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Effectiveness Of Low-Intensity Exercise and Cognitive Behavioral Therapy In Female Patients with Fibromyalgia

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ABSTRACT

Background: Fibromyalgia (FM) is a chronic neuroendocrine syndrome characterized by physical symptoms such as widespread pain, fatigue, and other psychological symptoms. This study aimed to reveal the effectiveness of low-intensity exercise and cognitive behavioral therapy for insomnia (CBT-i) on pain catastrophizing, endurance, quality of life (QoL), and quality of sleep among female patients with FM.

Methodology: A randomized controlled trial was conducted with 30 female patients with FM who were chosen based on the selection criteria. By using simple random sampling, those patients were randomly allocated to Group A and Group B. Group A (n=15) received a low-intensity exercise program combined with CBT-i, and Group B (n=15) received CBT including counseling, pain coping strategies such as mental imagery and relaxation techniques for a period of six weeks.

Results: Outcome variables such as pain catastrophizing, endurance, QoL, and quality of sleep were assessed before and after intervention. After treatment duration, all outcome variables significantly improved in Group A and Group B.

Conclusion: Group A treated with a low-intensity exercise program with CBT-i was found to be more effective in reducing pain catastrophizing and improving endurance, QoL, and quality of sleep than Group B treated with CBT only. A low-intensity exercise program with CBT-i would be beneficial in managing FM cases. Future studies can be conducted with a larger sample size of genders, long treatment duration, and follow-up measurements.

Keywords: *Fibromyalgia, Cognitive behavioral therapy, Cognitive behavioral therapy for insomnia, Pain catastrophizing, endurance.*

1. INTRODUCTION

Fibromyalgia (FM) is a rheumatic disease of unknown etiology, which is characterized by widespread pain and associated with multiple other symptoms, including fatigue, anxiety, and depression. The global prevalence of FM in the general population is 2.7%, representing a female-to-male ratio of 3:1, and the diagnosis is most often made in middle age. The pathophysiology of FM is complex and multifactorial, involving both peripheral and central mechanisms (Bellato et al., 2012). In the past, fibromyalgia was primarily considered a rheumatic disorder, but it is now recognized as a central nervous system sensitization disorder. The diagnostic criteria have shifted from reliance on tender points to a more comprehensive evaluation of the widespread nature of pain and associated symptoms (Sharie et al., 2024). Fibromyalgia is not a diagnosis of exclusion, and it is essential to conduct a careful differential diagnosis to rule out other potential causes of the patient's symptoms (Bellato et al., 2012).

FM is a problem related to the processing of pain in the brain. Patients with FM usually become hypersensitive to the perception of pain. Notably, FM presents with elevated excitatory neurotransmitters like glutamate and substance P, diminished serotonin and non-epinephrine levels in the descending antinociceptive pathways in the spinal cord, and dysregulation of dopamine. It is more common in women than men because of the following: higher levels of anxiety and depression use of maladaptive coping methods, altered input to the CNS, and hormonal effects of the menstrual cycle

(Andreano et al., 2018; Paller et al., 2009). There is no evidence of tissue inflammation despite symptoms of soft tissue pain. FM is a pain regulation disorder, as suggested by ongoing research, and is often classified as a form of central sensitization syndrome. It is also considered a neurosensory disorder where the individual cannot process pain in the brain. Moreover, the constant hypervigilance of pain is also associated with numerous psychological issues. Furthermore, FM may be considered to be a discrete diagnosis or constellation of symptoms characterized by central nervous system (CNS) pain amplification with concomitant fatigue, memory problems, and sleep and mood disturbances. The treatment methods, such as pharmacotherapy, patient education, cognitive behavioral therapy, and physiotherapy, effectively reduce FM symptoms. In particular, physiotherapy management for FM includes low-intensity therapeutic exercise, massage therapy, kinesiotherapy, electrotherapy, and hydrotherapy (Antunes & Marques, 2022; Santos et al., 2020; Wepner et al., 2014).

Among those physiotherapy techniques, low intensity therapeutic exercise seems effective and beneficial for FM cases by reducing fatigue and improving functional capacity. Low-intensity exercise program, combining endurance training, i.e., aerobic and resistance exercises aimed at improving endurance and coordination, and adapted to the symptomatology of patients (i.e., individualized and progressive) on pain catastrophizing and other psychological variables such as pain acceptance or self-perceived functional capacity in females with FM. In addition, cognitive behavioral therapy (CBT) is a proven technique to reduce pain catastrophizing, and cognitive behavioral therapy for insomnia (CBT-i) for improving sleep and overall QoL in females with FM. Further, it is a widely used psychological treatment for a wide range of health problems, including chronic pain (Bernardy et al., 2013; Cunningham & Shapiro, 2017).

It effectively enhances patients' beliefs in their abilities and develops ways to deal with health problems. It primarily focuses on changing negative thoughts and feelings that individuals may have of their physical and mental problems and changing their behavior accordingly. Patients learn skills (i.e., relaxation, activity pacing) to help them manage their pain better, develop different attitudes towards pain (i.e., more acceptance), or both. Behavioral and cognitive behavioral psychological therapies are used to manage chronic pain by attempting to change negative thoughts about pain and introduce behavior modification, including self-management techniques, to improve function and cope with pain. Besides, sleep disturbances play an essential role in the exacerbation of pain and other troubling symptoms reported by patients with fibromyalgia (FM). A previous study analyzed the efficacy of a cognitive-behavioral therapy for insomnia (CBT-i) versus a sleep hygiene education program for improving sleep and other clinical manifestations in FM. Notably; CBTi encompasses sleep hygiene, stimulus control, sleep restriction, cognitive therapy, and relaxation training. It is a valuable treatment that affects remission, sleep onset latency, wakefulness after sleep, sleep efficiency, and sleep quality in adults with insomnia, including older adults and adolescents (Cunningham & Shapiro, 2017; San & Arranz, 2024; Wang et al., 2016).

Based on the previous literature, low-intensity exercise program would improve catastrophism in females with FM, which results in an improvement in other related psychological and physical symptoms. CBTi improves sleep and different clinical manifestations in FM cases. Therefore, this study aims to compare the effects of low-intensity exercise program (i.e., aerobic and low-load resistance exercises) and CBT on pain catastrophism, endurance, QoL, and quality of sleep among female patients with FM.

2. METHODS

Study design and setting

A randomized controlled trial was conducted to compare the effects of a low-intensity exercise program (i.e., aerobic and low-load resistance exercises) and CBT on pain catastrophism, endurance, QoL, and quality of sleep among female patients with FM. This study was conducted at Sri Balaji Vidyapeeth School of Physiotherapy, Pondicherry. The study duration was 3 months. Besides, the sample size of 20 patients was estimated based on the standard deviation and variance obtained from the previous study in the software Openepi-Version-3.0.

Participants

This study applied the inclusion and exclusion criteria to recruit the study participants. According to the 2016 American College of Rheumatology, criteria for FM and having received pharmacological treatment for more than three months with no clinical improvement are selected. The inclusion criteria comprise i) female FM patients aged from 30 to 60 years and ii) those who adhered to the American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. The diagnostic criteria for fibromyalgia if the following three conditions are: 1) The widespread pain index (WPI) is 7, and the symptom severity (SS) scale score is 5, or WPI equals 3 to 6, and the SS scale score of 9, 2) Symptomatology has been present at a similar level for at least months, and 3) The patient does not demonstrate any other disorder that would otherwise explain the pain 20. In addition, the exclusion criteria embrace i) females aged below 30 and above 60 years, ii) those with pregnancy, iii) those patients with rheumatoid arthritis (intermediate stage and late stage), known severe cardiovascular disease (i.e., uncontrolled arterial hypertension/hypotension, atherosclerosis, cardiac pacemaker), severe osteoarthritis, peripheral neuropathy, hyperthyroidism (Graves diseases), neoplasia, iv) those underwent any surgery in the last four months, and v) those who are using psychoactive drugs or narcotics or disoriented patient.

Moreover, 30 female patients with FM were recruited based on the selection criteria and were assigned to one of two groups

using a simple random sampling method. Among the two groups, Group A received a low-intensity exercise program (i.e., aerobic and low-load resistance exercises aimed at improving endurance) combined with CBT-i. Group B received CBT only. Furthermore, the selected patients were evaluated with outcome variables such as pain catastrophizing, endurance, QoL, and quality of sleep before and after the intervention. The scales such as pain catastrophizing scale, rate of perceived exertion (RPE), revised fibromyalgia impact questionnaire (FIQ-R), and Pittsburgh sleep quality index (PSQI) were used to measure pain catastrophizing, endurance, QoL, and quality of sleep, respectively. Those were given detailed explanation of the training procedure, after complete explanation an informed consent letter was signed and collected from them for confirming their willingness to participate in the study. Furthermore, the exercise training was given for 6 weeks with three sessions per week. The pretest and posttest values were assessed before and after 6 weeks of training, respectively.

Interventions

In Group A (Experimental group), the participants were treated with a low-intensity exercise program (i.e., aerobic and low-load resistance exercises aimed at improving endurance) combined with CBT-i supervised by a physical therapist with expertise in therapeutic exercise. The exercises were designed according to exercise recommendations proposed by the 2014 Guide for the Prescription of Physical Exercise of the American College of Sports Medicine for improving muscle endurance 21, 22. The exercise program was administered for 18 sessions, which were performed thrice a week (60 min each) for six weeks. The sessions were divided into two stages: the first (i.e., sessions 1 to 6) was devoted to the participants' adjustment and familiarization with the exercise, and the second (i.e., sessions 7 to 18) aimed at personalized strength and coordination training. In this regard, training intensity was adjusted by controlling the individual's pain tolerance and self-perceived exertion using the visual analogue scale and Borg perceived exertion scale. Each session was divided into three parts: warm-up, training, and cool-down. The warm-up consists of slow walking and moving the main joint structures (neck, shoulders, elbows, wrists, hips, knees, and ankles) within the patient's range of motion. The training program includes squats with wall support, leg extension while prone lying, Bilateral dumbbell front raise while standing, standing hip abduction with a soft elastic band, chest lateral pull-ups while standing, shoulder external and internal rotation while standing, sitting down, and standing up from a chair without using arms, throwing a ball above the head and catching it, standing calf raises, and low step-ups. The cool-down consists of walking at a slow pace, overall trunk stretching, and deep breathing while lying on the floor.

Moreover, the training in the first stage (sessions 1 to 6) consisted of walking at a comfortable speed for 15 minutes, performing a 10-exercise circuit for 25 minutes, and cooling down for 20 minutes. In the second stage (5^{th} to 18^{th} session), after a 10-minute warm-up, the participants had to perform as many repetitions as possible in each exercise of the 10-exercise circuit for 40 minutes. Subsequently, they cooled down for 10 minutes. After some time, this method of progressing exercise makes the patient feel confident in training and more boosted to participate as they can see that they became familiarized with the training program. The initial stage of training is primarily involved in educating the patients with exercise and finding the individualized repetition maximum (RM) for each patient. Furthermore, the intensity of the exercise program varies or patients are grouped according to their muscle power, stamina, or RM for a proper session. The repetition of each exercise varies from 15-30 repetitions according to the patient's muscle endurance or capabilities. The patients were grouped together with similar muscle power and endurance for a better training program. For the prevention of patients' dropouts, the sessions were done in a group exercise manner so that the patient doesn't feel apart from their fellowmen due to their disability, it helps them socialize with people having same disability, and they feel confident and motivated during the group therapy and a competition spirit can be built quickly through group activities. Also, the patients were advised about the effect of proper training and individualized home care programs for reducing muscle soreness after training. Such effort helps the patient feels comfortable and motivated during the training process.

During warm up and cool down period, relaxing music, laughing therapy, task oriented fun activities such as ball throwing in a circle to one to another, using a dance move etc. helps the patients feel more enthusiastic and motivated during training. Hence, the patients only work outs for 25 to 35 minutes in total with intermittent rest period and the warm up and cool down period is used to motivate and boots their self-confidence and mental state. Thus, the patients feel more motivated to participate, thereby achieving fewer chances of dropping out. To reduce sleep deprivation, sleep diaries are provided to patients, and they are educated through CBTi protocol to replenish their quality of sleep.

In Group B (Control group), the participants were treated with CBT only for 18 sessions, comprising three sessions per week for six weeks. Each session lasted 45 minutes and included pain cope-up techniques, problem-solving counselling, relaxing breathing exercises, and mental imagery techniques. Precautions such as the time and date for the session were informed prior to the participants of groups through a common social media group. Proper communication with the group members helps to reduce dropouts or missing a session.

Statistical analysis

The collected data were analyzed using SPSS (Statistical Package for Social Sciences) for Windows, version 27.0. The Paired t-test was applied to reveal significant differences between pretest and posttest scores of outcome variables in each group separately. Furthermore, an unpaired t-test was employed to evaluate the effectiveness of treatment means on outcome

variables between the two groups. All statistical tests were performed at a 5% of level of significance.

3. RESULTS

Table - 1. Analysis of Pain catastrophizing, Endurance, Quality of Life, Quality of Sleep of Female Fibromyalgia patients in Low-intensity exercise program and CBT only group using Paired -t test

Outcome Variables	Groups	Pretest	Posttest	Mean Difference	P-value	95% CI	
		Mean ± SD	Mean ± SD			Lower	Upper
Pain Catastrophizing	A	36.466 ± 1.726	31.600 ± 2.131	4.866	0.000*	3.8229	5.9104
	B	35.200 ± 2.336	32.600 ± 2.529	2.600	0.000*	1.881	3.319
Endurance	A	6.667 ± 0.617	7.466 ± 0.639	0.800	0.000*	0.570	1.029
	B	6.886 ± 0.351	7.666 ± 0.487	0.780	0.042*	0.029	0.429
Quality of Life	A	55.600 ± 2.261	49.600 ± 2.412	6.000	0.000*	5.189	6.810
	B	54.733 ± 2.685	54.333 ± 2.581	0.400	0.014*	0.184	0.984
Quality of Sleep	A	13.133 ± 1.302	10.333 ± 0.816	2.800	0.000*	2.238	3.361
	B	11.933 ± 0.798	11.666 ± 0.975	0.267	0.001*	0.343	1.123

**Significant at 0.05 level (p<0.05)*

In this study, there were no dropouts of patients, and no adverse events observed during the treatment duration. While comparing the outcome variables between the pretest and posttest mean scores, there was a significant reduction in pain catastrophizing mean score, improvement in the mean scores of endurance, QoL, and quality of sleep in Group A ($p<0.05$). Likewise, Group B demonstrated a significant reduction in pain catastrophizing mean score, improvement in the mean scores of endurance, QoL, and quality of sleep ($p<0.05$) (Table 1). Specifically, Group A showed a better reduction in pain catastrophizing (mean difference of 4.866; 95% CI: 3.8229; 5.9104, $p<0.05$); endurance (mean difference of 0.800; 95% CI: -0.570, 1.029, $p<0.05$); QoL (mean difference of 6.000; 95% CI: 5.189, 6.810, $p<0.05$); quality of sleep (mean difference of 2.800; 95% CI: 2.238, 3.361, $p<0.05$) than Group B (Table 1).

Table - 2. Analysis of Pretest mean values of Pain catastrophizing, Endurance, Quality of Life, Quality of Sleep of Female Fibromyalgia patients in Low intensity exercise program and CBT only group using Unpaired -t test

Outcome Variables	Groups	Mean	Standard Deviation	P-value
Pain Catastrophizing	Group A	36.466	1.726	0.240^{NS}
	Group B	35.200	2.336	
Endurance	Group A	6.667	0.617	0.101^{NS}
	Group B	6.886	0.351	
Quality of Life	Group A	55.600	2.261	0.414^{NS}
	Group B	54.733	2.685	
Quality of Sleep	Group A	13.133	1.302	0.113^{NS}
	Group B	11.933	0.798	

^{NS}-Significant at 0.05 level (p<0.05)

Furthermore, the results of unpaired 't' test showed that there is no significant difference in the Pretest mean scores of all dependent variables such as pain catastrophizing, endurance, QoL, and quality of sleep before the application of the selected therapeutic interventions at the Pretest stage ($p>0.05$) (Table 2). In addition, there is a significant difference in the Posttest mean scores of pain catastrophizing, endurance, QoL, and quality of sleep ($p<0.05$). While considering the mean score of all outcome variables, Group A who received low intensity exercise program, is better than the Group B who received CBT

only (Table 3).

Table - 3. Analysis of Pain catastrophizing, Endurance, Quality of Life, Quality of Sleep of Female Fibromyalgia patients in Low intensity exercise program and CBT only group (Post-test analysis)

Outcome Variables	Groups	Mean	Standard Deviation	P-value
Pain Catastrophizing	Group A	31.600	2.131	0.000*
	Group B	32.600	2.529	
Endurance	Group A	7.466	0.639	0.031*
	Group B	7.666	0.487	
Quality of Life	Group A	49.600	2.412	0.000*
	Group B	54.333	2.581	
Quality of Sleep	Group A	10.333	0.816	0.029*
	Group B	11.666	0.975	

**Significant at 0.05 level (p<0.05)*

4. DISCUSSION

This study shows that a low intensity exercise protocol combining endurance training (i.e., aerobic and resistance training aimed at improving endurance) and CBT-i is effective for improving psychological features (i.e., pain catastrophizing), QoL, and physical conditioning such as endurance and functional capacity and quality of sleep in females with FM. Pain catastrophizing refers to a set of exaggerated and ruminating negative cognitions and emotions during perceived or actual painful stimulation (Alda et al., 2011) and has been linked with adverse pain related outcomes and FM-related disability and physical exercise reduce negative thoughts about pain, especially rumination (Crofford, 2015). This study shows a significant decrease in pain catastrophizing scores following low intensity exercise intervention. In line with this outcome, previous studies using physical exercise alone or in combination with psychological/cognitive techniques such as CBT-i reported beneficial effects on pain catastrophizing in people with FM or chronic pain, as disclosed by several studies. Furthermore, this outcome was supported by other studies which used combined physical and psychological therapy (i.e., Yoga) (Bernardy et al., 2013), physical exercise combined with Acceptance and Commitment Therapy (McCrae et al., 2018), and aerobic exercise, mainly in water, combined with CBT (Selvanathan et al., 2021). These studies suggest that psychological or/and physical techniques, either alone or in combination, may be beneficial to improve catastrophism in patients with chronic pain. However, these previous studies used standard physical exercise programs without taking into account a potential aggravation of symptoms experienced by females with FM (i.e., fatigue), which has been posited as the main cause of low adherence to physical exercise programs (Taguchi et al., 2021). On the other hand, the current study reports that a customized low intensity exercise with CBT-i group, adapted to the individual's self-perception of fatigue, improves pain catastrophizing more effectively than the control group receiving CBT.

Moreover, QoL is impaired in people with FM (Bushman, 2013). The low-intensity exercise group induced improvements in all the analyzed psychological constructs as well as in pain perception, which may have contributed to improving QoL (Carta et al., 2021). Many studies have shown that physical exercise improves QoL in the FM population, either through aerobic (Coelho et al., 2012), resistance (Crase & Rosato, 1979; Fave et al., 2018; Gónzalez-Sánchez et al., 2019), and flexibility (Crase & Rosato, 1979; Fave et al., 2018) exercises, protocols combining aerobic and resistance training (Penedo & Dahn, 2005). The FM patients reported more insomnia-related symptoms than either rheumatoid arthritis patients or the population sample. The higher prevalence of insomnia-related symptoms among FM patients was unexplained by depression or pain. However, previous studies failed to include CBT, which have been shown improvement in QoL in older adults (Pinter & Brainin, 2012). Yet, it has never before been implemented in females with FM. Thus, this study suggests that low-intensity exercise protocol along with CBT-I may be a useful tool to improve QoL in females with fibromyalgia. In this regard, it would be interesting to apply the proposed exercise protocol on an ongoing basis, as it has been shown that physical exercise positively affects QoL in people with FM (Carta et al., 2021).The positive results on the subjective physical conditioning are noteworthy, since people with FM who feel that they are unable to perform daily physical activities may avoid performing such activities and participating in low intensity exercise, which, in turn, may lead to objective physical deconditioning (Martinez et al., 2013) . Notably, the present study evaluated objective physical conditioning by means of 6MWT, which is an inexpensive, relatively quick, safe, and a well-tolerated technique for the prediction of the physical fatigue. Women with FM have been showing to display early aging and lower physical abilities compared to their age-

matched healthy counterparts, which resembles healthy senior adults (Gaudreault & Boulay, 2018). This study observed improvements in objective physical conditioning, which are in line with previous studies which implemented different types of exercises, such as aerobic (Antunes & Marques, 2022) or resistance exercises (Santos et al., 2020), or combined training (aerobic, resistance, flexibility, and patient education) (Antunes & Marques, 2022).

Besides, the aerobic and combined exercise interventions evoked improvements in FM-specific symptoms, depression. The magnitude of improvement that observed in the current study is similar to previous studies using aerobic exercise interventions. The more pronounced changes in FIQ score that observed in the latter studies likely are due to differences in characteristics of the participants or exercise programs, for example, frequency, intensity, duration, modality, and total volume of exercise. In the present study, participants in the AE and CE groups exercised at an intensity of 60% to 80% of HR_{max}, which has been recommended for optimizing cardiovascular adaptations in previously sedentary people, (Correa et al., 2017) and there is evidence that greater changes in total FIQ score can be evoked by exercise of this intensity in comparison to gentle aerobic exercise. Few studies have investigated the impact of chronic resistance (strength) or flexibility exercise in isolation on FMS-specific symptoms, assessed using the FIQ. However, a previous study reported no change in mean FIQ score after 12 weeks of strength-training exercises, (Gandhi et al., 2002) whereas another study reported a 21% improvement in average FIQ score after a 12-week program of strength-training exercises, but no change after a flexibility exercise regimen. Supervised strength or aerobic exercise programs have a greater impact on FIQ scores than flexibility training. Interestingly, the present study suggests that the improvement in FIQ score that can be evoked by 24 weeks of AE is neither enhanced nor diminished by replacing some of the AE time with resistance and flexibility exercises (Bowen et al., 2006; Silva et al., 2022).

Lastly, lack of adherence seems typical in FM patients, possibly due to post-exercise soreness. The average adherence inference studies were 85%, whereas adherence in the current study was 100%. This outcome may be due to the customized protocol that applied, which was duly tailored to each patient's symptoms. This study strongly believes that therapies aimed at FM patients should encourage participation by focusing on protocols with individualized work-loads, rather than relying on standard protocols.

5. LIMITATIONS AND RECOMMENDATIONS

This study was conducted for a short period of 6 weeks with a limited number of subjects. There was no follow-up after the end of treatment duration. It is recommended to conduct future studies with a larger sample size of both gender and long treatment duration for FM. Follow-up measurements for outcome variables can be included to reveal the long-term treatment effects of low intensity exercise program with CBT-I on FM. Further research can include other psychological outcome variables to measure psychological impairments resulting from FM.

6. CONCLUSION

This study revealed that a low-intensity exercise (i.e., aerobic and low-load resistance exercises) with CBT-i, and CBT only have shown a significant effect on pain catastrophizing, endurance, QoL, and quality of sleep among female patients with FM. Following 6-week interventions, Group A, who received a low-intensity exercise (i.e., aerobic and low-load resistance exercises) with CBT-i, was more effective than Group B, who received CBT only in reducing pain catastrophizing and improving endurance, QoL, and quality of sleep among female patients with FM. Hence, the findings of this study concluded that low intensity exercise along with CBT-I is found to be beneficial in reducing pain catastrophizing and improving endurance, QoL, and quality of sleep among female patients with FM.

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