similar to transcutaneous electrical nerve stimulation (TENS) [15].

Muscle strength depends on both the cross-sectional area of the muscle and on neural activity. The cross-sectional area of the quadriceps femoris muscle is within the normal range in persons with FM [16, 17], however, several studies have found that women with FM have significantly lower isometric and isokinetic strength in the quadriceps femoris than healthy individuals [18-20]. Reduced maximal muscle strength of knee extensors in FM has been associated with poor outcomes in functional tests related to daily living activities (sitting up and down on a chair, walking and ladder climbing) [21], this suggests that there is a defect in neural activity in muscles of FM patients. In WBV, the first adaptation affects neurological mechanisms and is independent of increased muscle mass. There are several possible explanations for the beneficial effects of WBV on muscle function in FM, including increased motor unit synchronization, co-contraction of synergistic muscles, increased inhibition of antagonistic muscles, and a repetitive muscle motion leading to a large boost in musculoskeletal structures due to changes in muscle stiffness in response to the vibration [22]. The decline of knee extensor strength in FM has been associated with gait disorders and pain, and may also contribute to balance problems. This is an important disease mechanism since balance problems are the sixth most frequent symptom in FM, affecting 45% of patients [23]. Patients with FM have impaired balance [24, 25], increased risk of falling [26], and gait problems [27].

Patients with chronic pain disorders like FM have associated structural changes in the central nervous system (CNS), including parts of the somatosensory and motor systems [28]. The somatosensory system is an integral component of the motor control system that facilitates the recognition of location and experience of peripheral stimuli and body position. In chronic pain, this system may be disrupted by alterations in peripheral and cortical processing, and FM patients with chronic pain typically describe diverse alterations of the somatosensory system [29].

Balance is a complex process that involves the reception and integration of sensory stimuli from three systems (somatosensory, vestibular and visual). When the visual system offers limited references, the development of balance is dependent on the other two systems. Previous studies reported the effects of visual aids on balance [29], but there is a lack of knowledge about the effects of reciprocal WBV on balance without vision in FM patients.

The effects of WBV on patients with FM was previously studied using vertical platforms, but the effects of WBV using a tilt platform with reciprocal vertical displacement on the left and right side of the fulcrum on pain, strength and the somatosensory system in FM have not studied. The purpose of this study was to investigate the effects of 3 weekly sessions of tilting WBV (6 repetitions of 45-60 seconds at 12.5 Hz), over a 12 week period, on pain, strength and the somatosensory system in FM patients.

2 Material and methods

2.1 Participants recruitment

The population comprised women who participated in a local FM association. The women were eligible if FM had been diagnosed by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology (ACR) [13]. Several exclusion criteria were applied: 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, and participation in regular physical exercise more than once a week for 30 minutes or longer during a 2-week period in the last 5 years.

A total of 60 potentially eligible participants responded and requested additional information (see Figure 1), but 19 of those candidates were subsequently excluded: three had participated in other therapies (massages and psychological treatment) that could potentially interact with the current intervention, ten had other severe diseases and did not meet the inclusion criteria, and six lived too far from the intervention setting. After the study protocol was explained, the 41 remaining female patients aged 41 to 65 years old gave their written informed consent to participate according to the updated Declaration of Helsinki. The project protocol was approved by the Biomedical Ethical Committee of the University of Extremadura.

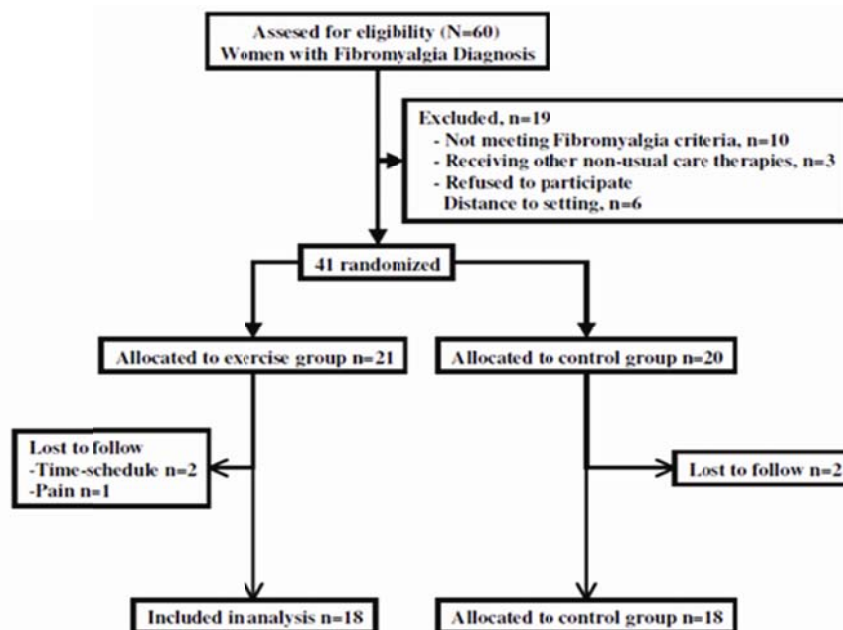


Figure 1. Flow Diagram of Participants

2.2 Design

We conducted a blinded randomized controlled trial (ISRCTN16950947). The participants were randomly assigned to either the vibration group (n = 21) or the control group (n = 20) by a research assistant using a random number table. Each participant was assigned a code number. Other members of the research team, who were blinded to the group assignment of each participant, conducted the study measurements. Additional members of the research team applied the intervention, and other team members performed the statistical analyses.

2.3 Intervention

All the 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 had a 30-minute instruction session on how to self-administer the 36 vibration sessions with the reciprocating Galileo Fitness Platform (Novotec Medical GmbH, Pforzheim, Germany), which oscillates through the medial axis, in contrast to other oscillating commercial platforms that oscillate uniformly up and down.

The intervention consisted of 3 sessions per week over a 12-week period. Each session included a 10-minute warm-up of slow walking and easy movements, and then 6 repetitions of WBV with a frequency of 12.5 Hz, with a 60 second rest interval between repetitions. The duration of each repetition was 30 seconds during the first month, 45 seconds during the

second month, and 60 seconds during the third month. The stance of the participants on the platform alternated between stance A and stance B for each repetition:

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 the left foot 4 mm 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 4 mm 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 and date a notebook after completing each vibration session. A research assistant also spoke to each participant once a week during a 3-minute phone conversation in order to check progression through the program, provide instructions, and give emotional support. During the 3-month study period, the participants of the control group continued their daily activities, which did not include any form of physical exercise similar to the exercises performed by the participants of the vibration group. The vibration program was implemented at the local FM association, and the measurements were performed at the Fitness and Quality of Life Laboratory at the University of Extremadura (Spain).

2.4 Outcome measures

2.4.1 Pain

Pain was assessed by measuring the pressure at which participants felt pain at each of 18 tender points according to ACR criteria^[1]. Pain was measured by the same trained person for each participant, using a Wagner FDIX™ Digital Algometer (Wagner, USA). The sum of the threshold pressure at all tender points was calculated. The pain threshold at each tender point was determined by applying increasing pressure with the algometer perpendicular to the tissue, at a rate 1Kg/s. Patients were asked to say “STOP” at the moment pressure became painful. The mean of two successive measurements at each tender point was used for the analysis. Tender points were scored as positive when the patient noted pain at a pressure of 4 kg/cm² or less.

A 7-day reliability test was conducted with 10 participants in our laboratory; the smallest real difference was 14.9% for widespread pain and 15.2% for knee pain.

2.4.2 Strength

Isometric, concentric and eccentric knee strength (flexion and extension) was always measured by the same trained person, using an isokinetic dynamometer (Biodex System 3). A 7-day reliability test was previously conducted in our laboratory^[30].

2.4.3 Somatosensory system

The somatosensory system was evaluated using a stabilometry platform, the Biodex Balance System (BBS; Biodex, USA). This instrument measures 3 indices: the medial-lateral stability index (MLSI), the anterior-posterior stability index (APSI) and the overall stability index (OSI), which is a composite of the MLSI and APSI^[31]. The patients are evaluated with both feet on the platform, with the dominant leg on the platform and with the non-dominant leg on the platform, and all the trials were performed with closed eyes. The duration in seconds^[32] or the number of trials required to complete 30 seconds were recorded^[33]. A 7-day reliability test was performed with 10 participants in our laboratory: the smallest real difference for OSI was 19.6% with both feet on the platform, 27.8% with the dominant leg and 31.2% with the non-dominant leg; and the smallest real difference for APSI was 18.7% with both feet on the platform, 26.3% with the dominant leg and 30.6% with the non-dominant leg.

2.5 Data analysis

A 7-day reliability study on pain and balance tests was conducted with 10 participants before the start of the study. The relative reliability was determined with Intraclass Correlation Coefficient (ICC)_{1,1} in two sessions^[34]. The absolute reliability was determined with the SEM [SEM= SD√(1-ICC), where SD is the average SD of day 1 and day 2, and the real minimum change (1.96 × √2 × SEM)]^[35].

Mean and standard deviation (SD) are given as descriptive statistics. Baseline characteristics were compared using Student's *t*-test for independent samples and the distribution of data was examined by Kolmogorov-Smirnov, with Lilliefors significance correction. Since the pre- and post-test measures are paired measures from the same subjects, we used the ANOVA for repeated measures.

Results were considered statistically significant when the significance values, *p*, were < .05. In addition to the *p* values, we provided detailed statistics including the mean and 95% confidence interval for better depicting the change within each group from baseline to 3 months, and the treatment effect. If the null value of the comparative measure, the mean, lies inside the confidence interval then the result is not statistically significant. These additional statistics are recommended for biomedical journals^[36] for helping readers to determine the size of differences and to compare results with other studies. The differences between post- and pre-test were used to describe the changes from baseline to 3 months, and the differences between groups in the change from baseline to 3 months were used to estimate the treatment effect. The mean and 95% confidence intervals of changes were calculated using Student's *t*-test for independent samples. In order to be useful to a wider spectrum of readers, we performed an efficacy analysis including persons who completed the intervention to study the specific effects of the protocol, and we also reported an intent-to-treat analysis. Cohen's coefficient was used to assess the change. A change of 0-0.2 was considered very small, a change of 0.2-0.6 was considered small, a change of 0.6-1.2 was considered moderate, a change of 1.2-2 was considered large and a change >2.0 was considered very large^[37].

All analyses were performed with SPSS software, version 16.0.

Table 1. Characteristics of Women with Fibromyalgia Who Followed the Whole body Vibration Exercise Program and Controls* (n = 36)

Group	Control (n = 18) (Mean ± SD)	Exercise (n = 18) (Mean ± SD)	<i>p</i>
Age (y)	53.0 (12.0)	52.4 (10.8)	.860
Weight (kg)	70.0 (10.5)	73.3 (14.4)	.384
Height (cm)	156.0 (4.7)	156.4 (5)	.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 (points)	53.6 (12.3)	59.2 (9.7)	.681
Isometric knee extension strength (Nm)	79.4 (25.9)	74.3 (28.7)	.585
Isometric knee flexion strength (Nm)	28.0(12.3)	24.8 (10.5)	.407
SP18TP (Kg/cm ²)	20.3 (7.8)	17.9 (6.8)	.959
2 leg eyes-closed			
Overall SI (°)	2.3 (1.0)	2.0 (1.2)	.368
Anterior-Posterior SI (°)	1.5 (0.7)	1.4 (0.8)	.543
Middle-Lateral SI (°)	1.4 (0.9)	1.1 (0.9)	.332
Single dominant leg eyes-closed			
Overall SI (°)	2.7 (0.7)	2.9 (0.7)	.583
Anterior-Posterior SI (°)	1.8 (0.6)	2.2 (0.7)	.253
Middle-Lateral SI (°)	1.5 (0.5)	1.4 (0.4)	.552
Single no dominant leg eyes-closed			
Overall SI (°)	3.1 (1.1)	2.7 (0.8)	.297
Anterior-Posterior SI (°)	2.3 (1.2)	2.0 (0.8)	.461
Middle-Lateral SI (°)	1.7 (0.5)	1.5 (0.4)	.578

*Values expressed as mean (SD); FIQ total score, Fibromyalgia Impact Questionnaire total score

Table 2. Effects of 3-month Whole Body Vibration Program in Fibromyalgia (n = 36). Efficacy Analysis

Outcome measure	Baseline		Post-treatment		Treatment effect Mean (95%CI)	p †	Effect size
	Control (n = 18) Mean (SD)	Exercise (n = 18) Mean (SD)	Control (n = 18) Mean (SD)	Exercise (n = 18) Mean (SD)			
Isometric knee extension strength (Nm)	79.42 (25.93)	81.66 (33.13)	77.81 (24.70)	90.21 (33.28)	10.16 (0.16 to 20.15)	.047	0.50
Isometric knee flexion strength (Nm)	28.07 (12.30)	24.16 (9.86)	26.63 (9.58)	27.92 (11.43)	4.58 (0.64 to 9.74)	.025	0.36
Concentric knee extension strength (Nm)	61.97 (23.02)	58.78 (21.85)	66.80 (24.39)	75.28 (19.93)	11.68 (1.64 to 21.70)	.024	0.82
Concentric knee flexion strength (Nm)	25.86 (9.97)	21.72 (6.86)	26.61 (9.43)	27.94 (8.84)	5.47 (2.01 to 8.93)	.003	1.11
Eccentric Knee flexion strength (Nm)	112.68 (35.42)	90.34 (31.01)	109.53 (37.73)	106.24 (32.87)	19.05 (-0.23 to 38.34)	.050	0.46
Knee R + Knee L (Kgf)	3.09 (1.87)	2.08 (1.02)	2.26 (1.11)	2.28 (1.18)	1.03 (0.12 to 1.94)	.028	0.51
Algometer Score (Kgf)	20.37 (7.82)	17.90 (6.88)	17.58 (6.63)	19.61 (7.52)	4.51 (1.31 to 7.69)	.007	0.24
2 leg eyes-closed							
Overall SI (°)	2.37 (1.08)	2.02 (1.20)	2.25 (1.21)	1.14 (0.70)	-0.75 (-1.40 to -0.10)	.023	-0.78
Anterior-Posterior SI (°)	1.57 (0.71)	1.41 (0.84)	1.52 (0.83)	0.76 (0.37)	-0.14 (-1.13 to -0.05)	.031	-0.75
Middle-Lateral SI (°)	1.48 (0.59)	1.17 (0.90)	1.37 (0.87)	0.71 (0.65)	-0.75 (-1.19 to -0.30)	.113	-1.23
Single dominant leg eyes-closed							
Overall SI (°)	2.74 (0.80)	2.90 (0.76)	2.86 (0.82)	1.54 (0.68)	-1.48 (-2.24 to -0.73)	<.001	-1.45
Anterior-Posterior SI (°)	1.88 (0.68)	2.20 (0.79)	1.93 (0.91)	1.10 (0.59)	-1.56 (-1.91 to -0.37)	.005	-1.09
Middle-Lateral SI (°)	1.56 (0.53)	1.45 (0.40)	1.67 (0.60)	0.82 (0.32)	-0.75 (-1.19 to -0.30)	.002	-1.23
Single no dominant leg eyes-closed							
Overall SI (°)	3.17 (1.19)	2.77 (0.80)	2.85 (0.80)	1.62 (0.79)	-0.81 (-1.66 to 0.01)	.049	-0.73
Anterior-Posterior SI (°)	2.30 (1.21)	2.01 (0.89)	2.17 (0.77)	0.99 (0.50)	-8.89 (-1.74 to -0.03)	.040	-0.77
Middle-Lateral SI (°)	1.73 (0.53)	1.50 (0.48)	1.44 (0.48)	1.06 (0.56)	-0.27 (-0.78 to 0.22)	.500	-0.40

*Values expressed as mean (SD); p †: p values from ANOVA for repeated measures adjusted by baseline data to compare different between groups after 3-month Whole Body Vibration program in fibromyalgia .

Table 3. Effects of 3-month Whole Body Vibration program in fibromyalgia (n = 41). Intent-to-treat analysis.

Outcome measure	Baseline		Post-treatment		Treatment effect Mean (95%CI)	p †	Effect size
	control (n=20) Mean (SD)	exercise (n=21) Mean (SD)	control (n=20) Mean (SD)	exercise (n=21) Mean (SD)			
Isometric knee extension strength (Nm)	79.28 (25.73)	80.14 (34.15)	77.68 (24.58)	87.28 (34.89)	8.13 (-0.11to17.59)	.053	0.62
Isometric knee flexion strength (Nm)	27.53 (12.25)	25.93 (10.02)	26.33 (9.74)	29.26 (11.01)	4.52 (0.56to8.49)	.026	0.34
Concentric knee extension strength (Nm)	61.21 (22.32)	58.51 (22.29)	65.44 (23.86)	72.34 (21.83)	9.6(0.45to18.75)	.040	0.68
Concentric knee flexion strength (Nm)	24.67 (10.17)	22.48 (6.57)	25.40 (9.70)	27.84 (8.12)	4.63(1.51to7.75)	.005	0.64
Eccentric Knee flexion strength (Nm)	111.25 (34.01)	95.79 (31.73)	108.08 (36.18)	108.67 (31.18)	16.05(-0.89to33.01)	.063	.62
Knee R + Knee L	28.74 (18.84)	2.30 (1.16)	2.10 (1.12)	2.35 (1.19)	0.81(8.09to66.00)	.047	0.66
Algometer Score (Kgf)	19.82 (7.64)	19.58 (7.47)	17.00 (6.58)	20.46 (71.86)	3.70 (0.09to16.22)	.014	0.83
2 leg eyes-closed							
Overall SI (°)	2.48 (1.04)	2.20 (1.28)	2.20 (1.15)	1.43 (1.07)	-0.76 (-1.40 to 1.10)	.024	-0.67
Anterior-Posterior SI (°)	1.58 (0.71)	1.47 (0.83)	1.53 (0.82)	0.91 (0.95)	-0.97 (-1.66 to -0.28)	.037	-0.07
Middle -Lateral SI (°)	1.61 (1.07)	1.35 (0.99)	1.51 (1.01)	0.93 (0.89)	-0.31 (-0.71 to 0.08)	.118	-0.50
Single dominant leg eyes-closed							
Overall SI (°)	2.79 (0.80)	2.96 (0.75)	2.91 (0.81)	1.81 (0.95)	-0.70 (-1.96 to -0.56)	<.001	-1
Anterior-Posterior SI (°)	2.03 (0.77)	2.31 (0.81)	2.08 (0.96)	1.38 (0.91)	-0.97 (-1.66 to -0.28)	.007	-0.88
Middle -Lateral SI (°)	1.64 (0.55)	1.46 (0.42)	1.76 (0.61)	0.93 (0.45)	-0.63 (-1.03 to -0.23)	.003	-0.71
Single no dominant leg eyes-closed							
Overall SI (°)	3.06 (1.16)	2.84 (0.84)	2.73 (0.83)	1.82 (0.89)	-0.70 (-1.42 to 0.02)	.050	-0.66
Anterior-Posterior SI (°)	2.26 (1.13)	2.11 (0.90)	2.13 (0.73)	1.21 (0.74)	-0.77 (-1.51 to -0.03)	.041	-0.21
Middle -Lateral SI (°)	1.72 (0.49)	1.46 (0.46)	1.44 (0.44)	1.05 (0.53)	-0.12 (-0.50 to 0.26)	.517	-0.22

*Values expressed as mean (SD); p †: p values from ANOVA for repeated measures adjusted by baseline data to compare different between groups after 3-month Whole Body Vibration program in fibromyalgia .intent-to-treat analysis.

3 Results

The participant characteristics for this study are summarized in Table 1. The control and experimental group were comparable with respect to all variables at baseline.

In efficacy analysis (see Table 2), the treatment effect on widespread pain was an improvement of 23.5% ($P < .05$) and on knee pain, an improvement of 40% ($P < .05$).

In the efficacy analysis (see Table 2), treatment resulted in an improved strength of greater than 19% ($P < .05$) in concentric knee extension and flexion. The treatment effect on balance with eyes closed was an improvement in OSI of greater than 25% ($P < .05$) and in APSI of greater than 40% ($P < .05$) in all positions evaluated.

In the intent to treat (ITT) analysis (see Table 3), the treatment effect was a 20% improvement in widespread pain ($P < .05$) and a 31% improvement in knee pain ($P < .05$). The treatment effect on strength was an improvement in concentric knee extension and flexion of greater than 15% ($P < .05$; see Table 3). The treatment effect on balance with eyes closed was an improvement in OSI of greater than 20% ($P < .05$) and in APSI of greater than 35% ($P < .05$) in all positions evaluated.

4 Discussion

Previous studies reported the feasibility and effectiveness of WBV in FM patients^[12, 38], including the effects of the WBV program used in the present study on health related quality of life and dynamic balance with visual feedback^[6, 39]. The present study showed that WBV also has beneficial effects on widespread pain, the somatosensory system and muscular strength (isometric, concentric and eccentric knee contractions). Our results allow a more detailed study of the mechanism of adaptation to tilting WBV in FM.

The current vibration program could serve as an additional resource for patients with FM that can easily be implemented in different settings (e.g. primary care, FM associations, clinics or gyms.) because the program can be readily self-administered in one small room after an initial instruction session. This is a particular advantage for patients living in socio-demographic areas lacking key resources such as gyms, warm-water pools, clinics or highly specialized FM technicians^[40, 41]. Only one participant dropped out of the program (5.5%) and this was due to pain in the legs. The remaining participants completed the program without secondary adverse effects (94.5%); this is an important outcome since 94.5% this is an important outcome since our adherence rate is substantially higher than that reported for other intervention studies with FM patients^[42, 43].

Previous studies have reported beneficial effects of WBV in a variety of populations, for example, the elderly^[9, 44-46], untrained females^[47, 48], postmenopausal women^[49, 50], Parkinson's disease^[51-53], multiple sclerosis^[54] and stroke^[55-57].

Previous studies suggest that the traditional exercise program alone has no effect on pain in patients with FM^[12, 41, 58]. Water therapy has been identified as an important therapy for pain in FM. Balneotherapy and dry-land training both deliver improvements in pain such as a reduction in the number of tender points^[59, 60]. Eight weeks of training with 5 different sessions per week (including one water session) led to a 40% improvement in body pain measured by the questionnaire Short Form 36^[41]. Jentoft *et al.*^[61] detected reductions in pain after 2 sessions per week in a heated pool for 20 weeks, while Gusi *et al.*^[62] found that three sessions per week in warm water decreased pain measured on VAS (29%) and pain/discomfort item of the EQ-5D (16%). Mannerkorpi *et al.*^[63] achieved a 15% reduction in pain with one pool-based session per week over a 6 month period. WBV is a new therapeutic approach and to our knowledge the study by Alentorn-Geli *et al.*^[12] is the only one study to investigate the effect of WBV on FM-related pain; these authors propose exercise plus supplementary vertical WBV as an effective approach for improving pain in FM. Our study used an intervention exclusively based on tilting WBV therapy and achieved a positive effect on pain relief measured by a digital algometer, indicating that WBV therapy alone can be effective in treating the most important symptoms of FM. In turn, this novel therapeutic approach may have beneficial effects on quality of life, physical functioning and health status in FM.

patients. An inherent problem in pain assessment is the subjective nature of the measurement, and many studies utilize the VAS scale or manual palpation, but these methods do not account for individual differences in pain perception. We aimed to avoid this problem by assessing pain with a digital algometer, which is a quantitative tool for assessment of pain commonly used in clinical practice^[64]. We measured pain over the whole body, but also focused specifically on the knees, which predominantly absorb the impacts transmitted by the platform.

Vibration strongly affects the afferent discharge from fast adapting mechanoreceptors and muscle spindles, and this is a likely mechanism to reduce the perception of pain. In addition to its effects on pain, we believe this process is related to improvement in balance because the gastrocnemius muscle is the agonist for control of forward postural sway, and the anterior tibialis muscle is the agonist for control of backward postural sway.

Patients with FM are deconditioned compared with normal subjects, with a reduction in maximal voluntary isokinetic strength in the quadriceps muscle that is thought to result from a primary muscle dysfunction^[65]. FM patients with many tender points have a significant reduction (45%) in peak torque isokinetic knee extension and flexion. Possible mechanisms for this reduced muscle function include pain, negative feedback on motor unit recruitment, peripheral neurogenic problems and lack of motivation^[65]. The increase in voluntary peak torque isokinetic strength (19%) in our study is probably due to the observed improvements in pain at tender points, allowing an improvement in the feedback to motor units, together with increased motivation to develop strength and to improve functions related to daily living (stair climbing, walking or sitting up and down on a chair).

Some studies using land-based resistance training have shown that exercise is effective for improving strength in FM^[66, 67], while Gusi *et al.*^[62] have shown that warm water therapy improves knee extensor and flexor strength for concentric actions at slow speed. In our study, we obtained similar results using self-administered therapy.

Balance problems are one of the 10 most debilitating symptoms of FM and occur in 45%-68% of patients^[68]. We propose that several factors contribute to balance problems in FM patients including vision problems, vestibular problems and changes in somatosensory impulses for pain^[28]. The somatosensory response is dependent on specific clinical and other factors such as reduction in muscle strength, and sensory or motor deficits^[69], and is also altered in FM^[70].

The first sensory inputs used in automatic postural control and postural orientation are the somatosensory input from muscle spindles, Golgi tendons, and superficial and deep cutaneous afferent nerves^[71]. However, proper balance also requires rapid and automatic corrections from the CNS. FM patients have abnormal perception of pain and slight somatosensory stimulation, and since our proposed therapy stimulates the CNS and may enhance activation of the somatosensory system, this may contribute to better postural control in FM patients.

The positive effect of WBV on the somatosensory system in patients with FM is a novel and important finding. This new technology has great potential to improve the quality of life in patients with pain and could help to clarify the specific mechanisms and adaptations of the somatosensory system, especially in FM patients.

Other authors have reported improvements in balance in FM when balance was measured with the eyes open. These improvements are likely due to training of the somatosensory system and to effects of vision^[6]. In our study, the improvements in balance occurred independent of visual inputs, suggesting that the therapy improves balance through stimulation of the somatosensory system.

We propose that interventions that combine balance training with exercise and vibratory exercise may be effective in improving balance and somatosensory function in FM.

5 Limitations

This study has several limitations. We relied on self-administration of the vibratory therapy, including auto-adjustment of the knee angles, and cannot be certain that each participant administered the therapy exactly as explained to them at the

start of the study. Only participants in the experimental group received weekly telephone calls during the WBV program. The social contact and support provided by these calls may have improved the motivation of this group in contrast to the control group, which did not receive the calls. In addition, members of the exercise group did a 10-minute warm-up of slow walking, so we cannot confirm that the observed improvements were solely due to WBV. The balance test was performed with eyes closed, thereby excluding effects of vision, and in this situation balance is maintained through the vestibule and the somatosensory system. Therefore, we cannot determine whether the improvements achieved were due solely to improvements in the somatosensory system or whether the vestibular system was also involved. In the current study we evaluated the effects of WBV on balance with closed eyes, and in future studies it will be important to control for medications used by the participants that may have an influence on postural control.

Further studies will be necessary to determine the optimal amount of WBV therapy and its relationship to the level of disability in FM. It will also be important to compare the effects of WBV therapy on anterior-posterior and middle-lateral balance using different postures on titling, vertical and stochastic platforms. Finally, a thorough assessment of the cost-effectiveness and cost-utility of WBV treatments is needed in order to ensure that this therapy can be provided to large populations of patients suffering from FM.

6 Conclusions

Twelve weeks of tilting whole body vibration therapy 3 times a week, with a frequency of 12.5 Hz, had a positive effect on muscle strength, the somatosensory system and pain in women with fibromyalgia. This study supports the development of novel approaches to physical therapy programs that utilize vibration therapy.

Ethics Committees approval

Approved by the Biomedical Ethics Committee of the University of Extremadura on 12/06/2005; reference number 11/05 (academic research funded in 2007). All participants gave their written informed consent to participate according to the updated Declaration of Helsinki, and the project protocol was approved by the Biomedical Ethics Committee of the University of Extremadura.

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Competing interests

The authors declare they have no competing interests

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