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The effect of physical therapy rehabilitation on fatigue and pain in female patients with fibromyalgia

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ABSTRACT

This study aimed to examine the impact of physical therapy rehabilitation program on fatigue, pain and quality of life in female patients with fibromyalgia. It was designed as a single-blinded, randomized, pre and post-test controlled trial. Eighty female patients, aged 25 to 45, diagnosed with fibromyalgia were selected from the Kasr Al Ainy rheumatology outpatient clinic. The participants were allocated into two equal groups using a randomization procedure. Group (A) (control group, n=40) received transcutaneous electric nerve stimulation (TENS), moist heat, core muscle retraining, and manual therapy for trigger points, 3 times/week, for 4 weeks. Group (B) (study group, n=40) received the same treatments as Group A, plus aerobic exercises, flexibility exercises, and cognitive behavioural therapy (CBT), 3 times/week, for 4 weeks. Both groups were assessed before and after treatment using the Fatigue Severity Scale (FSS) and the Fibromyalgia Impact Questionnaire (FIQ). Statistically significant improvements were observed in FSS and FIQ scores for both groups post-treatment ($p<0.05$). When the two groups were compared after therapy, the study group (B) showed significantly greater improvement in FSS and FIQ ($p<0.05$). These findings suggest that physical

therapy rehabilitation can effectively reduce fatigue, pain, and improve the quality of life for women with fibromyalgia.

KEYWORDS

Fibromyalgia; Physical Therapy; Fatigue; Pain; Female Patients

1. INTRODUCTION

Fibromyalgia syndrome (FMS) represents a chronic disorder distinguished by the presence of diffuse musculoskeletal pain, with its underlying causes still uncertain. Clinically, it is characterised by the presence of pains, tenderness in soft tissues, stiffness, exhaustion, sleep difficulties, and cognitive dysfunction (Giorgi et al., 2022). FMS affects between 2% and 8% of the population, and it is believed to be the most prevalent cause of musculoskeletal discomfort in women aged 25 to 55 (Marques et al., 2017). This syndrome belongs to the family of overlapping conditions known as central sensitization syndromes, which includes diffused pain. These syndromes are distinguished by symptoms of irritable bowel, dull diffused pain, cognitive dysfunction, tension migraines, and fatigue (Clauw, 2014).

Patient reports of chronic pain have been used to make the diagnosis of fibromyalgia in the lack of any objective biomarker (more than three months), fatigue, mood disturbances and cognitive decline. In 2016, the American College of Rheumatology (ACR) established the conclusive criteria for diagnosis of fibromyalgia which encompass the following: (1) The existence of widespread pain, characterised as pain experienced in a minimum of four out of five regions, specifically the four quadrants and the axial region. Based on the provided definition, it is recommended that jaw, chest, abdomen, headache, and face aches be excluded from the quadrant or regional classification of generalised pain. (2) Symptoms must persist at a consistent intensity for at least three months. A diagnosis of fibromyalgia can be made if the patient meets one of the following criteria: (1) a widespread pain index (WPI) score of ≥ 7 and a symptom severity scale (SSS) score of ≥ 5; or (2) a WPI score of 4 to 6, along with an SSS score of ≥ 9. A diagnosis of fibromyalgia remains valid regardless of the presence of other diagnoses, and the diagnosis does not preclude the existence of other medically significant conditions (Wolfe et al., 2016).

Fatigue is extremely prevalent among individuals with persistent pain disorders such as fibromyalgia (Hawker et al., 2011). It compromises daily activities and work performance in these patients (Cetin & Gokdemir, 2019). Additionally, patients experience cognitive impairment,

including cognitive fog, widespread pain, and anxiety, which negatively affect their quality of life (Galvez-Sánchez et al., 2019).

The current guidelines emphasize that the primary approach to therapy should include patient education and non-pharmacological treatments (Kundakci et al., 2021). Exercise, massage, myofascial release, electrotherapy, photobiomodulation therapy, and complementary therapies are various physical therapy interventions investigated in previous research (Antunes & Marques, 2022). Additionally, self-management techniques and other forms of behavior modification are taught to patients with chronic pain as part of cognitive behavioral therapy, aiming to help them better cope with their condition (Phelps et al., 2021).

Although it is well accepted that women with fibromyalgia experience cognitive deficits, particularly in working memory, planning, and processing speed, in addition to exhaustion and pain (Phelps et al., 2021), there is a lack of literature supporting a physical therapy rehabilitation program that holistically improves these symptoms. Thus, this study aims to examine the impact of physical therapy rehabilitation program on fatigue, pain and quality of life in female patients with fibromyalgia.

2. METHODS

2.1. Study Design

This study was designed as a single-blinded, randomized, pre-posttest controlled trial. The research was granted approval by the Ethics Committee of the Faculty of Physical Therapy at Cairo University, with the reference number (P.T.REC/012/003359).

2.2. Sample Size Calculation

The sample size calculation was performed using sample size calculator software, with a 95% confidence level and a margin of error (α) set at 5%. The expected effect size was estimated at 3% of the population, based on the latest prevalence study of patients with fibromyalgia (Cabo-Meseguer et al., 2017).

2.3. Participants

Eighty female patients diagnosed with fibromyalgia were selected from the Kasr Al Ainy rheumatology outpatient clinic. Their ages ranged from 25 to 45 years. Diagnoses were made based on the 2016 revised criteria of the American College of Rheumatology as follows: all participants

reported pain in at least four out of five body regions, had persistent symptoms for at least three months, and either had a WPI score ≥ 7 and an SSS score ≥ 5, or a WPI score of 4 to 6 with an SSS score ≥ 9. After documenting a detailed medical history, participants with a history of cancer, other autoimmune disorders (such as systemic lupus erythematosus or rheumatoid arthritis), knee or hip conditions that could prevent aerobic exercise, cognitive problems not caused by fibromyalgia, or visual or auditory impairments were excluded from the study.

2.4. Randomization

The participants were randomly divided into two equal groups (A & B) using a computer program (Microsoft Excel 2016) that generated a random number table. Participants were paired based on how frequently they matched their distribution code. There were no dropouts from the study after randomization (Figure 1).

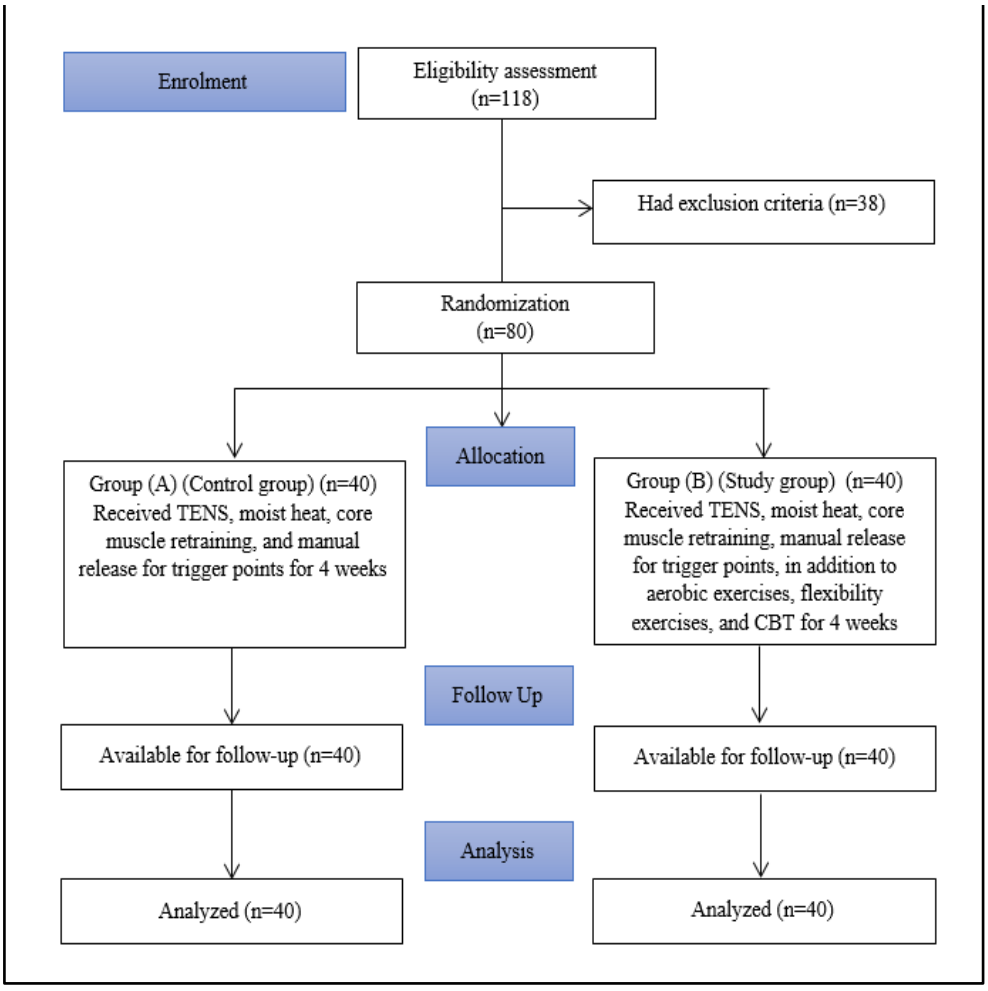

Figure 1. Flowchart of the study

In order to acquire the trust and cooperation of the study's participants, a comprehensive description of the study's investigations, goals and rationale, and a declaration regarding the questionnaire used to gather data were provided. They were reassured of the confidentiality of their data and their freedom to resign from the study at any time. Each participant proceeded to fulfil an informed consent form before engaging in the study. The trial lasted from September 2021 to May of 2023.

2.5. Interventions

Group (A) (control group) consisted of 40 participants who received transcutaneous electric nerve stimulation (TENS), moist heat, core muscle retraining, and manual therapy for trigger points, three sessions weekly, for a duration of four weeks, while group (B) (study group) included 40 participants who received TENS, moist heat, core muscle retraining, manual release for trigger points, in addition to aerobic exercises, flexibility exercises, and cognitive behavioural therapy (CBT) for the same duration as group (A).

All participants in both groups (A & B) received:

- TENS device (Enraf-Nonus, Netherland, Model: Sonopuis 492, SN:33.385): Two electrodes were applied on the painful sites of the patients as per the patients' complaints. The most common sites were cervical area, periscapular area, mid dorsal area, anterior aspect of the thigh, and low back area. The duration was 20 minutes, three sessions weekly, for 4 weeks (Coutaux, 2017).
- Moist heat: It was applied in form of hot packs on the painful sites after the exercises in combination with TENS application (Simon et al., 2015). The most common sites were cervical area, periscapular area, mid dorsal area. Anterior aspect of the thigh and low back area. The duration was 20 minutes, three sessions weekly, for 4 weeks.
- Core muscle training: It was done bilaterally in the form of bridging with leg elevation, quadriped with arm and leg movement, and shoulder elevation from crock lying position (Garrido-Ardila et al., 2020). The frequency was 15 repetitions per set for three sets, three times per week, for 4 weeks.
- Manual release of trigger points: It was done in the form of ischemic compression on the trigger points. The trigger points in the majority of the patients were in the upper trapezius, lattissmus dorsi, quadriceps, calf muscles, and hamstring muscles. The ischemic compression was done by pressing with the palmar aspect of the thumb of the therapist on the trigger point

for a duration of 60 to 90 seconds per point or till the therapist felt a pulsing sensation beneath the thumb (Rose et al., 2016).

All patients in group (B) received:

- Aerobic exercises: Participants engaged in aerobic activity on a treadmill and stationary bike. For the treadmill activity, it lasted 20 minutes with no inclination, a 5-minute warmup, and a 5-minute cooldown. Additionally, the stationary bike was used for 15 minutes, with the seat adjusted to ensure comfort and prevent excessive knee flexion, based on the patient's height (Bidonde et al., 2017).
- Flexibility exercises: They were done in the form of gentle stretches for the hamstrings, calf muscles, scaleni muscles, and pectoralis muscles. The duration of the stretch was 45 to 60 seconds, for three to five times, three times per week, for 4 weeks (Kim et al., 2019).
- Cognitive behavioral therapy (CBT): The process consisted of three distinct stages, including education, the acquisition of cognitive-behavioral therapy (CBT) skill sets, and the practical implementation of these skills in real-life scenarios. The educational phase of patient care aims to provide correct and reliable information regarding the ailment, as opposed to the prevalent occurrence of misinformation or contradictory data associated with fibromyalgia syndrome (FMS). The aforementioned elements encompassed the potential aetiologies, factors contributing to the persistence of the ailment, and the significance of the patient's active engagement in the therapeutic course. This phase may also encompass the acquisition of specific skills aimed at facilitating the process of adapting to living with Fibromyalgia Syndrome (FMS). The phase of cognitive-behavioral therapy (CBT) skill sets is centered on equipping individuals with the necessary abilities to effectively manage and alleviate pain. Possible interventions for individuals with fibromyalgia syndrome (FMS) encompass a range of strategies. These may encompass relaxation techniques, graded-activation to incrementally enhance activity levels while circumventing the prevalent "push-crash" cycle associated with FMS, optimising sleep patterns, modifying cognitive appraisals of pain, and addressing functional and emotional dimensions of coping with chronic illness. The individuals were instructed to compile a comprehensive inventory of their emotional states, behavioral patterns, and apprehensions, as well as their corresponding reactions, as an assigned academic task. The implementation phase of practical skills facilitated the patients' ability to use acquired knowledge within the context of their everyday experiences. According to Hall et al. (2018), the usual practice entailed assigning homework tasks that targeted the abilities

acquired in phase 2, with the intention of customizing them to suit the individual needs of the learners.

2.6. Outcome Measures

Impact of fibromyalgia on quality of life and pain

It was evaluated using fibromyalgia impact questionnaire (FIQ) for all participants in both groups before and after the treatment. The FIQ consists of ten components. The first item has 11 questions about physical functioning that are graded on a 4-point Likert scale. Item 2 and 3 ask patients to record how many days they experienced well-being and how many days they were unable to engage in work or household activities because of fibromyalgia symptoms. Items 4–10 are horizontal linear scales with ten-point intervals, allowing patients to value work difficulties, pain, weariness, morning tiredness, stiffness, anxiety, and sadness (Cetin and Gokdemir, 2019).

Fatigue level

Fatigue level was assessed in all participants in both groups before and after the treatment program using fatigue severity scale (FSS). The Fatigue Severity Scale (FSS) is a self-report scale comprising nine items about exhaustion, its severity, and how it impacts specific activities. This scale is designed to assess how fatigue affects individuals with a wide range of diseases. A score of 1 indicates significant disagreement and a score of 7 indicates great agreement on a scale of 1-7. Therefore, a score of nine is the lowest possible and 63 is the greatest. The higher the score, the more severely fatigued the person feels and the more their daily activities are affected. It takes about eight minutes to finish and is quite easy to comprehend (Cetin and Gokdemir, 2019).

2.7. Statistical analysis

The statistical analyses were conducted using SPSS for Windows, version 25 (SPSS Inc., Chicago, IL). The data were assessed for normality using the Shapiro-Wilk test ($p > 0.05$) and for homogeneity of variance using Levene's test ($p > 0.05$) before the final analysis. Since the data followed a normal distribution, parametric analysis was appropriate. All outcome variables were presented as means and standard deviations. Paired t-tests were used to compare outcomes before and after therapy within each group, while independent t-tests were used to compare between groups. Statistical significance was defined as a probability level of less than or equal to 0.05 ($p \leq 0.05$).

3. RESULTS

Both groups exhibited similar baseline characteristics (p>0.05) in terms of age and BMI, (Table 1).

Table 1. General characteristics of participants in both groups (A and B)

	Group A (control group) (n = 40)	**Group B (study group) (n = 40)**	**p-value**
Age (years)	28±9.01	25.85±7.65	0.76 ^{NS}
BMI (Kg/m^2)	28.03±1.7	27.98±1.58	0.94 ^{NS}

Note: NS (p > 0.05) indicates non-significant results, where p represents the probability value.

Improvements in the FSS and FIQ scores were statistically significant for both groups (A & B) (p<0.05). When the two groups were compared after therapy, group (B) demonstrated statistically significant improvements (p <0.05) (Table 2).

Table 2. Comparison of fatigue severity scale (FSS) and fibromyalgia impact questionnaire (FIQ) scores pre- and post-treatment for both groups (A and B)

		Group A (control group) (n = 40)	**Group B (study group) (n = 40)**	**p-value***
FSS	Pre treatment	56.33±7.34	56.58±7.65	0.882 ^{NS}
	Post treatment	49.88±7.37	18.13±5.50	0.0001^{S}
	p-value**	0.0001^{S}	0.0001^{S}	
FIQ	Pre treatment	86.00±5.43	85.68±5.82	0.797 ^{NS}
	Post treatment	75.73±5.62	46.43±5.70	0.0001^{S}
	p-value**	0.0001^{S}	0.0001^{S}	

*Note: * Inter-group comparison; ** intra-group comparison of the results pre and post treatment.*
^{NS} p>0.05 = non-significant, ^{S} p<0.05 = significant, p = probability.

4. DISCUSSION

Regarding the control group, our findings indicated significant improvements in FSS and FIQ scores after the treatment compared to before (p<0.05), indicating the valuable effect of TENS, moist heat, core muscle retraining, and manual therapy on improving fatigue, pain and quality of life in female patients with fibromyalgia. These results are consistent with Coutaux (2017), who discussed the use of TENS in patients experiencing chronic pain. They suggested that using TENS on the painful sites in patients with fibromyalgia can decrease the patient pain sensation and therefore,

improve the patient's quality of life. This finding aligns with our research outcomes, as both patient groups exhibited noteworthy enhancements in pain reduction and overall quality of life.

Additionally, these results agree with Ebadi et al. (2019), who conducted a systematic review on the impact of core muscle retraining on the patients with fibromyalgia, they found that core muscles retraining improved the patients' fatigue and mobility. The rational of using core muscles retraining in the study is that we know that pain causes delayed core muscle recruitment before and during the movement. This delayed recruitment causes sometimes increasing in the activity of the long two joint muscles (such as hamstrings), leading to more tightness in those muscles (Halliday et al., 2015). Therefore, we combined the core muscle retraining with the flexibility exercises to decrease the tightness and spasm the patients felt as much as we can. Moreover, our study results agree with Puentedura & Flynn (2016), who studied the impact of employing manual therapy as a means to alleviate pain and muscle spasms in those diagnosed with fibromyalgia. The mechanism behind the patient's improvement is unknown, but it is hypothesised that manual therapy increases the blood supply to the tight muscles, which in turn improves the muscle spasm.

Regarding the study group, the significant improvements noted in all the measured outcomes either within or between groups comparisons ($p<0.05$), which reflected the beneficial impact of the physical therapy rehabilitation program involving combined TENS, moist heat, core muscle retraining, manual trigger point release, as well as aerobic exercises, flexibility exercises, and CBT on improving fatigue, pain and quality of life in females with fibromyalgia. In agreement with our study results, Le Fur Bonnabesse et al. (2019) found that aerobic exercise improves mood and physical health by elevating serotonin and norepinephrine levels in the body via stimulation of the neuroendocrine system. Sluka et al. (2018) found that consistent aerobic exercise leads to an increase in endogenous opioid release in the brainstem, which in turn inhibit facilitatory neurons, hence decreasing facilitation. A decrease in SERT expression and phosphorylation of the NMDA receptor's NR1 subunit would result from this. Another reason why regular exercise can lessen the intensity of fibromyalgia's pain and other symptoms. Also, Park et al. (2021) concluded that beside the effect of core training in minimizing pain in fibromyalgia patients, it improves balance, postural control and decrease risk of fall which improves quality of life of the patients. In addition, it was found that moderate aerobic exercise enhance sleep quality as total sleep time was increased, and number of wakes up after onset of sleep decreased. This might explain how aerobic exercise decrease fatigue level in these patients (Kline, 2014).

The findings of our study align with those of Lorena et al. (2015), who concluded that incorporating stretching exercises into the program can facilitate the recovery of functional muscle length, alleviate stress, realign posture, and enhance amplitude, freedom, and awareness of movement. The results of this study align also with the research by Estévez-López et al. (2021), who proposed that the integration of various strategies, such as manual therapy and aerobic workouts, can lead to enhancements in patient well-being and aerobic capacity. There is a prevailing belief that engaging in aerobic workouts might enhance the overall well-being of individuals with fibromyalgia, as well as alleviate symptoms such as fatigue and sleep disturbances.

In addition, Kim et al. (2019) did a meta-analysis and systematic review on the impact of flexibility training on fibromyalgia. Stretching may help with pain and quality of life without causing any negative side effects. Furthermore, Bell et al. (2018) studied the impact of using CBT on subjects suffering from fibromyalgia and came with outcomes denoting that, CBT has a great impact on fatigue, self-imaging, body awareness and wellbeing in individuals experiencing chronic pain syndromes, especially fibromyalgia. Moreover, Hall et al. (2018) also studied the effect of using CBT on patients with fibromyalgia. They found that CBT has a positive effect on the patient's pain sensation and perception in addition to improving anxiety and, therefore, improves the quality of life. Our findings came also in line with Matsutani et al. (2023), who conducted a systematic review on the effect of different approaches on pain and fatigue in subjects suffering from fibromyalgia and suggested that flexibility, CBT, and aerobic exercises can improve the sense of fatigue and pain in cases of fibromyalgia.

5. LIMITATIONS

Two limitations were identified in this study. Firstly, the duration of the sessions was found to be lengthy for some participants. Secondly, it was observed that some patients needed additional time for the assessor to explain or translate certain items within the scale.

6. CONCLUSIONS

The findings of this study underscore the significant benefits of a comprehensive physical therapy program for women with fibromyalgia. This approach effectively addresses multiple aspects of the condition, including pain management, reduction in exhaustion, and enhancement of overall quality of life. The results demonstrate that comprehensive physical therapy not only alleviates the

intensity of pain experienced by participants but also mitigates feelings of fatigue, thereby improving daily functioning and overall well-being.

These findings highlight the importance of integrating comprehensive physical therapy into treatment plans for fibromyalgia, as it provides a valuable and effective means of addressing the multifaceted nature of the disorder and enhancing patients' overall health and life satisfaction.

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AUTHOR CONTRIBUTIONS

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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