


Benefits of adding stretching to a moderate-intensity aerobic exercise programme in women with fibromyalgia: a randomized controlled trial

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Abstract

Objective: To investigate the effects of adding stretching to a moderate-intensity aerobic exercise programme in women with fibromyalgia.

Design: Randomized controlled trial.

Subjects: Sixty-four female patients who were diagnosed with fibromyalgia syndrome based on the American College of Rheumatology criteria were recruited (mean age: 54.27 ± 6.94 years).

Interventions: The control group ($n = 32$) underwent supervised moderate-intensity cycling (50%–70% of the age-predicted maximum heart rate) three times per week for 12 weeks. The experimental group ($n = 32$) underwent the same exercise programme plus a stretching programme once per week for 12 weeks.

Main measures: The main measures of this study were sleep quality assessed by the Pittsburgh Sleep Quality Index and the Epworth Sleepiness Scale, the impact of fibromyalgia on quality of life assessed by the Fibromyalgia Impact Questionnaire, and pain perception assessed by the visual analogue scale at baseline, after 4 weeks, and after 12 weeks.

Results: The experimental group experienced significant improvements at 4-week measure compared with control group: Pittsburgh Sleep Quality Index ($P < 0.001$); Epworth Sleepiness Scale ($P = 0.002$); Fibromyalgia Impact Questionnaire (0.93 ± 7.39 , $P < 0.001$); and visual analogue scale (0.52 ± 0.05 ,

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$P < 0.001$). Also at 12-week measure, experimental group experienced significant improvements compared with control group: Pittsburgh Sleep Quality Index ($P < 0.001$), Epworth Sleepiness Scale ($P < 0.001$); Fibromyalgia Impact Questionnaire (1.15 ± 9.11 , $P < 0.001$); and visual analogue scale (0.81 ± 0.62 , $P < 0.001$).

Conclusion: Adding stretching to a moderate-intensity aerobic exercise programme increased sleep quality, decreased the impact of fibromyalgia on the quality of life, and reduced pain compared with just a moderate-intensity aerobic exercise programme in our sample of women with fibromyalgia.

Keywords

Fibromyalgia, sleep quality, quality of life, pain, stretching

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Introduction

Exercise therapy is frequently used in the treatment of fibromyalgia.¹ A recent systematic review with meta-analysis found that aerobic and strengthening exercises are effective for reducing pain.² Stretching programmes for fibromyalgia patients have also shown positive effects such as decreasing pain and improving quality of life.^{3,4} However, the use of stretching is still controversial.

While many clinical trials^{4,5} and systematic reviews^{2,6} concluded that both aerobic programmes and strength programmes have positive effects in patients with fibromyalgia, it is not known whether adding stretches has an additional benefit. To the best of our knowledge, this was the first randomized controlled trial evaluating the effect of adding stretching to a moderate-intensity aerobic programme, both in the short term (4-week intervention period) and after the end of the programme (12-week intervention period), in women with fibromyalgia.

Methods

This study is a randomized controlled double-blind trial with a parallel design that was conducted in the clinical laboratory of the Physiotherapy Department at Universidad Cardenal Herrera-CEU (Valencia) from August 2016 to February 2017. The study was approved by the Committee on Research and Clinical Trials of the Universidad Cardenal Herrera-CEU (Valencia; CEI 15/001) and conducted according to the guidelines of the World Medical

Association (WMA) Declaration of Helsinki (2013). This study was registered at ClinicalTrials.gov (registration number NCT02876965; note that there is an inconsistency with the trial registry regarding intervention protocol and duration due to a misinterpretation when transcribing the information). All patients were informed verbally and in writing about the study, and written consent was obtained. There is no financial affiliation (including research funding) or involvement with any commercial organization that has a direct financial interest in any matter included in this article.

Patients were recruited through the local fibromyalgia association, and each of them had a diagnosis of fibromyalgia syndrome (Figure 1), according to the American College of Rheumatology criteria.^{7,8} The exclusion criteria were as follows: any health condition for which physical exercise was contraindicated, a history of regular physical exercise (three times a week) in the previous three months, severe cardiopulmonary problems, a serious psychiatric disorder, inflammatory rheumatoid disease, or unstable hypertension.

Participants were randomly assigned to the experimental group or the control group using the computer software Epidat 4.1 as well as some pre-numbered envelopes. A researcher who did not participate in any other part of the study kept the group assignment concealed. After allocation, the main researcher presented an educational session about the diagnosis and treatment of fibromyalgia to all participants (control and experimental groups) and supervised the exercise protocols (both cycling

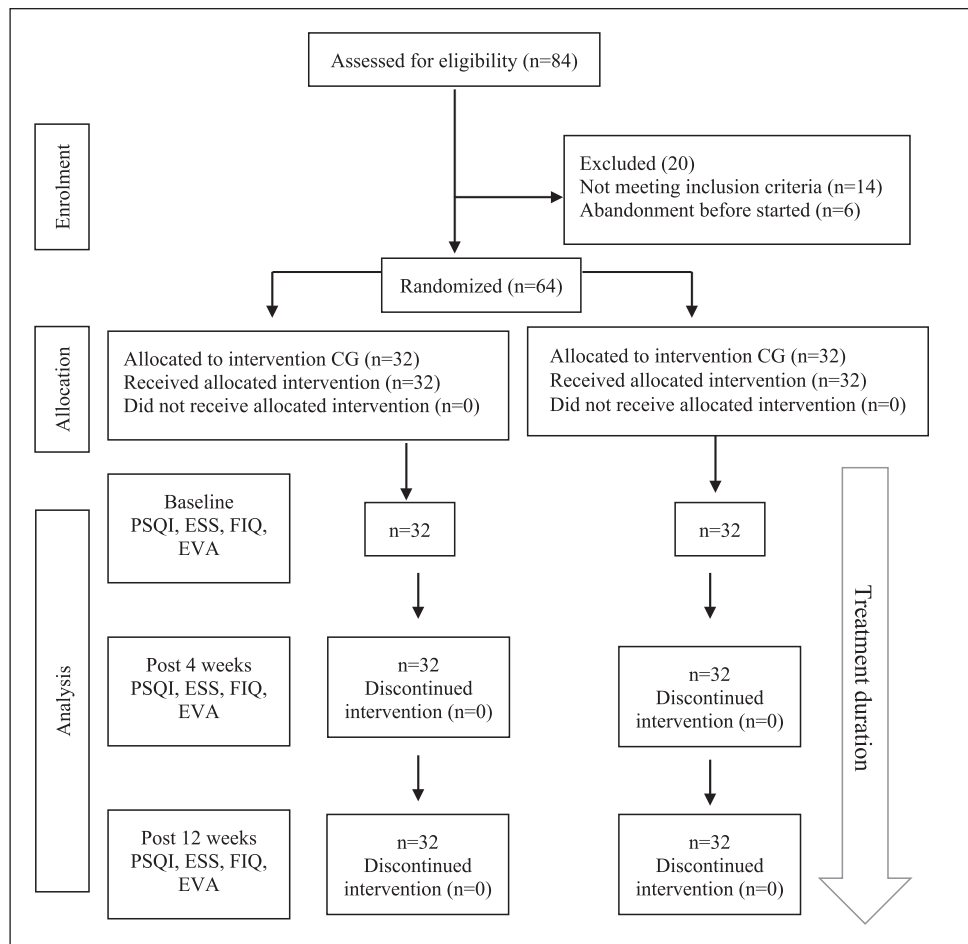


Figure 1. Consort diagram demonstrating patient flow through the 12-week treatment.

CG, control group; EG, experimental group; ESS, Epworth Sleepiness Scales; FIQ, Fibromyalgia Impact Questionnaire; PSQI, Pittsburgh Sleep Quality Index; VAS, visual analogue scale.

programme and stretching sessions). A researcher who did not know the participants' allocation collected the variable data.

The control group completed a supervised stationary cycling programme. The programme consisted of three 12-minute sessions per week for 12 weeks. Each session consisted of a 2-minute cycling warm-up and 10 minutes of moderate-intensity cycling (50%–70% of the age-predicted maximum heart rate; Table 1). In the first week, heart rate was monitored using a heart rate monitor (Polar®). From weeks 2 to 12, the intensity at which the participant could speak with ease while

performing the activity was used to find the target intensity.⁹

The experimental group undertook the same exercise programme as the control group, plus an additional 45 minutes stretching session per week for 12 weeks. Each session consisted of three repetitions of 10 seconds for each trunk muscle and two repetitions of 10 seconds for each extremity muscle. After each repetition, there was a 10-second pause (Figure 2).

Dependent variables are described as follows. All outcomes were measured at baseline, at 4 weeks, and at 12 weeks:

Table 1. Exercise programme.

	Duration	Frequency	Time per session	Exercise
Control group	12 weeks	Three sessions/ week	12 minutes/ session	Moderate intensity cycling 50%–70% of age-predicted maximum heart rate.
Experimental group	12 weeks	Three sessions/ week	12 minutes/ session	Moderate intensity cycling 50%–70% of age-predicted maximum heart rate.
		One session/ week	45 minutes/ session	Three repetitions of 10 seconds of trunk muscles Two repetitions of 10 seconds of extremities muscles

Trunk muscles: splenius cervicis, upper trapezius, lumbar longissimus, and iliocostalis.

Extremities muscles: pectoralis mayor, latissimus dorsi, posterior deltoid, shoulder internal rotators, shoulder external rotators, triceps brachii, lateral epicondyle muscles, medial epicondyle muscles, gastrocnemius, isquiotibialis muscles, quadriceps, Gluteus, piriformis, adductor muscles, and tibialis anterior.

- Sleep quality was measured using the Pittsburgh Sleep Quality Index, which is a self-administered questionnaire intended to assess sleep quality during the four preceding weeks and containing 19 questions yielding seven domains (range: 0–21, with higher scores indicating worse sleep quality).¹⁰ The validated Spanish version was used.¹¹
- Sleepiness was measured using the Epworth Sleepiness Scale, which is a self-administered questionnaire with eight questions that quantify an individual's sleepiness based on his or her tendency to fall asleep in daily situations (range: 0–24, with higher scores indicating greater sleepiness).¹² The validated Spanish version was used.¹³
- The impact of fibromyalgia on quality of life was measured using the Fibromyalgia Impact Questionnaire, which is a self-administered questionnaire intended to assess the impact of fibromyalgia on 10 dimensions, with scores ranging from 0 (no impact) to 10 (maximum impact). The first item contains 11 questions about the ability to perform activities of daily living. The remaining items contain a single question. The final score ranges from 0 to 100 points. The validated Spanish version was used.^{14,15}
- Pain perception was measured using a visual analogue scale, where patients indicated the intensity of their pain on a 10-point line. The line was labelled 'no pain' at point 0 and 'the worst pain you can imagine' at point 10. The distance from 0 was measured and scored between 0 and 10.^{16,17}

All statistical analyses were conducted using SPSS for Windows version 22.

Sample size was based on results obtained in a previous pilot study with 20 subjects: 10 in the intervention group and 10 in the control group.

In this study, the main dependent variable was impact on fibromyalgia (evaluated by the Fibromyalgia Impact Questionnaire). The average Fibromyalgia Impact Questionnaire score and SD were 80.74 (2.44) in the control group and 84.04 (4.12) in the intervention group. These results were used to determine effect size (the Cohen difference between two measurements), which was 0.95. To calculate the sample size, the alpha level was set at 0.5, the desired power (b) was 95%, and the ratio of the sample sizes of the two groups ($N2/N1$) was equal to 1. A two-tailed test was used. These assumptions generated a sample size of at least 30 participants per group, considering that 15% could be lost at follow-up. A total sample size of 64 subjects (32 per group) was determined using Gpower 3.0.18.24 software.

Differences were considered to be statistically significant with 95% confidence intervals and a P value <0.05 . The structure of this analysis was based on the objectives that were established for this study. Effectiveness for the impact of fibromyalgia on quality of life and sleep was analysed based on the two interventions (a programme of aerobic exercise and a programme that combined aerobic exercise and stretching) using a method that focused on the treatment. The Kolmogorov–Smirnov test together with the Lilliefors correction revealed a parametric distribution of data. A descriptive

analysis of the data was developed for our dependent variables.

Homogeneity among groups was also studied. Regarding gender, there was maximum homogeneity

(1.000) because both groups included the same number of women. For the rest of the variables, the Student's *t*-test for independent samples was applied.



Figure 2. (Continued)

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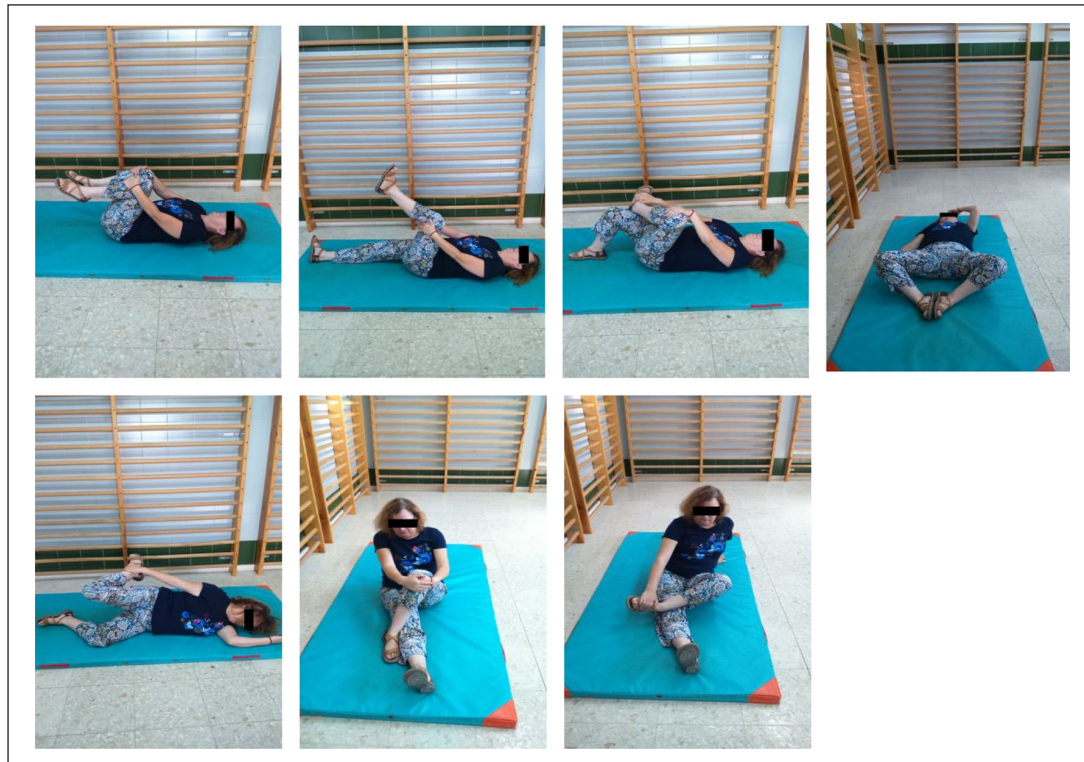


Figure 2. Stretching exercises: trunk muscles – splenius cervicis, upper trapezius, lumbar longissimus, and iliocostalis. Extremities muscles – pectoralis mayor, latissimus dorsi, posterior deltoid, shoulder internal rotators, shoulder external rotators, triceps brachii, lateral epicondyle muscles, medial epicondyle muscles, gastrocnemius, isquiotibialis muscles, Quadriceps, Gluteus, piriformis, adductor muscles, and tibialis anterior.

A descriptive analysis of the data was developed based on the average and its corresponding standard deviation of variables such as age, size, weight, and body mass index. The analysis assessed the differences in variables based on treatment, time, and interaction. This was assessed with a general linear model of repeated measures.

Sphericity was verified using Mauchly's test when the Greenhouse–Geisser correction had not been applied. The Bonferroni multiple comparison adjustment was made, and effect size was estimated using the eta-squared parameter (η^2).

For all dependent variables, the differences in scores between baseline and after 4 weeks of treatment and between baseline and after 12 weeks of treatment were calculated.

Results

In this study, 84 patients were assessed for eligibility. Among them, 64 patients were able to participate through the entire study period (Figure 1). The descriptive data for the sample are presented in Table 2. There was homogeneity in the variance between the groups; therefore, the assumption of sphericity was fulfilled.

For the Pittsburgh Sleep Quality Index variable, statistically significant differences between groups were found at 4 and at 12 week measurements with lower levels in the experimental group. The effect size was considered large ($\eta^2=0.64$; Table 3).¹⁸

For the Epworth Sleepiness Scales, statistically significant differences between groups were found at 4 and at 12 week measurements with lower

Table 2. Participant demographics and outcome measures at baseline.

	Total group	Control group	Experimental group	P value
Women	64	32	32	1.000
Age (years)	54.27 ± 6.94 (52.51, 56.04)	54.58 ± 8.52 (51.45, 57.71)	53.97 ± 5.00 (52.13, 55.80)	0.731
Height (m)	1.66 ± 0.07 (1.63, 1.69)	1.64 ± 0.08 (1.59, 1.70)	1.67 ± 0.06 (1.63, 1.71)	0.322
Body weight (kg)	57.12 ± 6.64 (54.43, 59.80)	55.35 ± 6.71 (51.29, 59.41)	58.28 ± 6.38 (55.05, 62.71)	0.180
BMI (kg/m ²)	20.73 ± 1.77 (20.01, 21.45)	20.46 ± 1.67 (19.45, 21.47)	21.00 ± 1.89 (19.85, 22.14)	0.450
PSQI (0–21)	15.05 ± 1.90 (14.57, 15.33)	14.68 ± 1.64 (14.08, 15.28)	15.42 ± 2.09 (14.65, 16.19)	0.126
ESS (0–24)	16.29 ± 0.07 (15.84, 16.74)	15.84 ± 1.57 (15.26, 16.42)	16.61 ± 1.68 (15.99, 17.23)	0.066
FIQ (0–100)	83.87 ± 3.83 (82.92, 84.82)	83.65 ± 3.36 (82.41, 84.88)	84.10 ± 4.12 (82.52, 85.61)	0.638
VAS (0–10)	7.85 ± 0.36 (7.76, 7.94)	7.92 ± 0.31 (7.80, 8.03)	7.79 ± 0.39 (7.64, 7.93)	0.161

BMI, Body mass index; ESS, Epworth Sleepiness Scales; FIQ, Fibromyalgia Impact Questionnaire; PSQI, Pittsburgh Sleep Quality Index; VAS, visual analogue scale.

Normal variable values are mean ± SD (95% confidence interval), except for females.

Table 3. Comparison between group control and group experimental at baseline and 4 weeks and at baseline and 12 weeks.

Time	Measures	Group control (mean (SD))	Group experimental (mean (SD))	PI- value	95% CI		Change score Baseline-4 weeks (mean (SD))	Change score Baseline-12 weeks (mean (SD))
					Lower bound	Upper bound		
4 weeks	PSQI	12.39 (1.45)	8.45 (1.33)	0.001	-4.64	-3.22		
	ESS	11.23 (1.33)	9.94 (1.75)	0.002	-2.08	-0.50		
	FIQ	69.81 (4.07)	64.32 (3.99)	0.001	-7.53	-3.43		
	VAS	7.33 (0.38)	6.68 (0.48)	0.001	-12.39	-8.82		
12 weeks	PSQI	10.45 (0.99)	5.42 (0.98)	0.001	-5.64	-4.62	4.67 (4.67)	5.87 (4.17)
	ESS	8.32 (1.30)	7.10 (0.83)	0.001	-1.78	-0.67	0.56 (4.45)	0.48 (3.77)
	FIQ	66.10 (4.21)	55.48 (2.63)	0.001	-0.87	-0.42	0.93 (7.39)	1.15 (9.11)
	VAS	6.71 (0.42)	5.77 (0.40)	0.001	-1.15	-0.72	0.52 (0.05)	0.81 (0.62)

ESS, Epworth Sleepiness Scales (score 0–24); FIQ, Fibromyalgia Impact Questionnaire (score 0–100); PSQI, Pittsburgh Sleep Quality Index (score 0–21); VAS, visual analogue scale (score 0–10).

PI comparison between group control and group experimental at baseline and 4 weeks and at baseline and 12 weeks. Change score from baseline at 4 weeks and 12 weeks.

levels in the experimental group. The effect size was considered small ($\eta^2=0.08$; Table 3).

For the Fibromyalgia Impact Questionnaire variable, statistically significant differences between groups were found at 4 and at 12 week measurements with lower levels in the experimental group. The effect size was considered medium ($\eta^2=0.46$; Table 3).

For the visual analogue scale variable, statistically significant differences between groups were found at 4 week and at 12 week measurements with

lower levels in the experimental group. The effect size was considered medium ($\eta^2=0.39$; Table 3).

Differences in the overall scores depend on the variables between baseline and 4-week treatments and baseline and 12-week treatments, which are shown in Table 3.

Discussion

The results of this study indicated that adding 45 minutes per week of stretching to a moderate-intensity

aerobic exercise programme increases the quality of sleep, decreases the impact of fibromyalgia on the quality of life, and reduces pain intensity in women with fibromyalgia in the short term and after the end of the treatment programme. Moreover, the lack of drop-outs or flares during the intervention time was significant. Therefore, our hypothesis that adding a stretching programme to a moderate-intensity aerobic programme would be beneficial in women with fibromyalgia was supported.

Although the pathophysiology of fibromyalgia syndrome is not well understood, the symptoms associated with this condition have been well described. Among these symptoms, a non-restful sleep is a critical symptom that is related to disability and has a positive correlation with all symptoms; therefore, it has been a target of fibromyalgia treatments.^{19,20} Our results showed that adding stretching to a moderate-intensity aerobic exercise programme produces significant improvements on both sleep quality and on sleepiness in the short and medium term. The Pittsburgh Sleep Quality Index scores were considered to show meaningful changes²¹ because there were large average reductions after treatment with a large effect size. The Epworth Sleepiness Scale scores were also considered to show meaningful changes²² because there were large average reductions after treatment, but effect size was small.

Our results are consistent with other studies in different populations; in a population of women with multiple sclerosis, Siengsukon et al.²³ showed a moderate improvement in sleep quality after a low-intensity walking and stretching programme. Tworoger et al.²⁴ and D'Aurea et al.²⁵ also showed improvement in their sleep quality after stretching in postmenopausal women and chronic insomnia patients. However, Calandre et al.¹⁹ found no improvements of sleep quality in fibromyalgia patients after stretching. These differences may be because of methodological issues. The main issues are that Calandre et al.¹⁹ used a stretching programme that was conducted in warm water, and this study used a combination of stretching and moderate-intensity aerobic programmes outside of a pool.

It is unclear how a stretching intervention may improve sleep quality. It has been observed that cognitive and somatic arousal has a negative impact on sleep.²⁶ Stretching has been shown to induce muscle

relaxation,²⁷ which may lead to a decreased somatic arousal and possibly an increased quality of sleep. In addition, being on an exercise schedule may have contributed to regulating the patients' circadian rhythm, which helps to reduce daytime sleepiness.

The results of the Fibromyalgia Impact Questionnaire showed that adding stretching exercises to an aerobic programme significantly decreased the impact of fibromyalgia on the quality of life in these patients over the short and medium term, and this decrease was considered to represent a meaningful change.²⁸

These results are consistent with the literature suggesting that aerobic exercise programmes,^{29,30} stretching programmes,^{4,5} and combined programmes³¹ decrease the impact of fibromyalgia on the patients' quality of life. However, a recent study³² did not find changes after a stretching programme. This could be due to the high attrition rate that was present in that study, which made it impossible to obtain the required sample size. Alternatively, the findings may have resulted from differences in the programmes, since López-Rodríguez used a stretching programme, while in this study a combined programme was used. In this study, the experimental group showed a significant decrease in Fibromyalgia Impact Questionnaire scores compared with the scores in the control group. This could justify the use of a stretching programme in addition to an aerobic programme to decrease the impact of fibromyalgia on the quality of life in fibromyalgia patients.

Pain is the most characteristic symptom and may be responsible for the low level of physical activity in fibromyalgia patients, leading to decreased physical function and disability.^{2,33} A significant reduction in pain after short- and medium-term interventions was observed. Pain scores were considered to have small significant changes.³⁴

This finding could be related to the improvements found in the Pittsburgh Sleep Quality Index and Epworth Sleepiness Scale scores. Non-restful sleep has been shown to be related to an increased perception of pain,³⁵ so an increase in sleep quality could result in a reduction in pain.

This pain reduction in fibromyalgia patients after exercise therapy has been widely reported in the literature for stretching programmes^{4,36} and combined programmes.^{31,37} However, some studies

reported no significant reduction in pain perception after a stretching programme³² or after a combined exercise programme.³⁷ These differences may be due to methodological issues such as type, frequency, duration, and intensity of exercise.

One of the main concerns related to exercise therapy is the lack of adherence to treatment, which leads to a high drop-out rate. This may be because of the exacerbation of symptoms related to physical activity (mechanical overexposure). To reduce a possible negative impact of exercise therapy in our population, we chose to decrease the amount of time and intensity of the exercise. The protocol can be considered scarce, but the absence of drop-outs, the absence of flares during the intervention, and the results obtained could justify the reduced time and intensity of the intervention in non-active women with fibromyalgia. Future studies with a larger sample size, longer intervention, and a follow-up are needed to confirm these results.

Some limitations of this trial should be considered when interpreting the results. First, only women were included, so the study should be replicated with men. Second, there was a lack of follow-up that would allow verification of whether the obtained effects have long-lasting effects. Third, the experimental group underwent 45 minutes of stretching in addition to the standard treatment, so the results could reflect the fact that the intervention group received a longer therapy time compared with the control group. Finally, the lack of a true control group (no exercise therapy) does not permit us to show the effects of both programmes compared with conventional drug therapy. However, the consistency of the findings, the high adherence, and the absence of significant symptom exacerbations are the strengths of this study.

The main implication of this study is that adding stretching exercises to an exercise programme have further benefits for women with fibromyalgia. Future research with longer study periods and a longer follow-up are needed to determine whether there is consistency in the results. Little is known about the mechanism by which stretching is effective in improving quality of sleep or the impact of fibromyalgia on quality of life and decreased pain. This gap in knowledge should be filled by future research.

Clinical messages

- Adding stretching exercises to a moderate-intensity aerobic programme has an added benefit compared with just a moderate-intensity aerobic programme on the quality of sleep, the impact of fibromyalgia on quality of life, and the pain intensity in women with fibromyalgia.
- These effects have been observed as soon as 4 weeks after treatment.

Clinical trial registration number

NCT02876965


Declaration of conflicting interests

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