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Original article

Randomized controlled trial of a therapeutic intervention group in patients with fibromyalgia syndrome

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ABSTRACT

Objective: To evaluate the efficacy of a weekly interdisciplinary program (WIP) consisted of educational activities, physical therapy, stretching, ergonomics, posture guidance combined with cognitive behavioral strategies and approaches to psychosocial and occupational factors in order to determine whether this intervention would be effective to short and medium-term improvement of symptoms in these patients.
Methods: This was a single-center study, randomized single blind controlled trial with a sample test group (T), with a diagnosis of FMS (n = 12), and a control group (C) subjected to Pain Clinic referral (n = 15). The instruments used at two different times were the Fibromyalgia Impact Questionnaire (FIQ), Visual Analogue Scale (VAS) and Post-Sleep Protocol (PSI). To assess quality of life, we used the SF-12.
Results: In samples, both groups were predominantly female, mean age of 42.5 ± 9.8 years, 43% married, average schooling of 8.3 ± 4.5 years. It was reported a mean of 4.2 years pain and an average of two years for the diagnosis of SFM from the group T. There was statistical difference between the groups in terms of efficacy post intervention WIP, in almost all outcome measures.
Conclusion: It was found that weekly interdisciplinary program (WIP) has contributed to improving the quality of life of patients with fibromyalgia.

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Estudo randomizado e controlado de uma intervenção terapêutica grupal em pacientes com síndrome fibromiálgica

Palavras-chave:
Fibromialgia
Estudo controlado
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RESUMO

Objetivo: Avaliar a eficácia de um programa interdisciplinar semanal (PIS) composto de atividades educativas, terapias físicas, alongamento, ergonomia, orientações posturais combinado com estratégias cognitivas e comportamentais e abordagens de aspectos psicossociais e ocupacionais, a fim de determinar se esta intervenção seria efetiva em curto e médio prazos para melhora dos sintomas destes pacientes.

Casuística e métodos: Trata-se de um estudo unicêntrico, randomizado, simples cego e controlado com amostra de um grupo-teste (T), com diagnóstico de SFM (n = 12), e de um grupo-controle (C) submetido a interconsulta na Clínica da Dor (n = 15). Os instrumentos utilizados em dois momentos distintos foram: Questionário de Impacto de Fibromialgia (FIQ), Escala Visual Analógica (EVA) e Protocolo Pós-Sono (PSI). Para avaliar a qualidade de vida, foi utilizado o Questionário SF-12.

Resultados: Na amostra dos dois grupos houve predomínio do gênero feminino, média de idade de 42,5±9,8 anos, 43% casados e média de escolaridade de 8,3±4,5 anos. Foi relatado um tempo médio de dor de 4,2 anos e uma média de dois anos para o diagnóstico de SFM no grupo T. Houve diferença estatística entre os grupos, em relação à eficácia pós-intervenção do PIS, em quase todos os desfechos analisados.

Conclusão: Verificou-se que o programa interdisciplinar semanal (PIS) contribuiu para melhora da qualidade de vida dos pacientes fibromiálgicos.

Introduction

The fibromyalgia syndrome (FMS) is a rheumatic syndrome of unknown etiology that predominantly affects women. It is characterized by diffuse and chronic musculoskeletal pain, in addition to specific anatomical sites with pain elicited by palpation, called tender points. Other symptoms such as fatigue, sleep disturbances, morning stiffness and psychological disorders such as anxiety and depression are often associated.[1-3]

Statistic data shows that FMS affects 3-5% of general population, occurring in all ages with chronic symptoms that can fluctuate throughout the day and with inactivity, compromising about a quarter of those affected.[3]

The clinical picture of FMS is complex, and several works[4,5] propose multidisciplinary teams to perform interventions, highlighting programs with exercise sessions,[4] relaxation,[5] stress management and compartmental cognitive therapy[6] that consist in extending the adherence to treatment and motivating patients to remain active.[7]

The mean duration of interdisciplinary programs varies from one to six months, usually performed with groups of 10 and 25 individuals. The justification for choosing this type of intervention proves itself by improving the quality of life and health status of patients with FMS.[8,9]

Regarding the pathogenesis of FMS, it is not well defined yet, although psychosomatic phenomena occur in most patients.[10] In addition to this possible effect, some areas of the nervous system functioning may represent a role in the pathogenesis of FMS, which include: changes in pain sensitivity,[11,12] and also on autonomic and neuroendocrine systems.[13-15] Bacterial and viral agents may also be related to the origin of this syndrome,[16] and there is some association between the disease and infection by hepatitis virus C.[11]

Considering that SFM probably has multifactorial etiology that still remains unclear, recent trials[17,18] reported that the reorientation of attention for the treatment of the patients to this combination of factors and the education of these patients (so that they can control their symptoms) are measures that could promote changes in behavior and improve their functional capacity.

Given this context, the objective of this trial was to evaluate the efficacy of a weekly interdisciplinary program (WIP) consisting of educational activities, physical therapy, stretching, ergonomics and postural orientations combined with cognitive-behavioral strategies and approaches to psychosocial and occupational features, in order to determine whether this intervention would be effective in the short and medium terms to improve the symptoms of these patients.

Patients and Methods

After approval by the Ethics and Research Committee from FAMERP (2384/2010) and with the Free and Informed Consent Form (FICF) already signed, we conducted this single-center, randomized, single-blind, controlled trial. The trial was conducted in two groups, with a duration of three months, comparing the weekly interdisciplinary program (WIP) to a control intervention consisting of educational guidelines for the prevention of pain, relaxation techniques, muscle stretching and body awareness. The sessions lasted 60 minutes each and happened once a week for 12 weeks for each of the study groups, being conducted by a physician, occupational thera-

pist, physiotherapist, psychologist and social worker. After participating in this program, a revaluation was performed using the same instruments.

To perform WIP, 12 patients diagnosed with FMS (test group – TG) were recruited according to criteria of the American College of Rheumatology,[1] of both genders, with enough cognitive level to understand the procedures and follow the directions given. Patients with psychiatric disease and no clinical follow-up in the Pain Clinic, Hospital de Base, were excluded. The control group (CG) consisted of patients who were in interconsultation in the Pain Clinic and without diagnosis of musculoskeletal and neurological disorders, or with disabling complaints in these systems, with a recommendation for walking (pelvic pain, migraine, inflammatory bowel pain post-herpetic neuralgia).

CG consisted of subjects matched for age and educational level in relation to TG (n = 15). The evaluation of the subjects in both groups was performed using the Fibromyalgia Impact Questionnaire (FIQ),[19] involving 20 questions divided into 10 items (functional capacity, feeling good, work absenteeism, interference of symptoms at work, pain, fatigue, morning stiffness, morning tiredness, anxiety and depression), in which nine of them have a higher score as the worst condition, with the exception of the item "feeling good". Seven of the nine items (4th to 10th) are scored using a visual analogue scale, i.e., between 0 and 10.

Functional capacity is estimated by answering 10 questions, with answers from 0 to 3, which are added at the end of the questionnaire, ranging between 0 and 30. The "work absenteeism" and "feeling good" questions are scored on weekdays, originally ranging from 0 to 5; the Visual Analogue Scale (VAS),[20] which consists of measuring the intensity of pain in the patient and is an important tool to verify more reliably the evolution of the patient during treatment and even at every visit, consists of a limited strip of 10 cm in length, representing a continuum of the painful experience; this strip has in her ends anchor-words: "no pain" and "worst pain possible". The participants are instructed to report the intensity of pain sensation to a point of this line, and the scores can range from zero to 10 and are obtained by measuring, in millimeters, the distance between the end anchored by the words "without pain" and the point marked by the participant; the Post-Sleep Protocol (PSP),[21] which assesses the sleep quality and features 30 items divided into three categories: pre-sleeping (at bedtime), during sleep and post-sleeping (awakening) (30-390; higher scores are related to better quality of sleep). To assess the quality of life, the Generic Quality of Life SF-12[22] questionnaire was used. It consists of 12 questions that address the physical component (functional capacity and limitation by physical aspects) and the mental component (pain, vitality, social functioning, limitations due to emotional problems and mental health), and their results are expressed by a score in a scale of zero to 100 by researched component (worst – best general health, cutoff score ≤ 50).

To assess depressive and anxiety symptoms, we used the Hospital Anxiety and Depression (HAD) scale,[23] translated and validated in Brazil, which consists of a self-report instrument containing 14 multiple choice questions, composed of two interleaved sub-scales: one for anxiety-state (7 questions) and another for depression-state (7 questions). HAD scores range from 0 to 21 points, and the subjects with scores < 7 are considered without significant clinical symptoms for anxiety and/or depression; scores ≥ 8 and ≤ 10, with mild symptoms; scores ≥ 11 and ≤ 14, with moderate symptoms; and scores ≥ 15 and ≤ 21, with severe symptoms of anxiety and/or depression.

During the sessions, exercises to strengthen the muscle and to improve cardiovascular fitness were conducted, consisting of stretching exercises of muscle groups of the shoulder and pelvic girdle, lower limb muscles, gluteus, abdominals and quadriceps, as well as body correction and awareness, and ergonomics. The sessions were initiated with relaxation techniques to combat muscle tension. Educational, psychosocial and occupational programs were also developed to help understand and manage fibromyalgia, with the monitoring of vital signs at the beginning and end of each treatment session and the questioning on the use of drugs by patients. All the participants were instructed and taught to practice a series of daily exercises at home. It emphasized the need to maintain the home exercise program, and guidelines were given on the correct way to perform ADLs and AVPs.

Analyses were performed using ANOVA. This descriptive parametric statistical test was selected for inferential analyses, because the dependent variables of this trial were quantitative (interval scale). The significance level used for the tests was 0.05.

Results

The twenty-seven subjects enrolled in both groups adhered totally to the program, with no occurrence of sample loss.

The mean age was 42.5 ± 9.8 years, ranging from 28-67 years; most of the participants were female (64%). The mean duration of pain was 4.2 years, with an average of two years for the clinical diagnosis of FMS in TG. Table 1 lists the characterization of the sample for the two groups (T and C).

During the experimental phase, all patients in the T group maintained their pharmacological routine. Significant difference was observed between the groups regarding the functional capacity and work absenteeism, observed in the FIQ questionnaire. As for the other questionnaires used in this trial, data of mean and standard deviation (SD) can be obtained from Table 2.

It is important to notice, in Fig. 1, the frequency of depressive and anxiety symptoms. It is noteworthy that 50% of patients with FMS in T group had depressive symptoms, and 33% had moderate to severe symptoms. 78% of these individuals had symptoms of anxiety, and in 43% of them the symptoms were severe.

Discussion

The actions performed in this trial by the weekly interdisciplinary program (WIP) demonstrated that the approach to individuals with FMS showed statistically significant clinical effects, as the increase of functional capacity and motivation, as well as greater control of symptoms such as sleep, anxiety and depression.

With regard to functional capacity, it was found that in group T the activities in WIP improved the energy that comes from the symptoms of chronic fatigue and stiffness, corroborating other trials.[23,24]

Other work on the impairment of muscle contractility in a group of fibromyalgia patients is associated with a higher perception of effort and reduced maximal exercise capacity. Due to this fact, the inclusion of physical activity in the treatment of these patients would improve their functional responses, with decreased fatigue and increased functional capacity.[25]

Firestone *et al.*[26] evaluated the impact of a program of group therapy for patients with fibromyalgia. The sessions consisted of behavioral modifications, stress reduction techniques, strategies to improve flexibility and physical performance, in addition to sessions for familial help. The sessions were held weekly for a period of six months. The authors report promising results obtained in the short and long terms.

There was also a decrease in symptoms of depression and anxiety in WIP participants.

Among the various factors affecting the QoL of fibromyalgia patients, Aliciati *et al.*[27] suggest that the presence of depression predisposes patients to impaired social functioning, and Clark *et al.*[23] reported that the inclusion of these patients in multidisciplinary groups favors the practice of daily living activities, mobility and quality of body movements and of physical fitness, thereby improving their quality of life.

Table 1 – Data on sociodemographic variables for T (n = 12) and C groups (n = 15)

Variable	Group	n	Mean ± SD	%
Age	Test	12	39,5±7,8	
	Control	15	45,5±8,3	
Gender	Test	12		Female 62
	Control	15		Female 55
Marital status	Test	12		Married 52 Single 28 Divorced 20
	Control	15		Married 43 Single 37 Divorced 13 Widowed 7
Education	Test	12	8,3 ± 4,5 years	Fundamental 32 Secondary 48 Superior 20
		15		Fundamental 37 Secondary 45 Superior 18
Employment situation	Test	12		Formal work 12 Sick-leave aid 58 Retired 4 Informal work 26
	Control	15		Formal work 20 Sick-leave aid 48 Retired 6 Informal work 26

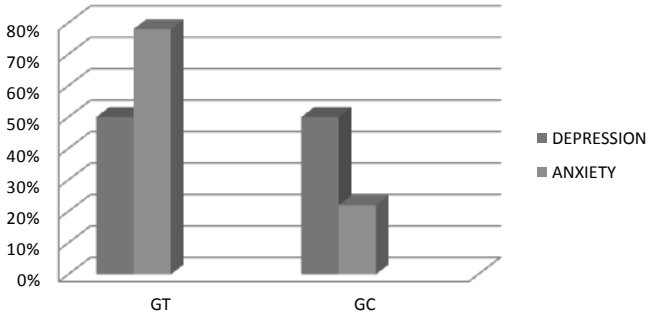

Fig. 1 – Distribution of fibromalgics according to the calculated mean of depression and anxiety symptoms

Table 2 – Change in mean values of FIQ, SF-12 and Post-Sleep Protocol (SIP) questionnaire domains throughout the follow-up period, expressed as mean ± standard deviation and variation

Instruments applied	1st review Mean and SD TG GC	2nd review Mean and SD TG GC	*p* value
FIQ			
functional capacity	12.4±7.7 9.3±5.9	10.8±5.4 8.2±5.8	0.04*
Feeling good	2.0±2.6 4.8±2.7	2.5±2.5 3.7±2.8	0.06
Work absences	0.0±0.0 0.0±0.1	0.1±0.6 0.2±0.9	0.20
Ability to work	6.6±2.8 5.1±3.1	5.7±3.0 2.4±2.8	0.03*
Pain	7.7±1.8 5.7±3.0	6.3±2.5 2.2±2.8	0.04*
Fatigue	7.5±2.3 5.7±2.0	6.9±2.5 3.1±3.1	0.04*
Sleep	6.6±3.0 4.1±3.1	5.8±2.8 2.3±2.3	0.06
Morning stiffness	7.5±2.5 5.3±7.9	5.9±3.0 1.8±2.3	0.03*
Anxiety	7.6±2.5 4.3±3.3	6.6±2.3 6.3±2.9	0.03*
Depression	7.0±2.5 3.4±3.1	6.2±2.8 5.4±3.2	0.04*
Total FIQ	64.9±27.7 47.7±37.2	56.8±27.4 35.6±28.9	0.03*
SF-12			
Physical component	48.5 52.3	59.5 62.3	0.03*
Mental component	38.5 48.5	67.5 78.5	0.001*
PSP			
At bedtime	38.6±13.6 51.4±8.6	53.4±5.6 68.3±7.8	0.04*
Overnight	72.2±8.6 91.2±6.4	92.3±8.4 98.3±7.4	0.03*

* statistically significant difference, $p < 0.05$.

Regarding the prescription of activities and exercises to patients with FMS, orientations, as well as pharmacological prescriptions with dose, duration and specific intervals, were performed. The concern in relation to the intensity and execution of the proposed and previously trained activities in WIP began gradually, considering the preferences of patients, their comorbidities, medication use, and functional capacity.

Corroborating this procedure, the trial by Miró *et al*.[28] involved different areas in action groups with expertise on fibromyalgia patients, showing that they are promoters of pain relief, generating well-being and contributing significantly to the quality of the patients' life.

Regarding the sleep, some trials[29,30] relate a worst sleeping period to a greater number of tender points in patients with fibromyalgia. Sleep disturbances were also associated with chronicity of pain complaints. It is known that individuals with chronic pain, such as those with FMS, have a persistent health condition that changes their life. The goal of their treatment is to control FMS and not to seek its elimination; therefore, the sleep pattern assessment becomes a sensitive indicator that should be considered. In this trial, after the intervention of WIP (with approaches focused on body biomechanics, kinesiology, ergonomics, psychosocial aspects and improvement of cardiorespiratory capacity), a better sleep pattern was noted in these individuals.

Follow-up studies with FMS patients are scarce, as well as those on the health care, that should have an interdisciplinary planning, but they have been performed separately by each professional.

The actions resultant of WIP revealed that the approach to patients with FMS should be multifactorial; this strategy enables the understanding of this syndrome as a summation of disorders that end up manifesting itself by the association of a variety of symptoms.

Conclusion

The treatment of fibromyalgia patients should follow multifactorial models; this will allow a systematic development of the necessary abilities to the transition from rehabilitation in the maintenance of an active and independent lifestyle.

Conflicts of interest

The authors declare no conflicts of interest.

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