Original Article

CLINICAL REHABILITATION

Clinical Rehabilitation
2020, Vol. 34(5) 630–645

DOI: 10.1177/0269215520911992
journals.sagepub.com/home/cre
SAGE

Effectiveness of acupuncture vs. core stability training in balance and functional capacity of women with fibromyalgia: a randomized controlled trial

Elisa María Garrido-Ardila[1], María Victoria González-López-Arza[1], Maria Jiménez-Palomares[1], Agustín García-Nogales[2] and Juan Rodríguez-Mansilla[1]

Abstract

Objective: This study investigated the effectiveness of a core stability training physiotherapy programme vs. acupuncture for the management of balance and functional capacity impairments of women with Fibromyalgia.

Design: Single-blind randomized controlled trial.

Setting: Outpatients setting.

Subjects: Women with Fibromyalgia and balance impairment.

Interventions: Participants were randomized to a core stability physiotherapy programme group ($n = 45$), acupuncture treatment group ($n = 45$) and control group ($n = 45$) for 13 weeks.

Main Measures: Measures were taken at baseline (week 0), postintervention (week 6) and follow-up (week 13). The primary outcome measures were static balance (posturography) and dynamic balance and functional mobility (Berg Balance Scale, timed up and go test and 10-m walk). The secondary outcome measure was functional capacity (Fibromyalgia Health Assessment Questionnaire and the physical function item from the Spanish Fibromyalgia Impact Questionnaire).

Results: In all, 103 participants completed the study. The results showed statistically significant improvements in the acupuncture and physiotherapy groups vs. the control group at week 6 regarding Berg Balance Scale ($P = 0.00$, both groups), timed up and go test ($P = 0.00$ and $P = 0.01$, respectively) and 10-m walk test at comfortable speed ($P = 0.02$ and $P = 0.03$, respectively). The 10-m walk test at maximum speed showed significance when comparing the physiotherapy and control group ($P = 0.03$). However, no

[1]Department of Medical-Surgical Therapy, University of Extremadura, Badajoz, Spain
[2]Department of Mathematics, University of Extremadura, Badajoz, Spain

Corresponding author:
Elisa María Garrido-Ardila, ADOLOR Research Group, Department of Medical-Surgical Therapy, Medicine Faculty, University of Extremadura, Avda. De Elvas, S/N, 06006 Badajoz, Spain.
Email: egarridoa@unex.es

significant differences were found between the physiotherapy and the acupuncture groups. In relation to functional capacity, the improvements achieved after the treatments were not statistically significant.
Conclusion: Core stability-based physiotherapy and acupuncture improve dynamic balance and postural control in women with Fibromyalgia.

Keywords
Fibromyalgia, core stability, acupuncture, balance, functional capacity

Received: 23 October 2018; accepted: 19 February 2020

Introduction

Balance impairment is a very frequent sign in persons with Fibromyalgia. It is considered one of the 10 most disabling symptoms with prevalence between 45% and 68%.[1] A study conducted by Jones et al.[1] showed how persons with Fibromyalgia had significant inferior scores on different balance aspects and had six times more falls when compared with healthy subjects. Besides, functional deficits have been identified in persons with Fibromyalgia in comparison with healthy subjects.[2] These deficits were related to factors such as physical activity levels including strength, aerobic endurance, static and dynamic balance, functional mobility and walking speed.[2] Functionality and balance impairments are closely related and have a significant impact in the quality of life of people with Fibromyalgia.[3]

Exercise is one of the treatment approaches where effectiveness in the management of Fibromyalgia is supported by stronger evidence.[4] Besides, recent reviews found that exercise has a positive effect on pain, physical function[5,6] and health-related quality of life[5] with no associated adverse effects. Among the different exercise modalities available, core stability training has shown its effectiveness by improving static and dynamic balance, functionality and risk of falls.[7,8] When core stability training interventions have been carried out with subjects with Fibromyalgia, improvements in pain, anxiety and quality of life have been achieved.[9,10]

Acupuncture has also been recommended for the management of Fibromyalgia.[11] While reviews provide positive evidence for efficacy in improving pain[12,13] and stiffness[12] in comparison to conventional treatment, no treatment or drug therapy, results obtained do not support the use of this therapy for physical function deficits. The benefits of acupuncture on balance impairments have been observed in subjects with conditions other than Fibromyalgia.[14,15]

The results available, therefore, suggest the potential of these treatment techniques in the rehabilitation of balance impairments in Fibromyalgia. However, no studies that analyse the effects of core stability training programmes or acupuncture therapy on balance of people with Fibromyalgia have been found in the literature.

Based on all this, the objective of this study was to assess the effectiveness of a core stability-based physiotherapy programme and acupuncture improving balance and functional capacity comparing both treatment approaches between them and with a control group.

Methods

This was a single-blind randomized controlled trial. The study took place within the University of Extremadura and the Fibromyalgia Associations from Badajoz and Olivenza in Extremadura (Spain) in an outpatient setting. The period of study was from September 2012 to October 2015. Ethical approval was received from the Bioethical Commission of the University of Extremadura in Spain (registration no.: 79/2013). The trial was retrospectively registered with the ClinicalTrials.gov registry (study identifier: NCT03638518). A written informed consent was signed by all the participants.

The target population was women diagnosed with Fibromyalgia from the mentioned Fibromyalgia Associations. Participants were recruited between January and December 2014. The inclusion criteria were women between the age of 18 and 71 years, diagnosed with Fibromyalgia by a specialized physician, having subjective sensation of balance impairments. The exclusion criteria were to present any medical contraindication for acupuncture and/or physiotherapy, phobia of needles, adverse reactions to medication that could influence balance, associated pathologies such as alcoholism or severe visual deficit, to have received acupuncture or core stability-based physiotherapy in two months prior to the intervention and to do physical exercises that train core stability such as pilates or yoga.

The sample consisted of 135 participants who were randomly allocated to a physiotherapy experimental group, an acupuncture experimental group or a control group (Figure 1). An independent researcher who was unrelated to any aspect of the trial was responsible for the randomization; 135 sealed envelopes containing the group names were introduced in an opaque bag. The independent researcher kept the bag closed at all times except for the moment when each participant took an envelope out. Then, he was in charge of opening the envelope. The allocation of each participant was concealed until assignment. After the baseline assessment, this individual informed the participants to which group she was allocated to. No one directly involved in the project had access to the randomization process or the list.

All participants attended three measurement sessions: one on entry into the study and prior to randomization (baseline – week 0), one after five weeks of treatment (postintervention – week 6) and one after a five-week follow-up period (follow-up – week 13). The University of Extremadura laboratories was the location where all measurement sessions took place. The assessor was a physiotherapist blinded to group allocation at all times. He was independent to the study and was not aware of the treatments applied or the objective of the therapy. Neither the participants nor their therapists were blind to the group assignment. Due to the nature of the treatment, they could clearly see which group the participant was allocated to.

A protocol was established to collect the data, and the following variables were measured:

- Epidemiological data: age, residence, education, working status/employment situation and concomitant treatment (medication);
- Primary outcome measures: Static balance, dynamic balance and functional mobility;
- Secondary outcome measures: Functional capacity.

The primary outcome measure of static balance was assessed through posturography with an optical sensor pressure platform (Wii-Fit Nintendo©). The participants stood with eyes opened on the platform, while their centre of gravity was calculated. Any deviation to the right or left was registered in percentage. Following this measurement, the participants stood up on one lower limb (one-leg stance test) during 30 seconds with eyes opened. The test was always performed with the same supporting foot. This test provided the balance stability values represented in percentage (0%–100%) where a higher value indicated a better balance.

In order to assess dynamic stability and functional mobility, the following tests were used:

Berg Balance Scale:[16,17] This scale was used to quantify the balance functional status and postural control. It assesses 14 items which are scored from 0 to 4 adding a maximum of 56 points. A better score indicates better balance and less risk of falls.

Timed up and go test:[18,19] This test measures dynamic balance and functional mobility. It measures the time that the person needs to stand up from a chair, walk 3 m, turn round, walk back and sit down again. The healthy subject is considered to perform the test in less than 10 seconds. If the person takes over 20 seconds, it indicates good balance and mobility and if it takes over 30 seconds shows that the person has deficiencies and the person is not independent or needs a mobility aid.

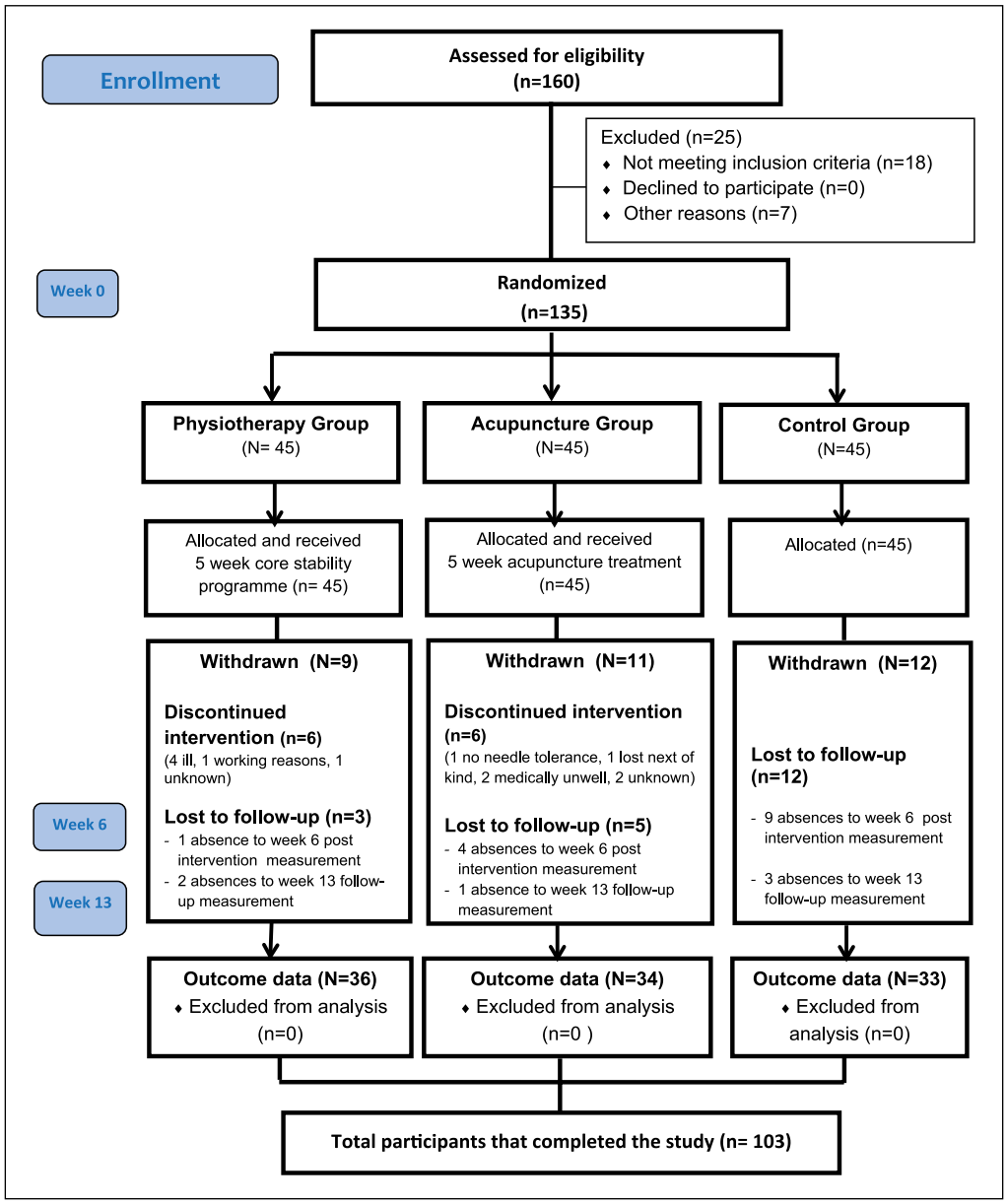

Figure 1. Flow diagram of study participation.

10-m walk test:[20] This test is a walking speed and performance assessment tool. These two characteristics are directly related to balance and risk of falls.[21] To complete the test, the participants must walk 10 m at a comfortable speed and at a maximum speed. The mean of the three trials completed at each speed was registered as the final value in metre/second. A higher value indicates better results.

The secondary outcome of functional capacity was measured with the Fibromyalgia Health

Assessment Questionnaire (FHAQ) and the physical function item from the Spanish Fibromyalgia Impact Questionnaire. The FHAQ[22] is a self-administered questionnaire composed by eight categories of functional activities with two or three specific activities each. The subject must indicate the difficulty found to perform these activities in the last week. The final score ranges from 0 to 3 where 0 indicates no functional impairment and 3 shows severe functional impairment.[23] The Spanish Fibromyalgia Impact Questionnaire[24] is an adaptation from the Fibromyalgia Impact questionnaire developed by Burckhardt et al.[25] in 1991. This questionnaire includes an item that specifically measures physical function (item 1). This item consists of 10 subitems and the score varies from 0 to 3. A higher score implies more functional impairment.

The data were also collected by the physiotherapist who conducted the treatment on adverse events for both experimental groups. In addition, reasons for missing outcome measurement or treatment sessions were also recorded.

Participants in both experimental groups were to receive two sessions of therapy per week with a total of 10 sessions. The control group did not receive any intervention. All participants continued with their routine medical treatment complying with the beneficence and non-maleficence principles of bioethics.

The physiotherapy experimental group received core stability-based physiotherapy treatment. The treatment was performed by a qualified physiotherapist member of the Spanish Chartered Society of Physiotherapists, trained in Kinetic Control® dynamic balance and sensorimotor system rehabilitation and the pilates method. She also had an extensive experience in core stability training applied in rehabilitation. The exercise programme was designed to be performed by adults independently mobile with or without mobility devices and considering the symptoms of Fibromyalgia.

Before the beginning of the treatment sessions, the basic principles of core stability exercises were explained to the participants. These involved transverse abdominis activation, correct alignment, breathing and correct positioning of the pelvis in neutral. The exercise programme included seven exercises performed in crook lying and side lying position on exercise mats. Cushions were used to allow the participants to be comfortable in all positions. The exercises in the crook lying position were core activation with breathing, single-leg lift with knees bent, single-leg slides, bridging and knee drop sideways. The exercises completed in side lying included hip external rotation with knees bent and hip abduction with knees straight. After each session, gentle stretching of the lower limbs and lumbar spine were performed. The sessions lasted 30 minutes and were administered in groups of no more than eight people. In all sessions, the physiotherapist guided the participants and reinforced the importance of the coordination of breathing and core activation. At all times during the intervention, the no pain rule was respected and fatigue was avoided.

In the acupuncture experimental group, the technique applied involved the use of the acupuncture points from Traditional Chinese Medicine. The point selection was based on their therapeutic effect and the Traditional Chinese Medicine interpretation of Fibromyalgia. This condition is caused by an alteration of the body's energy (*qi*) and blood (*xue*) movement that leads to their deficiencies and stasis mainly in the lower levels of the body.[26,27] This causes weakness, dizziness and balance impairments. As the Traditional Chinese Medicine aphorism says 'when the lower is insufficient, the high stumbles'. Therefore, the treatment approach must focus on the restoration of proper flow of these elements.[26,27]

The acupuncture points used were GV20 (*Baihui* 百会) which is located at the highest point in the head, in the mid-point of the line connecting the apexes of the two auricles. This point is considered as a connection of all the energy channels. GV20 is indicated to increase *qi* levels and for the treatment of balance impairments among other disorders; ST36 (*Zusanli* 足 三 里) which is found on the anterior aspect of the lower leg, 3 cun (width of a person's thumb at the level of the knuckle) below the inferior edge of the patella and 1 cun from the anterior crest of the tibia. This point harmonizes the energy and blood and has a *qi* toning and body strengthening effect. Therefore, it is indicated for

the treatment of disorders that present with fatigue and weakness. Its Chinese name refers to its ability to restore strength of the body and lower limbs allowing the person to walk for a very long distance; BL60 (*Kunlun* 昆仑) located on the foot, behind the external malleolus, in the depression between the tip of the external malleolus and the calcaneus tendon. This point facilitates the flow of the Traditional Chinese Medicine channels. It also regulates and tones the musculoskeletal system, especially the lumbar spine and the lower limbs.[28,29]

The acupuncturist explained to the participants the possible discomfort that they may experience when the needle was introduced. Besides, she described the *deQi* sensation and requested the participants to indicate when they felt it. They were informed about the secondary effects at the moment of signing the informed consent.

Patients laid supine on a treatment table with their legs exposed. The skin on the acupuncture points was prepared with 70% ethyl alcohol. All participants received five needle insertions in each session. One needle was inserted in GV20 point, while ST36 and BL60 insertions were done bilaterally. One-time-use disposable sterile stainless steel needles ($0.26 \times 50\,mm^2$) were inserted into acupuncture points. The needles used for GV20 were 0.5 cun long and those used for the rest of the points were 3 cun long. The depth of insertion was based on the recommendations for each point (normally between 8 and 30 mm)[28] and was also marked by reaching the *deQi* sensation by the participant. The *deQi* sensation is defined as the patient feeling an ache or heaviness in the area around the needle as well as the muscle twitch response that the acupuncturist can feel during the insertion of the needle. In order to obtain the *deQi*, the acupuncture needles were also manually manipulated with bidirectional rotational movements. The needles remained in place for 20 minutes and there were no further manipulations during the retention time. The techniques were administered by a qualified Traditional Chinese Medicine trained acupuncturist (ACMAS Superior School of Acupuncture of Seville and Beijing University 1997–2000) member of the Chartered Society of Physicians of Badajoz (Spain). The acupuncturist also had 22 years of experience and was professor in the University of Extremadura Acupuncture and Moxibustion Postgraduate Course.

The obtained data were analysed through the SPSS version 19.0 (statistical package for the social sciences). A descriptive analysis of the characteristics and the baseline measurements of the participants were performed. Their homogeneity was verified with an analysis of the variance (analysis of variance (ANOVA)) when the validity requirements allowed it or used the Kruskal–Wallis test when they did not (as in the case of the Berg Balance Scale and the one-leg stand test). A mixed model analysis was applied to compare the obtained values of the quantitative variables of the three study groups (physiotherapy, acupuncture and control) and at the three measurement times (baseline, final and follow-up). Statistical evaluation to study the relation between qualitative variables was performed through the Pearson chi-square tests and the Fisher exact test (used for the one-leg stand test). Furthermore, between-group differences at baseline, week 6 and week13 were calculated with a one-way ANOVA (F-test). Whether variances could be considered as equal or not equal was taken into account in the analysis. Finally, when the F-test was statistically significant, a multiple comparison analysis was carried out to explain the significance.

A value of $P < 0.05$ was considered for statistical significance for all tests. As the comparison was made between two groups, it was determined to complement the P-value with an absolute measure of the effect size (mean difference). This method was considered to be most appropriate to analyse the effect of the treatments applied.

No formal power calculation was carried out since the study relied upon the availability of the members of the Fibromyalgia Associations to participate. Based on the statistical guidelines[30] and the previous studies of our research group, it was anticipated that a minimum of 25 or 30 participants per group might be recruited and would be enough to justify the use of the statistical methods actually employed.

Results

Of the 160 women with Fibromyalgia assessed for eligibility to the trial over a 12-month period,

84.3% ($n=135$) were recruited and randomized. During the intervention and follow-up period, there were a total of 32 withdrawals. The corresponding data were excluded from the statistical analysis. Finally, 103 participants completed the study. A CONSORT flow diagram is given in Figure 1.

The baseline demographic and clinical characteristics for each group are shown in Table 1. There were no statistically significant between-group differences for the age of participants, the average time from diagnosis and the outcome measures.

Descriptive data for baseline, week 6 (postintervention) and week 13 (follow-up) measures (mean and standard deviation (SD)) are shown in Table 2.

Besides, the results of the one-way ANOVA carried out to analyse between-group differences at weeks 0, 6 and 13 can be seen in Table 3. When the *F*-test was significant, multiple comparisons were made to explain that significance.

The results regarding static balance indicated that neither the centre of gravity position nor the one-leg stance test was influenced by the intervention received in any of the groups. The data showed no statistically significant between-group differences in weeks 6 and 13. In relation to dynamic balance, the Berg Balance Scale and the timed up and go test experience statistically significant improvements after the intervention in the acupuncture and physiotherapy groups in weeks 6 and 13 in comparison with the control group. Moreover, both intervention groups obtained better scores in the 10-m walk test at comfortable speed after the treatments were completed (week 6). However, there were no significant differences between the three study groups in week 13. In contrast, the physiotherapy group showed statistically significant improvements in the 10-m walk at maximum speed at weeks 6 and 13, while the changes in the acupuncture group were not significant. Where the physical function is concerned, the results of the *F*-test showed no statistically significant between-group differences in weeks 6 and 13. Besides, it is important to highlight that no statistically significant differences between the acupuncture and the physiotherapy groups were found in any of the primary and secondary outcome measures.

Table 4 presents the data related to the mixed model analysis carried out to assess the changes experienced by each group along the study period in weeks 0, 6 and 13. As it can be appreciated by the data obtained, the control group showed no statistical significant differences between weeks 0, 6 and 13 in any of the outcome measures. Our results indicate significant improvements between weeks 0 and 6 in the Berg Balance Scale, timed up and go test and 10-m walk test at comfortable speed in the two intervention groups (acupuncture and physiotherapy). In the 10-m walk test at maximum speed, the physiotherapy group showed statistical significant improvements in week 6. The improvements were maintained at week 13 in both intervention groups for the timed up and go test and in the acupuncture group for the Berg Balance Scale.

The results related to the FHAQ and the physical function item of the Spanish version of the Fibromyalgia Impact Questionnaire (S-FIQ) indicated improvements from the descriptive analysis in relation to functional capacity in the acupuncture and physiotherapy groups after the treatments were completed. In contrast, the controls did not show any changes. However, the improvements found were not statistically significant as the analysis demonstrated.

In order to assess whether the sessions completed by the participants had influenced the results, a three-factor mixed model analysis was carried out. This analysis detected no significant differences in all outcome measures.

No adverse events occurred during the intervention in the acupuncture group. Only one woman from the physiotherapy group experienced knee pain exacerbation due to her arthritis and she had to rest during the last three sessions.

Discussion

The results of this study indicate that core stability-based physiotherapy and acupuncture improve dynamic balance and postural control in women with Fibromyalgia in comparison with the control group. Both intervention groups showed a slight improvement on functional capacity scores after the treatment as compared to the control group. Despite this, the changes in this outcome measure were not statistically significant.

Table 1. Baseline demographic and clinical characteristics of the participants.

Outcome measure	Group	*N*	Mean	Standard deviation	95% Confidence interval for the mean		Sig.
					Inferior limit	Superior limit	
Age (years)	Control	33	54.39	8.20	51.49	57.30	
	Physiotherapy	36	56.06	8.37	53.22	58.89	
	Acupuncture	34	56.15	7.90	53.39	58.90	
	Total	103	55.55	8.12	53.97	57.14	0.61
Years of diagnosis	Control	33	8.30	4.54	6.69	9.91	
	Physiotherapy	36	8.03	6.30	5.90	10.16	
	Acupuncture	34	8.59	5.18	6.78	10.39	
	Total	103	8.30	5.37	7.25	9.35	0.91
Centre of gravity position (%)	Control	33	53.36	2.83	52.36	54.37	
	Physiotherapy	36	54.58	4.34	53.12	56.05	
	Acupuncture	34	54.29	3.85	52.95	55.64	
	Total	103	54.10	3.75	53.37	54.83	0.38
One-leg stance test (%)	Control	33	61.48	16.97	55.47	67.50	
	Physiotherapy	36	65.69	17.29	59.85	71.54	
	Acupuncture	34	55.15	24.80	46.49	63.80	
	Total	103	60.86	20.28	56.90	64.83	0.09
Berg Balance Scale (0–56)	Control	33	42.64	5.75	40.60	44.67	
	Physiotherapy	36	41.06	11.43	37.19	44.92	
	Acupuncture	34	44.00	6.27	41.81	46.19	
	Total	103	42.53	8.33	40.91	44.16	0.34
Timed up and go test (seconds)	Control	33	11.85	2.35	11.02	12.68	
	Physiotherapy	36	12.72	5.71	10.79	14.65	
	Acupuncture	34	11.85	2.25	11.07	12.64	
	Total	103	12.16	3.84	11.41	12.90	0.55
10-m walk test at comfortable speed (m/s)	Control	33	0.71	0.14	0.66	0.76	
	Physiotherapy	36	0.70	0.14	0.65	0.75	
	Acupuncture	34	0.71	0.12	0.67	0.75	
	Total	103	0.70	0.14	0.68	0.73	0.92
10-m walk test at maximum speed (m/s)	Control	33	0.85	0.18	0.79	0.92	
	Physiotherapy	36	0.83	0.18	0.78	0.90	
	Acupuncture	34	0.86	0.17	0.80	0.92	
	Total	103	0.85	0.18	0.82	0.89	0.88
S-FIQ physical function item (0–10)	Control	33	4.20	1.81	3.55	4.84	
	Physiotherapy	36	4.37	1.97	3.70	5.04	
	Acupuncture	34	4.31	2.40	3.47	5.15	
	Total	103	4.29	2.05	3.89	4.70	0.94
Fibromyalgia Health Assessment Questionnaire (0–3)	Control	33	1.44	0.55	1.24	1.63	
	Physiotherapy	36	1.60	0.52	1.42	1.77	
	Acupuncture	34	1.33	0.46	1.17	1.49	
	Total	103	1.45	0.51	1.36	1.56	0.09

Sig.: Significance; S-FIQ: Spanish Fibromyalgia Impact Questionnaire.

Table 2. Outcome scores for each group at baseline (week 0), postintervention (week 6) and follow-up (week 13): mean and standard deviation.

Outcome measure	Group	*N*	Baseline (mean ± SD)	Week 6 (mean ± SD)	Week 13 (mean ± SD)
Centre of gravity position (%)	Control	33	53.36 ± 2.83	53.88 ± 3.14	53.76 ± 2.49
	Physiotherapy	36	54.58 ± 4.39	53.81 ± 2.53	53.69 ± 2.95
	Acupuncture	34	54.29 ± 3.85	53.38 ± 2.91	54.29 ± 3.10
One-leg stance test (%)	Control	33	61.48 ± 16.97	55.30 ± 20.69	60.06 ± 18.28
	Physiotherapy	36	65.69 ± 17.29	60.08 ± 21.19	64.22 ± 19.62
	Acupuncture	34	55.15 ± 24.80	62.29 ± 19.74	63.18 ± 20.59
Berg Balance Scale (0–56)	Control	33	42.64 ± 5.75	42.85 ± 7.74	42.73 ± 7.49
	Physiotherapy	36	41.06 ± 11.43	49.19 ± 9.14	47.28 ± 9.40
	Acupuncture	34	44.00 ± 6.27	49.47 ± 6.87	49.26 ± 5.44
Timed up and go test (seconds)	Control	33	11.85 ± 2.35	11.94 ± 2.40	11.97 ± 2.68
	Physiotherapy	36	12.72 ± 5.71	10.14 ± 2.54	10.56 ± 2.43
	Acupuncture	34	11.85 ± 2.25	9.85 ± 2.60	10.32 ± 1.82
10-m walk test at comfortable speed (m/s)	Control	33	0.71 ± 0.14	0.70 ± 0.13	0.68 ± 0.12
	Physiotherapy	36	0.70 ± 0.14	0.79 ± 0.16	0.74 ± 0.13
	Acupuncture	34	0.71 ± 0.12	0.79 ± 0.13	0.71 ± 0.11
10-m walk test at maximum speed (m/s)	Control	33	0.85 ± 0.18	0.82 ± 0.20	0.77 ± 0.14
	Physiotherapy	36	0.84 ± 0.18	0.93 ± 0.17	0.88 ± 0.18
	Acupuncture	34	0.86 ± 0.17	0.91 ± 0.17	0.83 ± 0.16
S-FIQ physical function item (0–10)	Control	33	4.20 ± 1.81	4.48 ± 2.07	4.48 ± 1.89
	Physiotherapy	36	4.37 ± 1.97	3.93 ± 1.86	4.33 ± 1.84
	Acupuncture	34	4.31 ± 2.40	3.72 ± 2.02	3.86 ± 2.20
Fibromyalgia Health Assessment Questionnaire (0–3)	Control	33	1.44 ± 0.55	1.42 ± 0.48	1.46 ± 0.42
	Physiotherapy	36	1.60 ± 0.52	1.47 ± 0.46	1.40 ± 0.41
	Acupuncture	34	1.33 ± 0.46	1.28 ± 0.48	1.29 ± 0.44

S-FIQ: Spanish Fibromyalgia Impact Questionnaire.

The initial values obtained in our study regarding the balance of the participants coincide with those obtained by Jones et al.,[1,31] Russek and Fulk,[32] and Rutledge et al.[33] as they also found that subjects with Fibromyalgia present balance deficits.

Static balance did not experience statistically significant improvements after both treatments were applied in comparison to the control group. Overall, concerning dynamic balance, both experimental groups achieved significant improvements vs. the control group. When comparing group differences, out of the four tests performed, the physiotherapy group showed statistically significant improvements in all the tests after the treatment. Whereas the acupuncture group achieved statistically significant improvements in three tests (Berg balance scale, timed up and go test and 10-m walk at comfortable speed). However, the differences between the acupuncture and the physiotherapy groups were not statistically significant.

No studies analysing the effects of acupuncture on the balance of subjects with Fibromyalgia were found in the literature. Nonetheless, our results coincide with those obtained by authors like Bergamaschi et al.,[34] Sautreuil et al.[14] and Liu et al.,[35] who studied this technique in other subjects and also obtained balance and postural control improvements.

Table 3. Between-group differences in weeks 0, 6 and 13: *P*-value when the *F*-test is not significant and mean difference (95% confidence interval (CI)) and *P*-value derived from multiple comparisons when the *F*-test is significant.

Outcome measure	Week	*F*-test		Multiple comparisons (only if *F*-test is significant)			
		F-test	*P*-value	Between-group differences (*N*)	Mean difference	95% CI for mean difference	*P*-value
Centre of gravity position (%)	0	0.98	0.38				
	6	0.30	0.74				
	13	0.46	0.64				
One-leg stance test (%)	0	2.46	0.09				
	6	1.01	0.37				
	13	0.42	0.66				
Berg Balance Scale (0–56)	0	1.1	0.4				
	6	7.37	**0.00**	ACP(34)–PT(36)	0.27	–4.34 to 4.90	0.99
				ACP(34)–C(33)	6.62	1.97 to 11.27	**0.00**
				PT(36)–C(33)	6.35	1.76 to 10.93	**0.00**
	13	6.41	**0.00**	ACP(34)–PT(36)	1.99	–2.4 to 6.37	0.52
				ACP(34)–C(33)	6.54	2.09 to 10.99	**0.00**
				PT(36)–C(33)	4.55	0.16 to 8.94	**0.04**
Timed up and go test (seconds)	0	0.60	0.55				
	6	6.78	**0.00**	ACP(34)–PT(36)	–0.29	–1.72 to 1.14	0.88
				ACP(34)–C(33)	–2.09	–3.55 to –0.62	**0.00**
				PT(36)–C(33)	–1.80	–3.24 to –0.36	**0.01**
	13	4.88	**0.01**	ACP(34)–PT(36)	–0.23	–1.56 to 1.10	0.91
				ACP(34)–C(33)	–1.65	–3.00 to –0.29	**0.01**
				PT(36)–C(33)	–1.41	–2.75 to –0.08	**0.04**

(Continued)

Table 3. (Continued)

Outcome measure	Week	*F*-test		Multiple comparisons (only if *F*-test is significant)			
		F-test	*P*-value	Between-group differences (*N*)	Mean difference	95% CI for mean difference	*P*-value
10-m walk test at comfortable speed (m/s)	0	0.09	0.92				
	6	4.66	**0.01**	ACP(34)–PT(36)	0.03	–0.08 to 0.83	0.99
				ACP(34)–C(33)	0.09	0.02 to 0.17	**0.02**
				PT(36)–C(33)	0.09	0.01 to 0.17	**0.03**
	13	2.43	0.09				
10-m walk test at maximum speed (m/s)	0	0.13	0.88				
	6	3.65	**0.03**	ACP(34)–PT(36)	–0.02	–0.13 to 0.08	0.84
				ACP(34)–C(33)	0.09	–0.02 to 0.19	0.12
				PT(36)–C(33)	0.11	0.01 to 0.22	**0.03**
	13	3.93	**0.02**	ACP(34)–PT(36)	–0.05	–0.14 to 0.04	0.44
				ACP(34)–C(33)	0.06	–0.03 to 0.15	0.27
				PT(36)–C(33)	0.11	0.02 to 0.20	**0.02**
S-FIQ physical function item (0–10)	0	0.60	0.94				
	6	1.32	0.27				
	13	0.89	0.42				
Fibromyalgia Health Assessment Questionnaire (0–3)	0	2.43	0.09				
	6	1.43	0.25				
	13	1.48	0.23				

CI: confidence interval; S-FIQ: Spanish Fibromyalgia Impact Questionnaire; C: control; PT: physiotherapy; ACP: acupuncture.
Bold values signifies the statistical significance.

Table 4. Changes between 0 and 6 weeks, 6 and 13 weeks, and 0 and 13 weeks for each group: 95% CI for the mean difference and *P*-value (derived from the mixed model analysis).

Outcome measure	Group	*N*	0–6 weeks: 95% CI for mean difference/*P*-value		6–13 weeks: 95% CI for mean difference/*P*-value		0–13 weeks: 95% CI for mean difference/*P*-value	
Centre of gravity position (%)	Control	33	–0.52 ± 1.47	0.49	0.12 ± 1.39	0.86	–0.39 ± 1.31	0.55
	Physiotherapy	36	0.78 ± 1.67	0.36	0.11 ± 1.29	0.86	0.89 ± 1.75	0.31
	Acupuncture	34	0.91 ± 1.67	0.28	–0.91 ± 1.46	0.27	0.00 ± 1.69	0.99
One-leg stance test (%)	Control	33	6.18 ± 9.31	0.19	–4.76 ± 9.60	0.33	1.42 ± 8.68	0.74
	Physiotherapy	36	5.61 ± 9.10	0.22	–4.14 ± 9.60	0.39	1.47 ± 8.69	0.74
	Acupuncture	34	–7.15 ± 10.86	0.19	–0.88 ± 9.77	0.86	–8.03 ± 11.04	0.15
Berg Balance Scale (0–56)	Control	33	–0.21 ± 3.36	0.90	–0.12 ± 3.75	0.95	–0.09 ± 3.29	0.96
	Physiotherapy	36	–0.10 ± 0.08	**0.02**	0.06 ± 0.08	0.16	–0.04 ± 0.09	0.37
	Acupuncture	34	–5.47 ± 3.19	**0.00**	0.21 ± 3.00	0.89	–5.27 ± 2.84	**0.00**
Timed up and go test (seconds)	Control	33	–0.91 ± 1.17	0.87	–0.03 ± 1.25	0.96	–0.12 ± 1.24	0.85
	Physiotherapy	36	2.58 ± 2.09	**0.02**	–0.42 ± 1.17	0.48	2.17 ± 2.08	**0.04**
	Acupuncture	34	2.00 ± 1.18	**0.00**	–0.47 ± 1.09	0.39	1.53 ± 0.99	**0.00**
10-m walk test at comfortable speed (m/s)	Control	33	0.01 ± 0.07	0.67	0.02 ± 0.06	0.55	0.03 ± 0.06	0.33
	Physiotherapy	36	–0.09 ± 0.07	**0.02**	0.04 ± 0.07	0.21	–0.04 ± 0.06	0.19
	Acupuncture	34	–0.79 ± 0.06	**0.01**	0.08 ± 0.06	**0.01**	–0.00 ± 0.06	0.96
10-m walk test at maximum speed (m/s)	Control	33	–0.03 ± 0.09	0.56	0.06 ± 0.09	0.21	0.082 ± 0.081	0.047
	Physiotherapy	36	–0.10 ± 0.08	**0.02**	0.06 ± 0.08	0.16	–0.04 ± 0.08	0.37
	Acupuncture	34	–0.05 ± 0.08	0.22	0.082 ± 0.08	**0.04**	0.03 ± 0.08	0.44
S-FIQ physical function item (0–10)	Control	33	–0.29 ± 0.96	0.55	0.01 ± 0.98	0.99	–0.28 ± 0.92	0.54
	Physiotherapy	36	0.44 ± 0.90	0.34	0.40 ± 0.87	0.37	0.04 ± 0.90	0.93
	Acupuncture	34	0.59 ± 1.07	0.28	–0.13 ± 1.02	0.80	0.45 ± 1.11	0.42
Fibromyalgia Health Assessment Questionnaire (0–3)	Control	33	0.02 ± 0.25	0.90	–0.04 ± 0.22	0.70	–0.03 ± 0.24	0.82
	Physiotherapy	36	0.13 ± 0.23	0.26	0.06 ± 0.21	0.54	0.20 ± 0.22	0.08
	Acupuncture	34	0.05 ± 0.23	0.67	–0.07 ± 0.16	0.95	0.04 ± 0.22	0.71

CI: confidence interval; S-FIQ: Spanish Fibromyalgia Impact Questionnaire.

In the study conducted by Liu et al.,[35] manipulation was applied to the needles after insertion in order to achieve *deQi* sensation. The intervention group showed an immediate improvement of balance in subjects who had a stroke. In contrast, the control group did not receive the needle manipulation and did not achieve any positive changes. The positive results obtained by these authors and in our study can be explained by the presence of *deQi* sensation during the puncture. This is based on the fact that this sensation has been clinically related to the effectiveness of the acupuncture.[36,37]

In addition, the use of the GV20 and BL60 acupuncture points may have influenced the improvements obtained in dynamic balance. We consider that this may be due to the toning and strengthening effect of the energy's body and the spine and lower limbs.[28,29] We coincide with Bergamaschi et al.[34] and Liu et al.[35] as they also used these points in their interventions.

Moreover, the results obtained by Sautreuil et al.[14] in subjects with multiple sclerosis coincide with our results. However, their treatment was individualized which differs from the methodology employed in the present study. Even though, according to the Traditional Chinese Medicine, individualized treatment would be the most appropriate,[13] in our study, specific points were selected and applied to all participants to meet the methodological quality requirements of clinical trials.[38]

In contrast, our study differs from those authors[14,34,35] in relation to the length of intervention. They carried out a follow-up measure after a very short time, which indicates short-term

improvements. Unlike these studies, ours achieved positive changes in balance which were maintained after five weeks of follow-up.

Regarding the physiotherapy treatment, although there are limited studies that analyse the effects of this approach on balance of subjects with Fibromyalgia, the most studied technique is physical exercise. Among this modality, balance exercises have shown positive effects in studies such as those from Demir-Göçmen et al.,[39] Gusi et al.,[40] Adsuar et al.,[41] Sañudo et al.[42] or Kibar et al.[43] However, no studies that conduct core stability exercise programmes in person with Fibromyalgia and analyse the effects on balance were found in the literature.

Our results can be contrasted with those obtained in studies that analysed the effects of core stability training in other subjects. In relation to the studies conducted in healthy adults, Cruz-Ferreira et al.[7] concluded in their systematic review that this type of exercise improved balance with a high level of evidence.

The authors that conducted their intervention with older adults[44–48] found improvements in static and dynamic balance[44–46] as well as in the risk of falling.[45] Besides, Guclu-Gunduz et al.[49] and Freeman et al.[50] obtained positive results after a core stability programme with person with multiple sclerosis. All these studies coincide with our findings in relation to the improvement of dynamic balance found in the physiotherapy group. We consider that this improvement could be based on the positive effects of the exercises on the core and trunk stability. In order to have an optimal postural control and balance, a correct alignment of the spine and head in relation to the gravity and the base of support is needed.[51]

The exercise programme applied in our intervention was designed to activate core muscles including local and global stabilizers of the spine. Scientific evidence has demonstrated that all these muscles play an essential role in stabilizing the spine and the pelvis and therefore improving their alignment.[52,53] In addition, local stabilizers, in particular, transverse abdominis, activate 30 milliseconds before shoulder movements and 110 milliseconds before lower limb movements to stabilize the spine and the pelvis.[54] This means providing proximal stability to allow better distal mobility of the upper and lower limbs[55] and therefore improving balance while functional movements are performed.

Our sample size was larger than in most of the studies that applied a core stability-based intervention[44–48] and therefore more representatives. However, the intervention period was superior in most of the other studies,[45,47–50] being between 8 and 12 weeks.

Regarding functional capacity, the studies found in the literature do not show scientific evidence that support acupuncture as a treatment that has a positive effect on this variable.[12,13,56,57] In contrast, our findings revealed that functional capacity improved after the treatment was completed, although it did not show statistical significance. Core stability exercise effects on functionality of women with Fibromyalgia have been studied by Altan et al..[10] Their programme consisted of three sessions a week during 12 weeks which was considerably longer than ours. A significant improvement on functional capacity was observed in the intervention group compared with the control group which differs slightly from our results. However, the limited studies available in the literature make it difficult to contrast results in a very comprehensive manner.

There are some limitations to this study. A treatment period of five weeks was established in order to allow the groups to be treated equally. This is the length of time needed to complete an acupuncture treatment cycle and also respects the minimum recommended for Fibromyalgia exercise programmes.[58] We consider that five weeks could have been insufficient to show significant changes in some of the measurements in the physiotherapy group as the patients usually take three to four sessions to familiarize with the principles of core stability exercises. This limitation was minimized with the guidance and close supervision of the physiotherapist during the sessions. Also, if the period of intervention was longer there was higher risk of absence and decrease in the adherence to the treatment. Finally, the total losses were 32 out of 135, a number that indicates a 23.7%. This figure is similar to the previous studies conducted with the same population in our region by Mejías Gil[59] and

inferior than the study carried out by Triviño Palomo.[60] Another limitation of this study was the great variability of symptoms and mood of the subjects with Fibromyalgia due to the characteristics of the condition. All the symptoms, in particular pain, could be influenced by unusual efforts, lack of sleep and stress[61] which can happen anytime. This could have had a negative impact on the results, not showing all the benefits that the treatments could provide to the participants.

The results of this study can have important implications in the clinical practice of the rehabilitation field. Our data show that a core stability-based physiotherapy programme and acupuncture improve dynamic balance in women with Fibromyalgia. They are two techniques that are increasingly used by practitioners these days, have a low cost and can be performed safely with the appropriate training. Fibromyalgia balance and functionality impairments have an important negative impact in the quality of life of the person and it involves high sanitary expenditure.[1,3] These consequences could be minimized with the use of the treatment approaches described in this study.

In any future research, we would recommend that core stability training and acupuncture was combined to assess whether better improvements in balance and functionality can be achieved. We would suggest increasing the treatment and follow-up periods as well as adding a monitoring method. This could enhance adherence to the treatment and reduce the rate of drop-outs leading to achieve more favourable results.

Clinical messages

- Acupuncture and core stability-based physiotherapy significantly improve dynamic balance in women with Fibromyalgia.
- There was no indication based on our results that supports which treatment approach is more effective (acupuncture or core stability-based physiotherapy) in the treatment of balance deficits.

Acknowledgements

We gratefully acknowledge the contribution and the collaboration of the Fibromyalgia Association from the city of Badajoz and Olivenza.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship and/or publication of this article.

ORCID iDs

Elisa María Garrido-Ardila https://orcid.org/0000-0002-4403-3029
Juan Rodríguez-Mansilla https://orcid.org/0000-0003-1734-1496

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