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Non-supervised breathing exercise regimen in women with fibromyalgia: A quasi-experimental exploratory study

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ABSTRACT

Objectives: To know the effectiveness and safety of non-supervised breathing exercise regimen by promoting patients' self-management, and to investigate if non-supervised breathing exercise regimen shows similar benefits to supervised regimen in improving pain and fibromyalgia (FM) impact on daily life.
Material and methods: Fifty-one women with FM were assigned to: supervised breathing exercise regimen group, non-supervised breathing exercise regimen group, and control group. Pain thresholds tolerance on tender points and FM impact on daily life were evaluated.
Results: After 12-weeks of breathing exercises statistical differences were not found between supervised and non-supervised regimen. However, supervised regimen showed additional improvements in pain thresholds tolerance and in pain-FIQ subscale.
Conclusion: Our results suggest that performing a non-supervised breathing exercise program could be as safe and effective as the supervised regimen. However, it was observed that there could be a tendency of supervised exercise regimen to show additional benefits in terms of pain.

1. Introduction

Fibromyalgia (FM) is a chronic syndrome mainly characterized by widespread musculoskeletal pain and is frequently associated with fatigue, muscular stiffness, sleep disturbance, mental disorders, disability and diminished quality of life [1–3]. The European League Against Rheumatism (EULAR-2017) has revised the recommendations providing that exercise is the only "strong for" therapy-based recommendation in the management of FM [4]. It has been reported that home-based exercise programs are useful to combat pain and other FM-related symptoms when these programs are checked by a specialist [5–7]. In fact, these types of exercise programs produce the same effects, in terms of pain, number of tender point and FM impact than supervised exercise programs, whenever the patient is motivated [8,9]. However, numerous authors have demonstrated that supervised exercise programs are more effective than home-based exercise programs in terms of pain and FM impact, when the programs are composed by different type of exercises [10]. The combination of different exercises could be the cue to obtain these differences with respect to home-based exercise programs [11]. In this line, Ramsay et al. [11] found no differences when the same exercise programs, carried out in both supervised and non-supervised regimen, were compared.

There are other three guidelines on the management of FM that were developed independently across three continents and agree with meditative movement therapies. Although there is no evidence that these therapies produce beneficial effects, they may be incorporated into self-management strategies [12]. In patients with FM, breathing exercises are only included in meditative movement therapies as Tai-Chi and Qigong or exercise multimodal programs. Related to Qigong, it has been reported that interventions in supervised regimen exert benefits on pain, physical and mental component of health-related quality of life (HRQoL), FM impact and fatigue [13,14]. Other studies have revealed that Tai-Chi program utilized in supervised regimen with qualified instructor showed positive effects on FM impact, pain, sleep,

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balance, functional capacity and quality of life [15–17]. In addition, a multimodal program in supervised regimen was carried out together with techniques of breathing, relaxation and physical exercises, which produced improvement in FM impact and flexibility [18]. Considering that the last guidelines in the management of FM are focused on non-pharmacologic modalities with the aim of improving HRQoL and, based on costs, availability, safety and patient preference [4], it would be interesting to know the effects of non-supervised breathing exercises regimen in patients with FM and to check whether that regimen show the same effectivity and safety than those performed in a supervised mode. Once a patient learns the breathing exercise technique, it could be carried out at home along the day, based on patient preferences and/or availability [19].

Taking everything into account, the goal of this study is to check the efficacy of a non-supervised breathing exercise regimen carried out at home to alleviate FM-related symptoms, and to check whether this technique offers the same benefits of a supervised regimen composed by the same type of exercises, in terms of pain alleviation and FM impact.

2. Material and methods

2.1. Design and participants

This quasi-experimental study was conducted between April and July 2014. All the participants were women with FM recruited from the Local Fibromyalgia Association.

Initially, in April 2014, 48 patients agreed to participate in the study. Only those patients who met the diagnosis of FM according to the 1990 and 2010 American College Rheumatology (ACR) criteria [1,20] were finally included in the study. Moreover, the exclusion criteria were: respiratory diseases, severe spinal injuries, severe musculoskeletal abnormalities, inflammatory rheumatic diseases, psychiatric disorders that increased the FM, and being not involved in physical/psychological therapies. Among the initially recruited patients, only 35 women were finally included in the study. These patients were randomized into a supervised group (SG; n = 18) or a control group (CG; n = 17) (Fig. 1).

The second phase of the study started in May 2014, when some patients (n = 18) who belonged to the Local Association of FM contacted with the research group showing interest to participate in the study. Within this group, 16 subjects complied with the inclusion criteria and were assigned to non-supervised group (N-SG). These patients should perform the same exercise programs than those of SG patients with the difference that the exercise program should be carried out at home without supervision.

Eight participants were lost during the follow-up assessment for either personal reasons or being absent during the last session (SG = 3; N-SG = 3; CG = 2). Fifteen participants in SG, thirteen in N-SG and fifteen in CG fully completed the study and were included in the final analysis (Fig. 1). Pain thresholds tolerance on tender points located on the upper part of patients' body and FM impact were assessed at baseline and after 12 weeks. This study was approved by the Committee on Biomedical Ethics of the university (ref: 12004) and followed the updates of the Helsinki Declaration.

2.2. Measurements

2.2.1. Pain thresholds tolerance on tender points

Pain thresholds tolerance in tender points located on the body trunk and neck, namely, low cervical, second rib, occiput, trapezius and supraspinatus, were measured in baseline and after 12 weeks using a digital pressure algometer (Digital Pain Meter, Miacalcic®, PB by NIM brevettato, Siena). The physician placed the rubber tip on the examination site and gradually increased the pressure at a rate of approximately 1 kg/cm^2 per second. Patients reported the moment when changes in the pressure exerted caused pain. The tender points were considered positive when patients manifested pain with a pressure $\leq$4 kg/cm^2.

2.2.2. Fibromyalgia impact

FM impact on patients' daily life was evaluated using the Portuguese version of the Fibromyalgia Impact Questionnaire (FIQ) [21]. This instrument evaluates functional capacity to perform daily activities, well-being, work missed, job ability, along with symptoms of pain, fatigue,

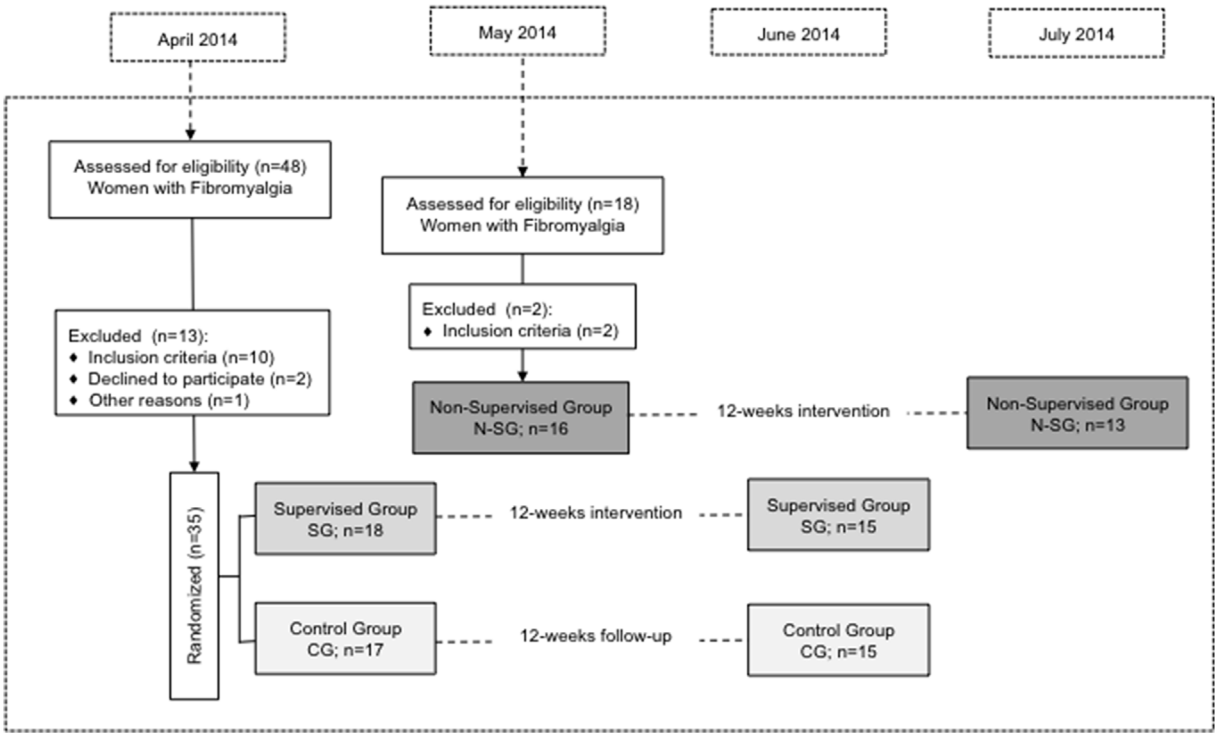


Fig. 1. Recruiting flowchart.

Table 1
Sociodemographic characteristics of women with fibromyalgia at baseline.

	SG (n = 15)	N-SG (n = 13)	CG (n = 15)	¶p	♯p	§p
Age (years)[a]	54.1 ± 9.3	50.9 ± 11.9	50.8 ± 8.7	0.342	0.968	0.430
Body mass index (kg/m^2)[a]	25.1 ± 3.7	25.6 ± 5.6	27.9 ± 6.1	0.157	0.210	0.876
Number of tender points (scale 1–18)[a]	16.9 ± 1.8	17.1 ± 1.9	16.8 ± 2.4	0.933	0.682	0.704
Duration of condition (years)[a]	14.7 ± 12.4	13.4 ± 7.6	20.5 ± 13.3	0.263	0.094	0.732
Diagnostic (years)[a]	5.3 ± 3.19	7.7 ± 4.5	7.9 ± 5.36	0.130	0.920	0.106
Number of specific drugs (antidepressives, muscular relaxants, analgesics)[a]	2.3 ± 1.9	2.2 ± 1.8	2.4 ± 1.4	0.913	0.854	0.897
Employment status[b]				0.895	0.796	0.584
Blue-collar	35.7%	20.0%	23.1%			
White-collar	28.6%	33.3%	46.2%			
Unemployed	35.7%	46.7%	30.8%			
Education level[b]				0.121	0.074	0.368
Primary School	35.7%	40.0%	46.2%			
Secondary School	50.0%	53.3%	38.5%			
University Degree	14.3%	6.7%	15.3%			

[a] Values expressed as mean ± standard deviation; p-values of one-way ANOVA (¶p: SG and CG; ♯p: N-SG and CG; §p: SG and N-SG).
[b] Values expressed as percentage; p-values of analysis of Chi-square (¶p: SG and CG; ♯p: N-SG and CG; §p: SG and N-SG). SG = supervised group, N-SG = non-supervised group, CG = control group.

morning tiredness, stiffness, anxiety and depression. The scale of each item runs from 0 (no impact of the syndrome) to 10 (very affected by the syndrome). The FIQ total score ranges from 0 to 100, where a higher score indicates a greater influence of FM on daily life.

2.3. Breathing exercises program

The breathing exercises program was previously published in our pilot randomized controlled trial [22]. Each session of 30 min was focused on breathing exercises that strengthened and lengthened the skeletal muscles of the thorax and abdomen, including 5 breathing exercises (3 min each), which were performed in the form of a circuit (2 circuits/session). Breathing exercises instructions were as follows: 1) awareness of breathing: in the supine position, inspire by the nose and exhale slowly through the mouth with lips half-closed; 2) costal expansion: in the supine position, with arms along the body with a stick held by the hands. Raise the arms, inspire and exhale, and lower your arms; 3) diaphragmatic breathing - exercise 1: in the supine position, overlapping hands in the diaphragm located in the abdominal region: inspire by the nose and exhale slowly through the mouth with lips half-closed; 4) diaphragmatic breathing - exercise 2: in the prone position, with a folded towel under the diaphragm located in the abdominal region: inspire through your nose and exhale slowly through the mouth with lips half-closed; 5) diaphragmatic breathing - exercise 3: in the supine position, with a weight of 1 kg on the diaphragm located in the abdominal region: inspire by the nose and exhale slowly through the mouth with lips half-closed.

2.3.1. Supervised group

SG performed breathing exercise program for 12 weeks consisting of daily sessions of 30 min, one weekly exercise class being supervised by a qualified instructor in breathing exercises and 6 sessions/week being done at home by means of audiovisual training in digital video disc (DVD) technology [23]. This DVD was supplied to the participants at the beginning of the study, besides a visual guide and oral explanation on how to perform all the breathing exercises. All participants were indicated to perform gradual intensity accordingly with their individual ability.

2.3.2. Non-supervised group

N-SG performed breathing exercise program at home for 12 weeks. In a single exercise session, it was taught the breathing exercises by the same instructor. After this single exercise session, all other sessions were non-supervised at home regarding audiovisual training by means of DVD [23] technology (30 min/session for 7 days/week). All participants of the N-SG were indicated to perform gradual intensity accordingly with their individual ability and were phoned once a week to control the performance of the sessions and encourage them.

2.3.3. Control group

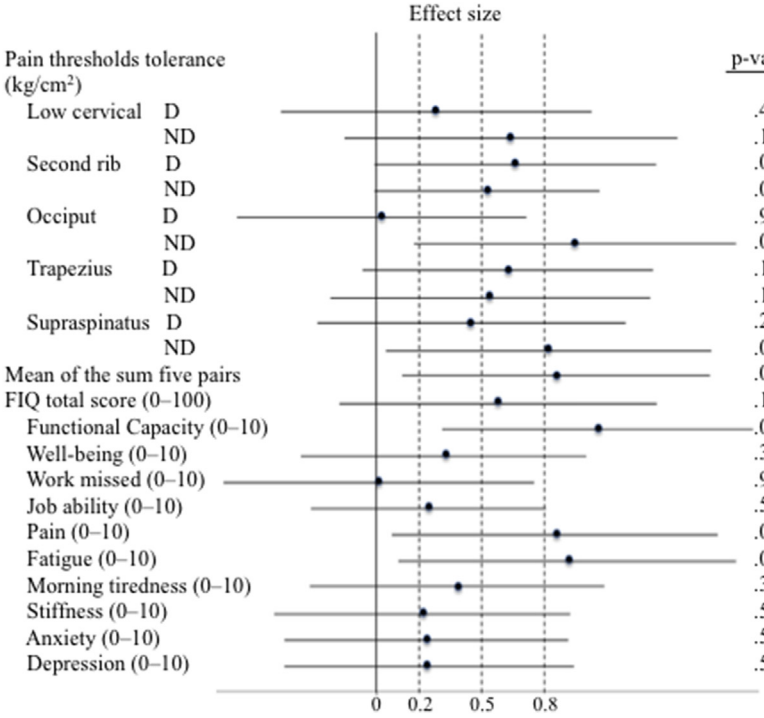
The participants of the CG continued to follow normal daily activities, which did not include any form of exercise related to these programs, during the 12-week period.

2.4. Data analysis

The Kolmogorov-Smirnov test with the correction of Lillifort was initially used for tested normality of data. Between groups differences at the baseline characteristics were tested using One-way ANOVA test for continuous variables and Chi-square test for categorical variables. General linear model (GLM) Univariate of ANOVA was used to show the effects of breathing exercises in supervised regimen, on one hand, and in non-supervised regimen, on the other hand. Effects of supervised breathing exercises regimen were showed as percentage change relative to the initial status in the SG minus percentage change relative to the initial status in the CG (ΔSG–ΔCG). Effects of non-supervised breathing exercises regimen were showed as percentage change relative to the initial status in the N-SG minus percentage change relative to the initial status in the CG (ΔN-SG–ΔCG). The percentage change relative to the initial status was calculated using compute variable in statistical package SPSS: $[(Variable_{12\text{-week}}–Variable_{baseline})/Variable_{baseline}] \times 100$. GLM Univariate of ANOVA also was used to compare both regimens of breathing exercises. The differences between regimens in percentage were obtained as follows: effects of supervised breathing exercises regimen minus effects of non-supervised breathing exercises regimen. Effect sizes (ES) were measured using eta square (η^2) [24]. Additionally, for a better comparison with other studies, all ES η^2 were transformed in standardized units, ES Cohen's *d*, using computation program (www.psychometrica.de) [25]. Statistical analyses were performed using the statistical package SPSS v.22 (IBM, New York, USA). For all tests the significance level was set at $p < .05$.

3. Results

Any significant differences between groups were observed in sociodemographic characteristics of women with FM at baseline (Table 1).



Pain thresholds tolerance (kg/cm²)		p-value	Baseline SG	Baseline CG	Effects of supervised regimen ΔSG – ΔCG
Low cervical	D	.471	1.11±0.42	0.96±0.50	28.1 (-50.5 – 106.9)
	ND	.108	1.05±0.37	0.89±0.44	37.8 (-8.9 – 84.5)
Second rib	D	.094	1.98±0.65	1.86±0.71	28.3 (-5.2 – 61.7)
	ND	.045	2.04±0.73	1.88±0.74	33.2 (-2.2 – 68.2)
Occiput	D	.952	1.70±0.77	1.59±0.80	1.0 (-34.6 – 36.7)
	ND	.019	1.65±0.85	1.53±0.78	48.2 (8.4 – 88.2)
Trapezius	D	.100	2.34±1.05	2.14±0.82	23.9 (-4.2 – 52.6)
	ND	.156	2.50±1.01	2.23±0.75	18.8 (-7.6 – 45.3)
Supraspinatus	D	.246	1.93±1.17	1.61±0.58	35.2 (-26.4 – 95.9)
	ND	.038	2.08±1.03	1.99±0.61	63.1 (4.4 – 122.0)
Mean of the sum five pairs		.029	1.88±0.70	1.71±0.53	27.3 (3.0 – 51.4)
FIQ total score (0–100)		.141	70.3±15.7	73.1±8.3	-12.7 (-29.8 – 4.5)
Functional Capacity (0–10)		.007	4.89±1.69	5.25±2.16	-43.4 (-73.8 – -12.9)
Well-being (0–10)		.382	7.39±2.24	9.18±1.99	-19.7 (-65.2 – 25.8)
Work missed (0–10)		.989	4.26±2.63	3.14±2.07	-0.8 (-118.7 – 117.1)
Job ability (0–10)		.553	7.13±1.99	8.35±1.64	5.4 (-13.1 – 24.2)
Pain (0–10)		.025	7.26±2.28	7.78±2.00	-20.2 (-36.4 – -2.6)
Fatigue (0–10)		.017	7.80±1.85	7.71±2.09	-39.5 (-71.4 – -7.4)
Morning tiredness (0–10)		.308	7.46±2.06	8.42±1.34	-12.9 (-38.5 – 12.6)
Stiffness (0–10)		.548	7.73±1.83	7.92±2.20	-11.3 (-49.5 – 26.9)
Anxiety (0–10)		.517	7.86±2.23	7.71±2.12	-12.1 (-49.5 – 25.7)
Depression (0–10)		.523	7.93±2.40	7.57±2.13	-15.9 (-66.3 – 34.5)

Fig. 2. Effects of supervised breathing exercises regimen on pain thresholds tolerance and fibromyalgia impact.

3.1. Effects of supervised breathing exercise regimen

Fig. 2 shows the ES Cohen's *d*, p-values, descriptive statistic at baseline, and percentage relative change to the initial status of pain thresholds in tender points and FM impact. Relative changes to initial status showed significant benefits in favour of the SG, with large ES, in functional capacity-FIQ (−43.4%), pain-FIQ (−20.2%), fatigue-FIQ (−39.5%), pain thresholds tolerance for mean of the sum of five pairs of tender points (+27.3%), occiput (+48.2%) and supraspinatus (+63.1%), as well as with moderate ES for second rib (+33.2%). The rate of compliance with training sessions in supervised regimen was 93.6%.

3.2. Effects of non-supervised breathing exercise regimen

In Fig. 3, it is shown the ES Cohen's *d*, p-values, descriptive statistic at baseline, and percentage relative change to the initial status of pain thresholds in tender points and FM impact. Relative changes to initial status showed significant benefits in favour of the N-SG, with large ES, in functional capacity-FIQ (−45.9%), fatigue-FIQ (−37.5%) and pain thresholds in supraspinatus (+47.2%), as well as moderate ES for pain thresholds in second rib (+30.1%). The rate of compliance with training sessions in non-supervised regimen was 81.3%.

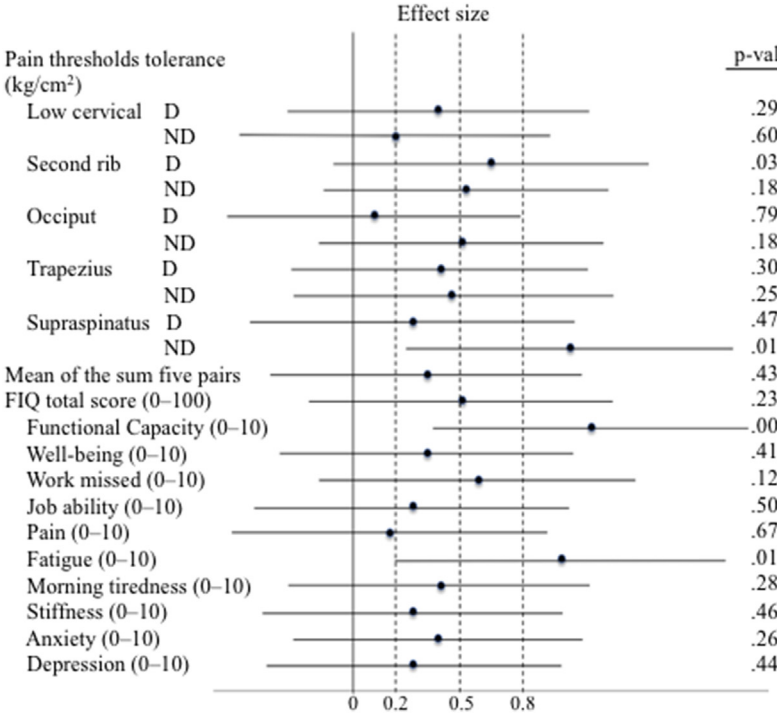
3.3. Comparison between breathing exercise regimens

No significant differences were found between both breathing exercise regimens in terms of pain threshold. However, the change between both regimens, expressed in percentage, showed a tendency towards supervised exercise regimen to show additional benefits in pain threshold of low cervical, supraspinatus, occiput, trapezius, second rib and the mean of the sum of five pairs (Fig. 4). Fig. 5 showed that the differences between both breathing exercise regimens for the vast majority of FIQ subscales were lower than 5%. Only the FIQ subscales of work missed and job ability showed differences ≈15% in favour of non-supervised regimen. On the other hand, pain-FIQ subscale showed a difference in favour of supervised regimen (−14.1%).

4. Discussion

For the sake of clarity, we would like to point out that results concerning the supervised breathing exercise regimen have been solely included in the present study in order to compare both types of regimens, since the effectiveness of breathing exercises in supervised regimen in the management of pain and FM impact on daily life have been already reported in a recent pilot randomized controlled trial study [22]. In the present study, no statistically significant differences were found between non-supervised and supervised exercises regimens on pain thresholds tolerance on tender points and FM impact. Nonetheless, it was observed that there could be a tendency of supervised exercise regimen to show additional benefits in the mean of the sum of five pairs of tender points and FIQ-pain scale. It may be therefore considered that breathing exercises carried out under non-supervised regimen could be effective and safe for FM patients, and that such exercises may foster patients' self-management.

Previous studies analysed the non-supervised exercise regime but the definition of "non-supervised" and "home-based" were unclear [5,7,8,11]. In our study, to reduce confounding definitions, it was defined supervised regime as attending exercise class with an instructor ≥1 day per week (with or without extra sessions at home), whereas non-supervised regime was defined as home-based exercise only, without weekly classes of exercise guided by an instructor (although it may include some initial training session). There are inconsistent data on whether patients should perform non-supervised or supervised exercise regimen. In this sense, some studies suggested that supervised regimen could be more beneficial. For example, 12 weeks of supervised regimen in group therapy (gym-based aerobic exercise or pool-based aquatic exercise) showed significant benefits on pain and FM impact when it was compared with non-supervised regimen of 15-min/day for 12 weeks of home-based isometric strength exercise [10], although the differences in the type of exercises included in the two regimens could have contribute to these results. However, other studies did not demonstrate any significant difference between non-supervised and supervised exercise regimens when similar exercise programs were compared. For instance, a program of 12 weeks including stretching and



Pain thresholds tolerance (kg/cm²)		p-value	Baseline N-SG	Baseline CG	Effects of non-supervised regimen ΔN-SG – ΔCG
Low cervical	D	.297	0.75±0.26	0.96±0.50	2.0 (-61.5 – 65.6)
	ND	.608	0.80±0.20	0.89±0.44	12.9 (-26.6 – 52.2)
Second rib	D	.034	1.45±0.61	1.86±0.71	30.1 (-5.9 – 66.1)
	ND	.189	1.47±0.54	1.88±0.74	25.3 (-11.4 – 62.1)
Occiput	D	.794	1.80±0.60	1.59±0.80	-4.9 (-39.9 – 30.0)
	ND	.189	1.54±0.61	1.53±0.78	29.5 (-5.6 – 69.8)
Trapezius	D	.309	2.00±0.55	2.14±0.82	17,7 (-16.5 – 51.9)
	ND	.259	2.05±0.52	2.23±0.75	18.3 (-11.7 – 48.4)
Supraspinatus	D	.470	1.76±0.55	1.61±0.58	17.4 (-41.9 – 76.7)
	ND	.018	2.15±0.68	1.99±0.61	47.2 (-5.7 – 99.4)
Mean of the sum five pairs		.432	1.58±0.38	1.71±0.53	22.3 (-1.1 – 45.8)
FIQ total score (0–100)		.230	65.2±9.6	73.1±8.3	-9.8 (-27.6 – 7.8)
Functional Capacity (0–10)		.006	4.92±1.10	5.24±2.16	-45.9 (-74.1 – -17.8)
Well-being (0–10)		.415	4.86±2.58	9.18±1.99	-18.1 (-56.6 – 20.4)
Work missed (0–10)		.120	5.67±2.23	3.14±2.07	-15.9 (-58.5 – 26.9)
Job ability (0–10)		.503	6.46±1.59	8.35±1.64	-7.7 (-28.4 – 12.9)
Pain (0–10)		.678	6.80±1.69	7.78±2.00	-6.1 (-32.0 – 19.7)
Fatigue (0–10)		.017	8.26±1.16	7.71±2.09	-37.5 (-64.9 – -10.2)
Morning tiredness (0–10)		.286	8.13±1.64	8.42±1.34	-9.0 (-22.8 – 4.7)
Stiffness (0–10)		.461	6.73±1.83	7.92±2.20	-10.7 (-43.0 – 21.6)
Anxiety (0–10)		.264	7.06±1.79	7.71±2.12	-16.3 (-49.7 – 17.2)
Depression (0–10)		.441	6.26±2.34	7.57±2.13	-13.9 (-57.7 – 29.8)

Fig. 3. Effects of non-supervised breathing exercises regimen on pain thresholds tolerance and fibromyalgia impact.

balance-coordination exercises [8] or aerobic exercises, stretching and relaxation techniques [11]. Nonetheless, according to the current study, there could be a tendency in supervised exercise regimen to show additional benefits in pain-VAS, FIQ total score and total myalgia score (without statistically significant differences between regimens) [8,11]. Likewise, aquatic exercise programs, including aerobic exercises, active

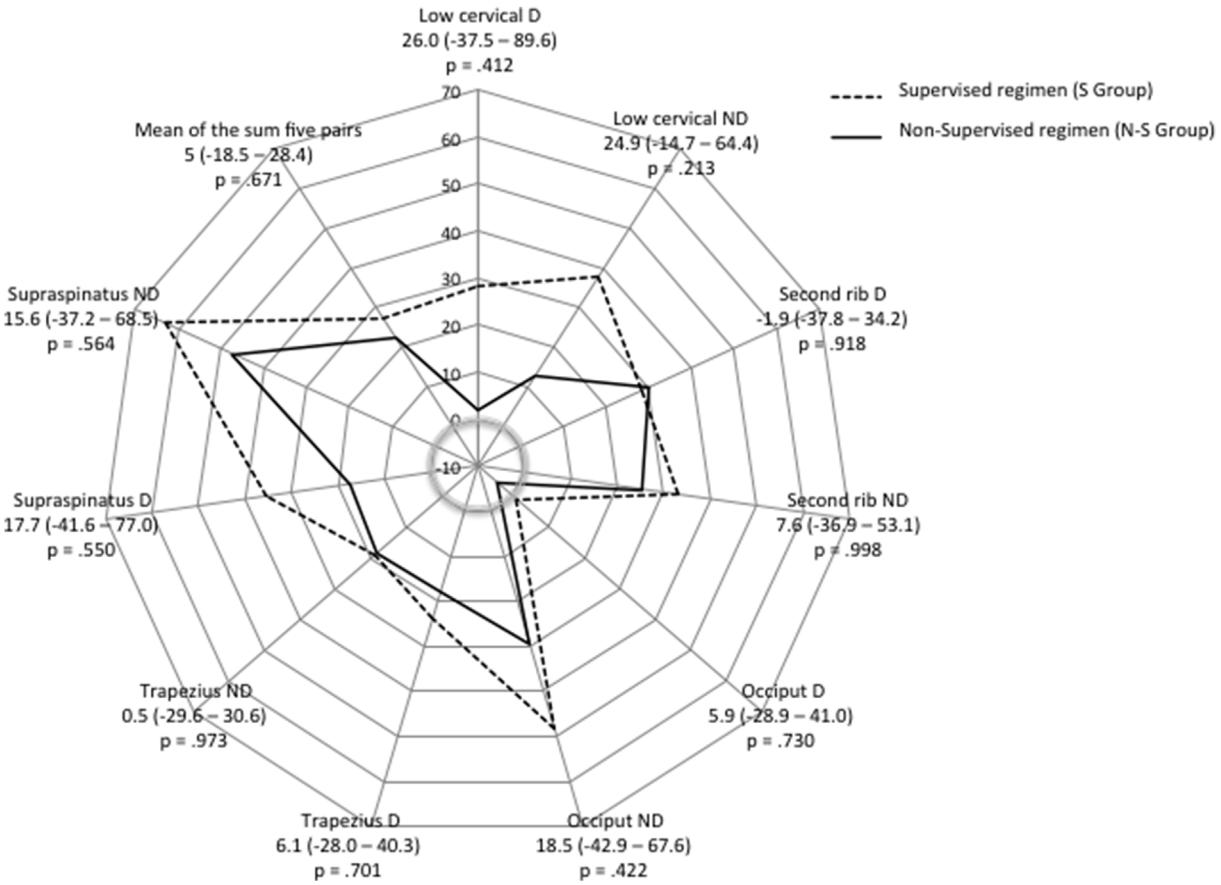


Fig. 4. Comparison between breathing exercise regimens: pain thresholds tolerance.

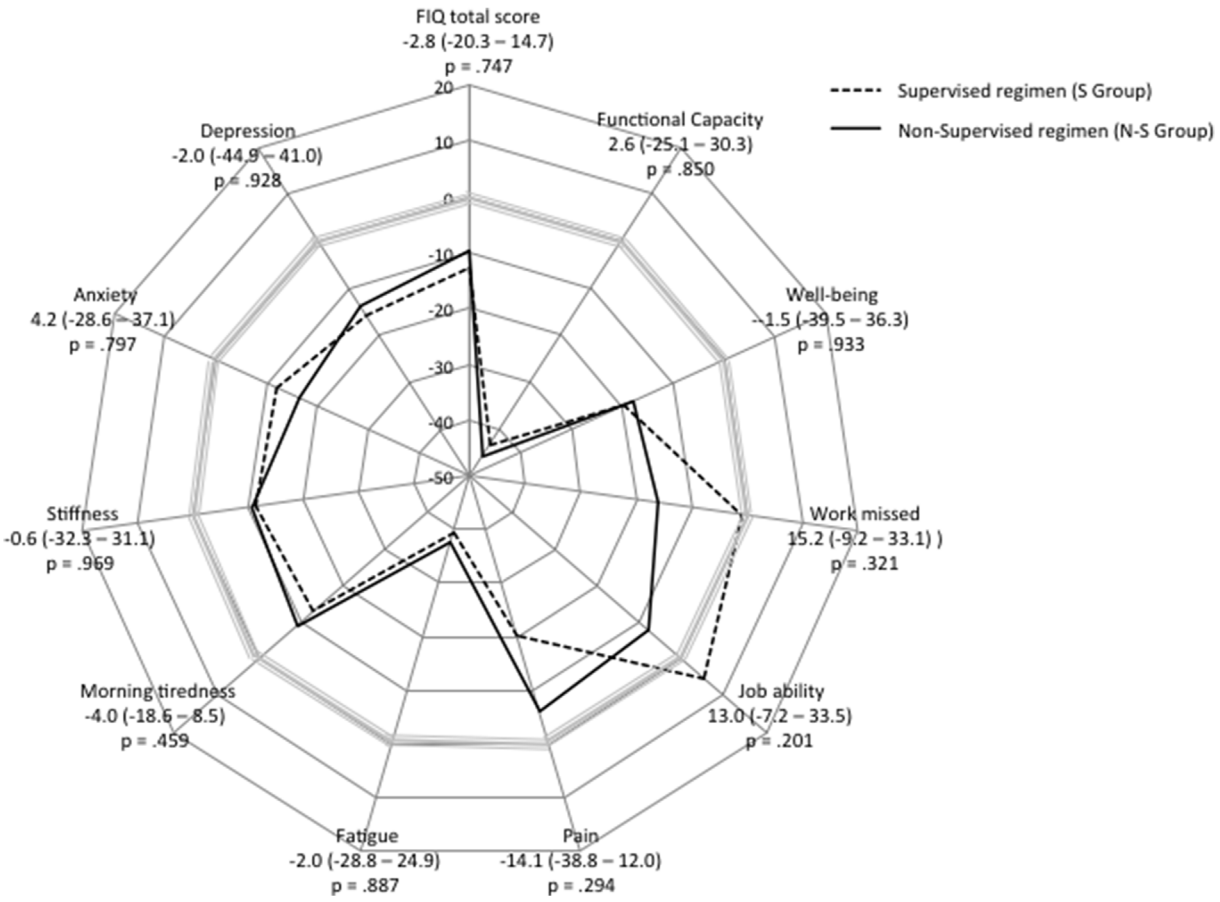


Fig. 5. Comparison between breathing exercise regimens: fibromyalgia impact.

range of motion, relaxation and stretching in supervised exercise and non-supervised exercise regimens, did not resulted in significant differences between regimens [9], although supervised regimen provided greater benefits in pain-VAS and number of tender points. Like all these previous studies, our findings failed to show statistically significant differences between supervised and non-supervised breathing exercise regimens. However, if the magnitude of change in standardized units ES Cohen's *d* of both regimens of exercise separately is considered, supervised regimen showed ES larger in additional variables as pain thresholds tolerance in occiput and in the mean of the sum of five pairs of tender points and FIQ-pain scale. Considering changes from baseline in supervised and non-supervised regimens, our study showed improvements of 27.3% and 22.3%, respectively, in the mean of the sum of five pairs of tender points. Despite the large magnitude of change observed for supervised regimen, it is considered minimally important (< 30%) following the recommendations for classifying pain responses in patients' chronic pain for clinical trials [26]. Besides, FIQ-pain scale showed improvements of −20.2% and −6.1% in supervised and non-supervised regimens, respectively, the supervised regimen showing larger magnitude of change. In this sense, although the absence of significant differences in FIQ-pain scale suggest that both regimens are evenly effective, results should be interpreted with caution because only a 2-point improvement on a scale from 0 to 10 is considered as clinically important difference [27]. However, it can be observed that both exercise regimens produce coincident improvements with large magnitude of change in pain thresholds tolerance in supraspinatus, FIQ-functional capacity and FIQ-fatigue. Regarding pain thresholds tolerance in supraspinatus, both regimens showed a clinically important decreased [26] in pain after the intervention. Unfortunately, in FIQ-functional and FIQ-fatigue scales there were no minimal clinically important differences to be discussed. Anyway, our findings displayed a large magnitude of change that could be considered as relevant improvement.

On the other hand, non-supervised exercise regimens are cheaper but compliance could be difficult to guarantee [8,9]. In this sense, in order for a program of non-supervised exercise regime to be successful and that there is no high rates of withdrawal, an adequate motivational work must be carried out with patients [8]. This could be a key element to achieve successful programs of non-supervised exercise regimen. If there is regular attendance and control, even if it is not in-person, non-supervised exercise regime can be effective, as observed in our study, in which the participants reported high levels of exercise compliance (81.3%). This rate differs from percentages of 50% and ≈67% of compliance in non-supervised regimen observed in other studies [5,11]. One possible explanation for these large differences could be that, in our study, verbal explanations and demonstration of each exercise were provided by means of a DVD, which could be visualized while performing the exercises at home. Thus, DVD technology could be also key to comply with exercises in non-supervised regime [28].

The present study also included limitations, which require further discussion. First, the participants in the N-SG were not randomized and, although there were no statistically significant differences between groups at baseline, this could increase potential bias and limit the implications observed. Second, the limited size of the sample may have contributed to decreasing statistical power to detect changes in some variables. Despite of the fact that our trial showed positive effects in numerous variables and changes due to the treatment effect, caution should be applied when inferring conclusions to other populations with different backgrounds: gender female, age (≈52 years old), long duration of symptoms (≈16 years), and high number of tender points (≈17 tender points).

5. Conclusions

The results of this study suggest that performing a non-supervised breathing exercise program could be as safe and effective as the supervised regimen, as long as there is a specialist-guided exercise training, DVD-based audiovisual aid is provided, adherence to the regimen is checked by phone, and participants show appropriate motivation on a weekly base. Despite there could be a tendency of supervised exercise regimen to show additional benefits in terms of pain, further studies are necessary to confirm the results reported in the current pilot study.

Conflicts of interest

Authors have no conflict of interest to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ctcp.2019.02.006.

References

[1] F. Wolfe, H.A. Smythe, M.B. Yunus, et al., The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the multicenter criteria committee, Arthritis Rheum. 33 (1990) 160–172.
[2] S.L. Silverman, J. Harnett, G. Zlateva, J. Mardekian, Identifying fibromyalgia-associated symptoms and conditions from a clinical perspective: a step toward evaluating healthcare resource utilization in fibromyalgia, Pain Pract. 10 (2010) 520–529, https://doi.org/10.1111/j.1533-2500.2010.00383.x.
[3] P. Henningsen, T. Zimmermann, H. Sattel, Medically unexplained physical symptoms, anxiety, and depression: a meta-analytic review, Psychosom. Med. 65 (2003) 528–533.
[4] G.J. Macfarlane, C. Kronisch, L.E. Dean, et al., EULAR revised recommendations for the management of fibromyalgia, Ann. Rheum. Dis. 76 (2017) 318–328, https://doi.org/10.1136/annrheumdis-2016-209724.
[5] D. da Costa, M. Abrahamowicz, I. Lowensteyn, et al., A randomized clinical trial of an individualized home-based exercise programme for women with fibromyalgia, Rheumatology 44 (2005) 1422–1427, https://doi.org/10.1093/rheumatology/kei032.
[6] M. Vural, T.D. Berkol, Z. Erdogdu, K. Pekedis, B. Kuçukserat, C. Aksoy, Evaluation of the effectiveness of an aerobic exercise program and the personality characteristics of patients with fibromyalgia syndrome: a pilot study, J. Phys. Ther. Sci. 26 (2014) 1561–1565, https://doi.org/10.1589/jpts.26.1561.
[7] R.N. Harden, S. Song, J. Fasen, et al., Home-based aerobic conditioning for management of symptoms of fibromyalgia: a pilot study, Pain Med. 13 (2012) 835–842, https://doi.org/10.1111/j.1526-4637.2012.01384.x.
[8] D. Demir-Göçmen, L. Altan, N. Korkmaz, R. Arabacı, Effect of supervised exercise program including balance exercises on the balance status and clinical signs in patients with fibromyalgia, Rheumatol. Int. 33 (2013) 743–750, https://doi.org/10.1007/s00296-012-2444-y.
[9] D. Evcik, I. Yigit, H. Pusak, V. Kavuncu, Effectiveness of aquatic therapy in the treatment of fibromyalgia syndrome: a randomized controlled open study, Rheumatol. Int. 28 (2008) 885–890, https://doi.org/10.1007/s00296-008-0538-3.
[10] D. Sevimli, E. Kozanoglu, R. Guzel, A. Doganay, The effects of aquatic, isometric strength-stretching and aerobic exercise on physical and psychological parameters of female patients with fibromyalgia syndrome, J. Phys. Ther. Sci. 27 (2015) 1781–1786, https://doi.org/10.1589/jpts.27.1781.
[11] C. Ramsay, J. Moreland, M. Ho, S. Joyce, S. Walker, T. Pullar, An observer-blinded comparison of supervised and unsupervised aerobic exercise regimens in fibromyalgia, Rheumatology 39 (2000) 501–505.
[12] J. Ablin, M.A. Fitzcharles, D. Buskila, Y. Shir, C. Sommer, W. Häuser, Treatment of fibromyalgia syndrome: recommendations of recent evidence-based interdisciplinary guidelines with special emphasis on complementary and alternative therapies, Evid. Based Complement. Altern. Med. 2013 (2013) 485272, https://doi.org/10.1155/2013/485272.
[13] W. Liu, L. Zahner, M. Cornell, et al., Benefit of Qigong exercise in patients with fibromyalgia: a pilot study, Int. J. Neurosci. 122 (2012) 657–664, https://doi.org/10.3109/00207454.2012.707713.
[14] M. Lynch, J. Sawynok, C. Hiew, D. Marcon, A randomized controlled trial of qigong for fibromyalgia, Arthritis Res. Ther. 14 (2012) R178, https://doi.org/10.1186/ar3931.
[15] K.D. Jones, C.A. Sherman, S.D. Mist, J.W. Carson, R.M. Bennett, F. Li, A randomized controlled trial of 8-form Tai chi improves symptoms and functional mobility in fibromyalgia patients, Clin. Rheumatol. 31 (2012) 1205–1214, https://doi.org/10.1007/s10067-012-1996-2.
[16] A. Romero-Zurita, A. Carbonell-Baeza, V.A. Aparicio, J.R. Ruiz, P. Tercedor, M. Delgado-Fernández, Effectiveness of a tai-chi training and detraining on functional capacity, symptomatology and psychological outcomes in women with fibromyalgia, Evid. Based Complement. Alternat. Med. 2012 (2012) 614196, https://doi.org/10.1155/2012/614196.
[17] C. Wang, C.H. Schmid, R. Rones, et al., A randomized trial of tai chi for fibromyalgia, N. Engl. J. Med. 363 (2010) 743–754, https://doi.org/10.1056/NEJMoa0912611.
[18] C. Ayan, M.J. Alvarez, B. Alonso-Cortés, M.J. Barrientos, M. Valencia, V. Martín, Health education home-based program in females with fibromyalgia: a pilot study, J. Back Musculoskelet. Rehabil. 22 (2009) 99–105, https://doi.org/10.3233/BMR-2009-0222.
[19] M. Garrido, M.Y. Castaño, C. Biehl-Printes, et al., Effects of a respiratory functional training program on pain and sleep quality in patients with fibromyalgia: a pilot study, Complement, Ther. Clin. Pract. 28 (2017) 116–121, https://doi.org/10.1016/j.ctcp.2017.05.013.
[20] F. Wolfe, D.J. Clauw, M.A. Fitzcharles, et al., The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity, Arthritis Care Res. 62 (2010) 600–610, https://doi.org/10.1002/acr.20140.
[21] Mda L. Rosado, J.P. Pereira, J.P. da Fonseca, J.C. Branco, Cultural adaptation and validation of the “fibromyalgia impact Questionnaire”- Portuguese version, Acta Reumatol. Port. 31 (2006) 157–165.
[22] P. Tomas-Carus, J.C. Branco, A. Raimundo, J.A. Parraca, N. Batalha, C. Biehl-Printes, Breathing exercises must be a real and effective intervention to consider in women with fibromyalgia: a pilot randomized controlled trial, J. Alternative Compl. Med. 24 (2018) 825–832, https://doi.org/10.1089/acm.2017.0335.
[23] C. Biehl-Printes, R. da Costa, Fibromialgia em movimento. Prática diária de exercícios [CD-ROM: sound, color, M/4 3/4 in], Myos – Associação Nacional Contra a Fibromialgia e Síndrome da Fadiga Crónica, Lisbon, (2006).
[24] J. Cohen, Statistical Power Analysis for the Behavioral Sciences, second ed., Erlbaum, Hillsdale, 1988.
[25] W. Lenhard, A. Lenhard, Calculation of Effect Sizes, Psychometrica, Dettelbach, 2016.
[26] R.H. Dworkin, D.C. Turk, K.W. Wyrwich, et al., Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations, J. Pain 9 (2008) 105–121, https://doi.org/10.1016/j.jpain.2007.09.005.
[27] P.J. Mease, M. Spaeth, D.J. Clauw, et al., Estimation of minimum clinically important difference for pain in fibromyalgia, Arthritis Care Res. 63 (2011) 821–826, https://doi.org/10.1002/acr.20449.
[28] G. Kingston, M.A. Gray, G. Williams, A critical review of the evidence on the use of videotapes or DVD to promote patient compliance with home programmes, Disabil. Rehabil. Assist. Technol. 5 (2010) 153–163, https://doi.org/10.3109/17483101003671709.