The therapeutic effects of whole body vibration in patients with fibromyalgia. A randomized controlled trial.

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Objectives

To evaluate the efficacy of a 12-week therapy program that involves the use of a whole body vibration in patients with fibromyalgia.

Design

Single-blind randomized controlled trial.

Setting

Fibromyalgia Association in Palma (Balearic Islands).

Participants

Patients diagnosed with fibromyalgia according to the criteria of the American College of Rheumatology, were recruited from different Fibromyalgia associations in Mallorca (n=40).

Intervention

A neuromuscular training with a rotational whole body vibration platform during 12 weeks. The control group received no physiotherapy treatment.

Outcomes

The following variables were assessed before, after and three months after the therapy program: Fibromyalgia impact questionnaire, pain intensity, quality of life, sensitivity measurements (pressure pain thresholds, vibration thresholds), motor function tasks (Berg scale, six-minute walk test, isometric back muscle strength) and static and dynamic balance.

Results

Improvements in the indexes of functional disability, static equilibrium and vibration sensitivity were consistent with the reduction of pain sensitivity.

Conclusions

The intervention group improved almost all parameters immediately after the therapy program, in contrast to the control group that showed no changes. These improvements were not maintained in the follow-up.

Keywords

Vibration, fibromyalgia, proprioception, postural balance.

Contribution of paper

* Fibromyalgia is a chronic pain disease with few effective therapeutic options.

* Whole body vibration improves pain, somatosensory sensitivity, balance, functional motor outcomes and quality of life in patients with fibromyalgia.

* Continuous use of whole body vibration can be an effective therapeutic option in patients with fibromyalgia.

Introduction

Fibromyalgia (FM) is a chronic syndrome characterized by widespread pain sensitivity, fatigue and cognitive symptoms. It affects 3-5% of general population, women predominantly [1-3]. It has few effective therapeutic options available. For this reason, it is necessary to adopt effective treatments able to reduce its symptomatology. Neuromodulator agents, antidepressants or muscle relaxants are the most successful pharmacotherapies in its treatment. [4, 5] Some studies have proposed different therapies like individualized moderate-intensity exercise [6, 7] or Tai-chi [8] with good results [9] as well as other therapies like herbal medications or acupuncture [10-12].

The whole-body vibration (WBV) has proven to improve health status [13-16], strength [17-20], static and dynamic balance [17, 19], physical function [18], pain and quality of life [21, 22]. From our knowledge, all the previous studies combined WBV with

an associated exercise program. Thus, it remains uncertain the active component of the therapy leading to the specific effects of WBV [23]. The objective of this randomized controlled trial was to compare the effects of a 12-week therapy program consisting in the use of WBV with a control group, which did not perform any therapy program.

Methods

Participants

The prevalence of fibromyalgia in Spain is 2.4%. The Balearic Islands have about 20,000 people affected by fibromyalgia, with a 21:1 female/male ratio [24]. A sample size calculation was performed using the GRANMO calculator (http://www.imim.es) with a confidence interval of 95% and an accuracy of the estimate of 5%. Consequently, we recruited forty patients from different associations during December of 2018. The Ethics Committee of the Balearic Islands approved the study (IB-2586/15 PI) and it was registered at ClinicalTrials.gov (NCT03782181). Randomization was performed in two stages: generation of numbers and blind allocation. The envelopes indicated which group the participants would be included in were opened after informed consent was obtained. It was not possible to blind therapists but the outcome assessors were not informed about the allocation of patients in the respective groups.

All participants met the inclusion criteria: (A) age between 30 and 65 years, and (B) diagnosis of fibromyalgia according with the American College of Rheumatology [1]. Exclusion criteria were history of severe trauma, peripheral nerve entrapment, inflammatory rheumatic diseases and pregnancy. We used a 1:1 allocation ratio and the 40 participants were randomly allocated into one of the groups. A single-blinded, 1:1 parallel-group, randomized controlled trial was conducted. On the day of admission, a physiotherapist informed patients about the study and asked them to participate. A

randomization list was created by a statistician and administered by a secretary in sequentially numbered, sealed envelopes. After baseline testing, the envelope was opened by the physiotherapist.

Assessments

The intervention group performed a program consisted of maintaining 3 different positions on the platform during vibration: standing with both feet on the platform for 45 seconds, unilateral static position, 22 seconds with each leg. These sessions were held individually in the gymnasium of the Fibromyalgia Association in Palma and the entire program was supervised by a physiotherapist trained in WBV. Participants in the control group did not perform any program. The intervention was performed during the winter of 2019 and the follow-up 3 months after the end of the therapy. Two types of platforms can deliver WBV. One is a vertical vibration device that induces oscillations over a vertical axis. The second one is a rotational vibration device that induces reciprocal displacements on the left and right sides of a fulcrum. Some studies using vertical vibration have shown an improvement in the anteroposterior stability [17], while studies using rotational vibration showed an improvement of the mediolateral stability, more related to the risk of falls [18]. We opted for using the rotational vibration and WBV was programmed according with the parameters published by previous bibliography [22]: 20 Hz of frequency, and 3 mm of amplitude. Assessment of all outcomes in both groups was undertaken at baseline, immediately after the therapy and 3 months after the end of the program.

Self-Report Questionnaires

Fibromyalgia impact questionnaire. This is a validated instrument designed to quantify the overall impact of fibromyalgia. We used the Spanish version of the questionnaire [25].

Visual analogue pain scale [26]. Each participant was asked to indicate their current level of pain using a 20 cm visual analogue scale ranging from 0 to 100. This has been reported to be a reliable method for assessing pain [26].

Quality of Life Index [27]. This is a self-report questionnaire, previously used to assess quality of life in patients with fibromyalgia [28]. We used the Spanish version [27].

Sensitivity measures

Pressure pain sensitivity was assessed by means of the measure of pressure pain thresholds, expressed in Newtons. This method has demonstrated its reliability to assess pain sensitivity [29, 30]. Pressure stimuli were applied on two bilateral body locations: epicondyles and index finger. The pressure pain threshold was defined as the pressure value considered as painful by the participant.

Vibration thresholds were evaluated by using a Vibratron (Physitemp Instruments), which consists of a controller and two transducers used to determine the intensity of the vibratory stimulus perceived by the patient. The testing started with an intensity above the threshold, and then it was gradually reduced, asking participants to indicate when the vibration was not perceived. Vibration values displayed on the control unit are the amplitude of vibration, proportional to the square of applied voltage [31, 32].

Motor function tasks

*Berg scale***.** This is a functional assessment tool, consisting of 14 functional tasks. The general scores range from 0 to 56. It has been previously used in patients with fibromyalgia to assess balance [33].

Six-minute walking test. This is a functional test in which the patient walks as far as possible during 6 minutes. It has been validated for patients with fibromyalgia [34, 35].

Isometric back muscle strength was determined by a dynamometer (T.K.K.5002). Participants were asked to pull extending their back, trying to put the body as vertical as possible. This test has proven to be reliable in the assessment of back muscle strength [21].

Static and dynamic balance

Static balance was assessed by using a modified version of the Romberg's test [36]. Postural control is dependent on input from three peripheral modalities: vision, vestibular apparatus and proprioception. Asking the participants to close their eyes during the Romberg's test helps to uncover any disordered proprioception. We analyzed the body sway during the test performance. Participants were situated below a webcam (© Logitech) placed at a mean distance of 50 cm from the participant's head. The participant was asked to remain in orthostatic position with feet parallels, arms extended along the body and eyes closed for 1 minute [37]. Velocity and body sway in the anterior-posterior and medial-lateral directions were extracted and analyzed by the software CvMob, which produces similar results than posturography [38].

Dynamic balance was assessed by means of a gait task. Participants were instructed to walk on a 4 meters carpet. Optical markers were attached at the lateral condyle of the femur, great trochanter and lateral malleolus. Subject's motion was digitally recorded with a video camera at 210 frames per second (CasioExilimEX-FS10). The camera was positioned at a distance of 4 meters from the carpet. Changes in position and velocity along the x-axis were analyzed by CvMob [36, 38].

Statistical analysis

Analyses were performed using two-way analysis of variance, with the between-factor GROUP and the within-subject factor TIME. Effect size was calculated by means of the Cohen's d and it was interpreted as small (~0.25), medium (~0.5), or large (>0.8). The significance level was set at 0.05. All the analyses were performed using SPSS Statistics.

Results

The forty subjects enrolled in the groups adhered totally to the program, with no occurrence of sample loss. The mean age was 52.5 ± 8.3 years. Most of the participants were female (90%). The mean duration of pain was 7.3 years, with an average of 3 years for the clinical diagnosis of fibromyalgia.

Both groups were similar in their sociodemographic characteristics (all $p>.05$). Table 1 displays the characteristics of the participants of both groups. Most patients were taking analgesics, anxiolytics and antidepressants (Table 2). For medical reasons, medication was not discontinued during the study.

Self-Report Questionnaires

Fibromyalgia impact questionnaire scores showed a main effect TIME ($F (2, 76) =87.47$, $p<.001$), showing lower scores in the post-treatment than in the pre-treatment or follow-up (both $p<.001$). An interaction effect GROUP x TIME ($F (2, 76) =88.24$, $p<.001$), indicated that these effects were produced only in the intervention group. Post-hoc mean comparisons revealed that participants in the intervention group significantly decreased their scores from the pre- to the post-treatment ($p<.001$, Cohen's $d=5.22$ and effect size of 0.93) but these scores increased from the post-treatment to the follow-up ($p<.001$, Cohen's $d =-5.14$ and effect size of -0.93).

Visual analogue pain scale showed a significant main effect TIME (F (2, 76) =40.69, p<.001) with lower scores in the post-treatment than in the pre-treatment or follow-up (both p < 0.001). An interaction effect GROUP x TIME (F(2,76)=41.34, p<.001) indicated that only the intervention group reported lower pain scores in the post-treatment and follow-up compared to the pre-treatment (both p<.01, Cohen's d > 8.30 and effect size >.97), although scores in the follow-up were higher than in the post-treatment (p<.001, Cohen's d =-5.94 and effect size of -0.95). Moreover, the intervention group showed higher scores than the control group in the pre-treatment (p =.006) but lower scores in the post-treatment (p=.005). No differences between groups were found in the follow-up.

In the *Quality of Life Index* a significant interaction effect GROUP x TIME F(2, 76)=19.65, p<.001) revealed that the intervention group perceived higher quality of life in the post-treatment than in the pre-treatment (p<.001, Cohen's d =-3.55 and effect size of -0.87), although it decreased again between the post-treatment and the follow-up (p<.001, Cohen's d =3.67 and effect size of 0.87.). No significant changes were observed in the control group. Main effects TIME (F (2, 76) =20.08, p<.001) and GROUP (F (2, 76) =20.08, p<.001) showed the same time pattern and indicated higher quality of life in the intervention group than in the control (p=.045).

Sensitivity measures

For *pressure pain thresholds*, interaction effects GROUP x TIME in both body locations (both F > 38.50, both p<.001) indicated an increasing of thresholds from the pre-treatment to the post-treatment (all p<.001, all Cohen's d >-2.45 and effect size >-0.77) only in the intervention group. Nevertheless, thresholds decreased again from the post-treatment to the follow-up (all p<.001, Cohen's d =2.33 and effect size of 0.76).

Vibration thresholds showed interaction effects GROUP x TIME in both body locations (both F >27.60, both p<.001) indicating a reduction of thresholds from the pre-treatment to the post-treatment (all p<.001, all Cohen's d >2.92 and effect size >0.82) and an increment from the post-treatment to the follow-up (all p<.001, Cohen's d >-2.91 and effect size >-0.82) only in the intervention group. In both body locations, thresholds at post-treatment were lower in the intervention than in the control (both p<.004).

Motor function tasks

The *Berg scale* showed a significant interaction effect GROUP x TIME (F (2, 76) =73.60, p<.001). Post-hoc mean comparisons revealed that participants in the intervention group significantly improved their scores from the pre- to the post-treatment (p<.001, Cohen's d =-7.19 and effect size of -0.96) but these scores decreased from the post-treatment to the follow-up (p<.001, Cohen's d =7.17 and effect size of 0.96). Moreover, the intervention group showed higher scores than the control group in the post-treatment (p=.001). Main effects TIME (F (2, 76) =106.32, p<.001) confirmed this time pattern.

The *Six-minute walking test* showed significant effects TIME (F (2, 76) =16.56, p<.001) and GROUP x TIME (F (2, 76) =34.87, p<.001). Post-hoc mean comparisons revealed that participants in the intervention group significantly improved their scores from the pre- to the post-treatment (p<.001, Cohen's d =-4.00 and effect size of -0.89), although these scores decreased from the post-treatment to the follow-up (p<.001, Cohen's d =3.76 and effect size of 0.88). No significant changes were observed in the control group.

Isometric back muscle strength also showed significant effects TIME (F (2, 76) =5.95, p=.009) and GROUP x TIME (F (2, 76) =13.90, p<.001). Post-hoc mean comparisons revealed that participants in the intervention group significantly improved their back muscle strength from the pre- to the post-treatment (p<.001, Cohen's d =-2.17 and effect size of -

0.73) but this strength decreased from the post-treatment to the follow-up (p=.001, Cohen's d =1.62 and effect size of 0.63).

Static and dynamic balance

In *static balance*, sway in the medial-lateral axis, as well as mean sway velocity showed significant effects TIME (all F>5.83, all p<.01) and GROUP x TIME (all F>3.34, all p<.05). Again, post-hoc mean comparisons revealed that participants in the intervention group increased significantly their mean velocity values and decreased their sway values from the pre- to the post-treatment (all p<.001, all Cohen's d >5, all effect size >.78), although these improvements were reduced between the post-treatment and the follow-up (all p>.05, Cohen's d >-3.5, effect size >-0.87). The intervention group displayed slower and shorter sways than the control group only in the post-treatment assessment (all p<.01). No significant statistical effects were found in the anteroposterior sway.

Regarding the dynamic balance, no significant differences were found in any of the parameters except gait speed, where a main effect TIME (F(2, 76)=13.88, p<.001) and an interaction effect GROUP x TIME (F(2, 76)=3.34, p=.047) revealed again an improvement only in the intervention group between the pre- and the post-treatment, and a decline between the post-treatment and the follow-up (both p<.001, Cohen's d =-3.28 and 1.37, effect size of -0.85 and 0.57, respectively). The intervention group was faster than the control group in the post-treatment (p=.008).

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