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A 12-week physical training program – effects on fibromyalgia patients

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Abstract. *Background*. Fibromyalgia is a common musculoskeletal disorder characterized by widespread chronic pain, fatigue, sleep disorders, depression or anxiety and cognitive alterations. It has several therapy options, physical exercise being one of the most recommended. *The purpose* of this study was to examine the effects of a combined training program on pain and associated symptoms in fibromyalgia patients. *Methods* The study included 34 patients who underwent a 12-week physical training program. The program included 3 weeks of flexibility exercises, 3 weeks of postural hygiene and balance exercises, 3 weeks of aerobic exercises and 3 weeks of Pilates. We monitored the number of tender points, pain rated by the patient and measured with a digital algometer in 6 points of the body, level of anxiety and depression and disease impact. All the parameters were evaluated before and after the program, as well as 4 months after the program was over. *Results*: The average number of tender points dropped from an initial 12 to 5.6, scores for pain registered a 43% decrease and disease impact diminished from 53.1 to 39.1 ($p<0.001$). The pain threshold indicated by the algometer improved on all measured points. Positive results in these parameters were still observed at follow-up. No significant results were found for depression and anxiety. *Conclusion:* a mixed training program improves the level of pain, number of tender points, disease impact and quality of life in fibromyalgia patients.
Key words*: fibromyalgia, mixed training program, algometry, pain.*

Introduction

Fibromyalgia (FM) is one of the most frequent musculoskeletal disorders and perhaps the most enigmatic (1). It can be defined as a clinical entity characterized by widespread chronic pain of uncertain origin and unexplained by other diseases or alterations (2). It usually occurs in middle-aged women who complain of generalized pain, stiffness, fatigue, sleep disorders and cognitive alterations (memory and concentration problems, information processing speed) (3). It is frequently accompanied by multiple unexplained organic symptoms (dysmenhorrea, irritable bowel syndrome) as well as anxiety and depression thus having a great impact on day to day life (4). The load imposed by core FM symptoms translates into limitations of productivity, personal and family life, as well as a reduced ability to complete simple activities of daily living (5,6) generating costs of billions every year.

The estimated prevalence is between 3 and 10%, although the data may be inexact due to the low level of knowledge regarding this disease (7).

Although the exact cause of FM is unknown, it is suggested that a combination of biological, psychological and social factors leads to pain amplification and central sensitization to peripheral stimuli (8). There is no golden standard for diagnosis, but at present, the most used criteria are the ones set in 1990 by the American College of Rheumatology (ACR).

They include (9): generalized pain, in the left and right side of the body, above and bellow the waist, for at least 3 months. In addition, axial skeletal pain must be present; pain in 11 of 18 tender points on digital palpation with an approximate force of 4kg.

In 2010 the ACR suggested symptom-based practical criteria for clinical diagnosis of FM (3) to complement the previous ones. The new criteria (table I) recognize a wise spectrum of manifestations and severity of symptoms such as fatigue, waking unrefreshed, cognitive and somatic symptoms. They are given values from 0 to 3 resulting in a symptom severity score (SSS) and are combined with a widespread pain index (WPI) of 19 areas of the body.

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Table I. Criteria for Fibromyalgia (American College of Rheumatology, 2010)*

1. WPI ≥7 and SSS score ≥5; or WPI 3–6 and SSS score ≥9
2. Symptoms have been present at a similar level for at least 3 months
3. The patient does not have a disorder that would otherwise explain the pain

1. WPI: Number of areas where the patient has pain (score: 0–19)

•Shoulder girdle, left	• Hip (buttock, trochanter), left	•Jaw, left	•Upper back
•Shoulder girdle, right	•Hip (buttock, trochanter), right	•Jaw, right	•Lower back
•Upper arm, left	•Lower arm, left	•Upper leg, left	•Lower leg, left
•Upper arm, right	•Lower arm, right	•Upper leg, right	•Lower leg, right
•Chest	•Neck	•Abdomen	

2. SSS score: Sum of the severity of the three symptoms, plus the extent (severity) of somatic symptoms in general (final score: 0–12)

2.1 Severity somatic symptoms: •Fatigue •Waking unrefreshed •Cognitive symptoms

For each of the three symptoms above, indicate the level of severity over the past week using the following scale: 0 = no problem; 1 = slight or mild problems; 2 = moderate, considerable problems, often present and/or at a moderate level; 3 = severe: persuasive, continuous, life-disturbing problems.

2.2 Somatic symptoms in general

Considering somatic symptoms in general, indicate whether the patient has no symptoms (0), few symptoms (1), a moderate number of symptoms (2), or a great deal of symptoms (3)

•Chest pain	•Blurred vision	•Constipation	•Fatigue/tiredness
•Fever	•Dry eyes	•Diarrhea	•Insomnia
•Frequent urination	•Easy bruising	•Dry mouth	•Depression
•Headache	•Hair loss	•Heartburn	•Dizziness
•Muscle pain	•Hives/welts	•Loss of appetite	•Seizures
•Muscle weakness	•Itching	•Nausea	•Hearing difficulties
•Numbness/tingling	•Rash	•Loss of/change in taste	•Nervousness
•Shortness of breath	•Sun sensitivity	•Vomiting	•Wheezing
•Pain/cramps in the abdomen	•Oral ulcers	•Irritable bowel syndrome	•Ringing in ears
•Painful urination and bladder spasms	•Raynaud's phenomenon	•Pain in the upper abdomen	•Problems with thinking or remembering

**Data from Wolfe et al. (3)*

The FM syndrome was the object of a considerable number of therapeutic attempts, most of them with uncertain and unconfirmed results. The most recommended are antidepressants, antiepileptic medicine, as well as cognitive-behavioral therapy and physical exercise. In what regards the type of exercise, many forms of training have been studied, including aquatic and land-based exercise regimes involving aerobic, strength, flexibility and mixed format exercise interventions (10). While the most consistent results have been demonstrated for aerobic and strengthening exercise (11), there is no optimal application overall (12). Pilates recently has become a fast-growing popular form of exercise recommended both for healthy people and for those involved in rehabilitation (10), with positive results in FM (13).

Material and Method

The aim of this interventional study was to evaluate the effects of a combined training program on pain and associated symptoms in patients with FM. The goal was to improve physical function, some psychological aspects and quality of life as a whole for these patients.

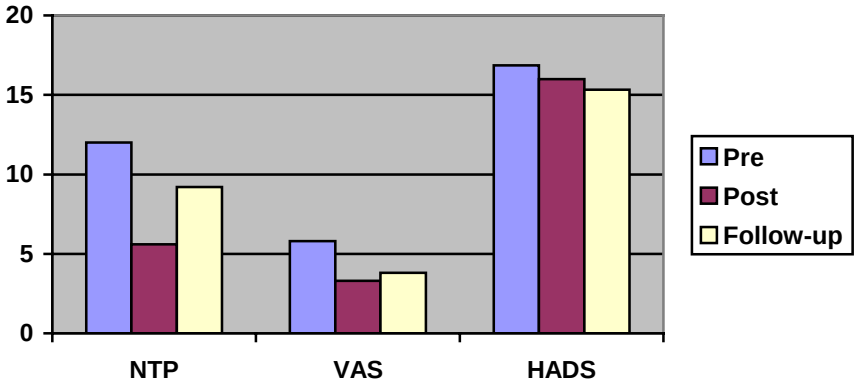
The study included 34 patients (5 males, 29 females) previously diagnosed with FM, with an average age of 52,9 years. They were selected from the rehabilitation clinics of the Emergency County Hospital and the Municipal Hospital of Craiova, Romania. The diagnosis was set after medical history and physical examination, considering the 1990 ACR criteria for diagnosing FM. There was no interference with the medication the participants were on.

All patients signed an informed consent before taking part to the study. Exclusion criteria were: illiteracy, pregnancy, any disease that requires immediate medical treatment or prevents the subjects from performing physical exercise.
The subjects, divided into 3 smaller groups depending on their schedule, underwent a 12-week exercise program. The training program took place in the rehabilitation gym of the University of Medicine and Pharmacy of Craiova, in groups of 8 to 10 patients. Each session was conducted and supervised both by a rehabilitation doctor and a kynetotherapy specialist. Patients attended one session per week at the gym and were required to perform 2 identical sessions at home every week. The duration of each session was of 20 minutes at first, slowly increasing in duration and intensity as weeks went by, with a maximum duration of one hour. All patients received a layout of each session with suggestive images, in order to enable the performing of the exact same exercises.
The training program included 3 stretching sessions, 3 aerobic sessions, 3 postural hygiene and balance sessions and 3 sessions of Pilates. Each session began with warm-up and included exercises for the central axis of the body, as well as for the upper and lower limbs. Some of the sessions ended with cycloergometer work-out. Most exercises were presented with one or two alternatives, depending on each patient's physical condition. The goal was to enable every patient to achieve the same result without forcing them over the limit.
All subjects were tested before and after the training program. A follow-up evaluation was performed at 4 months after the exercises were completed. The monitored parameters were: disease impact: Fibromyalgia Impact Questionnaire (FIQ); anxiety and depression: Hospital Anxiety and depression Scale (HADS); number of tender points (NTP); pain rated by the patient on a visual analogue scale (VAS); pain level measured with a digital algometer.
The FIQ is a self-administered questionnaire that captures the overall effect of FM symptoms on the patient. It measures the subject's status, progress and outcome in 10 areas including pain, fatigue, anxiety and depression, stiffness, work and physical impairment, making it a rather complete and helpful asset in monitoring FM. Higher scores indicate a greater impact of FM on the person.
In order to quantify the pain threshold, we used a SBMedic digital algometer. This is a device that applies pressure on certain areas of the body, at a constant rate until the patient starts to experience pain. At that point, the patient pushes a button that allows the algometer to register a numeric value (measured in kiloPascals). Measurements were performed on 6 areas, both on the left and right side of the body: second metacarpian space, the side of the calfs in the anterior tibial muscle and lateral of the 5^{th} cervical vertebra. Each point was measured 3 times, an average of these values being noted.
All the data was gathered and introduced in a specially designed database. The statistical analysis of the data was performed with the use of the Statistical Package for the Social Sciences. The standard statistical methods were used to compute the means and standard deviations. The One Sample T Test was used to compare the differences between the means at each of the 3 moments, for each variable individually. The Correlation function was applied to compute the association between the average values of the parameters.

Results

Of the total of 34 patients initially included in the study, only 27 completed the program (2 males, 25 females). Improvements were obtained for most of the studied parameters. Differences between NTP, VAS and FIQ at the initial and second measurement were highly significant ($p<0.001$) from the statistical point of view. The average number of tender points dropped from an initial 12 to 5.6 at the end of the training program, while VAS registered a 43% decrease over the same period (Chart 1). Some improvements continued to be noticed 4 months after the program was ended, especially for the level of pain experienced by the patient. A small improvement was also found in regards to the anxiety and depression level. HADS continued to diminish even after the completion of the program, registering its lowest level at follow-up (Chart 1).

Chart 1. Evolution of NTP,VAS,HADS



As shown in Table II, significant differences could be seen between the initial and final two FIQ values. At follow-up, the FIQ mean was almost at the same value as it was at the ending of the 3 months exercise training program.

Table II. Evolution of FIQ scores

	t	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
				Lower	Upper
FIQ1	10.242	.000	53.16467	42.0311	64.2982
FIQ2	7.743	.000	39.11467	28.2794	49.9499
FIQ3	7.827	.000	41.29667	29.9809	52.6124

The values of pain rated on the VAS post-training program were correlated with the number of tender points (Pearson Correlation 0,515) and FIQ (Pearson Correlation 0.581). In addition, a strong correlation was found between FIQ and number of tender points (Pearson Correlation 0.726) at the end of the program.

As far as the level of pain is concerned, higher thresholds were registered at the end of the training program for all the measured points. However, the evolution of the values up to the final measuring was different for each body region. Table III offers a synthesis of the measured means for the left side of the body at all 3 evaluation moments.

Table III. Evolution of algometery

	Minimum	Maximum	Mean	Std. Deviation
CERV-pre	103.00	243.00	157.7143	39.48209
CERV-post	102.66	289.00	173.2350	47.78002
CERV-follow-up	115.66	203.33	154.9589	28.69711
HAND-pre	123.00	276.00	198.2143	47.17101
HAND-post	115.33	268.66	214.5200	42.97810
HAND-follow-up	111.33	245.00	180.7389	38.10910
LEG-pre1S	131.00	353.00	259.9286	70.30972
LEG-post	151.66	460.33	286.6864	83.22823
LEG-follow-up	171.33	431.66	315.8111	82.26942

When asked which type of exercise they liked most and considered to be most useful, 74% of the patients responded that flexibility exercises were their favorites. Two thirds of the participants reported continuing the exercise at home, once the 12-week training program was over.

Discussion

Our results are in agreement with those of other studies in regards to the benefits of physical exercise on FM patients. In his review, Hauser et al (14) had concluded on how aerobic exercise interventions were shown to reduce pain, fatigue and improve the quality of life of FM patients. Moreover, better effects on depression were found in that research than in ours.

Busch (11), based on a large number of studies, also demonstrated that mixed exercise training (combination of aerobic and/or strength and/or flexibility exercises) leads to large improvements in pain and physical function. In addition, Altan et al (13), investigating the effects of Pilates on fibromyalgics, obtained improvements in pain visual analogue scores and FIQ results compared to control participants who performed home-based relaxation and stretching exercises.

Unlike other studies (14) where the positive effects on pain were no longer obvious at follow-up and only small benefits were still observed on the quality of life, our study maintains significant improvements at follow-up in the number of tender points, level of pain rated by the patient and disease impact (FIQ).

When it comes to monitoring results in regards to pain, most commonly used are the tender points count (15), and the level of pain rated by the patient on different scales, especially VAS. Clinical palpation and subjectively rated pain, despite their central role in the diagnosis and monitoring of FM, are scientifically debatable. An improvement in objectivity and a better acceptance of the myofascial pain by the medical community has been obtained by the use of algometry (16).

When evaluating the benefits of exercise for people with FM, it is important to consider possible adverse effects of exercise, such as an increase in symptoms (pain, stiffness, fatigue) and musculoskeletal problems (planter fasciitis, impingement syndrome) (10). Even if we did not note any of these complications, the drop-out rate in our study (20.5%) was similar to the average drop-out rate among FM participants assigned to aerobic exercise groups (22%) (11). This is probably due to the fact that some of the patients experienced an increase in symptoms, or that they had very little confidence in the program. Nevertheless, providing more options for each exercise and thus individualizing the program to one's condition, may have determined the majority of patients to complete the program. In addition, the variety of exercises of a mixed training program, is a possible cause for a drop-out rate that is slightly lower than average.

Improving the patient's physical condition was not the sole concern of our study. The psychological impact was one of our major concerns. We attempted to influence it through the psychological effects of physical activity per se, but also through working in groups. It is considered that the membership to a group of people with similar complaints and problems, helps the patient find relief and understanding, increase the number of friends and social circle and, at the same time, make a healthy use of their free time (2). However, we obtained only slight improvements in the level of anxiety and depression, leading to the conclusion that more specific therapies (cognitive-behavioral therapy, relaxation techniques, music therapy) may be needed.

Conclusions

A mixed training program including flexibility, aerobic, postural hygiene and balance exercises and pilates improves pain, disease impact as perceived by the patient and quality of life in FM subjects. Offering such a variety of exercises and alternatives to the execution of each one makes physical activity more appealing and motivates the patient to overcome possible initial increase in symptoms. Significant benefic effects are maintained 4 months after the completion of the program, underlining the importance of physical training over time.

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