The effect of a 6-week exercise programme and whole body vibration on strength and quality of life in women with fibromyalgia: a randomised study

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ABSTRACT

Objectives. The aim of this study was to investigate the effectiveness of a 6-week traditional exercise programme with supplementary whole-body vibration (WBV) in improving strength and health status in women with fibromyalgia (FM).

Methods. Thirty postmenopausal women with FM (mean (SD) age: 59 (7.90) years) were randomised into one of two groups, one intervention group (n=15), GEV which combined exercise training (two days a week) with three days of WBV (3 sets of 45s at 20Hz-3 mm and four sets of unilateral static squats at 20Hz-2mm) and another control group (n=15), that performed the same physical activity programme but without vibration training (GEnV). The Fibromyalgia Impact Questionnaire (FIQ) and the global score of the SF-36 were used to assess functional capacity and quality of life. Two additional tests were employed to assess muscle strength. Baseline data and pre-test and post-test data were collected before and after the six-week intervention period.

Results. Significant improvements in all outcomes measured were found from baseline in both groups. A 5% improvement from baseline in total FIQ score was observed in the exercise groups (p≤0.05), and was accompanied by reductions in SF36 scores of 9.8% (p<0.001) and 7.9% (p<0.001) in the GEV and GEnV group, respectively. Improvements were also observed in muscle strength in both groups but greater in the GEV group.

Conclusion The results suggest that women with FMS can gain additional health benefits by engaging in a 6-week traditional exercise programme with supplementary WBV.

Introduction

Fibromyalgia (FM) is a common syndrome characterised by chronic widespread musculoskeletal pain, accompanied by a complex symptomatology which often includes sleep disturbance, stiffness, psychological dysfunction, and deconditioning, with muscle, and bodily fatigue in general (1, 2). This combined symptom experience has a considerable impact on daily activities, work capacity and the quality of life (QOL) of this patient group (3, 4, 5). The etiology or specific pathogenic mechanisms operating in FM are not completely understood, and while the lack of fitness has been attributed to a decrease in physical activity (6,7), there is no evidence supporting primary muscle pathology in this syndrome (8, 9). In order to improve fitness and positively influence patients' QOL, exercise has been suggested as the main non-pharmacological strategy in the management of patients with FM (5, 10, 11). Both aerobic capacity and muscle strength can be improved by specific training programmes with no risk to the patient (5). However, despite exercise being recognised as an essential strategy in the management of FM, not all clinically relevant aspects of exercise prescription or specific parameters for its prescription have been identified (12).

Research exploring exercise intervention has tended to focus on the effects of different aerobic exercise programmes (13-16) or strength training regimens (4, 6, 17). Recently, Bircan *et al.* (18) compared aerobic exercise with strength training in a group of patients with FM. Both interventions demonstrated significant improvements in pain, sleep, fatigue, tender point count, and fitness. However, there was no difference between groups in their impact

on symptoms and QOL. Valkeinen et al. (19) also demonstrated that by combining aerobic and strengthening exercises, symptoms and functional performance were improved in post-menopausal women with FM. However, despite a high number of available studies that have evaluated the impact of combined strategies (including physical exercise) in the management of this syndrome, the findings are not clear (5, 20). Additionally, Nampiaparampil and Shmerling, (21) report that unaccustomed exercise may exacerbate pain and fatigue, which can result in poor adherence to exercise interventions and high rates of attrition from clinical trials in this area. For these reasons there is a need to seek new strategies that will enable clinicians to harness the benefits of exercise in FM but will not exacerbate patients' symptoms.

Whole body vibration training (WBV) may represent one such strategy, and has been used with success in sports training and in the rehabilitation of different patient populations (22, 23). This type of training is done on a vibratory platform that generates a mechanical stimulus that increases the muscles gravitational load (24), producing a defensive response from the muscular system to increase stiffness and so reduces vibration transmission in the body. This mechanism results in the activation of the "tonic vibration reflex" (TVR), producing a reflex muscle contraction (25). The effect of WBV training on the body appears to be a combination of aerobic and strength training. Many studies have attempted to establish the potential benefits of this type of training showing improvements in strength (26, 27), postural control (28) and flexibility (29). It has also been found that WBV training is easy to apply in untrained and older people with low levels of fitness (30). However, its application in FM is new and indeed novel; and there has been only limited evaluation of its effect on specific symptoms such as pain or muscle fatigue (31, 32) or QOL (33).

Given the need to develop new intervention strategies for patients with FMS that improve fitness, function and QOL, it is hypothesised that the com-

bination of aerobic exercise training and strengthening, induced with WBV training, may be useful in FM. The aim of the current study, therefore, is to assess the effect of 6 weeks of exercise training, based on a combination of strengthening and muscular endurance exercises, and supplemented with WBV.

Methods

Participants

Thirty postmenopausal women (mean (SD) age: 59 (7.90) years) diagnosed with FM based on the American College of Rheumatology criteria (1) participated in the study. Patients were recruited from two sources: (i) from rheumatology clinics based in hospital or the community and (ii) through different local FM patient support groups in Spain. After giving informed written consent, participants were randomised into one of two groups (randomisation was by a computer generated random number table), one intervention group (n=15) that combined exercise training with WBV (GEV), and another control group (n=15) that performed the same physical activity programme but without vibration training (GEnV). Randomisation was carried out by Luis Carrasco who was not directly involved in the day-to-day running of the study. Exclusion criteria included the presence of inflammatory rheumatic disorders or degenerative joint diseases, psychiatric disorders, and respiratory or cardiovascular diseases that could interfere with the physical activity programme. Subjects who were performing structured physical activity for at least two days a week or had psychological therapy during the six months prior the study were also excluded.

Procedures

Participants were asked to perform two familiarisation sessions (48hrs apart) where they were instructed to use the vibratory platform and also informed about the tests used to assess physical fitness. The six-week intervention period consisted of two exercise-training sessions per week (Tuesday and Thursday) for both groups and three sessions with WBV (Monday, Wednesday and Friday) just for the GEV group. All sessions

were supervised by the same instructor with experience in treating women with FM. Baseline data, and pre-test and post-test data were collected before and after the six-week intervention period by an outcome assessor who was blind to group allocation. The project was approved by the Research Ethics Committee of the University of Seville and was conducted following the guidelines of the Helsinki declaration.

Combined exercise sessions lasted approximately 1 hour (56±4min), where participants performed aerobic exercise in short intervals (4–6 intervals of 2–3 min, 1-2 min rest between intervals). The intensity varied between 50-69% of maximum heart rate (HR_{max}) calculated based on the formula (207–0.7*age) proposed by Gellish et al. (34). Sessions also included flexibility exercises (8-9 exercises; 1 x 3 reps keeping the stretch position for 30s) and also strengthening exercises of the major muscle groups (8 exercises, 1 x 8-10 reps with 1-3 kg). Heart rate (HR) was recorded each session to allow evaluation of the appropriate dose of exercise for each subject every week.

Regarding the vibration protocol, the Galileo Fitness® platform (Novotech, Germany) was used. Participants were submitted to a frequency of 20 Hz and variable amplitude of 2-3mm. Each session was three sets of 45s with 120s recovery between sets (amplitude=3mm) and four sets of 15s. The first three sets were performed bilaterally for 45s at a frequency of 20Hz (amplitude=3mm) after 120s recovery between sets. Participants completed four sets of unilateral static squats at a frequency of 20Hz (amplitude=2mm) for six weeks. Participants completed 15s of the exercise with the right leg and then immediately completed 15s on the left leg, and this was considered one set. During the vibration session, participants stood with both knees in 120° isometric knee flexion (half squatting position) as measured by a goniometer.

Assessment of functional capacity and quality of life

To assess functional capacity, the Fibromyalgia Impact Questionnaire (FIQ) (35) was used. This instrument

was designed to detect changes in the overall condition of patients with FMS. It includes 10 questions about patients' wellbeing, and physical and work capacity experienced by patients during the last week. Each item was normalised on a 0–10 point scale with higher scores indicating greater symptoms or illness. QOL was analysed by using the global score of the SF-36 (Medical Outcome Study-MOS) (36).

Assessment of strength and muscle resistance

Two different tests were used to assess muscle strength. (i) In order to determine maximum power (Pmax), the participants were asked to do a half squat in which they were placed in front of a multipower machine with guided weight, bending the knees up to 120° and grasping the bar at shoulder height. They had to extend the knees with arms fully extended (avoiding the shoulder movement and elbow flexion) and controlling the trunk maintained vertically. The test was performed three times with 30s recovery between each attempt. The most powerful ??, recorded in watts, was used for analysis. (ii) After 120s recovery, subjects were asked to complete as many repetitions as possible of the previous exercise during 60s, in order to estimate muscle endurance. A Fatigue Index (FI) expressed as the decline in performance of the peak torque of the first five repetitions to the last five repetitions was calculated (average of the P_{max} developed in the first five repetitions/average of the Pmax developed in the last five repetitions). The number of repetitions correctly performed in 60s (REP) was also measured. All outcomes were assessed with the system of measurement of dynamic forces T-FORCE system® (Ergotech Consulting, Spain).

Data analysis

Demographic characteristics of participants were compared between groups with the Chi Squared (χ^2) test for categorical variables (marital status and education level) and independent t-test for continuous ones. Differences between outcome measures at baseline for the GEV and GEnV groups were tested

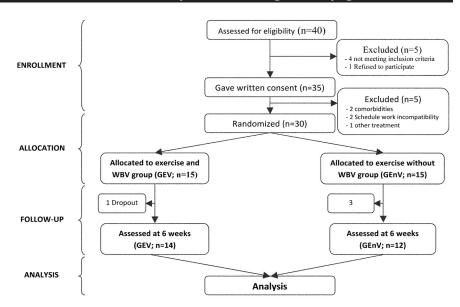


Fig. 1. Flow of participants through the trial.

Table I. Baseline characteristics of the participants.

	GEV $(n = 15)$	GEnV $(n = 15)$	<i>p</i> -value
Age mean (SD)	57.89 (6.23)	60.13 (9.42)	0.398
Weight mean (SD)	73.05 (11.53)	70.84 (10.31)	0.579
Height mean (SD)	155.19 (5.97)	159.27 (6.01)	0.068
Marital status (n)			0.310
Single	0	1	
Married	14	11	
Widow	1	1	
Separated	0	2	
Education level (n)			0.096
Unfinished studies	0	0	
Primary school	8	10	
Secondary school	7	5	
University degree	0	0	

GEV: Experimental group with WBV; GEnV: Experimental group without WBV. Data of age, weight and height are expressed as mean (SD).

using analyses of variance (ANOVA) for continuous variables. 1-way ANO-VAs were used to compare pre- and post-test values within groups.

Results

Twenty-six women completed the sixweek intervention and were included in the analysis. One patient in the GEV and three in the GEnV dropped out of the study. The reasons for dropping out included: illness, participant unable to commit due to work commitments, and unable to do exercise after an injury (Fig. 1).

Descriptive characteristics of patients are presented in Table I. Com-

parison of demographic variables showed no significant between group differences at baseline for age, weight, height, marital status or educational attainment (all *p*-values >0.05).

Table II demonstrates that there were no significant differences between groups, in any outcome measure, at baseline. However, following the intervention there were significant between group differences in the global score of the SF-36 in favour of the WBV training group t=2.116; p=0.044. Within group analysis also demonstrated statistically significant differences in the number of squats performed (p<0.05) and in global score of the SF36 (p<0.05) for

Table II. Outcome scores at baseline and after 6-week intervention period.

Outcomes	Baseline			6 Weeks		
	GEV	GEnV	p-value (between group)	GEV	GEnV	p-value (between group)
Pmax (mean (SD))	81.29 (28.34)	80.92 (24.17)	0.972	87.05 (19.72)	85.01 (19.73)	0.795
REP	24.71 (6.26)	22.08 (9.21)	0.397	28.71 (5.25)*	23.75 (7.87)	0.067
FI	0.90 (0.06)	0.91 (0.14)	0.907	0.97 (0.17)	0.96 (0.05)	0.903
FIQ (0-80)	48.89 (12.08)	56.66 (11.58)	0.089	43.79 (12.31)*	49.81 (14.87)*	0.261
SF36 Global score (0-100)	44.16 (18.88)	33.58 (12.10)	0.086	54.00 (15.83)*	42.51 (11.30)*	0.044

GEV: Experimental group with WBV; GEnV: Experimental group without WBV. Data expressed as mean (SD). *: p<0.05 on within group analysis. Pmax: maximum power reached in a half squat, Rep: number of half squat completed in 60 s., FI: Fatigue Index, FIQ: Fibromyalgia Impact Questionnaire, SF 36: Short Form 36.

the GEV group. Both groups also had significant improvements in FIQ scores (p<0.05) from baseline.

Table II also shows that there were no between group differences in maximal power output (P_{max}) or difference in Fatigue (FI) between groups.

Discussion

The aim of this study was to determine if supplementing a six-week exercise programme with WBV resulted in greater improvement in QOL and functional ability in women with FM, over an exercise programme alone. The results have shown that both interventions resulted in significant improvements in SF36 and FIQ scores. However, the group experiencing WBV in addition to exercise also showed significant improvement in muscular function (REP). The findings from this study suggest therefore, that WBV offers additional benefits, over and above exercise, to women with FM.

Several systematic reviews have evaluated the effect of physical exercise on physical fitness, functional capacity and QOL in women with FM (5, 11, 37, 38). Despite the number of available studies that have evaluated the impact of physical exercise in the management of this syndrome, the findings, while encouraging, are not conclusive (5). In this respect, this study is consistent with previous work and demonstrates changes over 5% in overall FIQ score in both groups. These improvements are similar to those reflected in previous studies with more intensive exercise programmes (4, 39-41). Improvements in functional capacity seem to have a direct impact on QOL of these patients (42). This is also evidenced in the current study if we observe the improvements experienced in the SF-36 global score in both groups (GEV: 9.84%; GEnV: 7.90%). Numerous authors (13, 18, 43) also compared the effect of a short-term physical exercise programme showing significant improvements in functional ability and pain (SF-36). On the other hand, studies evaluating WBV training in FM are relatively rare. Alentorn et al. (32) evaluated the effect of a traditional exercise programme based on aerobic exercise, stretching and relaxation (two days a week), supplemented with mechanical vibration training (30Hz, 2mm) where participants performed six exercises (30s each one, with 3min recovery between repetitions). Thirty patients were randomly allocated in three groups (vibration and exercise, exercise alone and a control group). After a six-week intervention period, these authors showed that traditional exercise group supplemented with WBV reduced participants' pain and fatigue, while exercise alone showed no improvements in these outcomes. In another study, Danko et al. (31) used a vibratory-assisted exercise programme that involved performing sixteen exercises twice a week, for a total of eight weeks. At the end of the intervention, patients again reported improvements in pain and fatigue. Saggini et al. (44) showed that it was possible to achieve improvements in the functional capacity of women with chronic fatigue syndrome who performed aerobic exercise and mechanical vibration (18–22Hz, 10mm) for six months. After this therapy the perception of fatigue and muscle pain decreased, improving participants' QOL. The findings from the current study provide further evidence that exercise supplemented with WBV improves QOL in FMS. However, this study also provides additional evidence that muscle function is further enhanced by the addition of WBV to a standard exercise programme.

There is some limited evidence that strengthening exercises can improve muscle strength and function in FMS (11, 19, 38), and the current study gives further weight to that evidence. In this regard, this current study has demonstrated minor changes in muscle strength and endurance (Pmax, FI and REP) after six weeks training. P_{max} increased by 21.34% (5.75±34.20 W) in GEV, versus 8.21% (4.09±8.22 W) in GEnV. These results are consistent with those from previous studies with mechanical vibrations that have reflected improvements in these variables with clinical populations after short-term interventions, (45, 46).

The results obtained in the current study confirm the hypothesis that WBV with exercise results in greater improvement than exercise alone. Studies such as Rees *et al.* (47), assessed a programme based on WBV (26 Hz, 5–8 mm) of eight weeks, three times a week, with 43 untrained seniors (23 men, 20 women, 66-85 years) and showed a significant increase of 8.1% in one isokinetic test with knee

extension movement. Although results were similar to those of the group that underwent conventional training, results in both groups were higher than those reached by the control group without exercise. This same research group showed, in a group of 30 elderly people (73.7±4.6 years), improvement in the ankle strength (flexion: 3.69%; extension: 4.17%) and power (flexion: 3.89%; extension: 2.96%) after 8 weeks of strength exercise *versus* WBV training complemented with physical exercise, although the differences found were not significant (26).

This current study has two main limitations. Firstly, the sample size may have resulted in a type II error, i.e. the study may not have been sufficiently powered to detect differences between groups where they exist. However, the findings from the current study suggest that this novel treatment intervention is acceptable to patients and may have some beneficial effects. Nevertheless, further studies examining the effectiveness of WBV should ensure that they are appropriately powered to reduce the possibility of type II error. Secondly, the programme duration may have been too short, since previous studies based on long-term interventions showed greater improvement (48). However, the practicalities of delivering long-term interventions in the clinical setting need to be considered. The intervention used in this study of a six-week duration period is easily transferable to the clinic.

In summary, a short-term programme based on physical exercise with or without WBV training, brings slight improvements in both functional capacity and strength in women with FM. However, these improvements are most noticeable after a physical exercise programme implemented with low-magnitude mechanical vibration (18 Hz, 2–3mm).

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