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ORIGINAL ARTICLE

Effects of photobiomodulation and an aerobic exercise on the level of pain and quality of life in women with fibromyalgia

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Abstract

To evaluate the effectiveness of photobiomodulation (PBM) in conjunction with an aerobic exercise program (AEP) on the level of pain and quality of life of women with fibromyalgia (FM). Methods: A double-blinded randomized controlled trial in which 51 participants with FM were allocated into 4 groups: control group (CG) ($n=12$); active PBM group (APG) ($n=12$); AEP and placebo PBM group (EPPG) ($n=13$); AEP and active PBM group (EAPG) ($n=14$). AEP was performed on an ergometric bicycle; and a PBM (with an increase dosage regime) [20 J, 32 J and 40 J] was applied using a cluster device. Both interventions were performed twice a week for 12 weeks. A mixed generalized model analysis was performed, evaluating the time (initial and final) and group (EAPG, EPPG, APG and CG) interaction. All analyses were based on intent-to-treat for a significance level of $p \leq 0.05$. Results: The intra-group analysis demonstrated that all treated groups presented a significant improvement in the level of pain and quality of life comparing the initial and final evaluation ($p < 0.05$). Values for SF-36 and 6-minute walk test increased significant in intragroup analysis for EPPG comparing the initial and final evaluation. No intergroup differences were observed. Conclusions: Both exercised and PBM irradiated volunteers present improvements in the variables analyzed. However, further studies should be performed, with other PBM parameters to determine the best regime of irradiation to optimize the positive effects of physical exercises in FM patients.

Keywords Fibromyalgia · Chronic pain syndromes · Physiotherapy · Quality of life · Pain assessment and management

Introduction

Fibromyalgia (FM) is a chronic illness characterized by widespread pain and other symptoms, such as sleep alterations and fatigue, with or without a well-defined underlying organic disease [1]. Symptoms experienced (including also non-refreshed sleep, mood disturbance and cognitive impairment) lead to significant reductions in the quality of life [2, 3].

Nonpharmacologic therapies have been highlighted as effective methods to relieve symptoms of FM, among them being physical exercise [4, 5]. Physical exercise increases or maintains functional skills, muscle strength, aerobic resistance, flexibility, balance and fatigue levels, with a significant improvement in the quality of life of this population [5–8]. Ollevier et al. [9] demonstrated that a program of exercises consisting of both physical and cognitive therapies in patients with FM (for 12 weeks, twice a week), significantly improved the level of pain, distance covered in

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the 6-minute walk test (6MWT) and the quality of life of the treated individuals. However, the multi-causal etiology of FM and the symptomology, requires the need for developing additional treatments as part of a multimodal approach to care [10] especially when exercise is too difficult to engage in.

It is worth highlighting, sometimes to perform physical exercises can be painful and analgesics may be necessary to decrease pain, to facilitate adherence to an exercise program [12, 13]. In this context, studies have found that photobiomodulation (PBM) can decrease the level of pain in different populations, including those with FM [11–13]. The analgesic effects of PBM are based on the promotion of microcirculation vasodilation, endorphin production, activation of endogenous opioid receptors [14] and in the increase in the nociceptive threshold by altering axonal flow [15]. For patients with FM, in addition to the analgesic effects, PBM has also presented positive effects on the level of fatigue, depression and anxiety [10]. In addition, Silva et al. [16] showed that the combined therapy improved the pain threshold in women with FM.

The hypothesis of the present work is that PBM (used in a progressive increase dosage over time in order to promote greater stimulation throughout the treatment as well as the exercise load progression) associated with an AEP would lead to an improvement of pain and quality of life in this population. The aim of this study was to investigate the effects of PBM and AEP on the level of pain and quality of life of females with FM, since this is the gender most affected by the disease. The secondary aim was to investigate the effects of the interventions on the level of fatigue, ability to walk and balance as secondary outcomes.

Methods

Trial design

This is a four-arm double-blinded, randomized a controlled clinical trial. The eligible participants were randomized into 4 different groups:

1) control group (CG): participants with FM who did not receive any treatment;
2) active PBM group (APG): participants with FM who received only PBM;
3) exercise and placebo PBM group (EPPG): participants with FM who received AEP and placebo PBM;
4) exercise and active PBM group (EAPG): participants with FM who received AEP with active PBM.

A researcher not participating in the study, conducted the allocation drawing procedures. Participants were blinded as to group allocation.

The randomization procedure was performed through a computer program that created a random table of numbers in which each number corresponded to groups A, B, C, or D. A researcher conducted the drawing procedures without informing the participants and evaluators which PBM (placebo or active) would be applied. Thus, participants and researchers were blinded to the allocation of treatment. The data collection started in October, 2021 and the final assessment occurred in November 2022.

Ethical aspects

The present study was approved by the Ethics Committee of the Federal University of São Paulo (CAAE 4 4863420.7.0000.5505) and registered in the Brazilian Clinical Trials Registry under number RBR-6gm4ysj (registration date: 02/25/2022). Each potential participant received an explanation of study procedures and signed an informed consent form if they agreed to take part in the study.

Participants and settings

All evaluations and interventions occurred were recruited in primary care at the "Recovery and Physiotherapy Section of the Orla/Intermediate Zone – SERFIS". All the participants were informed of the procedures involved in the study including evaluations, the therapeutic interventions and possible risks of the study, and were informed to continue to receive their previous pharmacological prescribed treatments.

The inclusion criteria were

Diagnosis of FM according to the criteria of the American College of Rheumatology [17]; age between 18 and 60 years; female; education level for understanding the questionnaires; classified as irregularly active according to the International Physical Activity Questionnaire - short version (IPAQ).

The exclusion criteria were

Uncontrolled systemic diseases; neurological and musculoskeletal conditions that may directly interfere with assessments and treatment; pregnancy; malnutrition [Body Mass Index (BMI) < 18.5] or morbid obesity (BMI ≥ 40); absolute PBM contraindication (neoplasia).

Sample size

Sample size calculation was performed by the computer software G*Power version 3.1.9.2 (Heinrich-Heine-Universität Düsseldorf, 2010–2019), considerate of the two-way ANOVA statistical test for four intervention groups. The calculation was based on the Visual Analog Scale (VAS) of pain, thus, a 40% change in the pain variable was considered to determine the size of the sample effect, from previous studies demonstrated in the literature. A sample size of 48 participants was calculated (Beta error: 95%; Alpha error: 5%, Effect Size: 0.40).

Outcome measurements

Each participant was interviewed by an investigator to assess eligibility criteria. The eligible participants underwent an initial evaluation (T0) and were re-evaluated after 12 weeks (T1).

Experimental procedures

1. VAS assesses the patient's self-reported pain constituted by a straight line with the endpoints defining extreme limits such as 0 means no pain and 100 the worst imaginable pain. The participant marked their pain between the two endpoints and the distance between 'no pain' and the mark was recorded [18].
2. The pressure pain threshold (PPT) was analyzed by a digital algometer (DD-2000 model, InstruthermVR, São Paulo, Brazil), and applied, bilaterally, on upper trapezius muscles, biceps brachii muscles, quadriceps muscles, hamstrings muscles and gastrocnemius muscles. Pressure was exerted using the flat tip (1 cm2) of the device in direct contact with the skin at the "fast" velocity on the "peak hold" function 1 kg/second (specification of the digital DD-200 algometer from InstruthermVR). Participants were instructed to indicate the sensation of pain due to the applied pressure.
3. The Short Form Health Survey 36 (SF-36) is a questionnaire that has 8 components of quality of life. The total score for each domain ranges from 0 to 100, with the highest value representing a more favorable condition. [19]
4. Fibromyalgia Impact Questionnaire-Revised (FIQR) has 21 questions organized into three domains: function, overall impact, and symptoms. Higher FIQR scores indicate a greater impact of FM on individual's quality of life [20]. The FIQR score is the sum of the three domain scores: function, general impact and symptoms.
5. Timed Up-and-Go (TUG) test quantifies, in seconds, the functional mobility through the time the individual needs to perform. The quantification of time was performed using an automatic timer that has high reliability [21].
6. The 6MWT was carried out in a flat location, with a course of 30 m in a straight line, and applied always by the same examiner with verbal encouragement during the course. The Borg perceived exertion rate with conventional Borg scale (6–20 points) and heart frequency and rate (HR) were monitored throughout the test [22].
7. Fatigue Severity Scale (FSS): Fatigue Severity Scale (FSS): is a composite instrument with 9 items that quantifies self-reported fatigue. The higher the score, the greater the symptom severity [23].

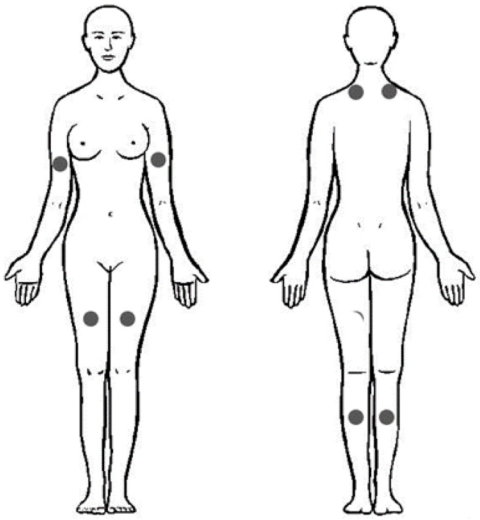
Therapeutic interventions

Aerobic exercise program

AEP used in the present study was based on the work of Bidonde et al. [7] and American College of Sports Medicine [24]. AEP consisted of 12 consecutive weeks, twice a week, with the following steps: AEP is performed using an ergometric bicycle (Kikos Pro Kv9.5Ix) with load progression training (20 min): level 1 for the first 8 sessions, level 2 for the next 8 sessions and level 3 for the last 8 sessions. The pedaling frequency (rpm/Watts) was controlled by maximum heart rate (HR_{max}), in which the participant maintained a moderate intensity between 75 and 80% of the predicted HR_{max}. The participants were encouraged to increase the pedaling frequency, rpm/Watts, if the HR was below the HR_{max} stipulated by the prediction equation or decreasing if the HR was above the expected HR_{max}, during 20 min. At the end of the AEP, the participants performed stretching of the biceps, trapezius, hamstrings, quadriceps and gastrocnemius muscle groups, once every 30 s each muscle group bilaterally. To estimate the predicted HR of the participants, a prediction equation was used "$208 - 0.7 \times$ age". This equation was based on a study that determined how the HR formulas predicted by age can be used in a population of people with FM [25].

PBM application

PBM irradiation was performed over the areas where PPT was assessed, bilaterally upper trapezius, biceps brachii, quadriceps, hamstrings and gastrocnemius muscles (Fig. 1). EPPG and EAPG received PBM immediately after each AEP session and APG received only PBM irradiation 12 consecutive weeks, twice a week. All participants as well



Parameters	Values
Wavelength	808nm
Operation mode	continuous
Power	100mW
Total energy per point	20/32/40J
Application time per point	50/80/100s
Diode beam area	0.07 cm^2

Fig. 1 PBM points and parameters adopted in this study. nm: nanometer, mW:milliwatts, J: joules, cm^2: square centimeters

Table 1 Demographic and anthropometric data of the participants

Groups/variables	Age (years)	Body mass (kg)	Height (m)	BMI (kg/m^2)
CG	57.75 ± 3.79	73.16 ± 18.13	1.59 ± 0.05	28.89 ± 7.76
APG	44.16 ± 12.15	77.1 ± 15,69	1.67 ± 0.06	27.60 ± 5.38
EPPG	57.15 ± 5.35	69.98 ± 8.28	1.62 ± 0.06	26.58 ± 3.55
EAPG	51.21 ± 111.20	75.71 ± 13.60	1.59 ± 0.04	30.14 ± 4.32

kg: kilograms; m: meters; kg/m^2: kilograms per meter square, EPPG: exercise and placebo PBM group; EAPG: exercise and active PBM group; APG: active PBM group; and CG: control group

as the person responsible for data collection and analyzing were blinded to the participant group allocation, and the sessions were individualized to participants.

The equipment used was an Antares® (IBRAMED, Amparo, SP, Brazil), cluster probe with 7 diodes (with a total area of the cluster of 2 mm in diameter). It is worthwhile to emphasize that the equipment was calibrated by the manufacturer before the experiments. However, the irradiation parameters used are shown in Fig. 1.

Statistical analysis

Data were analyzed using IBM SPSS Statistics software (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp). The homogeneity of the variances and the normality of the distribution were verified using the Levene and Kolmogorov-Smirnov tests, respectively. An intention-to-treat analysis was performed and, for missing data, the results obtained in the last available evaluation of each participant were repeated [26]. A mixed generalized model analysis was performed for the outcomes of interest, evaluating the time (initial and final) and group (EAPG, EPPG, APG and CG) interactions. The Bonferroni test was used *post hoc* for significant interactions and a significance level of $p \leq 0.05$ was adopted for all tests.

Results

The baseline demographic and anthropometric data from the participants are demonstrated in Table 1. No statistical differences were found among the groups for any variable.

The participants' flowchart is presented in Fig. 2.

The intragroup analysis of VAS revealed a significant reduction in the level of pain after the intervention period in all treated groups (EPPG: 7.7 ± 1.9 vs. 3.9 ± 2.7; EAPG: 6.3 ± 1.2 vs. 4.5 ± 2.4; APG: 6.4 ± 1.8 vs. 4.1 ± 2.7; $p \leq 0.05$) (Fig. 3). However, no intergroup difference was observed.

The pain values obtained from pressure algometry are presented in Table 2. For the right biceps muscle, and right and left gastrocnemius muscles, the intragroup evaluation demonstrated a significant improvement for EPPG and EAPG comparing the initial and final evaluation. For the right and left trapezius muscle, the intragroup evaluation demonstrated a significant increase (improvement) for EPPG comparing the initial and final evaluation. For left side biceps muscle, left side quadriceps muscle and right-side quadriceps muscle, the intragroup evaluation demonstrated a significant increase in the EPPG comparing the initial and final evaluation. For the right-side trapezius and right-side gastrocnemius muscles, the intragroup evaluation demonstrated a significant increase for APG comparing the initial and final evaluation.

The analysis of the FIQR data demonstrated a significant decrease in the values found for all treated groups comparing the initial and final evaluation (EPPG: 70.6 ± 15.9 vs. 50.4 ± 19.3, EAPG: 72.3 ± 13.3 vs. 52.7 ± 25.3, APG: 70.5 ± 20.7 vs. 48.2 ± 24.5; $p \leq 0.05$) as showed in Fig. 4a. For SF36 questionnaire, the intragroup analysis showed a significant increase of quality of life in the EPPG participants (EPPG: 38.4.6 ± 20.2 vs. 55.7 ± 20.2; $p \leq 0.05$) after intervention as showed in Fig. 4b.

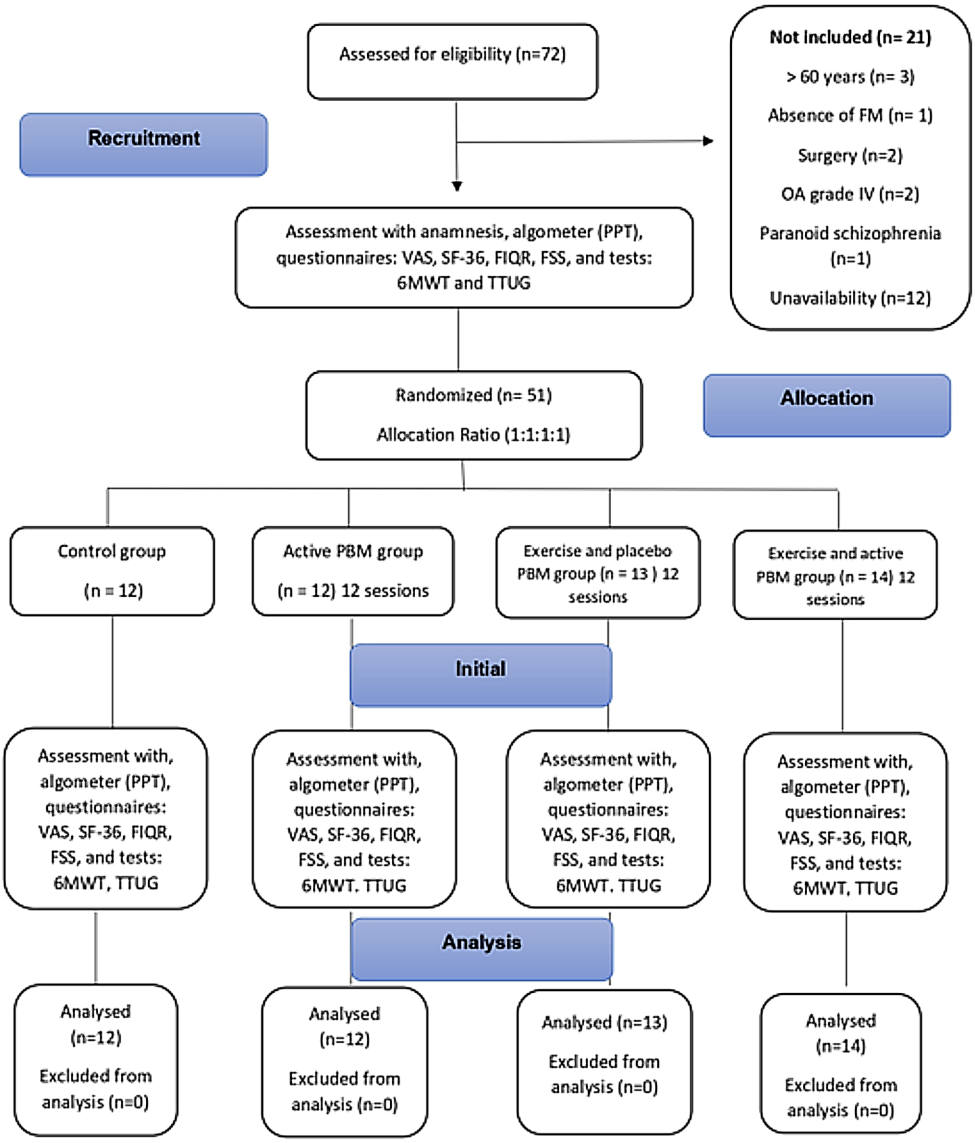


Fig. 2 Flowchart of participants

The TUG testing demonstrated a significant decrease in time taken to do the test, in the intra-group analysis for all treated groups (EPPG, EAPG and APG) in the values found in the evaluation and re-evaluation (Fig. 5a). The 6MWT demonstrated a significant increase in the distance walked in the participants of the EPPG comparing the evaluation and the re-evaluation (Fig. 5b). The fatigue threshold measured by FSS demonstrated a significant improvement for all treated groups in the intragroup evaluation (APG, EPPG and EAPG) after the intervention (Fig. 5c).

Discussion

In the present study, the participants who performed only the AEP or received only the PBM application demonstrated a significant intragroup difference for all parameters evaluated, demonstrating the effect of both interventions when applied alone.

It is well known that physical exercise programs are an efficient non-pharmacological intervention to manage the symptoms of FM, especially pain [5, 6]. Sosa-Reina et al. [5] concluded that aerobic and muscle-strengthening exercises are the most effective ways of reducing pain and improving global well-being in people with FM. The AEP for 30 to 60 min at an intensity of 50–80% of HRmax (2–3 times/week for a period of 4–6 months) and muscle strengthening exercises (1–3 sets of 8–11 exercises, 8–10 repetitions with a load of 3.1 kg or 45% of 1 repetition maximum (RM) seem to be most effective in decreasing pain in people with FM [5]. In this context, these statements corroborate the results found in the present study, that demonstrated a decrease in the level of pain in the exercised participants with FM. Moreover, PBM application also produced positive results

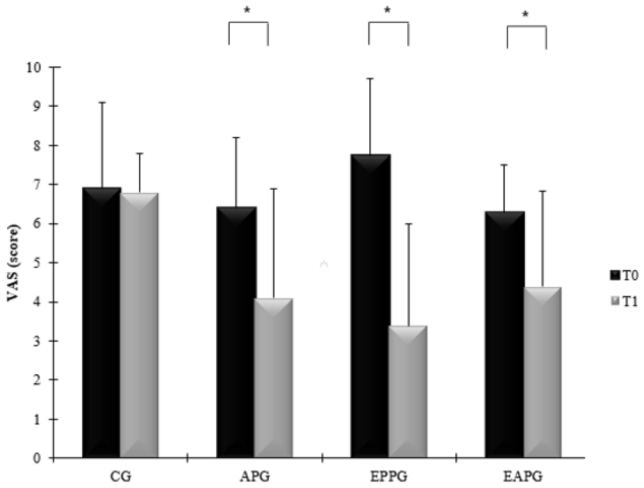


Fig. 3 Means and standard deviation of VAS measures of all groups at T0 and T1 moments. VAS: visual analogue scale; EPPG: exercise and placebo PBM group; EAPG: exercise and active PBM group; APG: active PBM group; and CG: control group; T0: baseline evaluation; T1: evaluation after 12 weeks of intervention; * significant statistical difference

for decreasing the level of pain after the period of intervention, confirming the positive effects of PBM when used with progressive increase in the dose over the treatment period explaining by the analgesic effects of PBM [27]. Interestingly, in this study, PBM has not optimized the positive effects of the exercise program on the pain level, as appears to have been the case in other study [16]. As a possible explanation, the progressive increase in the dosage regime used in this study may have constituted an excessive stimulus for the exercised participants, instead of offering the energy needed throughout the treatment like exercise load progression, exceeding the optimum stimulus for managing pain levels. In contrast, Silva et al., [16] demonstrated that, by combining PBM and physical exercises, a decrease in the level of pain in people with FM is observable.

Furthermore, the psychosocial disturbances, balance impairments and functional incapacity present in people with FM are closely related and have a significant impact on the quality of life in this population [27]. In the present study, all the treated participants presented an intragroup significant increase in the quality of life after the intervention period. Rodríguez-Mansilla et al. [28], investigating the effects of an active exercise program in women with FM, demonstrated an increase in their well-being scores, a decrease in pain and improvement in the quality of life. Also, Silva et al., [16] used a treadmill with a load established through 75% of the HR_{max}, performed for 30 min, 2x/week for 10 weeks combined with PBM (cluster device) at 11 anatomical points. The authors reported an association

Table 2 Means and standard deviation of algometer measures (in kg/cm^2) of all groups in T0 and T1 moments

	CG ($n=11$)		APG ($n=12$)		EPPG ($n=13$)		EAPG ($n=14$)	
Variables/ moments	T0	T1	T0	T1	T0	T1	T0	T1
Right biceps	1.65 ± 0.59	1.66 ± 0.58	1.35 ± 0.65	1.70 ± 0.77	1.67 ± 0.59	2.01 ± 0.58*	1.52 ± 0.80	1.89 ± 0.63*
Left biceps	1.84 ± 0.58	1.96 ± 0.54	1.25 ± 0.53	1.56 ± 0.73	1.73 ± 0.70	1.84 ± 0.40	1.34 ± 0.46	2.00 ± 0.94*
Right upper trapezius	2,10 ± 0,79	2,30 ± 0,98	1,73 ± 0,94	2,28 ± 1,13*	1,87 ± 0,91	2,92 ± 1,11*	1,53 ± 0,80	1,89 ± 0,63
Left upper trapezius	2,06 ± 0,78	2,18 ± 0,86	1,91 ± 0,90	2,22 ± 0,92	1,81 ± 0,90	2,72 ± 0,90*	1,89 ± 0,82	2,32 ± 0,87
Right quadriceps	3,10 ± 1,42	2,85 ± 1,10	2,03 ± 0,88	2,51 ± 1,16	2,65 ± 1,08	2,88 ± 1,00	2,23 ± 0,85	2,90 ± 1,13*
Left quadriceps	2,68 ± 1,11	2,78 ± 1,19	2,02 ± 1,02	2,58 ± 1,33	2,64 ± 0,97	3,34 ± 1,18*	2,21 ± 0,89	2,63 ± 1,16
Right gastrocnemius	2,85 ± 0,88	3,06 ± 1,32	2,18 ± 1,22	2,70 ± 1,54*	2,13 ± 1,29	3,27 ± 1,49*	2,14 ± 0,68	3,23 ± 1,52*
Left gastrocnemius	3,08 ± 1,34	3,08 ± 1,41	1,88 ± 1,11	2,91 ± 1,60	2,20 ± 1,26	3,30 ± 1,49*	1,98 ± 1,25	3,06 ± 1,62*

CG: Control Group; APG: Active PBM Group; EPPG: Exercise and Placebo PBM Group; EAPG: Exercise and Active PBM Group; T0: Baseline Evaluation; T1: Evaluation after 12 weeks of intervention

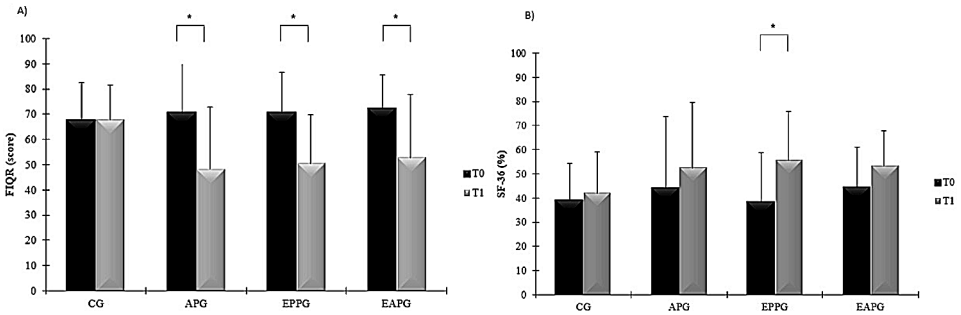


Fig. 4 Means and standard deviation of FIQR and SF-36 outcome measures of all groups at T0 and T1. FIQR: Revised Fibromyalgia Impact Questionnaire; SF-36: Short Form Health Survey 36; EPPG: exercise and placebo PBM group; EAPG: exercise and active PBM group; APG: active PBM group; and CG: control group; T0: baseline evaluation; T1: evaluation after 12 weeks of intervention; * significant statistical difference

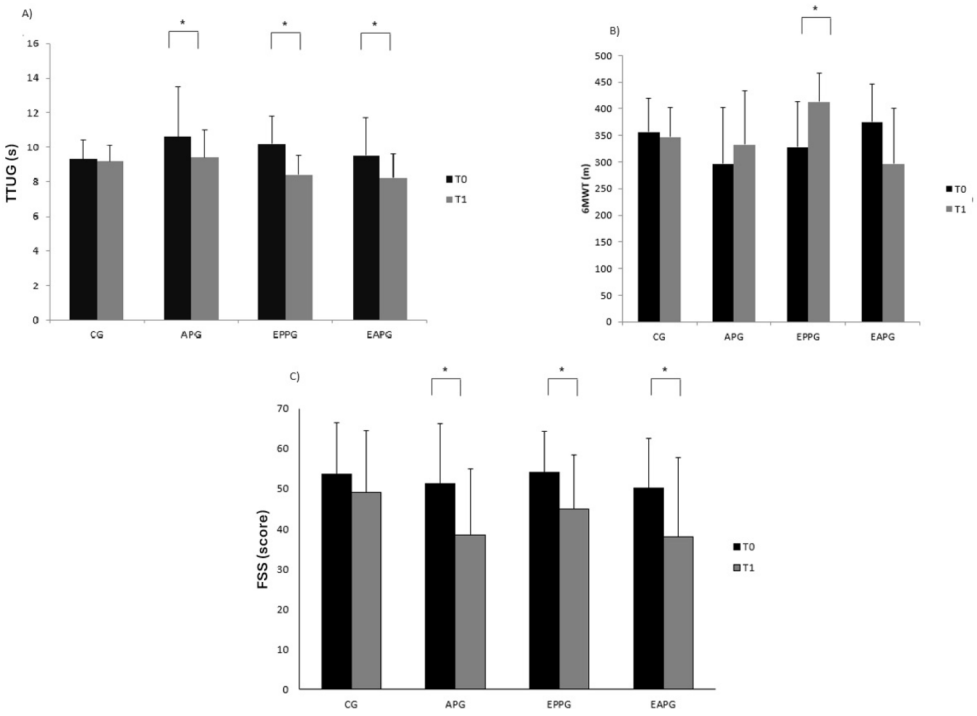


Fig. 5 Means and standard deviation of TTUG, 6MWT and FSS outcome measures of all groups at T0 and T1. TTUG: Test Timed Up-and-Go; 6MWT: 6-minutes walking test; FSS: Fatigue Severity Scale; EPPG: exercise and placebo PBM group; EAPG: exercise and active PBM group; APG: active PBM group; CG: control group; T0: baseline evaluation; T1: evaluation after 12 weeks of intervention; s: seconds; m: meters. * significant statistical difference

of both therapies, presenting a more pronounced effect on quality of life in this population.

Measures of the level of fatigue showed a significant improvement in all treated groups. It is known that more than 80% of people with FM experience severe fatigue and this is considered a FM diagnostic criterion, being one of the priority targets for treatment [29]. Similarly to the other studies [7, 30], the irradiated participants showed an improvement in the levels of fatigue. Yeh et al. [10] demonstrated that PBM produced a significant reduction in the severity of fatigue, stiffness, depression and anxiety in participants with FM. The positive effect of PBM on the FM-related fatigue levels may be related to the effects of PBM on the stimulation of mitochondrial respiration, adenosine triphosphate (ATP) production and cellular energy [12].

Moreover, TTUG and 6-MWT are simple and practical tests, used in many studies to evaluate functional capacity of individuals with FM [31]. Improved TTUG and 6-MWT values were observed for the trained participants after the AEP (with or without the association with PBM). This outcome can be explained by the type of exercise training performed. The irradiated participants presented a significant intragroup change only in the TUG test, which was the same behavior found for the exercised and PBM-irradiated participants.

Physical exercise and PBM have positive effects on knee OA patients due to its analgesic and anti-inflammatory effects, decreasing swelling and pain and improving function [17]. Also, the association of both therapies might be a promising therapeutical intervention to manage the symptoms of OA, thus becoming important to substantiate gains in pain relief which has direct implications for strength and functionality of people with knee OA. However, in the present study, combining PBM and exercise has not culminated in any significant extra effect on the variables evaluated.

The present study was pioneer in investigating the PBM effects using a cluster device (in a progressive increase of the dosage over time) in patients with FM. Also, it is worthwhile to point out that a strength of this work is the irradiation using a cluster device, optimizing the PBM application (offering the possibility of delivering a higher energy in short period of time). However, the present study included a small size sample per group, which may limit the extension of the positive effects of both therapeutical interventions to all patients with the diagnostic of FM. Moreover, the inclusion of long-term follow-up assessments should be introduced in future studies.

Conclusion

In the present study, AEP and PBM produced positive effects on the improvement of all the primary and secondary outcomes evaluated in the present study of women with FM. However, further studies should be performed, with other PBM parameters to determine the best regime of irradiation to optimize the positive effects of physical exercises in FM patients. As this study was limited to relatively short-term evaluation of the performance of AEP and PBM to provide

control / management of the symptoms related to the FM, information on the long-term performance of this therapeutic modality, as well as evaluation of the most suitable PBM parameters remains to be resolved.

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Declarations

Ethical approval The study was carried out in accordance with the ethical standards of our institution.

Conflict of interest The authors have no conflicts of interest to declare.

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