Effects of respiratory muscle training on respiratory efficiency and health-related quality of life in sedentary women with fibromyalgia: a randomised controlled trial

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Abstract

Objective

Fibromyalgia syndrome (FM) is a complex disease that is mainly characterised by chronic pain, fatigue, and sleep disturbances and may be precipitated or worsened by many stressors. The aim of this study was to examine the effects of respiratory muscle training (RMT) on respiratory efficiency and health-related quality of life (HRQoL) in women with FM.

Methods

A total of 30 women with FM were included in the intention to treat analyses: 15 were assigned to the RMT group and 15 to the control group. The intervention consisted of 12 weeks of RMT. The primary outcome was the change in pulmonary function assessed by global body plethysmography at 12 weeks compared with baseline. Secondary outcomes included changes of scores in HRQoL assessed by the Short Form 36 Health Survey-Portuguese version.

Results

The maximal inspiratory pressure (MIP) improved by 17.5% (p-value = .033), maximal expiratory pressure (MEP) improved 21.6% (p-value = 0.045) and maximum occlusion pressure (P0.1 max) increased 27.7% (p-value = 0.007). HRQoL improved in the dimensions of physical function, physical role, bodily pain and vitality (p-value <0.05).

Conclusion

RMT results in a significant improvement of respiratory efficiency and HRQoL after 12 weeks. RMT could be an effective therapy to enhance respiratory function and quality of life in women with FM.

Key words

fibromyalgia, respiratory muscle training, respiratory efficiency, quality of life

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Introduction

Fibromyalgia syndrome (FM) is characterised by chronic pain, fatigue, sleep disturbances and functional symptoms (1–3). Fatigue, anxiety and/or depression disorders, lower health-related quality of life (HRQoL), sleep disturbances, lack of concentration, and impaired cognitive memory and function are clinical features recognised as non-specific pain-related symptoms in FM (1). The widespread pain experienced by people who have FM can reach regions related to the system, leading to respiratory disturbances such as reduced chest expansion, maximal ventilatory volume, maximum inspiratory, and maximum expiratory pressures (4). Therefore, dyspnoea is common due to respiratory muscle weakness; consequently, the presence of general fatigue is usually related (4). Hence, improving the strength and endurance of the respiratory muscles could be a strategy to alleviate the aforementioned respiratory disorders. In this way, the participation of patients with FM in exercise programmes has been reported as one of the main therapies in managing fibromyalgia (5). Respiratory muscle training (RMT) is a therapy used in several pathologies to improve respiratory capacity. There is evidence about the positive effect of RMT in patients with chronic obstructive pulmonary disease (COPD) (6), amyotrophic lateral sclerosis (ALS) (7), and COVID-19 (8–10). In addition to the effects obtained on respiratory capacity, studies have found how patients experience improvements in QoL. Klimczak *et al.* (11) found a better self-perception of HRQoL in patients with chronic obstructive pulmonary disease (COPD). Positive effects were also found in patients with asthma (12) or patients who are post-COVID-19 (10).

Based on the above, it was hypothesised that subjects with FM had little strength in the respiratory muscles and reduced diaphragmatic functionality. Also, these abnormalities are related to lower HRQoL. So, this study aimed to examine the effects of RMT on respiratory efficiency and HRQoL in sedentary women with FM.

Materials and method

Participants

The patients were recruited by advertisements at the National Fibromyalgia Association – Myos (Lisbon District). They were included if they met the diagnosis of FM according to the American College Rheumatology (ACR) criteria (1). The exclusion criteria were severe spinal injuries, severe musculoskeletal abnormalities, inflammatory rheumatic diseases, psychiatric disorders, and participation in another psychological or physical therapy. After written informed consent was obtained, 35 patients were randomised pairwise into an exercise group (EG; n=18) or a control group (CG; n=17). Two patients were excluded as they failed to attend at least 90% of the training sessions, and three were excluded because they missed the follow-up assessment. Finally, 15 patients in the EG and 15 in the CG fully completed the study protocol (Fig. 1).

The sample size was calculated utilising the software Granmo (13). Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 15 subjects are necessary for the first group and 15 for the second to recognise, as statistically significant, a difference greater than or equal to 1 unit in the pain score of the Fibromyalgia Impact Questionnaire, and the common standard deviation was assumed to be 1.1 (14). The correlation coefficient between the initial and final measurement was 0.7 (15). A drop-out rate of 20% was anticipated.

Respiratory efficiency and functional status were assessed at baseline and immediately after 12 weeks of RMT. The same specialist in the evaluation performed each test to reduce variability and improve consistency in the assessment process. The specialist was blinded to the patient's condition and group assignment. Randomisation was carried out by a staff member who was not otherwise involved in the study. This randomised controlled trial (ISRCTN37081460) was approved by the Committee on Biomedical Ethics of the University (document 12004) and followed the updates of the 1975 Declaration of Helsinki, amended by the 59th WMA General Assembly, Seoul, Republic of Korea, October 2008 (16).

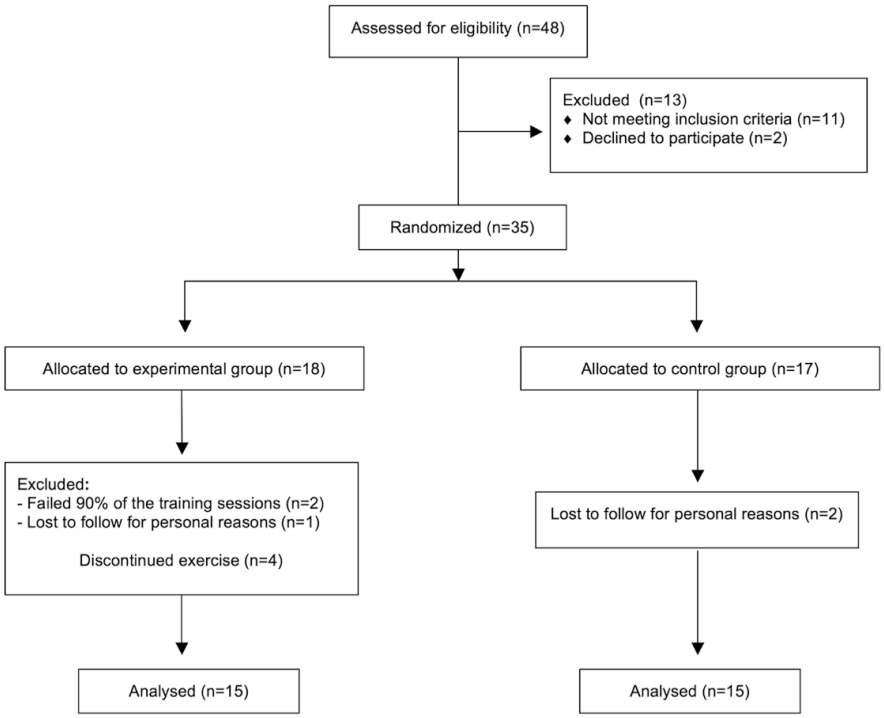

Fig. 1. Flow of participants through the trial.

Measurements

- Functional respiratory evaluation

Pulmonary function tests were assessed by global body plethysmography (Masterlab, Medizintechnik mit System Erich Jaeger Gmbh®, Wuerzburg, Germany, 1995), with specific software. All units in Masterlab are based on a powerful computer system with high storage capacity. The conventional pulmonary function test was used, which was based on the determination by spirometry (ventilatory proof) and maximum respiratory pressure (MRP). For the respiratory function test material required, a mouthpiece inserted into a one-way valve is needed, which is associated with an occlusion device placed on the inspiratory side of this valve. The face of the inspiratory valve is connected to the pneumotachograph, with the pressure transducer, and the pressure signal electronically integrated to volume. Spirometry was used as a diagnostic evaluation with the aim of excluding additional diseases. The following parameters were monitored: forced vital capacity (FVC), maximum expiratory volume in the first second (FEV1), Tiffeneau = FEV1/FVC ratio and maximal expiratory flow at 50% of FVC (MEF50). In the study of muscular efficiency, two parameters were monitored: the maximal inspiratory pressure (MIP) and maximum occlusion pressure (P0.1 max). The maximal expiratory pressure (MEP) was measured as a component of evaluating respiratory muscles. All persons involved were unaware of the measurement of maximal respiratory pressures.

The standard protocol for the determination of spirometry, patients must make a maximal inspiration and then forcibly expel the air for as long and as quickly as possible (forced capacity manoeuvre – FVC). The FEV1 is obtained in the same manoeuvre in the first second of expiration. The Tiffeneau index is determined by the equation FEV1/FVC, and MEF50 is obtained through the expiratory curve in the flow-volume curve. The determination of the MRP is carried out at the mouth, in a static way (sitting) by asking the patient to make a maximum effort against an occluded airway. To obtain the MIP, the patient is asked to exhale to residual volume (RV) (*i.e.* to a maximum expiration and then a forced inspiratory manoeuvre). The MEP is measured after a maximal inspiration to total lung capacity (TLC) and then a forced expiratory manoeuvre. A high MIP (>-80 cmH_2O = 7.85 Kpa) or a high MEP (>90 cmH_2O = 8.80 Kpa) inspiratory or expiratory weakness are excluded as clinically important. For the measurement of P01.max, the patient was asked to do a forced inspiration, after expiration of the home, being recorded to mouth inspiratory pressure 0.1 sec (time of occlusion valve), which does not interfere with the ventilation of the patient. A minimum of five attempts were carried out to demonstrate a consistent effort, being two of these maximum reproducible manoeuvres (*i.e.* that did not differ between themselves more than 5%) (17).

- Health-related quality of life

HRQOL was evaluated using the Short Form 36 Health Survey (SF-36)-Portuguese version (18). This questionnaire includes 36 items grouped in eight dimensions: physical function (PF), role physical (RP), body pain (BP), general health (GH), vitality (VT), social function (SF), role emotional (RE) and mental health (MH). The scale of each component runs from 0, 'very poor', to 100, 'very good'.

- Intervention

Each session of RMT included five breathing exercises (3 minutes for each), which were performed in the form of a circuit: an exercise on awareness of breathing, an exercise on costal expansion, and three exercises on diaphragmatic breathing. Breathing exercises were as follows: 1) awareness of breathing: in the supine position, inspire through the nose and exhale through the mouth with lips half-closed slowly; 2) costal expansion: in the supine position, with arms along the body with a stick held by the hands, raise the arms and inhale 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 through the nose and exhale through the mouth with lips half-closed slowly, 4) diaphragmatic breathing - exercise 2: in the prone position, with a folded towel under the diaphragm located in the abdominal region: inspire through the nose and exhale through the mouth with lips half-closed slowly, 5) diaphragmatic breath-

Table I. Sociodemographic characteristics of patients with fibromyalgia at the baseline.

	EG (n=15)	CG (n=15)	*p*
Age (years) [a]	54.1 ± 9.3	50.8 ± 8.7	0.342
Weight (kg) [a]	62.1 ± 8.7	70.9 ± 15.2	0.072
Height (m) [a]	1.57 ± 0.1	1.59 ± 0.1	0.447
Body mass index (kg/m^2) [a]	25.1 ± 3.7	27.9 ± 6.1	0.157
Number of tender points (scale 1-18) [a]	16.9 ± 1.8	16.8 ± 2.4	0.933
Duration of condition (years) [a]	14.7 ± 12.4	20.5 ± 13.3	0.263
Diagnostic (years) [a]	5.3 ± 3.19	7.9 ± 5.36	0.130
Number of specific drugs (antidepressives, muscular relaxants, analgesics) [a]	2.3 ± 1.9	2.4 ± 1.4	0.913
Employment status [b]			0.895
- Blue-collar	35.7%	23.1%	
- White-collar	28.6%	46.2%	
- Unemployed	35.7%	30.8%	
Education level [b]:			0.121
- Primary School	35.7%	46.2%	
- Secondary School	50.0%	38.5%	
- University Degree	14.3%	15.3%	

ing - exercise 3: in the supine position, with a weight of 1 kg on the diaphragm located in the abdominal region: inspire through the nose and exhale through the mouth with lips half-closed slowly. The participants performed two circuits, with a total session time of 30 minutes, three times a week.

Data analysis

Statistical software package version 4 (PAST - PAleontological Statistics Software) was used to test the normality of data using the Kolmogorov-Smirnov test and Box-Cox power transformation (19). Statistical significance was set up at an alpha level of 0.05. Between groups, the baseline characteristics were tested using one-way ANOVA tests for continuous variables and chi-square test for categorical variables. The treatment effects were calculated via standardised difference or effect size (ES) using ANCOVA adjusted for baseline (ES, 95% confidence interval (CI)). Threshold values for Cohen's ES statistics were >0.2 (small), >0.6 (moderate), and >1.2 (large) (20). Quantitative chances of beneficial/better, similar/trivial, or detrimental/poorer effect were assessed qualitatively as follows: <1%, almost certainly not; >1–5%, very unlikely; >5–25%, unlikely; >25–75%, possible; >75–95%, likely; >95–99%, very likely; and >99%, most likely (20). If the chance that the true

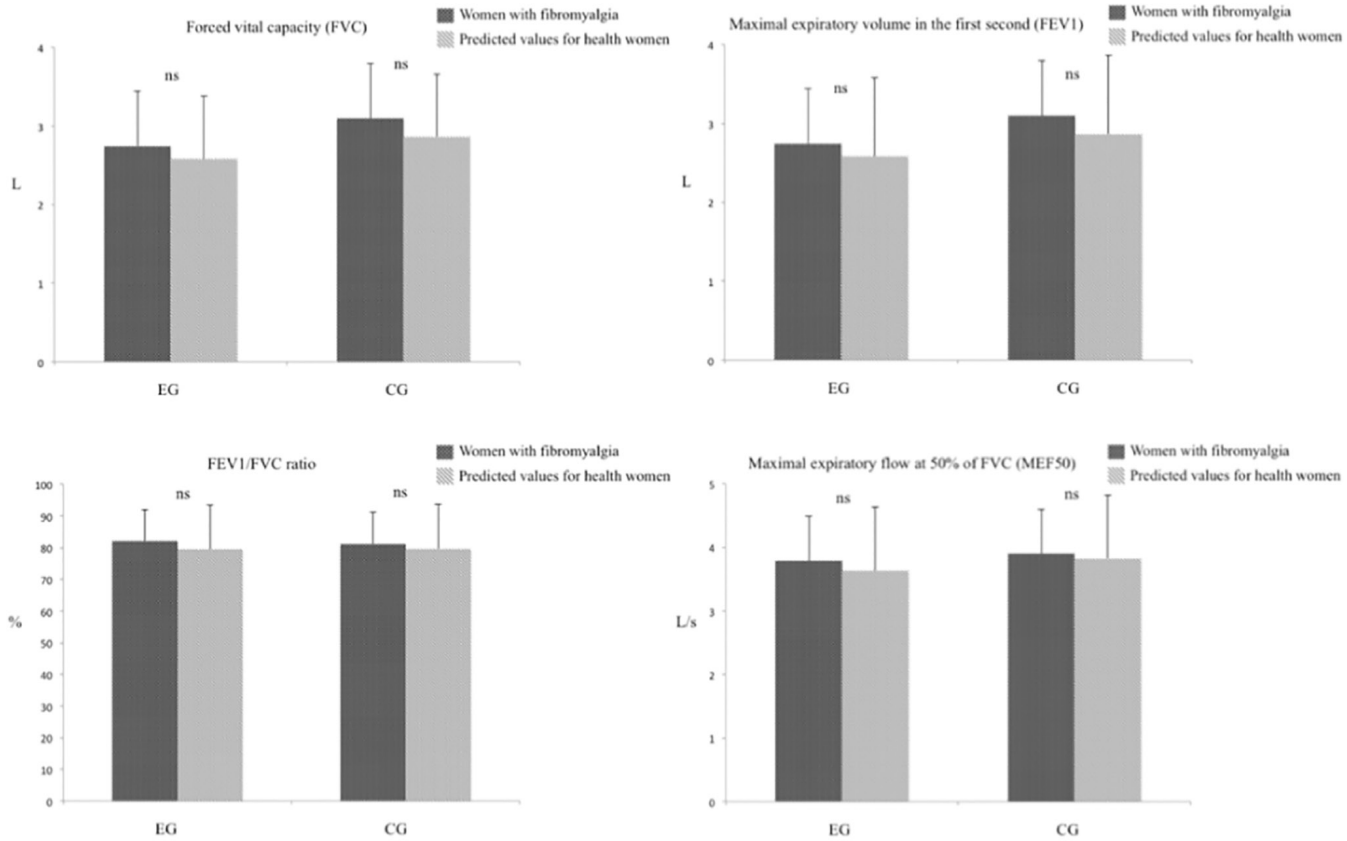

Fig. 2. Ventilatory parameters used as a diagnostic to exclude respiratory diseases in baseline.
Values expressed as mean and standard deviation in women with fibromyalgia syndrome and predicted values for healthy persons calculated according to sex, age and height in software (Medizintechnik mit System Erich Jaeger Gmbh®, Wuerzburg, Germany) at baseline.
FVC: forced vital capacity; FEV1: maximal expiratory volume in the first second; FEV1/FVC ratio; MEF50: maximal expiratory flow at 50% of FVC; EG: experimental group; CG: control group; ns: no significant differences.
p-value of paired-samples t-test.

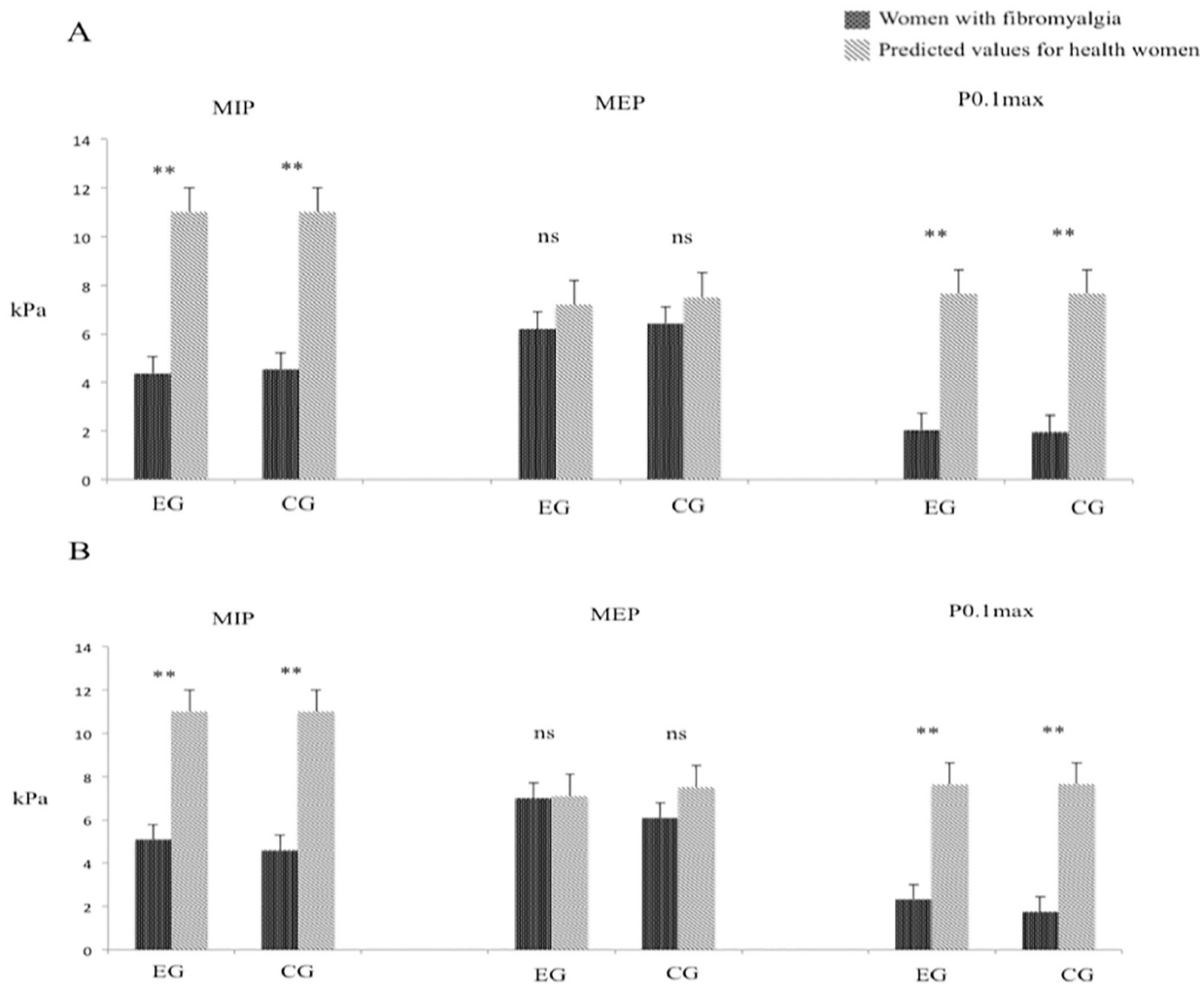

Fig. 3. Maximum respiratory pressures.
Values expressed as mean and standard deviation for women with fibromyalgia syndrome and predicted values for healthy persons calculated according to sex, age and height in software (Medizintechnik mit System Erich Jaeger Gmbh®, Wuerzburg, Germany) at baseline (A) and after 12 weeks of intervention (B). MIP: maximum inspiratory pressure; MEP: maximum expiratory pressure; P0.1max: maximum occlusion pressure; EG; experimental group; CG; control group; ns: no significant differences.
p-value of paired-samples t-test. ***p*<0.01.

value is >25% beneficial and >0.5% chance that it is harmful, the clinical effect was considered unclear. However, the clinical inference was declared as beneficial when the odds ratio of benefit/harm was >66% (20). These analyses were performed in a specific Excel spreadsheet for control trial analysis from sportsci.org.

Results

Baseline data did not show any significant differences between the EG and the CG in sociodemographic characteristics (Table I). Also, there were no observed significant differences between groups in baseline in ventilatory parameters compared to predicted values calculated for healthy people used to exclude respiratory diseases (Fig. 2). Additionally, significant differences were observed in the MIP and P0.1 max in favour of predicted values calculated for healthy persons at baseline and after 12 weeks of RMT. However, for MEP, no significant difference was observed (Fig. 3).

Effects on respiratory efficiency and thresholds of pain tolerance in tender points

Table II shows the improvements of RMT after 12 weeks of intervention. Data were obtained through ANCOVA analysis after adjusting for baseline values. So, we found statistically significant (*p*-value <0.05) and beneficial effects on respiratory efficiency in favour of the EG. In percentual terms, MIP increased 17.5% (95% CI (0.6–31.5)), MEP increased 21.6% (95% CI (-9.6–63.5)) and P0.1 max increased 27.7% (95% CI (6.5–23.4)). Additionally, these increases was interpreted according to Cohen's effect sizes, as small and moderate, as follows: MIP ES=0.36; MEP ES=0.38; and P0.1 max ES=0.63. The chances that the effect was beneficial were 83%, 74%, and 96%, respectively. Finally, the clinical inference based on a threshold >66% on odds ratio was likely, possibly, and very likely beneficial, respectively.

Effects on functional status and health-related quality of life

Table II also shows the changes in HRQoL dimensions. The EG experi-

Table II. Respiratory efficiency and health-related quality of life in sedentary women with fibromyalgia at baseline and after 12 weeks of respiratory muscle training.

	Baseline		12 weeks		Changes		Quantitative chances as %			Clinical inference	*p*-value
	EG (n=15)	CG (n=15)	EG (n=15)	CG (n=15)	Δ% (95%CI)	ES (95%CI)	harmful	trivial	beneficial		
Respiratory efficiency											
MIP (kPa)	4.37 ± 1.95	4.54 ± 2.17	5.24 ± 1.86	4.60 ± 1.96	17.5 (0.6 – 31.5)	0.36 (0.01 – 0.71)	0	17	83	likely beneficial	.033
MEP (kPa)	6.20 ± 2.49	6.42 ± 2.11	7.03 ± 2.33	6.15 ± 2.25	21.6 (-9.6 – 63.5)	0.38 (-0.20 – 0.96)	2	24	74	posibly beneficial	.045
P0.1 max (kPa)	2.04 ± 0.63	1.95 ± 0.75	2.33 ± 0.71	0.25 ± 0.70	27.7 (6.5 – 23.4)	0.63 (0.16 – 1.10)	0	3	96	very likely beneficial	.007
HRQoL											
Physical functioning	33.66 ± 14.61	42.33 ± 17.40	40.00 ± 15.52	34.33 ± 15.69	56.0 (10.6 – 119.9)	0.93 (0.21 – 1.65)	0	2	98	very likely beneficial	.008
Physical role	37.50 ± 22.65	29.16 ± 16.97	40.41 ± 15.82	23.75 ± 19.65	131.5 (1.4 – 314.2)	1.49 (0.02 – 2.95)	0	3	96	very likely beneficial	.021
Bodily pain	28.40 ± 13.79	22.30 ± 11.20	42.36 ± 15.52	22.86 ± 13.27	78.3 (-37.5 – 390.2)	1.17 (0.75 – 2.69)	11	6	84	likely beneficial	.002
General health	34.26 ± 16.31	26.33 ± 12.74	36.26 15.67	27.66 ± 12.37	-0.5 (-30.4 – 42.2)	-0.01 (-0.56 – 0.54)	22	54	24	unclear	.487
Vitality	29.58 ± 16.27	19.58 ± 12.69	33.33 ± 10.99	17.50 ± 13.61	51.2 (-31.0 – 131.5)	1.52 (0.69 – 3.31)	9	14	78	likely beneficial	.007
Social functioning	50.50 ± 17.40	31.66 ± 21.58	47.50 ± 14.33	30.83 ± 17.59	-19.0 (-52.0 – 36.7)	-0.42 (-1.45 – 0.62)	12	22	66	unclear	.162
Emotional role	45.00 ± 24.35	34.44 ± 19.63	39.44 ± 25.09	36.66 ± 31.77	21.1 (-45.5 – 169.1)	0.34 (-1.06 – 1.73)	58	20	22	unclear	.726
Mental health	40.66 ± 21.28	41.00 ± 16.05	35.00 ± 20.44	39.66 ± 23.18	-16.3 (-52.6 – 47.7)	-0.35 (-1.49 – 0.78)	16	23	61	unclear	.530

Values expressed as Mean ± SD.

EG: experimental group; CG: control group; MIP: maximum inspiratory pressure; MEP: maximum expiratory pressure; P0.1max: maximum occlusion pressure.

† P values of analysis of covariance adjusted for baseline values to compare differences between groups at 12 weeks. Δ% (95%CI): percentage changes and 95% confidence limits. ES (95%CI): Effect Size and 95% confidence limits. HRQoL: Health-related Quality of Life.

enced an improvement statistically significant (p-value <0.05) in half of the dimensions of HRQoL. According to ES, there were improvements on physical functioning ES=0.93 (95% CI (0.21–0.65)), physical role ES=1.49 (95% CI (0.02–2.95)), bodily pain ES=1.17 (95% CI (0.75–2.69)) and vitality ES=1.52 (95% CI 0.69–3.31)). The chances that the effect was beneficial were 98%, 96%, 84%, and 78%, respectively, and the clinical inference was between very likely and likely beneficial. However, the rest of the dimensions presented an unclear clinical inference.

Discussion

To our knowledge, no study has investigated the effect of RMT on respiratory efficiency and HRQoL in women with FM. The main findings revealed that participation in 12 weeks of RMT increased respiratory efficiency and HRQoL partially. The EG showed improvements in the MIP, MEP and P0.1 max compared to pre-training values, while the CG remained unchanged or even decreased. After 12 weeks of RMT, these enhancements in the EG could be explained in part by improving the strength of the diaphragm, intercostals, abdominals, scalenus, and sternocleidomastoid muscles, which are involved in the mechanical respiratory action, and also could be explained by a reduced pain intensity in regions related to the respiratory mechanism.

In agreement with our results, RMT has been documented to improve respiratory efficiency in a wide range of diseases. In a study by Budweiser *et al*. (21) where 28 patients with restrictive thoracic disease underwent in home-based RMT for 3 months, the MIP increased 27.6% in the EG compared to the CG. In agreement, Kornanong *et al*. (22) showed that a specific RMT programme over 8 weeks in people with chronic renal failure improved the MIP 12.44% in the EG compared to the CG. As well, Chung *et al*. (23) found that 12 weeks of RMT in asthmatic patients enhanced the MIP 29.8% in the EG. In this sense, our study found improvements in several respiratory parameters, such as 17.5% in MIP, 21.6% in MEP, and 27.7% in P0.1 max, in the EG.

In addition to the observed changes in respiratory efficiency variables, the individuals also experienced improvements in half the dimensions of the HRQoL. Concretely, physical functioning, physical role, bodily pain, and vitality enhanced after RMT. These changes are consistent with the findings in previous studies in women affected by fibromyalgia. Several studies have found that participation in physical exercise programmes based on Chinese breathing and relaxation techniques improved HRQoL. For example, Lynch *et al*. (24) showed that physical and mental dimensions improved; Haak *et al*. (25) found improvements in general HRQoL after 7 weeks of practicing Qigong exercises. Lastly, Bongi *et al*. (26) showed that the improvements in some dimensions of HRQoL were associated with completing 6 weeks of Qigong exercises.

The observed gain in respiratory efficiency and HRQoL could be associated with an improvement of endurance and strength of muscles related to the respiratory mechanism. In this sense, it has been shown that fibromyalgia patients present lower endurance and strength in respiratory muscles compared with healthy individuals (27-29). Therefore, we could hypothesise that improvements in respiratory efficiency and HRQoL could be related to the gain in endurance and strength in respiratory muscles.

Other factors related to improved respiratory efficiency and a better perception of quality of life could be an increase in pain threshold. It is known that fibromyalgia is related to widespread pain (1). It seems to be that, in individuals with fibromyalgia, the widespread pain could be related to an alteration of cortical excitability (30, 31). According to several studies, physical exercise evokes analgesia, reducing cortical excitability (32, 33). In our study, the individuals experienced changes in bodily pain and respiratory efficiency. Therefore, these improvements may be due to central and peripheral nervous system adaptations due to muscular respiratory exercises. The hypothesis is in line with findings in previous studies that found that, after exercise, opioid and serotonergic mechanisms could modulate pain-related symptoms (30, 32-34). Besides this, the diffuse noxious inhibitory controls (DNICs) (mechanisms by which neurons responsive to stimulation from one location may be inhibited by other painful, noxious stimuli applied to another location in the body) (35) related to exercise could play an important role. In this sense, it has been shown that individuals with fibromyalgia have this mechanism damped (31). Consequently, and following results observed in patients with chronic pain, the respiratory exercises could activate the DNIC mechanism and could be the underlying factor behind the improvements in pain perception (32, 34, 36).

The present study also included limitations, which require further discussion. First, the limited size of the sample may have contributed to decreasing statistical power to detect changes. Second, the physical activity of participants was not controlled via an accelerometer, so this could present an important bias in the improvements obtained in our programme. Although our study was a randomised controlled trial, the inferences drawn about the improvements in respiratory parameters and HRQoL must be cautious, especially when doing them on another type of population with chronic pain. However, the findings of the present study could be included in future physical exercise programmes for people with fibromyalgia, since it appears that a respiratory exercise programme improves respiratory capacity, pain perception and quality of life.

Conclusions

This study indicates that a RMT programme could be an effective therapy to enhance respiratory efficiency and HRQoL in people with FM, including better body pain perception.

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