

The Effect of Patient Education in Treatment of Fibromyalgia: A Randomized Controlled Trial

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ABSTRACT

Objective: Fibromyalgia syndrome (FMS) can be treated with a variety of pharmaceutical and non-pharmacological approaches. The purpose of this study was to evaluate the effects of patient education and a home exercise program on FMS patients' pain, fatigue, functioning, and quality of life.

Materials and Methods: The study included patients who satisfied the American College of Rheumatology's FMS criteria. They were split up into two groups at random. A schedule of at-home exercise was given to both groups. Furthermore, Group 2 patients participated in patient education sessions. At baseline and eight weeks later, both groups underwent examinations. Evaluation criteria included the Nottingham Health Profile (NHP) for quality of life, the Beck Depression Inventory (BDI) for psychological status, the Visual Analogue Scale for pain severity (VASp) and exhaustion (VASf), and the Fibromyalgia Impact Questionnaire (FIQ) for functional status.

Results: The primary clinical and demographic characteristics of the two groups were comparable at baseline. Although the values of VASp ($p=0.014$), VASf ($p=0.011$), BDI ($p=0.043$), NHP subscales ($p<0.05$), FIQ ($p=0.012$) showed statistically significant improvements in Group 2, only Group 1's FIQ score significantly improved ($p=0.027$). There were substantial differences in VASp ($p=0.026$), VASf ($p<0.001$), BDI ($p<0.001$), and all NHP subscales except sleep problems, FIQ scores ($p=0.036$) between the two groups in favor of Group 2 at the end of eight weeks.

Conclusion: Patients with FMS should receive patient education in addition to home-based exercise, which is an effective treatment for reducing symptoms, enhancing psychological well-being, and improving quality of life.

Keywords: Fibromyalgia syndrome, fibromyalgia treatment, patient education

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INTRODUCTION

Fibromyalgia Syndrome (FMS) is a complex and multifaceted chronic condition that profoundly impacts patients' quality of life (QoL). FMS is a chronic pain syndrome that is manifested by widespread body pain, tenderness in specific anatomical regions, anxiety, sleep disturbance, depression,^[1] and fatigue, and can significantly impair QoL for those who experience it.^[2,3] It is more prevalent in females (75–95%) and between

the ages of 40 and 60 years.^[2,3] According to Marques et al.,^[4] the frequency of FMS varies from 0.2% to 8.8% in various nations. Women's FMS prevalence rates ranged from 2.4% to 6.8%. Although its etiology is not clear, various factors including impaired muscle microcirculation, sleep disorders, abnormality in central pain mechanisms, decrease in biological amines, and metabolic and immunological disorders have been suggested to have a role.^[5]



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Treatment of FMS is quite difficult and currently only a small number of effective therapy methods are available. The approach should be multidisciplinary and should be tailored to the patient rather than the disease. Although the main pharmacological and non-pharmacological therapeutic options include patient education, cognitive and behavioral treatment, physical therapy and hydrotherapy, exercise, acupuncture, and drug therapy, there is no universally accepted view of the best course of action.^[6] Numerous current research in the literature emphasize how important exercise is in the treatment of patients with fibromyalgia.^[7,8] However, few studies have been conducted on the impact of patients education in treatment process.

This randomized trial sought to determine how patient education affected the functional and symptomatic status, psychological well-being, and QoL of patients with FMS.

MATERIALS and METHODS

Patients with FMS who were recently diagnosed using the American College of Rheumatology's (ACR) 1990 diagnostic criteria were chosen to participate in the study. Patients were identified using the ICD-10 code M79.7.

The Declaration of Helsinki's ethical guidelines were followed in the conduct of this investigation. The study's ethical approval was obtained from the Bezmialem Vakif University Faculty of Medicine Ethics Committee on 06.01.2012 with approval number B.30.2.BAV.0.05.05-194.

Individuals could take part in the trial if, they had fulfilled the ACR 1990 diagnostic criteria for FMS, they were aged between 18 and 60 years, They were able to comprehend the questionnaire's contents, education and the exercise program, they were capable of doing physical exercise on their own.

The exclusion criteria included patients receiving regular pharmacological treatment for FMS, previous participation in an educational program about FMS, having mental retardation, vision or hearing problems, currently exercising on a regular basis, patients with known systemic, metabolic, endocrine, neurological, or psychiatric disease, history of malignancy, patients with bleeding diathesis.

Along with their demographic details (age, gender, body mass index (BMI, kg/m²), occupation, and educational attainment), the patients were also asked about their tender points (TPs) and the length of time they had been experiencing symptoms. Points that were painful with digital palpation carried out by applying pressure to the sensitive areas at a rate of around 4 kg/cm² (until the thumb pulp was whitened) were accepted as TPs.

In this study, sixty-eight patients were recruited. A telephone invitation to participate in the study was sent to sixty-two patients. Of 62 patients, 8 subjects were excluded from the study: 5 due to social unavailability and 3 because they refused to participate. Ultimately, the study comprised fifty patients. Participants in the study were assigned to either an exercise regimen.

(Group I) or an exercise regimen with a patient education meeting about FMS (Group II), and the ratio of allocation was 1:1. Without being involved in the clinical conduct of the experiment, biostatisticians created a computer-generated randomization scheme. A physical medicine and rehabilitation resident conducted the random allocation sequence. The study did not include any blind participants. At baseline and during the eighth week of interventions, every case was assessed. Six patients in Group I and 4 patients in Group II were unable to complete the study due to health or travel issues. The remaining 50 participants were eligible for analysis.

Patient Education

Education was given by a physical medicine and rehabilitation resident using standard texts and visual slides in a one-hour seminar. Two physical medicine and rehabilitation specialists and physiotherapists also attend the seminars. Three seminars were performed by dividing the patients in Group II into 3 groups, each consisting 10 subjects, and the questions of participants were answered. The content of the patient education program was summarized in Table 1. In addition, the patients were provided with written materials comprising summary of the topics explained during patient education.

Exercise

Both groups were given the same home-based exercise program. This program consisted of 20 minutes of stretching exercises, relaxation exercises active joint range of motion (ROM) exercises, and 20 minutes of aerobic exercise (jogging). These exercises were demonstrated by a physiotherapist and taught to the patients. Every patient received an exercise manual booklet. For eight weeks, they were required to complete this workout regimen on their own, three times a week, for at least forty minutes each time.

Evaluation Parameters

The degree of pain was evaluated with a 0- to 10-cm visual analog scale (VAS) (0 no pain-10 severe pain).

Fatigue was assessed by a 0-10 cm VAS (0 no fatigue- 10 extremely fatigue).^[9]

The Beck Depression Inventory (BDI), a self-reported questionnaire with 21 items, was used to gauge the severity of

Table 1. Content of the education program implemented in FMS

Theoretical	What is FMS? Description of signs and symptoms and concomitant complaints
	Reasons that enhance or reduce pain
	Psychosocial factors that are effective in pain
	Pharmacological and non-pharmacological treatment of the disease
	Detailed information on diet
	Coping methods for FM
	Gaining skills for coping with problems in daily life
	Importance of exercise
	Regulation of sleep and enhancing sleep quality
	Developing behavioral strategies
	Teaching to specify a target
Practice	Combining theoretical information with practice
	Relaxation methods (Deep breathing techniques)
	Exercising and its importance

FMS: Fibromyalgia syndrome

depression. Each item is presented in a multiple-choice format. The highest score is 63. Higher scores represent more severe symptoms.^[10]

Health status was assessed using the Fibromyalgia Impact Questionnaire (FIQ), a reliable self-administered instrument. Its development and validation for use in FMS were carried out. It consists of 10 items: physical functioning, feel good, work missed, job ability, pain, sleep, fatigue, morning stiffness, anxiety, and depression with a score ranging from 0 to 100.^[11,12] A greater score reflects a heavier symptom burden and poorer physical function. QoL of the patients was assessed by the Nottingham Health Profile (NHP). The questionnaire consists of 38 items divided into 6 dimensions assessing self-perceived emotional, social, and physical health problems including energy, pain, physical activity, sleep, emotional reactions, and social isolation.^[13]

All participants gave written informed consent before taking part in the research in line with the ethical standards of the Declaration of Helsinki.

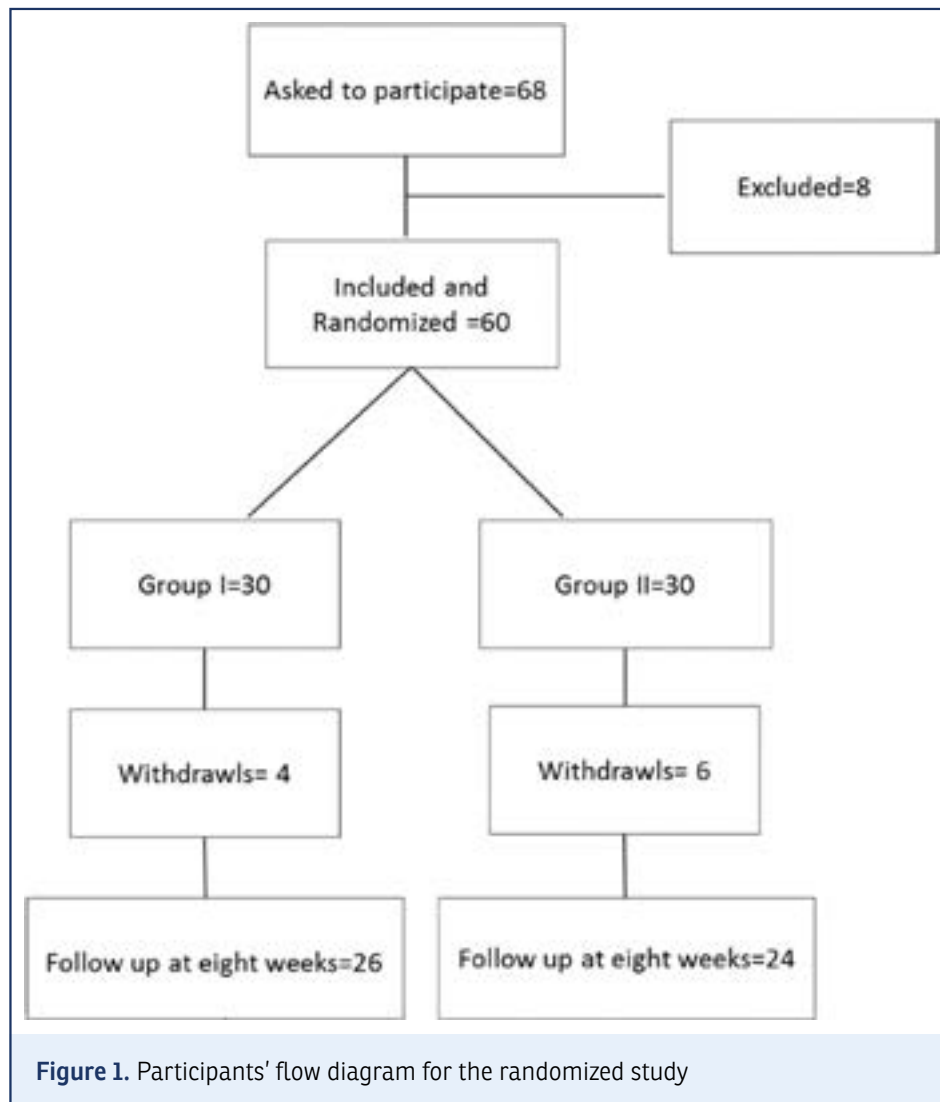
Statistical Analysis

The data were analyzed with the help of SPSS software (Statistical Package for Social Sciences) 17.00 for Windows v.17.0 (SPSS Inc., Chicago, IL, USA). All analyses adhered to an intention-to-treat/per-protocol principle. In descriptive analyses, categorical data were presented as numbers and percentages, while continuous data were represented by means and standard deviations (SD). The Kolmogorov-Smirnov test was used to confirm the normal distribution. Differences within groups and between groups were examined. To an-

alyze the differences between pretreatment and posttreatment values within groups, Wilcoxon's signed rank test was applied for non-normally distributed variables, while the paired sample t-test was used for normally distributed variables. Unpaired t-tests were used for continuous variables to make between-group comparisons, while the chi-squared test or Fisher's exact test was applied for categorical variables when appropriate. All analyses were deemed statistically significant at the 0.05 level.

RESULTS

All patients in Group I and 23 patients (95.6%) in Group II were female. Twenty-three (88.5%) patients in Group I and 21(87.5%) patients in Group II were married (Fig. 1). The patients' demographic details are displayed in Table 2. The values are shown as mean±SD or n (%) where relevant. Whilst VAS-pain, VAS-fatigue and BDI scores at baseline showed a non-significant decrease after treatment in the exercise group, the decrease observed in the patient education group was statistically significant ($p=0.014$, $p=0.011$). While there was a significant decrease in the patient education group in terms of BDI scores ($p=0.043$), contrarily, an increase was observed in the exercise group. Although no significant difference was determined in the baseline FIQ scores of both groups when compared to scores obtained after treatment, the difference in the education group was higher ($p<0.05$) (Table 3). As for the NHP subscales, the exercise group showed no significant improvement in any parameters post-treatment, whereas the education group experienced significant improvements in all parameters except for sleep (Table 3).



DISCUSSION

The current study's findings emphasize the value of education in the management of fibromyalgia sufferers. Despite there being no statistically significant differences at baseline, a substantial improvement in disease activity, depression, and QoL measures was noted in the group that underwent education as opposed to the group that only underwent exercise.

In recent years, the literature has frequently drawn attention to the relevance of exercise in treating FMS. García-Martínez et al.^[7] compared the impact of exercise in fibromyalgia patients in a controlled trial and observed substantial improvement in self-esteem, sense of self, muscle induration, flexibility, FIQ, and all parameters of the SF-36 questionnaire except for the overall health sub-group at the end of a 3-month period.

Besides, there are numerous studies suggesting that exercise has an improving effect on depression in patients with fibro-

myalgia.^[14-16] In efficacy and therapeutic analyses, Gowans et al.^[14] found that exercise significantly improved fibromyalgia patients' BDI ratings.^[15-17] However, although a few, there are studies suggesting that exercise has no contribution to the improvement of depression.^[18] The results of the present study reveal that exercise alone, without patient education, does not provide a significant improvement in depressive symptoms and complaints in fibromyalgia patients.

Considering the subdimensions of NHP, neither group's sleep significantly improved. The current study's findings suggest that patient education and exercise have no short-term effects on sleep disorders in FMS.

In recent years, attention has been drawn to the effect of patient education on the therapeutic process in fibromyalgia; some studies have been conducted and favorable outcomes have been obtained. Burckhardt et al.^[19] investigated the ef-

Table 2. Demographic characteristics of the patients (mean±SD)

	Group I (exercise) (n=26)		Group II (exercise plus education) (n=24)	
	n	%	n	%
Age (years)	41.50±8.76		39.5±10.60	
BMI (kg/m ²)	26.15±4.23		27.19±3.73	
Disease duration (years)	4.58±4.00		5.04±4.15	
Number of painful points	13.35±1.29		13.71±1.46	
Level of Education				
Primary school	14	53.8	13	54.2
Secondary school	1	3.8	1	4.2
High school	6	23.1	7	23.2
University	5	19.2	3	12.5
Job				
Housewife	17	65.4	19	79.2
Teacher	5	19.2	3	12.5
Student	–	–	1	4.29
Other	4	15.4	1	4.2

Table 3. Results of baseline and 8-week assessments

	Exercise group		p	Education group		p	p
	Baseline	8 th week	Intra group	Baseline	8 th week	Intra group	Intergroup
VAS p	7.50±1.45	7.54±1.17	0.64	7.38±1.17	6.17±1.97	0.014	0.026
VAS f	7.54±1.21	7.69±1.23	0.72	7.50±1.18	6.17±2.12	0.011	<0.001
BDI	16.23±5.49	16.62±3.92	0.28	14.71±7.21	13.17±6.91	0.043	<0.001
FIQ	67.46±9.97	64.85±9.01	0.02	63.65±13.95	57.69± 9.66	0.012	0.036
NHPpa	52.40±18.38	53.37±14.39	0.16	53.65±20.01	39.58±18.31	<0.001	<0.001
NHPeL	78.17±20.98	84.59±19.42	0.51	80.53±23.93	63.85±30.96	<0.001	0.042
NHPp	81.25±12.87	76.44±14.29	0.23	78.13±13.91	64.58±16.35	0.031	<0.001
NHPeR	57.21±16.82	57.63±14.05	0.52	78.13±13.91	64.58±16.35	0.011	0.026
NHPs	51.54±18.91	54.81±23.26	0.82	50.83±20.41	52.50±22.70	0.536	0.956
NHPsi	45.38±25.65	46.92±22.59	0.84	46.04±26.33	27.50±22.70	0.024	<0.001

VASp: Visual analogue scale for pain severity and exhaustion; VASf: Visual analogue scale for exhaustion; BDI: Beck depression inventory; FIQ: Fibromyalgia impact questionnaire; NHP: Nottingham health profile.

fect of patient education and physical exercise on the symptoms of FMS. They demonstrated a significant positive effect in terms of QoL and self-reliance. Despair, the number of days feeling bad, physical dysfunction, and pain in the tender points decreased in one or both groups in the test performed 6 weeks after the completion of treatment.

In an investigation on the effectiveness of group treatment for fibromyalgia, Bennett et al.^[20] used formal lectures, and group meetings emphasizing behavior change, stress-reduction approaches, and methods to increase flexibility and fitness. They determined a statistically significant improvement in VAS fatigue after the conclusion of the thera-

py. However, the participants were on regular exercise, they were applied trigger-point injections, spraying and stretching techniques, and received tricyclic antidepressants.

Although there was no discernible improvement in the current research except for the FIQ scores in the patients performing home exercise alone, there was a noticeable improvement in the FIQ, VAS, NHF, and BDI results at the end of 8 weeks in the group that received education.

Likewise, Rooks et al.^[21] randomly divided 207 FMS patients into 4 groups; the first group performed aerobic exercise, the second group performed strengthening and flexibility exercise, the third group received patient education, and the fourth group received a combination of these. Patient education was given as a program consisting of 7 sessions. After the 16-week course of treatment, the greatest improvement in physical functioning was in the group that received combination therapy and this effect continued until the 6th month.

CONCLUSION

The present study revealed that an exercise program alone, without patient education, has no favorable effects on depression, pain, and QoL of patients with fibromyalgia but makes a beneficial contribution to functional status. The inadequate response in the exercise group can be addressed by the reality that the patients might not have performed the exercises regularly and they might not have received the adequate psychological support gained by the education, since the exercise program was a home exercise program. Performing group exercises under supervision in the hospital might have had a different impact on the outcomes.

Moreover, the lack of monitoring of long-term changes is a limitation of the study. Nevertheless, the arrangement of education as a group therapy ensuring the participation of the patient and its financial convenience are important advantages.

In order to address misunderstandings and irrational expectations, the first step in treating patients with a diagnosis of FMS is to educate them about the condition and clarify that it is not a fatal illness. The aim of education in FMS is to improve patient consciousness in order to cope with symptom fluctuations by developing self-management and self-reliance and to convert negative perceptions such as the thought of being precluded and incapable into positive feelings.^[5] The patient's awareness of his/her illness and ensuring patient cooperation are important factors affecting response to treatment. As adequate time cannot be given for non-pharmacological therapies of FMS patients in outpatient clinics, the patients do not receive adequate information about their disease and ways to

cope with the disease.^[22] Recent studies have highlighted the role of inflammation in FMS pathogenesis and its association with conditions like temporomandibular disorders (TMD), further emphasizing the need for multidisciplinary management approaches.^[23,24] The current study's findings show that, despite the brief duration of education, patient education is crucial for improving functional status and QoL as well as for fostering self-reliance and self-management.

Disclosures

Ethics Committee Approval: The study was approved by the Bezmialem Vakıf University Faculty of Medicine Ethics Committee (No: B.30.2.BAV.0.05.05-194, Date: 06/01/2012).

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