

Influence of multidisciplinary therapeutic approach on fibromyalgia patients

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Abstract. There is no specific cure for fibromyalgia (FM), but combined non-pharmacologic and pharmacologic treatments may mitigate symptoms and improve quality of life in patients. The aim of the present study was to monitor patient response to several types of therapy, including cognitive-behavioral and occupational therapy, and kinetic therapy, as compared to a control group that was not subjected to any form of therapy. The study included 98 FM patients, all women, out of which 32 received cognitive-behavioral therapy and occupational therapy (CBT+OT), 34 kinetic therapy (KT) and 32 participated as controls. The evaluation protocol comprised two questionnaires developed in order to assess the patient's condition as fully as possible: Fibromyalgia Impact Questionnaire (FIQ) and Fibro Fatigue (FF) scale. At the pre-evaluation there were no significant inter-group differences. At post-evaluation significant differences were observed between the control sample and the group subjected to kinetic therapy ($P < 0.05$). FIQ scores decreased in the CBT+OT group too, but less than that in the KT group. The FF scale registered notable evolutions in time for the group subjected to kinetic therapy. In order to control and improve most of the FM symptoms, besides proper medication, we suggest an interdisciplinary intervention mainly focusing on long-term individualized kinetic therapy. The simultaneous integration of a cognitive-behavioural and

occupational therapy intervention could be the element that completes the complex treatment of FM patients.

Introduction

Fibromyalgia (FM) is one of the most frequent musculoskeletal disorder and perhaps the most enigmatic one (1). FM is the third most common rheumatic disorder after low back pain and osteoarthritis (2). United States findings suggest a primary care prevalence of 3.4% whereas a European Community study estimated an overall prevalence of 4.7% (3). The most effective approach for the treatment of FM depends on the efficient management of pharmacological treatment combined with cognitive-behavioral therapy, physical exercise and occupational therapy (4). The combination of these four therapies has been shown to improve the efficacy of the treatment and to reduce the global impact of FM on the patient, improving the quality of life and the capacity to participate in the activities of daily living (5). Cognitive-behavioral therapy (CBT) is a form of psychotherapy that was developed in the mid to late 20th century. It is the most efficient form of psychological intervention for the treatment of anxiety and depression, chronic pain, inflammatory pain and FM with all its associated symptoms (6).

A recent review synthesized the short- and long-term effects of different psychological interventions on FM and showed significant improvements in the perception of pain, sleeping problems, depression and grievous thoughts, besides the benefits on functional status (7). However, it has been demonstrated that instructions alone are more effective when combined with cognitive-behavioral therapy regarding sleep quality, evaluated by both subjective and objective parameters (8). In addition, it has been shown that cognitive-behavioral therapy can be a tool in the management of sleep dysfunction in adults as well as children with FM (9). The positive results are also achieved in other aspects of behavior such as attention disturbance and daily functioning (10,11). Coming to support all these facts, the 2008 EULAR recommendations also suggested the beneficial results of cognitive-behavioral therapy on function and pain (12).

The importance of physical exercise in the FM syndrome has been observed for decades. The fact that there are no pharmacological treatments with undoubted efficacy has led to the

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appearance of other types of therapy such as kinetic therapy, among others. The type of exercise program to influence the majority of FM symptoms (pain, fatigue, physical function, global health, depression) in a positive way is aerobic exercise, but the one to have the best results in improving complaints is strength exercise (13,14).

The aim of the present study was to monitor patient response to several types of therapy including cognitive-behavioral and occupational therapy, kinetic therapy, as compared to a control group that was not subjected to any form of therapy.

Materials and methods

Ethics statement. This study was approved by the Academic and Scientific Ethics and Deontology Committee of the University of Medicine and Pharmacy in Craiova (Registration no. 23/2015) in accordance with the European Union Guidelines (Declaration of Helsinki). All the patients signed an information and acceptance form, i.e., informed consent, to be included in the present study.

Participants. The objective of our prospective study was to evaluate the effects of a multidisciplinary interventional program on disease impact for fibromyalgic patients. The population sample included three groups of patients, all of them women that had been previously diagnosed with FM. Two of the groups were subjected to an interventional program, while the third group participated as a control sample. One of the interventional groups was subjected to a program including CBT and occupational therapy (OT), another one was involved in a kinetic program (KT) including aerobic exercise, postural hygiene exercise, stretching and Pilates.

We conducted a randomized, longitudinal, controlled trial on 98 FM patients, all women over 5 years, between March, 2015 and December, 2019. The participants were selected from the Rehabilitation and Physical Medicine Department of the County Emergency Hospital of Craiova, Romania. The inclusion criteria that allowed the patients to participate in this study (both in the interventional as well as in the control groups) were: Women over the age of 18 years, a confirmed diagnosis of FM according to the 2010 ACR Preliminary Diagnostic Criteria (2), patients monitored and treated by a physician for the chronic pain problem, regardless of the pharmacological treatment the patient is undergoing.

The exclusion criteria that disabled the patients from participating in this study were: Uncooperative patients, alcoholism, severe psychiatric disorders, associated conditions that may otherwise explain the evolution of the symptoms and patients with severe associated conditions or traumatic injuries that disabled them from performing a physical exercise program.

Materials and measures. From the total number of 40 patients included in the cognitive behavioral plus occupational therapy program (CBT+OT) arm, only 32 attended all evaluations and at least 70% of the program sessions. The patients with poor compliance to the treatment were excluded from the statistical analysis. In the group that underwent kinetic therapy (KT), of all the invited patients, 42 had initially accepted to participate. However, 34 patients were included in the database (for the

complete and correct participation of all evaluations and for attending at least 70% of the program sessions). In the control group (Controls), 42 initially accepted to take part in the program even though in the end 32 participants were included in the data base (for the complete and correct participation to all evaluations). Therefore, the total population of this study included 98 FM patients, all women, out of which 32 received cognitive-behavioral therapy and occupational therapy, 34 kinetic therapy, and 32 participated as controls.

Mean age was 52.4 (SD, 7.2) years for cognitive-behavioral therapy and occupational therapy group. In kinetic therapy group the mean age was 55.3 (SD 7.2), and in controls group the mean age was 56.3 (SD 8.8) with small differences between the groups ($P < 0.05$). The socio-demographic data for each group is presented in Table I, no significant differences between groups being observed. As far as the clinical data are concerned, the patients reported the onset of pain, on average, 9 years before the diagnoses of FM were set. Notable differences between the groups were also registered concerning the comorbidities. The most common associated condition was anxiety or depression registered by 92.8% of participants in CBT+OT, followed by chronic fatigue syndrome (74%) and tension headaches with an average of 73%, as shown in Table I.

For the individuals that underwent CBT+OT or KT, the patients that had agreed to participate were telephonically summoned to a first introductory meeting. The objectives and development of the study were explained, stating the fact that their participation was completely voluntary and that they could abandon the program at any time they wanted to. Once they had agreed to participate, they were asked to sign an informed consent form. They also had to fill in an evaluation protocol (Pre). From that moment on, the subjects attended 12 sessions (one session a week) in groups of maximum 10-12 patients. The duration of each session was 2 h for the individual subjected to cognitive-behavioral plus occupational therapy.

The kinetic sample was divided into 3 groups of maximum 10-12 patients. The kinetic therapy intervention included four types of sessions: Aerobic exercise and balance, postural hygiene, stretching and pilates. Patients attended one session per week at the gym and were recommended to try to perform the exercises at home two more times a week, if their physical status allowed it. Each session initially lasted ~20 min, slowly increasing in duration and intensity, reaching a maximum duration of 1 h. 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 while others ended with breathing and relaxation exercises. Most exercises were presented with one or two alternatives, depending on each patient's physical condition.

Once the program ended, all the participants were asked to fill in the same evaluation protocol (Post) and were summoned 4 months later for follow-up monitoring (Follow-up). The Evaluation Protocol was comprised of two questionnaires developed in order to assess the patient's condition as fully as possible. It contained the following: Fibromyalgia Impact Questionnaire (FIQ) with 10 items referring to the patient's status over the last week and Fibro Fatigue (FF) scale.

FF is a scale designed to evaluate the changes in the development and severity of FM and Chronic Fatigue Syndrome (15).

Table I. Clinical diagnosis data.

Socio-demographic data	CBT+OT (n=32)	Kinetic therapy (n=34)	Controls (n=32)
Age: mean ± SD	52.4 (7.2)	55.3 (7.2)	56.3 (8.8)
Year of diagnosis: Mean ± SD	2001.3 (7.5)	2009.3 (2)	2003.6 (4.6)
Year of pain onset: Mean ± SD	1995.7 (9.7)	2000.8 (7.3)	1990.7 (11.6)
Irritable bowel syndrome (%)	53.5	23.5	29
Chronic fatigue syndrome (%)	74	20.6	63.3
Tension headaches (%)	73	52.9	77.4
Endocrine disorders (%)	44.8	41.2	25.8
Rheumatic disorders (%)	59.2	2.9	64.5
Anxiety or depression (%)	92.8	52.9	83.8
Other associated conditions (%)	45.4	55.8	45.4

th, therapy; n, number of patients; SD, standard deviation; CBT, cognitive-behavioral therapy; OT, occupational therapy.

It contains 14 items regarding pain, muscle tension, fatigue, concentration difficulties, memory loss, irritability, sadness, sleep problems, vegetative disorders, irritable bowel, headache, infection, sexual activity and family life. Each item was rated on a scale of 0 (no problem) to 6 (incapacity). The higher the score, the more severe the FM symptoms. The first item (FIQ1-functional impairment) contained 10 questions that asked the subject how often he was able to perform household chores and daily activities such as shopping, vacuuming, cooking, making the beds, washing the dishes, visiting friends, driving. The answers were rated from 0 (always) to 4 (never). The second and third item asked the number of days during the last week that the patient had felt well and, respectively, the number of days the individual could not work owing to FM. For the last 7 items the patient was asked to assess on a scale from 1 (absent) to 10 (very intense); the level of pain, fatigue, stiffness, anxiety, depression as well as how tired the individual felt in the morning or how the FM symptoms affected ability to work.

Statistical analysis. The Statistical Package for Social Sciences (SPSS) version 20 (IBM Corporation) was used in order to analyze the database. Before processing the data, we first verified the premises of normality and homocedasticity given the fact that the samples were superior to the limit of 30 subjects. For the normality part we used the Kolmogorov-Smirnov test whose null hypothesis claims normality. It was rejected if the significance was ≤ 0.05 .

Results

FIQ total score. For the sample involved in cognitive-behavioral therapy and occupational therapy the only significant difference was between the first and second evaluation ($P < 0.05$). The scores from the group subjected to kinetic therapy registered a significant decrease from the initial evaluation to the post-evaluation ($P < 0.005$) and follow-up ($P < 0.005$). For the control sample, there was a significant difference noted between the pre- and follow-up evaluations ($P < 0.05$). The means and standard deviations obtained by computing the FIQ

total score, in all three groups at all evaluation moments, are presented in Table II.

At the pre-evaluation there were no significant inter-group differences. At post-evaluation significant differences were observed between the control sample and the group subjected to kinetic therapy ($P < 0.05$). FIQ scores decreased in the CBT+OT group too, but less than that in the KT group.

At the follow-up, the FIQ scores in CBT+OT group returned to values close to the initial ones, without a statistically significant difference between the CBT and control groups ($P < 0.05$). FIQ values in KT group remain significantly lower than the control group values, without statistical significance.

Fibro fatigue scale. The Fibro Fatigue (FF) scale registered notable evolutions in time for the group subjected to kinetic therapy. The initial score (mean=44.57) suffered a decrease until the post-evaluation (mean=37.5, $P < 0.05$), which then slowly started to increase up to follow-up (mean=39.81). The most important scores of the Fibro Fatigue scale are shown in Fig. 1.

Between groups, significant statistical differences were observed for the pair: Group subjected to kinetic therapy-control sample ($P < 0.05$ at Pre, $P < 0.005$ at Post, $P < 0.01$ at follow-up) and the pair of groups involved either in kinetic therapy or in cognitive-behavioral plus occupational therapy ($P < 0.05$ at Pre, $P < 0.005$ at Post and $P < 0.005$ at Follow-up).

Discussion

The two major non-pharmacologic techniques that are constantly used in the treatment of FM are cognitive-behavioral therapy and physical exercise. Cognitive-behavioral therapy has been used in the management of chronic pain for more than 20 years. It is implemented as a semi-instructive, short-term psychotherapy where the patient plays an active role in assisting the therapist (6). Cognitive-behavioral therapy can help reduce pain, fatigue, improve emotional well-being, lift the spirit and perhaps enhance physical and social functioning (6).

By comparing cognitive-behavioral therapy with kinetic therapy, we hoped to shed some light on the benefits of

Table II. Total FIQ scores.

Group	FIQ total Pre	FIQ total Post	FIQ total follow-up
CBT+OT mean ± SD	71 (15.9)	62.6 (20.2)	68.6 (15.7)
KT mean ± SD	69.4 (16.1)	50.8 (17.6)	52.8 (17.9)
Controls mean ± SD	74.3 (11.5)	70.7 (15.9)	68.9 (17.5)

SD, standard deviation; FIQ, Fibromyalgia Impact Questionnaire; CBT, cognitive-behavioral therapy; OT, occupational therapy; KT, kinetic therapy.

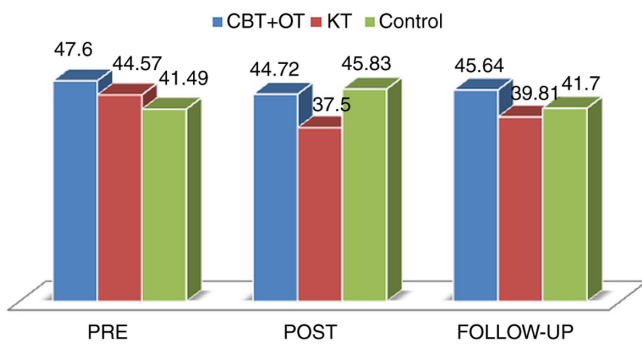


Figure 1. Scores of the Fibro Fatigue scale.

each one and on the areas for which each of them is best suited. Cognitive-behavioral therapy techniques, by offering short-term goal-oriented psychotherapy, emphasize changes in thought patterns and behaviors rather than providing deep insight (16). Among their benefits, when compared to other forms of psychological intervention, we can mention the facts that the positive effects of cognitive-behavioral therapy can be reached in as many as 10-20 sessions and that it can be performed in groups (16). As for occupational therapy, it represents a rather new area of interest for FM, given the level of disruption to the employment status of such patients including reduced working hours, becoming disabled or taking early retirement (17-19). To the best of our knowledge, there are no data published concerning occupational therapy as a unique intervention in FM, except in combination with other forms of therapy. We chose to incorporate this type of therapy together with cognitive-behavioral therapy in order to address one of the significant aspects of the important economic burden that FM causes, that of the impact on work. An aspect worth mentioning is the reality that in the case of interdisciplinary interventions, as was the cognitive-behavioral therapy and occupational therapy, it is practically impossible to determine the input of each component separately.

Supervised exercise programs have been demonstrated to reduce the severity of FM symptoms and successfully improve the level of pain, functional status and quality of life (20). There is no other mention in literature, except for a previous study (21), of a mixed program that includes besides the three major types of exercise, balance exercises and Pilates. Balance problems, regardless of their cause (increased age, side effects to medication, reduced muscle strength, impaired cognition), have been widely reported by FM patients (45% of a large 2,596 persons survey) (22). This fact was the basis for introducing balance exercises in the kinetic program. Moreover, Pilates

programs are known to combine physical, psychological, spiritual and behavioral elements that may be especially beneficial for subjects with FM (23). These patients present a wide variety of physical and emotional complaints. We considered that a combination between conventional exercise training and this oriental holistic mind and body approach would help make the interventional program a more appealing one and at the same time it would offer more consistency in influencing as many FM symptoms as possible.

Since drop-out rates are significant for FM patients, ranging from 10% for the untreated control groups to 22% for the patients involved in physical exercise programs (24), adherence to the interventional program was one of our major concerns. However, in the present study, a total of 80% of the initial participants managed to complete the cognitive-behavioral plus occupational therapy program and 81%, the kinetic therapy program. The highest drop-out rate was registered for the control group, 24% of the initially interested patients having abandoned the study. However, we included in the analysis only those patients who participated in a certain percentage of the intervention sessions.

The preservation of the therapy benefits in the long term as a lasting improved quality of life is one of the main concerns in treating FM. The disease perception monitored with the help of the FIQ in the CB and OT group was considerably lower, possibly due to the direct action of intervention in daily activities and improving responsibilities. The reality that most of the improvements registered by the group subjected to cognitive-behavioral therapy and occupational therapy were still significant four months after the conclusion of the intervention is an indicator of the fact that the patients had properly acquired an important part of the techniques they were supposed to learn and included them in their own life style.

In the kinetic group, the benefits to each symptom in particular led to a reduction in the scores of the FIQ and the FF scale. Moreover, the significant improvement in pain and other symptoms resulted in lower medication consumption and thus, reduced medical costs necessary in order to treat the disease. At follow-up evaluation very significant improvements were still maintained for the FIQ score and medication intake, but smaller ones for the FF.

The scores of the parameters vary between different investigations, as well as between different countries. For instance, the FIQ total score was on average 54.8 in a French study (20), 55.8 in a Canadian sample (25), 68 in a Mexican FM population (26) and 70.8 in a Turkish investigation (27). In the present study, the FIQ average score, prior to commencing the program was 65.9.

All of our patients were women. Even if recent studies identified differences by sex in clinical features and modes of treatment (28,29), little is known about differences in outcomes by sex for the same modes and intensities of treatment and which treatment modes best benefit males or females with fibromyalgia.

The results clearly of the present study showed the superiority of kinetic therapy even if benefits were also obtained by cognitive-behavioral plus occupational therapy. Based on the experience of this study, we can offer some suggestions as perspectives for future research. In order to control and improve most of the FM symptoms, besides proper medication, we propose an interdisciplinary intervention mainly focusing on long-term individualized kinetic therapy that is initially performed under the close supervision of specialized professionals and subsequently continued at home. The simultaneous integration of a cognitive-behavioral and occupational therapy intervention, which mainly targets the neglected psychological and labor aspects of this condition, could be the element that completes the complex treatment of FM patients.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

SP, VP, FD, RP and DM were involved in the conception of the study and data analysis; SP, DD, VP, RP and DR contributed to data curation; SP, VP, DR and DM were involved in the writing process; VP, FD, RP, DM and SP performed literature data review; and SP and VP reviewed the final manuscript. All authors have read and agreed to the published version of the manuscript.

Ethics approval and consent to participate

This study was approved by the Academic and Scientific Ethics and Deontology Committee of the University of Medicine and Pharmacy in Craiova (registration no. 23/2015) in accordance with the European Union Guidelines (Declaration of Helsinki). Written informed consent was obtained for patient participation.

Patients consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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