Strengthening exercises using swiss ball improve pain, health status, quality of life and muscle strength in patients with fibromyalgia: a randomized controlled trial

J. S. Arakaki, F. Jennings, G. Q. Estrela, V. d.G. Cruz Martinelli, J. Natour

Universidade Federal de São Paulo - UNIFESP, São Paulo, Brazil

SUMMARY

The aim was to evaluate the effectiveness of strengthening exercises using the Swiss ball in patients with fibromyalgia through a randomized controlled trial with intention to treat analyses.

A total of 60 patients with fibromyalgia met the inclusion criteria and were randomly allocated to either the Swiss ball exercise group (n=30) or a stretching group (n=30).

All patients participated in 40-minute training sessions 3 times per week for 12 weeks.

Pain (Visual Analogue Scale 0-100); muscle strength (One Repetition Maximum test); health status (Fibromyalgia Impact Questionnaire Revised); quality of life (Short Form-36 questionnaire) were evaluated at baseline, and after 6 and 12 weeks of training.

The Swiss ball group showed a statistically significant improvement in VAS (0-100) (p<0.001), SF-36 (p<0.05) and Fibromyalgia Impact Questionnaire (p<0.001) compared with the stretching group.

The results of this study proved that the treatment for fibromyalgia with strengthening exercises and the use of the Swiss ball led to improvement of pain, quality of life, muscle strength and decreased the need for medications for this disease compared to stretching exercises, without negative effects.

Key words: Swiss ball; strengthening exercise; stretching exercise, non pharmacological therapy

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■ INTRODUCTION

Fibromyalgia is a syndrome (FBS) characterized by chronic widespread pain, sleep disturbance, fatigue, reduction in overall physical fitness, and other symptoms that cause impairment of quality of life (1). Its treatment is a clinical challenge, since no specific effective therapeutic strategy is available yet. Consequently, a multidisciplinary treatment plan consisting of medications, psychosocial therapy and physical activity is recommended (2).

Physical exercises have been recommended to improve the symptoms of the disease, especially muscle pain and fatigue (3). A review study showed that stretching exercises compared with resistance training are beneficial to patients with FMS. Muscle stretching exercises proved to be the most effective method to improve quality of life, especially with regard to physical functioning and pain, whereas resistance exercises were more effective in reducing depression (4).

The Swiss ball is used in musculoskeletal rehabilitation and physical conditioning programs. Muscle strengthening performed with the aid of this ball can improve joint and muscle stability, and proprioception (5). It can increase muscle strength, endurance, flexibility, and coordination and be used to improve the perceptual balancing ability. Trunk stabilization exercises with a Swiss ball can also improve core muscle activation and physical functions as well as enhance balance (6). However, there are no studies in the literature, which examined the effects of muscle strengthening in patients with FMS.

The purpose of this study was to evaluate the effectiveness of muscle strengthening using the Swiss ball in improving

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Corresponding author: Josiander Spolidoro Arakaki Universidade Federal de São Paulo – UNIFESP Rua Padre Lamberto Martin, 26 Jardim Pinheiros CEP: 05596-140, São, Brazil E-mail: josiand@hotmail.com

	Lateral rise - sitting on the ball, abduct of the upper limb against resistance. Main muscles involved: medial and anterior deltoid
	Triceps - sitting on the ball, hold the dumbbell with both hands, raise your arms so they are perpendicular to the ground, then flex and extend the forearms. Main mus- cles involved: triceps, deltoid.
	Squat - standing position, with the support of the ball in the lumbar area, squat with weights in hands. Main mus- cles involved: quadriceps, hamstrings, gluteus maximus and middle rectus abdominis and latissimus dorsi.
À	Abdominal - supine on the ball, with a load on the pec- toral region and lumbar spine on the ball, flex the trunk. Main muscles involved: rectus abdominis, external and internal oblique, gluteus.
	Biceps - sitting on the ball holding the dumbbell perform flexion and extension of the elbow against resistance. Main muscles involved: biceps, radial brachiobasilic.
	Unilateral row - standing position, with one leg flexed supporting the knee on the ball and the other extended. Supporting one hand on the ball and the other holding a dumbbell, perform the elbow flexion and extension movement. Main muscles involved: major round, minor round, rhomboid and anterior serratus.
	Reverse crucifix - prone on the ball, kneeling on a pillow, extend arms completely. Main muscles involved: poste- rior deltoid, teres major, teres minor, trapezius
R	Crucifix - supine on the ball, with thoracic and lumbar spine on the ball, abduct the upper limbs. Main muscles involved: pectoralis major, long head of the biceps.

Figure 1 - Strengthening exercise using the Swiss ball for patients with fibromyalgia.

pain, health related quality of life, muscle strength and overall quality of life in patients with FMS.

MATERIALS AND METHODS

This study was based on a parallel group randomised controlled design. Patients were screened for participation in the study from January 2009 to July 2021. The study was approved by the Federal University of São Paulo and all participants read and signed the Free and Informed Consent Form. The trial was registered on Clinical-Trials.gov (NCT02063750) and this manuscript was prepared according to the CON-SORT statement.

After medical consultation at the university clinic and confirmation of the diagnosis of FMS, patients were referred for study selection. Consecutive patients aged 20 to 65, seen at our outpatient clinic who met the ACR 90 criteria, were included in the study, Patients were randomized based on a 1:1 ratio by a blinded investigator into two groups (7). Opaque envelopes with patient numbers were used to keep the allocation confidential. The allocation was revealed to the physical therapist responsible for the treatment after the initial assessment. All evaluations were carried out by a blind investigator, who was unaware of the study. The inclusion criteria were as follows: women with FMS and physically able to perform physical exercises. Exclusion criteria were uncontrolled hypertension, decompensated cardiac disease, history of syncope or exercise-induced arrhythmias and decompensated diabetes, severe psychiatric illness (uncontrolled depression and anxiety, personality disorders, cognitive disorders such as dementia and substance abuse), history of regular exercise at least twice a week for the last 6 months and any other condition that could prevent the patient from performing physical exercises.

The Swiss ball group performed eight muscle strengthening exercises using a Swiss ball with a 65 cm-diameter (Oneal Gym Ball, Taiwan), an antiburst quality brand, gray color, and dumbbells with different loads. Each training session lasted 40

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minutes and was performed three times a week for 12 weeks. The exercises were performed in three sets of 12 repetitions, with a recovery interval of one to two minutes between the exercises, which alternated between upper limbs, lower limbs and abdomen. The load used was 60% of one repetition maximum (Figure 1).

The stretching group performed stretching exercises that targeted the same muscles trained in the Swiss ball group in the same rehabilitation center and was supervised by a physical trainer. The participants remained in the stretching position for three sets of 30 seconds for each exercise. The total session lasted 40 minutes. All patients in the stretching group performed the stretching exercises three times a week for a period of twelve weeks.

All patients underwent a baseline medical evaluation to confirm the diagnosis of FMS and ensure that all inclusion/exclusion criteria were/were not met. An assessment was performed immediately before the random allocation to the group (T0), after six weeks (T6) and after 12 weeks (T12) by an investigator who was unaware of the group allocation. The investigator was a physiotherapist with experience in the outcomes measured.

The primary outcome was pain assessed by the Visual Analogue Scale, whereby patients have to indicate the pain intensity by assigning scores from 0 cm to 100 cm (8). The secondary outcomes were the healthrelated quality of life assessed using the FIQr that globally assesses the main complaints (pain, fatigue, stiffness, sleep, memory, anxiety, depression, tenderness, and balance) and physical fitness in FMS (9). To measure muscle strength, the One Maximum Repetition test was used. This test measures the maximum muscle strength (maximum load) of a single motion. The evaluation was performed for each exercise included in the program, using dumbbells. In addition, the load settings for patients in the Swiss ball group were evaluated using the One Maximum Repetition test with the goal to increase intensity (10).

The overall quality of life was assessed using the SF-36 questionnaire. This question-



Figure 2 - Flowchart of selection and randomization of patients with fibromyalgia included in the study.

naire consists of eight domains: physical functioning, physical aspect, bodily pain, general health perceptions, vitality, social functioning, and emotional role (11).

As regards analgesics consumption during the study, patients were instructed to use oral paracetamol 500 mg up to four times a day, in case of pain worsening. Daily consumption was reported in a separate worksheet and collected at the end of the program.

The sample size was calculated using the outcome variable Visual Analogue Scale for pain with a 0.05 significance level and a power of 90%. Based on previous studies, we considered the Visual Analogue Scale standard deviation to be equal to 2 and sig-

Table I - Clinical and demographic characteristics of patients.

Variable mean (SD±)	Swiss ball group n = 30	Stretching group n = 30	р
Skin color - white:non white (n)	20:10	18:12	0.592#
Age in years - mean SD±	47.4 (9.0)	47.3 (8.7)	0.954§
Marital status (n)			
Single	5	4	
Married	21	21	0.116#
Divorced	4	1	
Others	0	4	
Education in years - mean SD±	8.7 (4.0)	8.0 (3.4)	0.659
Disease duration in years - mean SD±	8.9 (6.3)	9.3 (8.5)	0.795
Weight in kg - mean SD±	73.64 (14.8)	71.1 (10.7)	0.442
BMI - mean SD±	28.56 (5.73)	28.02 (3.88)	1.000
Other diseases - n (%)			
Hypertension	12 (40%)	9 (30%)	0.417#
Dyslipidemia	1 (3.3%)	2 (6.7%)	1.000*
Hyperthyroidism	0 (0%)	1 (0.3%)	0.230#
Depression	0 (0%)	2 (0.6%)	0.230#
Medication - n (%)			
Tricyclic antidepressant	10 (33.3%)	4 (13.3%)	0.125#
Antidepressant - Amitriptyline	8 (26.7%)	11 (36.7%)	0.402#
Cyclobenzaprine	2 (6.7%)	8 (26.7%)	0.080#
Physical activity – n (%)	6 (20%)	1 (36.6%)	0.329#

SD±, standard deviation; BMI, body mass index; *x2 test; Mann-Whitney test; [§]t-Student test; *Fisher's exact test.

Table II - Pain evaluation (VAS), health status (FIQr) and analgesics use (paracetamol 500 mg) in the two groups.

Variable mean SD±	Swiss ball group n = 30	Stretching group n = 30	p intergroup	
VAS				
ТО	75 (26)	72 (20)	0.717	
Т6	50 (28)ª	65 (22)	0.022	
T12	33 (32) ^{ab}	53 (26)ª	0.010	
p intragroup	p<0.001	p=0.019		
FlQr				
ТО	6.72 (1.89)	7.13 (1.25)	0.326	
Т6	4.50 (2.55) ^a	6.36 (1.57)	0.001	
T12	3.68 (2.69) ^{ab}	5.39 (2.01) ^{ab}	0.007	
p intragroup	p<0.001	p=0.001		
Analgesics capsules				
Т6	13.3 (20.7)	13.0 (21.9)		
T12	7.7 (9.2)	11.0 (22.8)		

a = p<0.05 compared to T0; b = p<0.05 compared to T6; Test t-student P* Mann Whiney 0.747.

nificant differences between the means of groups to be equal to 2.0 cm (2, 10). The calculation was based on comparisons of two samples using MINITAB 14.0 software.

Statistical analyses were performed using SPSS software version 17.0 (Chicago, IL, USA). The chi-square test and Fisher's exact test were used to evaluate the homogeneity of the sample in the baseline for categorical variables. The t-student test for independent samples was used for normally distributed, quantitative variables, and the Mann-Whitney test was used for nonnormally distributed quantitative variables. To compare the study groups over time, a repeated ANOVA measurement was performed.

RESULTS

Two hundred and thirteen patients were eligible to participate in the study. However, 153 were not included, mainly because they were unable to travel twice a week to the rehabilitation center for 3 months due to time constraints or they did not meet the inclusion criteria, or for personal problems. In the end, only 60 patients were included in the program (Figure 2). At baseline, both groups were homogeneous for their clinical and demographic characteristics (Table I). In the Visual Analogue Scale assessment of pain and health-related quality of life by Fibromyalgia Impact Questionnaire, both groups improved compared to baseline. The Swiss ball group had a significantly better improvement in pain and in Fibromyalgia Impact Questionnaire scores compared with the stretching group at T6 and T12. The use of analgesics (acetaminophen 500 mg) in both groups decreased during the program (Table II). The overall quality of life evaluated by SF 36 improved in both groups, with statistically significant differences between them. However, in the domains of physical aspects, pain, vitality and emotional aspects, the initial assessment had different scores as there was a higher score in the group that performed strength exercises with the help of the Swiss ball (Table III).

Both groups managed to increase loads in all exercises. The improvement in muscle strength in the Swiss ball group was statistically better than in the stretching group (Table IV).

Two patients of the Swiss ball group left the study due to family problems and moving to a different city, and four patients in the stretching group gave up the program because of family problems and kinship deaths. No adverse effects related to the exercises were reported by the patients.

DISCUSSION AND CONCLUSIONS

There is evidence that physical exercise is an effective instrument for improving physical fitness, health and quality of life and offers beneficial effects in terms of symptoms improvement in patients with FMS (4, 11, 12). Exercises for FMS consisted in a program of physical exercises for voluntary muscular contraction which has the potential of relieving symptoms, improving function, improving or preventing deformities (13). The results of our study suggested a positive effect of physical exercise, with the group on the exercise programme with the Swiss ball showing a statistical improvement for pain. Swiss ball strengthening can improve strength, endurance, flexibility, coordination, balance, and therefore improve the performance of activities of daily living. This Swiss ball exercise program also improved poor balance, which can be present in patients with FMS (14).

Both groups had a similar history of physical exercise, as they were not practicing any type of activity three months before the program. A minority of patients reported having practiced walking or some other type of physical activity, but still had no experience with muscle strengthening exercises. Most women with FMS are sedentary and the negative impact that the disease has on their body probably explains the lack of past experiences with exercise. Like in other studies on strength training with women affected by FMS, the average body mass index of the patients was 28 for

Table III - Assessment of general quality of life by SF-36 (Short Form HealthSurvey) at different times of assessment.

Domains SF-36	Swiss ball group	Stretching group	p intergroup		
Functional Capacity		1	1		
TO	29.2 (27.0)	32.2 (15.5)	0.607		
T6	51.2 (23.6) ^a	40.0 (18.8) ^a	0.47		
T12	58.3 (25.8) ^a	45.5 (18.6) ^a	0.32		
p intragroup	p<0.001	p=0.001			
Physical role					
ТО	25.5 (33.7)	8.3 (21.1)	0.001		
Т6	44.0 (38.6) ^a	17.5 (29.5)ª	0.001		
T12	53.0 (39.9)ª	25.8 (40.2)ª	0.001		
p intragroup	p<0.001	p<0.001			
Pain					
ТО	31.0 (20.7)	23.9 (13.7)	0.04		
Т6	40.7 (23.1) ^a	29.5 (18.0)ª	0.04		
T12	45.1 (25.7) ^a	38.0 (19.5)ª	0.04		
p intragroup	p<0.001	p<0.001			
General health status	5				
ТО	44.3 (23.1)	39.9 (25.8)	0.635		
T6	52.1 (28.9)ª	51.2 (26.6)ª	0.635		
T12	58.8 (27.2) ^{ab}	56.1 (27.0) ^{ab}	0.635		
p intragroup	p<0.001	p<0.001			
Vitality					
ТО	39.4 (19.6)	30.0 (17.0)	0.018		
T6	50.2 (25.3)ª	38.5 (18.7)ª	0.018		
T12	57.3 (22.1) ^{ab}	47.3 (20.5) ^{ab}	0.018		
p intragroup	p <0.001	p<0.001			
Social role					
ТО	47.3 (28.2)	40.4 (25.6)	0.197		
Т6	61.4 (32.5)ª	50.4 (26.6) ^a	0.197		
T12	65.0 (29.2)ª	58.8 (27.1)ª	0.197		
p intragroup	p<0.001	p<0.001			
Emotional aspects					
ТО	43.3 (43.1)	15.6 (30.0)	0.001		
Т6	53.9 (43.8)	19.9 (31.9)	0.001		
T12	58.1 (44.1) ^a	39.9 (47.3) ^a	0.001		
p intragroup	p=0.019	p=0.019			
Mental health					
ТО	39.9 (27.8)	40.4 (16.6)	0.668		
Т6	52.3 (32.3)ª	44.5 (18.3)ª	0.668		
T12	55.1 (30.4)ª	55.2 (23.6)ª	0.668		
p intragroup	p<0.001	p<0.001			

a = p<0.05 compared to T0; b = p<0.05 compared to T6.

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Exercise weight kg mean SD±	Swiss ball Group	Stretching Group	p Intergroup
LATERAL RISE		•	
ТО	2.1 (1.4)	1.7 (1.2)	0.252
Т6	3.2 (1.3)	2.0 (1.2)	0.000
T12	3.8 (1.4) ^{ab}	2.5 (1.2) ^{ab}	0.000
p intragroup	p<0.001	p=0.002	
OVERHEAD TRICEP EXTENS	SION		
ТО	3.6 (2.4)	3.0 (2.2)	0.287
Т6	5.8 (2.3) ^a	3.6 (2.1)	0.000
T12	7.0 (2.8) ^{ab}	4.6 (2.5) ^{ab}	0.001
p intragroup	p<0.001	p=0.002	
SQUAT		` `	
ТО	5.4 (2.6)	5.0 (2.9)	0.157
Т6	8.5 (3.0)ª	6.1 (2.9)ª	0.003
T12	11.3 (4.0) ^{ab}	7.5 (4.2)ª	0.001
p intragroup	p<0.001	p=0.003	
ABDOMINAL			. ?
ТО	7.8 (5.8)	7.0 (5.3)	0.594
Т6	13.8 (7.7)ª	9.3 (6.5)	0.016
T12	19.6 (10.8) ^{ab}	12.5 (7.1) ^{ab}	0.004
p intragroup	p<0.001	p<0.001	
SIMULTANEOUS BICEPS CU	IRL		
ТО	3.5 (1.8)	2.8 (1.8)	0.005
Т6	4.7 (1.6) ^a	3.4 (1.8) ^a	0.005
T12	5.8 (2.1) ^{ab}	4.2 (1.8) ^{ab}	0.005
p intragroup	p<0.001	p<0.001	
ONE-ARM DUMBELL ROW			
ТО	5.8 (3.3)	4.7 (3.2)	0.207
Т6	9.1 (3.4) ^a	6.3 (3.9) ^a	0.004
T12	12.1 (4.6) ^{ab}	8.0 (4.5) ^{ab}	0.001
p intragroup	p<0.001	p<0.001	
REVERSE CRUCIFIX			
ТО	2.2 (1.2)	1.7 (0.8)	0.092
Т6	3.2 (1.1)ª	1.9 (1.0)	0.000
T12	3.8 (1.3) ^{ab}	2.3 (1.0) ^{ab}	0.000
p intragroup	p<0.001	p=0.010	
CRUCIFIX			
ТО	2.4 (1.4)	1.8 (1.1)	0.057
Т6	3.6 (1.2)ª	2.3 (1.3) ^a	0.000
T12	4.2 (1.6) ^{ab}	2.8 (1.5) ^{ab}	0.001
p intragroup	p<0.001	p=0.003	

 Table IV - Evaluation of muscle strength through maximal repetition of 1 RM of both groups over time.

a = p<0.05 compared to T0; b = p<0.05; test ANOVA.

both groups. This high value is probably due to their sedentary life style (15).

In this study, a statistical decrease in pain was seen over time in the group practising Swiss ball strengthening exercises. This is consistent with the results reported by Valkeinen et al. (16), who also showed improvement in pain in the group that performed strengthening exercises. However, Valkeinen et al. (16) did not find any difference between the group that underwent strengthening exercises and controls, probably because the two groups were not homogeneous in the initial assessment of pain. Similarly, Jones et al. (17) showed that the group on strengthening exercises improved the pain scores, but without difference compared to the control group that performed flexibility exercises. The present study demonstrated a statistical improvement in pain in the intervention group that performed the strength exercise with the aid of the Swiss ball compared to the controls, demonstrating a better effectiveness of the muscle strengthening programs in relation to the stretching group. As for health-related quality of life, the intervention group showed a statistically better improvement compared to the stretching group. Similar results were found by Sosa-Reina et al. (18), in a study where mixed exercises (aerobic, strengthening and stretching) performed at home were compared with the usual care and patients' education. Kingsley et al. (19) used force training with gym equipment in women with FMS (n=9) and healthy women (n=15). Compared to this study, we adopted a different methodological approach, because, we opted for a specific exercise protocol using a Swiss ball as an unstable platform and dumbbells, and a homogeneous, entirely female population. In our study, the increase in muscle strength was observed in the intervention group in the second evaluation, and after 12 weeks. Studies by Hakkinen (20) and Valkeinen (16) also used strength training with gym equipment and applied the 1 RM test in women with FMS. These studies reported an increase in strength after 16 and 21 weeks of training and demonstrated improvement in FMS symptoms, which were similar to our results.

A study by Kingsley et al. (21) demonstrated the positive effects of strength training in women with FMS applied for a period of 12 weeks, using 11 types of exercises twice a week with sets of 8-12 repetitions and 40-60% intensity extracted from the exercise test maximum repetition. The design of the study by Kingsley et al. (21) was remarkably similar to ours in terms of duration, series, repetitions of exercises and load used. The strength training program that was used by the authors used conventional training equipment. The results, however, showed no statistical differences between the control group and the intervention group in the Fibromyalgia Impact Questionnaire score, despite the increase in muscle strength over time. This result may be due to the small sample size.

We also evaluated the general quality of life of the patients, using the SF-36 questionnaire (14).

Bircan et al. (22) compared an aerobic exercise program with a muscle strengthening program for 8 weeks in a study of 30 women with FMS. The authors reported improvement in seven SF-36 domains in both groups. This result is similar to the outcome of this study with the use of Swiss ball and stretching. Globally, all these results demonstrate that all forms of exercise (strengthening and stretching) have positive effects on the overall quality of life of patients with FMS.

Our program targeted many muscle groups, rather than selected ones. Regarding the frequency of training, we followed the American College of Sports Medicine raccomendations, whereby a rigid training program makes it possible to achieve the clinical benefits in terms of pain relief, quality of life and muscle strength (23, 24). We did not find specific studies using the Swiss ball in a population of patients with FMS. Few studies measured changes in activation and muscle strength, comparing in healthy subjects conventional exercises with exercises on unstable platforms and using electromyography as an evaluation tool (25, 26). Our idea of prescribing exercises using the Swiss ball for patients with FMS derived from studies that used muscle strength and dumbbell exercises on unstable and stable surfaces in healthy individuals. On unstable surfaces there is a greater recruitment of muscle fibers from the body musculature when an exercise is performed for a specific muscle, as it is performed in propriception (27).

The stretching group of this study also showed improvement in pain and healthrelated quality of life parameters, although to a lesser extent compared to that observed in the Swiss ball group. We attributed the clinical improvement of stretching group to the positive effects of stretching exercises and the interruption of inactivity that characterised the total population before inclusion in the study. The group that performed the stretching also performed the evaluations, showing a small increase in muscular strength. Patient adherence to the exercise regimen was 85%. The most commonly reported reasons for missing sessions were medical visits and family problems and had a similar frequency to that found in other studies on women (28). The high adherence of patients to the exercise program was probably due to the patients feeling a sense of improvement in their pain and symptoms in the first weeks of training and because it was performed in a group. Both groups showed less use of analgesic medication during the first weeks of training. This may have occurred because of the improvement in FMS symptoms due to exercise programme. No adverse events were observed, thus showing that patients with FMS were able to perform strengthening exercises with the aid of the Swiss ball without difficulty. The same data were reported in other studies using muscle strengthening exercises (17, 29).

The limitations of this study are the short duration of the program and the lack of a control group without any physical intervention. We chose a 12-week duration, because the adherence to a longtime exercise program can be difficult for patients, especially in Brazil where the economy is unstable and related costs maybe excessive. Therefore, our study also demonstrated that short exercise programs are followed with great adherence.

Our results demonstrate that a personalized program of Swiss ball strengthening exercises may be an effective complementary option for FMS treatment in the short term. Patient limits should be respected without exceeding their physical capacity, under the supervision of a health professional who knows the mechanisms of the disease. According to the results of this study, treatment of FMS with muscle strengthening exercises using the Swiss ball successfully improves pain, health-related quality of life and muscle strength. This is probably due to the amelioration of proprioception and the recruitment of more muscle fibers to perform the exercises, which does not occur with stretching exercises only. The strengthening exercise program with the help of the Swiss ball is safe and well tolerated by patients with FMS.

CLINICAL MESSAGES

- Twelve weeks of a progressive strengthening program with a Swiss ball was compared to stretching exercises.
- Each treatment was effective in improving pain and functional well-being of the patients.
- Differences were found between the two groups in terms of pain VAS, pain, physical aspects, vitality and emotional aspects of the SF 36 questionnaire (not only) and the total score of FIQr questionnaire with better results for the experimental group. The patients on the exercise program were also more satisfied with the treatment and felt less pain than those who performed stretching exercises.

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Contributions

All authors read and approved the final version of the article. JSA, FJ, JN, conception and design of the study, data acquisition, analysis and interpretation; JSA, FJ, GEQ, VCM, JN, writing of the article.

Conflict of interests

The authors declare no potential conflict of interests.

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