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The effects of long- and short-term interdisciplinary treatment approaches in women with fibromyalgia: a randomized controlled trial

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Abstract We investigated the effects of long- and short-term interdisciplinary treatment approaches for reducing symptoms and improving health-related quality of life (HRQoL) and physical functions of patients with fibromyalgia and compared the effects of two different interdisciplinary treatment approaches. We conducted a prospective, randomized, controlled trial involving 66 women with fibromyalgia eligible for the study at a university hospital setting. The patients were randomized into three groups (allocation ratio 1:1:1) using a computer-generated random numbers: a long-term interdisciplinary treatment group (LG, $n = 22$) that participated in 10 sessions (3-h once-weekly session for 10 weeks) of cognitive behavioral therapy (CBT) together with exercise training and other fibromyalgia related educational programs (two full days); a short-term interdisciplinary treatment group (SG, $n = 22$) that received two full days of educational, exercise, and CBT programs; and a control group (CG, $n = 22$). The patients were evaluated at baseline and 6 months after treatment using the visual analog scale (pain, fatigue, and sleep), Fibromyalgia Impact Questionnaire, Beck Depression Inventory, Short Form-36, tender point numbers, and pressure algometry as primary outcomes. The statistical analysis was confined to the 'per-protocol' set. No blinding was performed. The number of patients analyzed was 21 in the LG, 19 in the SG, and 19 in the CG. The intensity of pain ($p < 0.001$), severity of fatigue ($p = 0.048$), number of tender points ($p = 0.002$), and pressure pain threshold ($p = 0.012$) decreased significantly in both the LG and SG groups compared with controls. Moreover, physical functions ($p = 0.017$) and physical components of the HRQoL ($p = 0.036$) improved significantly in the intervention groups compared with the controls. However, there was no significant difference between intervention groups and the control group at the end of study in terms of quality of sleep ($p = 0.055$), severity of depressive symptoms ($p = 0.696$), and mental components of the HRQoL ($p = 0.229$). Finally, with the exception of the severity of fatigue and physical components of the HRQoL, there was no obvious significant difference between the efficacies of the two treatment approaches when compared with controls; the long-term treatment was found more effective in reducing pain than the short-term. Both, long- and short-term interdisciplinary treatments were effective in reducing the severity of some symptoms and disease activity in patients with fibromyalgia. The short-term program well meets the needs of women with fibromyalgia particularly in relation to pain and health status as measured using FIQ; however, a long-term program may be beneficial in reducing fatigue and improving physical function to a higher extent.

Keywords Fibromyalgia · Treatment · Multidisciplinary · Interdisciplinary · Multicomponent · Cognitive behavioral therapy

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Introduction

Fibromyalgia (FM) is a multi-systemic disease, characterized by chronic, widespread musculoskeletal pain [1]. FM is a common rheumatologic disease, with a prevalence ranging from 3.4 to 4.9 % and 1.0 to 12.5 % in Americas and Europe, respectively, based on 1990 American College of Rheumatology (ACR) diagnostic criteria [2] in female adolescents or adults at the age range of older than 15, 18, or 30 (depending on studies) [3]. It predominantly affects women aged between 40 and 50 years. Comorbidities seen with FM, such as fatigue, sleep disorders, stiffness, depression, anxiety, and cognitive dysfunctions, impair the individual's health-related quality of life (HRQoL), as well as reduce coping skills and ability to communicate [4].

Treatment methods for FM differ from patient to patient because there is no standardization for treatment protocols. Methods that use a single treatment do not yield satisfactory clinical results [5–7]. Due to the difficulty of treating patients with FM and controlling the disease with pharmacologic or physical therapy agents, multicomponent treatment approaches have been recommended, including psychosocial and behavioral treatment methods, and educational strategies [8–12]. The duration of multicomponent programs shows a considerable variance, usually ranging from 6 weeks to 6 months, and strong evidence exists that these interventions improve the key symptoms in patients with FM [13]. Recent guidelines also recommend disease-related education with clear explanations for reducing anxiety to allow patients to take control of their chronic pain [7].

Chronic pain and disability in patients with FM result from a somatic pathology and from psychologic or social factors. For this reason, most of the multidisciplinary and interdisciplinary treatment protocols are based on cognitive behavioral therapy (CBT), which can alter cognitive processes. A combination of methods, such as relaxation techniques that target muscle tension and education on controlling activity levels and speed, aid in achieving better clinical results [8].

The aim of this study was to determine the effects of long- and short-term interdisciplinary treatment approaches (education, exercise, and CBT) on reducing pain, fatigue, sleep quality, and depressive symptoms, and on improving the HRQoL and physical functions in women with FM who have been followed up for long periods and have not responded to other treatment methods.

Methods

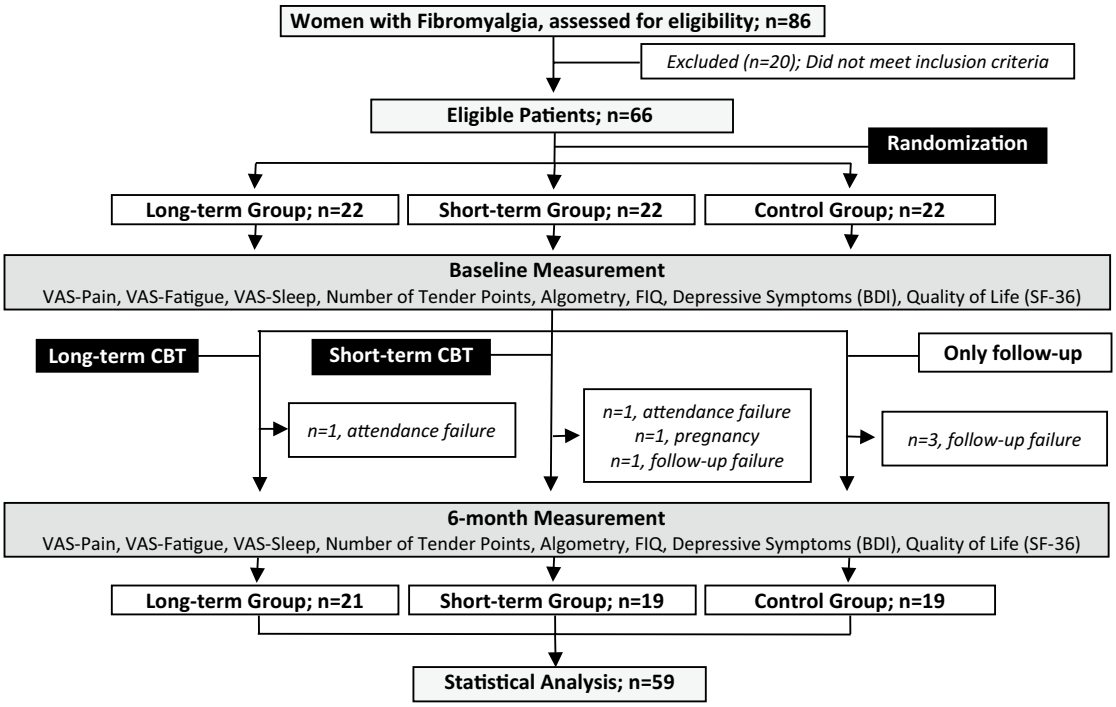
The present study was a 6-month prospective, randomized controlled trial that was conducted at the Department of Physical Medicine and Rehabilitation in the Faculty Hospital. The study protocol was approved by the local ethics committee. The participants provided written informed consent.

Participants

Eighty-six consecutive patients with FM, who were referred to our department, were recruited for the study. Among these patients, a total of 66 women who met the eligibility criteria were included in the study. The inclusion criteria were as follows: (i) women with FM, aged 25–60 years; (ii) diagnosis of FM according to the 1990 ACR diagnostic criteria [2]; (iii) followed up for at least six months after FM diagnosis; (iv) pain intensity of at least marked as five on the 10 cm visual analog scale (VAS) with 1-cm segments from 0 to 10, despite existing treatment; and (v) presence of at least five years of primary school education. Exclusion criteria were as follows: (i) previous diagnosis of an endocrine, neuromuscular, infectious, or inflammatory disease; (ii) presence of hepatic or renal disease; (iii) malignancy; (iv) history of severe trauma; (v) advanced psychiatric diseases; (vi) serious physical comorbidities; and (vii) pregnancy.

According to the order of presentation to the outpatient clinic, eligible participants were randomly allocated to one of the three groups using a computer-generated random numbers program with an allocation ratio of 1:1:1 and without varying blocks: the long-term interdisciplinary treatment group (LG, $n = 22$), the short-term interdisciplinary treatment group (SG, $n = 22$), and the control group (CG, $n = 22$). The patients in the LG participated in a 10-session extended CBT program (one 3-h session per week for 10 weeks), together with exercise training (one full day) and an educational program (one full day). The patients who were allocated in the SG received a compacted interdisciplinary treatment program that consisted of educational items, exercise training, and a brief CBT program over two consecutive days. The patients in the CG did not participate in any program and were advised to continue their previous treatments without any change. The patients realized control visits once a month after the baseline visit and/or after the completing of interventions. No blinding was performed for the patients, outcome or data assessors. The CONSORT flow diagram proposed for RCTs of non-pharmacologic treatment [14] is presented in Fig. 1 including the reasons for exclusion of the patients assessed for eligibility as well as the reasons for withdrawals/dropouts in the randomized groups.

Demographic characteristics (age, weight, height, marital status, and education level) and past medical history such as duration of symptoms, time of diagnosis, history of previous operations, major trauma, psychiatric



VAS, Visual Analogue Scale; **FIQ**, Fibromyalgia Impact Questionnaire; **SF-36**, Short Form-36; **BDI**, Beck Depression Inventory; **CBT**, Cognitive-Behavioral Therapy

Fig. 1 Participant flow and study profile

disease, pharmacologic and non-pharmacologic treatment approaches for the treatment of FM, consumption of alcohol, coffee, and smoking habits were obtained at the baseline assessment.

All of the included patients had adequately received at least one type of the pharmacological agents (tricyclic antidepressants, nonsteroidal anti-inflammatory drugs, serotonin–norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, gabapentin or pregabalin) and/or non-pharmacological therapies (exercise, physical modalities, massage and/or acupuncture) before beginning the study.

Outcome measures

All measurements were performed at the beginning of the study and at the end of the sixth month following the completion of CBT.

Pain intensity

Pain intensity was assessed using the VAS. Patients were asked about the average pain intensity that they had felt in the past week, and were requested to mark the intensity of pain on the 0–10 segmented 10 cm VAS [15, 16].

Fatigue and sleep quality

Severity of fatigue and sleep quality were assessed using the VAS. Patients were asked to mark the severity of fatigue and sleep quality in the past week in boxes consisting of numbers from zero to 10 [16].

Number of tender points

To assess pain tenderness, we determined the tender points count by thumb palpation on 18 FM tender points according to the 1990 ACR Fibromyalgia Diagnostic Criteria [2]. The amount of thumb pressure gradually increased until the fingernail bed turned pale (equivalent to about 4 kg/cm^2). For a tender point to be considered "positive," the patient stated that the palpation was painful.

Pressure pain threshold

The tenderness of each trigger point was measured with a pressure algometer (Pain Diagnostics & Thermography, Great Neck, NY, USA) as pressure pain threshold [16, 17], defined as the minimum pressure that makes pain. To determine the pressure pain threshold, we perpendicularly

applied the algometer on the tender points and increased the pressure at a rate of one kg of pressure per second.

Physical functioning and general health assessment

The assessment of general health and functional status was performed using the Fibromyalgia Impact Questionnaire (FIQ), which is an evaluation scale specific to FM [18]. The FIQ is composed of 10 questions that evaluate disease intensity, disability, and effects on different parameters (functional capacity, well-being, sick leave, ability to work, pain, fatigue, sleep, morning stiffness, anxiety, and depression). The general score ranges from zero to 80, and patients with severe disease activity present with higher scores [16, 18]. The reliability and validity of the FIQ in Turkish has been previously established [19].

Depressive symptoms

The severity of depressive symptoms was assessed using the Beck Depression Inventory (BDI) [20]. This scale consists of 21 categories that evaluate physical, emotional, cognitive, and motivational symptoms of depression such as hopelessness, irritability, guilt, or feelings of being punished, fatigue, and weight loss. Each category is scored from 0 to 3 [16, 20]. Validation of the Turkish version of BDI has been established [21].

Health-related quality of life

Medical Outcomes Study (MOS) 36-Item Short Form Health Survey (SF-36) [22] was used for the assessment of HRQoL. The SF-36 is composed of 36 questions, eight subscales, and also two summary scales: physical component summary (PCS) and mental component summary (MCS) scores. We preferred to use the PCS and MCS scores instead of the eight subscales to decrease the number of statistical analyses. The scores on the PCS and the MCS range from 0 (the worst) to 100 (the best) [16, 22]. The validity and reliability of the SF-36 in Turkish was assessed by Kocyigit et al. [23].

Interventions

The patients in the CG did not participate in any of the treatment programs, but continued with their current medical treatments, their normal daily living and current physical activity levels. They were advised not to try new treatment methods and to inform the investigators if they received new treatment.

In the long-term interdisciplinary treatment program, the patients participated in a scientific and interactive educational program for one session (one full day) at first, which was hosted by the investigators at our clinic. The program provided information on the definition of the disease, epidemiology, risk factors, clinical signs and symptoms, diagnostic criteria, etiopathogenesis, clinical course, and treatment options. The patients then participated in one session (one full day) of an exercise education program in which the benefits of exercise, its significance in FM treatment, and exercise types were explained. In addition, aerobic, stretching, and strengthening exercises were demonstrated, in which the participants were then given time to practice. Personal home exercise programs were also prescribed to be carried out during the whole study period, the frequency for aerobic exercises (in the form of walking) being 3 days a week for 20–30 min and for strengthening and stretching exercises and relaxation techniques being 5 days a week, twice a day with five repetitions for each exercise. In the following weeks, a PhD qualified psychologist on clinical psychology and CBT held 10 sessions of the CBT program, the content of which including the key elements as outlined in the review by Bennett and Nelson [24], for 10 weeks (one 3-h session per week) for the patients under the supervision of the investigators. Details of the CBT program undertaken with the long-term interdisciplinary treatment group are summarized in Online Resource 1.

In the short-term interdisciplinary treatment program, the patients spent two successive days participating in education, exercise, and CBT programs. After the 4-h education program, the patients participated in the exercise program for four more hours; the contents of program regarding education and exercise description (though shortened) as well as exercise prescription for the whole study period were the same as those described above for the long-term interdisciplinary treatment program. A psychologist held two CBT sessions (3 h/day) for the patients, under the supervision of investigators, the details of which are summarized in Online Resource 2.

Statistical analysis

All analyses were conducted using the Statistical Package for the Social Sciences software, version 17.0 for Windows (SPSS, Chicago, IL, USA). The normality of distribution was determined using the Shapiro–Wilk test. We preferred to use nonparametric tests in all statistical analyses because the data was not distributed normally. Descriptive data were presented as means and standard deviations. The homogeneity between the three groups was assessed using the Kruskal–Wallis test. To compare the posttest—pretest changes within each group, we used the Wilcoxon signed-rank test for two related samples. Improvement percent [(posttest group mean—pretest group mean)/(pretest group mean) × 100] was calculated for each group and compared using the Kruskal–Wallis test. Significance level was set at $p \leq 0.05$. The pair-wise comparisons were determined

Table 1 Homogeneity of demographic and outcome variables between three groups at baseline

	Long-term ($n = 21$)		Short-term ($n = 19$)		Control ($n = 19$)		$P^{\dagger}$
	n	%	*n*	%	*n*	%	
Marital status							
Single	5	23.8	3	15.8	4	21.1	0.820
Married	16	76.2	16	84.2	15	78.9	
Education level							
Below high school	12	57.1	8	42.1	14	73.7	0.148
High school and above	9	42.9	11	57.9	5	26.3	
Job							
Housewife or tired	16	76.2	13	68.4	16	84.2	0.526
Active employees	5	23.8	6	31.6	3	15.8	
	Mean ± SD	Min–Max	Mean ± SD	Min–Max	Mean ± SD	Min–Max	$P^{\dagger}$
Age (years)	38.3 ± 9.8	25–59	43.2 ± 9.2	27–58	43.7 ± 1.1	26–60	0.168
BMI (kg/m^2)	24.4 ± 4.1	17.4–35.6	23.8 ± 3.5	19.3–32.0	24.7 ± 3.4	17.0–31.1	0.503
Duration of symptoms (months)	68.6 ± 54.0	12–180	112.9–81.8	24–360	88.4 ± 61.7	24–240	0.119
VAS-pain (0–10)	8.2 ± 0.9	7–10	7.6 ± 0.8	6–9	7.5 ± 0.9	6–9	0.053
VAS-fatigue (0–10)	8.9 ± 1.7	5–10	8.4 ± 1.8	5–10	8.1 ± 2.5	0–10	0.34
VAS-sleep (0–10)	7.2 ± 2.8	0–10	5.2 ± 2.8	0–8	5.8 ± 2.7	0–9	0.022
Tender points (*n*)	16.1 ± 2.0	12–18	15.4 ± 1.8	12–18	15.6 ± 2.4	12–18	0.550
Algometry (kg/cm^2)	2.9 ± 0.6	1.4–4.2	2.9 ± 0.5	1.7–3.6	2.9 ± 0.5	1.9–3.9	0.973
FIQ (0–100)	71.6 ± 14.2	37.9–88.1	67.7 ± 12.0	47.0–84.5	65.5 ± 13.2	45.9–88.4	0.291
BDI (0–63)	23.4 ± 11.0	6.0–41.0	20.7 ± 6.6	7.0–34.0	21.4 ± 10.4	7.0–46.0	0.706
SF-36, PCS (0–100)	32.8 ± 7.9	20.8–52.2	36.5 ± 8.7	24.8–54.0	36.0 ± 7.2	24.3–50.8	0.360
SF-36, MCS (0–100)	30.4 ± 11.7	13.8–53.4	33.2 ± 8.9	20.3–52.6	36.1 ± 9.8	18.3–50.1	0.188

BMI body mass index, *VAS* visual analog scale, *FIQ* Fibromyalgia Impact Questionnaire, *BDI* Beck Depression Inventory, *SF-36* Short Form-36, *PCS* physical component summary, *MCS* mental component summary, *SD* standard deviation, *Min* minimum, *Max* maximum

† The Kruskal–Wallis test, $\alpha = 0.05$

using Mann–Whitney *U* tests and the significance level for the multiple comparison test was defined as 0.016 using Bonferroni correction (*P* value = 0.05/number of pair-wise comparisons). Statistical analyses were confined to the 'per-protocol set' (those who completed the trial in conformity with the study protocol) without any 'intention-to-treat' analysis due to the absence of any outcome measures after randomization/treatment for the withdrawals/dropouts.

Results

Participants' characteristics

Of the 66 patients who began the study, a total of seven participants withdrew from the study (Fig. 1) due to pregnancy (one patient in the SG), insufficient follow-up (one in the SG and three in the CG), and attendance failure (one in the LG and one in the SG). The dropout patients were not included in the statistical analysis. The demographic and clinical characteristics of the participants are shown in Table 1. No significant difference existed between the three groups in terms of demographic characteristics.

Outcome measures

As seen in Table 1, there was no significant difference at the baseline assessment between the three groups in terms of all outcome measures except for VAS-sleep scores.

The VAS-pain values decreased in both LG (−38.3 %) and SG (−22.8 %). A nonsignificant increase in the VAS-pain values (+1.5 %) was observed in the CG after the 6-month period (Table 2). The between-groups comparison revealed a significant difference between the three groups. The pair-wise comparison indicated that these changes were significant in both the LG and SG compared with the CG. In addition, there was a significant difference between the LG and SG in relation to pain.

Participants in the LG (−29.8 %) and SG (−15.7 %) had a decrease in the VAS-fatigue values after the 6-month period (Table 2), whereas an increase was observed in the CG (+1.8 %). The between-groups comparison displayed

Table 2 Changes in the all outcome measures by intervention groups from the baseline to the 6 month

	Mean (SD)		Within-group†	Between-groups comparisons		
	Baseline	6-Month	Changes (%)	$p^{¥}$	Pairwise	$P^{Ψ}$
VAS-pain (0–10)						
LG	8.2 ± 0.9	5.1 ± 2.4	−38.3***	<0.001	LG vs CG	<0.001
SG	7.6 ± 0.8	5.8 ± 1.0	−22.8***		SG vs CG	<0.001
CG	7.5 ± 0.9	7.6 ± 1.4	+1.5		LG vs SG	0.047
VAS-fatigue (0–10)						
LG	8.9 ± 1.7	6.0 ± 3.0	−29.8**	0.048	LG vs CG	0.014
SG	8.4 ± 1.8	6.8 ± 2.2	−15.7*		SG vs CG	0.234
CG	8.1 ± 2.5	8.0 ± 1.5	+1.8		LG vs SG	0.236
VAS-sleep (0–10)						
LG	7.2 ± 2.8	3.0 ± 2.8	−45.0**	0.055	LG vs CG	N/A
SG	5.2 ± 2.8	3.1 ± 2.5	+33.7		SG vs CG	N/A
CG	5.8 ± 2.7	4.9 ± 3.0	+52.3		LG vs SG	N/A
Tender points (number)						
LG	16.1 ± 2.0	10.6 ± 4.4	−34.8***	0.002	LG vs CG	<0.001
SG	15.4 ± 1.8	11.4 ± 3.5	−24.5**		SG vs CG	0.014
CG	15.6 ± 2.4	14.4 ± 3.9	−5.8		LG vs SG	0.247
Algometry (kg/cm^2)						
LG	2.9 ± 0.6	3.8 ± 0.7	+34.2**	0.012	LG vs CG	0.029
SG	2.9 ± 0.5	3.8 ± 0.5	+36.3***		SG vs CG	0.002
CG	2.9 ± 0.5	3.2 ± 0.6	+16.6		LG vs SG	0.915
FIQ (0–100)						
LG	71.6 ± 14.2	53.9 ± 19.3	−22.1**	0.017	LG vs CG	0.011
SG	67.7 ± 12.0	54.5 ± 14.2	−18.9**		SG vs CG	0.015
CG	65.5 ± 13.2	65.5 ± 11.5	+3.2		LG vs SG	0.789
BDI (0–63)						
LG	23.4 ± 11.0	16.6 ± 9.6	−12.3*	0.696	LG vs CG	N/A
SG	20.7 ± 6.6	15.0 ± 10.2	−24.9*		SG vs CG	N/A
CG	21.4 ± 10.4	18.7 ± 9.5	+0.2		LG vs SG	N/A
SF-36-PCS (0–100)						
LG	32.8 ± 7.9	39.9 ± 7.5	+27.3**	0.036	LG vs CG	0.007
SG	36.5 ± 8.7	39.6 ± 8.1	+13.4		SG vs CG	0.212
CG	36.0 ± 7.2	34.3 ± 8.1	−2.2		LG vs SG	0.294
SF-36-MCS (0–100)						
LG	30.4 ± 11.7	40.7 ± 12.3	+60.0*	0.229	LG vs CG	N/A
SG	33.2 ± 8.9	40.2 ± 10.0	+28.7		SG vs CG	N/A
CG	36.1 ± 9.8	37.6 ± 10.0	+12.7		LG vs SG	N/A

LG long-term group, *SG* short-term group, *CG* control group, *SD* standard deviation, *VAS* visual analog scale, *FIQ* Fibromyalgia Impact Questionnaire, *BDI* Beck Depression Inventory, *SF-36* Short Form-36, *PCS* physical component summary, *MCS* mental component summary, *N/A* not applicable

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

† Within-group comparison by Wilcoxon signed-rank test

¥ Between-groups comparisons by Kruskal–Wallis test

Ψ Pair-wise comparisons using Mann–Whitney *U* tests with Bonferroni correction, significance level: $p < 0.016$

a significant difference among the three groups and the pair-wise comparison determined a significant difference between the LG and CG. The VAS-sleep values decreased in the LG (−45.0 %) and increased in the SG (+33.7 %). The between-groups comparison revealed no significant differences between the three groups.

As seen in Table 2, there was a significant decrease during the 6-month period in the number of tender points in both the LG (−34.8 %) and SG (−24.5 %), and a non-significant decrease in the CG (−5.8 %). When the groups were compared in terms of tender point numbers, there was a significant difference among the three groups. The pair-wise comparisons indicated that there was a significant decrease in both the LG and SG compared with the CG. The pressure pain threshold level increased in all groups during the 6-month period; however, these changes were more pronounced in the LG (+34.2 %) and SG (+36.3 %) compared with the CG (+16.6 %). In the between-groups comparison, there was a significant difference among the three groups. The pair-wise comparison indicated significant differences in both the LG and SG compared with the CG. Also, the FIQ scores decreased in the LG (−22.1 %) and SG (−18.9 %); in contrast, there was an increase (+3.2) in the CG after 6 months. In the between-groups comparison, there was a significant difference among the study groups. The pair-wise comparison indicated significant differences in both the LG and SG compared with the CG.

The BDI scores decreased in the LG (−12.3 %) and SG (−24.9 %); however, there was no significant difference in the between-groups comparison. The PCS scores increased in the LG (+27.3 %) and SG (+13.4 %), whereas there was a decline in the CG (−2.2 %). When the groups were compared, there was a significant difference between the three groups. The pair-wise comparison revealed a significant difference between the LG and CG. The MCS scores increased in all of the three groups during the 6-month period (Table 2); however, no significant difference was found between the study groups.

The patients in the intervention groups reported no harms or adverse events regarding CBT and/or exercise training except for occasional mild increases in pain after some exercise sessions.

Discussion

Our findings indicate that both the long- and short-term interdisciplinary treatment approaches were effective in reducing pain intensity and tender point numbers, increasing pressure pain threshold levels, and controlling disease activity as measured using FIQ in women with FM. Moreover, only the long-term treatment program was effective in decreasing fatigue and improving physical components of HRQoL. Both treatment programs were not found to be effective in reducing depressive symptoms, increasing sleep quality, or improving mental components of HRQoL. When the long- and short-term interdisciplinary treatment approaches were compared with each other, no evident difference was found between the two treatment programs with regard to influences on assessed variables except for pain which showed a significantly higher reduction in the LG than in the SG.

In accordance with our results, the literature suggests that multidisciplinary/interdisciplinary treatment, also called multicomponent treatment, is effective for reducing pain intensity and/or point tenderness in FM [24–26]. The significant effect size for pain reduction in the meta-analysis on multicomponent treatment (including education and exercise in all studies and elements of CBT in four studies out of nine) by Häuser et al. [13] was calculated as −0.37 at post-treatment; however, significant long-term effects could not be demonstrated. Some other studies using the combination of education, exercise, and CBT pointed to significant reduction in pain intensity in the long-term (at 6 months) [27] and both the pain intensity and the number of tender points as well as an increase in pressure pain threshold at 2, 5, and 12 months [28]. With regard to psychological methods, in a meta-analysis, CBT was determined to be more effective in reducing pain intensity than others such as education and relaxation therapy [26]. It seems that varying results in studies on pain and pain-related variables in terms of the maintenance of the effects in the long-term might be attributable to the components of the multidisciplinary approaches (inclusion of only education + exercise or additionally CBT) and also to the content of the CBT. We believe that the CBT program in our study aiming to enhance awareness of the relationship between stressful life events, emotions/thoughts/behaviors, and symptomatic patterns, to develop skills to cope with stressful life events and pain, and to increase the ability to express emotions and opinions was the important determinant of reduction in both pain intensity and point tenderness in the long-term.

Regarding fatigue in our study, there was a significant decrease in its severity at 6 months after the long- and short-term programs, the decrease being statistically significant in the LG and not in the SG when compared with the CG. In the meta-analysis by Hauser et al. [13] evaluating nine trials seven of which having assessed outcomes at post-treatment and two with long-term follow-ups, no sufficient evidence was found to suggest that multidisciplinary treatment was effective on fatigue in the long-term, despite post-treatment efficacy. An important point in this meta-analysis was that when the studies were subgrouped with regard to the duration of multicomponent treatment, a significant effect was observed in treatments with ≥30 h but not in treatments <30 h [13]. The effects of multidisciplinary treatment on fatigue varied in other studies. While Redondo et al. [29] observed a significant improvement in fatigue intensity in both the exercise (five 45 min sessions/week × 8 weeks followed by home exercises) and

CBT (2.5 h/week × 8 weeks) groups at post-treatment and but not at 6 and 12 months, van Koulil et al. [30] noted improvements in fatigue with a multidisciplinary program of 10 weeks at 6 months, in parallel with our results in the LG. It may be speculated that the longer the multidisciplinary program (particularly the CBT component), the higher the persistence of the reduction in fatigue is. This notion can explain why our LG showed a statistically significant difference in fatigue intensity when compared with CG and why the SG did not. The stressing of CBT component rather than exercise for long-term effects on fatigue is supported by the findings of the most recent Cochrane review by Bernardy et al. [31] which showed a significant effect of CBT on fatigue at both post-treatment and long-term follow-ups. Significant favorable post-treatment effects (not in the long-term) of aerobic exercise on fatigue have also been shown in systematic reviews and meta-analyses including studies with more structured and supervised aerobic exercise programs [32, 33]. Long periods of home-based exercise training presumed to be maintained till the 6-month assessment in our study could be expected to favorably influence fatigue. However, in line with the findings by Redondo et al. [29] in the head-to-head comparison study of aerobic exercise with CBT who found improvement in fatigue at the end of 8-weeks of supervised exercise and not at the follow-ups, the influence of home-based training on fatigue remains to be elucidated. Moreover, Lera et al. [34], comparing the effectiveness of two multidisciplinary programs with CBT (15 ninety-minute weekly sessions) and without pointed to the better effectiveness of the former than that of the latter program in women with fatigue at post-treatment and also at 6 months of follow-up.

In our study, there was no significant improvement in the sleep quality of patients in the LG and SG, despite our findings of improvement in pain in both intervention groups and fatigue in the LG. Since sleep disturbance is known to be closely related to pain and fatigue with a reciprocal influence [35], one would expect a decrease in sleep disturbance parallel to decrease in fatigue and pain. While our results were consistent with those of Häuser et al. [13], who reported that a multidisciplinary treatment did not affect sleep quality based on a low-quality study, contrastingly, Glombiewski et al. [26] indicated that CBT and relaxation techniques were effective in improving sleep quality. Regarding CBT, it is important to note that in the Cochrane review on CBT by Bernardy et al. [31], while none of the studies assessing sleep using VAS [29, 36, 37] found a significant effect either at post-treatment or long-term follow-up at 6 months and 1 year [29] or at 4 years [36], studies using sleep-specific questionnaires such as the Karolinska Sleep Questionnaire [38, 39], the Insomnia Symptom Questionnaire [40, 41], or Medical Outcomes Study Sleep Scale [42, 43] demonstrated a significant favorable effect both at post-treatment and also at 6-month follow-up [39, 41, 43]. Furthermore, in other research, Casanueva-Fernández et al. [44] and Martínez et al. [45], using the Pittsburgh Sleep Quality Index [46], demonstrated the significant effect of a multidisciplinary treatment [44] and CBT-insomnia [45], respectively, on sleep both at post-treatment and at one month [44] and 3- and 6-month follow-up [45]. It is also noteworthy that studies providing evidence on the efficacy of CBT on sleep quality did include CBT targeting insomnia [41, 43, 45] as well as education on sleep hygiene [39], the significant effects of which on sleep quality has been shown in one of the studies [45], while not in the other [41] when applied as a single therapy. It appears that there are two major points to consider regarding the evidence on the effectiveness of multidisciplinary programs on sleep: the outcome measurement used to assess sleep and the content of the CBT program. Specific interventions targeting insomnia include stimulus control therapy with the aim of sleep scheduling, relaxation techniques, paradoxical intention, sleep restriction therapy, and CBT as recommended with evidence of effectiveness and education on sleep hygiene and imagery training without sufficient evidence of efficacy [47]. Considering aforementioned literature, the lack of improvement in the sleep quality of patients in either treatment group in our study may have resulted from the measurement of sleep using VAS and not using a sleep-specific questionnaire as well as the content of our CBT program not specifically targeting insomnia and not including all of the recommended elements or those with potential efficacy such as sleep hygiene [47]. The statistically significantly higher VAS-sleep scores at baseline, indicating poorer sleep, in the LG than that in the SG and CG (Table 1) may have also contributed to the lack of a favorable outcome regarding sleep.

The long- and short-term treatment programs were effective in improving health status. There are many studies with data in accordance with our findings in terms of improvement in health status as measured by FIQ following either long-term [27, 48–50] or short-term [51, 52] multidisciplinary treatment programs with significant improvements in total FIQ scores at both post-treatment and/or at long-term follow-ups (between 6 and 12 months) [27, 48, 49, 52] or at short-term follow-ups (between 1 and 4 months) [50, 51].

With regard to depressive symptoms, our results indicated that neither the long- nor short-term approaches were effective at decreasing their severity. This finding might be due to the fact that in the current study there was no specific intervention to reduce the intensity of depressive symptoms except for ‘free sharing’ sessions with some elements expected to improve depressive mood. Similar to our study, Lemstra et al. [53] demonstrated a decrease in depressive symptoms at 6 months, however, without statistical significance. Also, some other studies found no significant

difference in the intensity of depressive symptoms compared with pre-treatment values [27, 29, 54]. However, in the meta-analysis by Hauser et al. [13] reduction in depressive symptoms at post-treatment was reported. Martinez et al., [45] demonstrated significant decreases in depression in the CBT-insomnia group. Likewise, Papadopoulou et al. [55] found a small but significant effect size for the effectiveness of multidisciplinary treatment on depression; however, this efficacy disappeared when low-quality trials were excluded. It is highly likely that the diversity in the contents of the multidisciplinary programs may affect the outcomes on depression.

Finally, the robust effect of our interventions on physical components of HRQoL in the LG and a trend of efficacy in the SG, but not on mental components in any intervention group is not a surprising finding. According to Kroenke and Swindle, favorable effects of CBT on physical outcomes do not necessarily depend on favorable changes in psychological outcomes, occurring independently. Indeed, CBT shows the most prominent and rapid effect on physical outcomes [56]. Similarly, Redondo et al. [29] detected an improvement in the subscales of physical function and general health subscales of SF-36 scores in the CBT group at 6-month follow-up, but not in mental function-related items. In contradiction with our findings, Martins et al. [57] found significant improvements in HRQoL (both in PCS and MCS) after a 12-week multidisciplinary treatment program. Amris et al. [58] also found improvements in both PCS and MCS scores after a 2-week multicomponent program in the intervention group but not in the controls; however, difference between the changes in the groups was not found statistically significant. Angst et al. [59] using a 4-week interdisciplinary program, found significant improvements in MCS scores in patients with FM at discharge, and also at 3 and 6 months of follow-ups; however, PCS scores were found to improve at only discharge. Again, discrepancies between findings across studies might be explained by the diversity of the contents and the duration of the multidisciplinary programs.

Our study conveys an important message that a short-term multidisciplinary treatment is comparable to a long-term program in well addressing some major symptoms of FM such as pain and health status as measured using FIQ. The utility of a 1.5-day or 1-week multidisciplinary FM program was also reported by Vincent et al. in a case series with some improvements in pain, physical function, and fatigue [60]. However, in order to meet the short version of the OMERACT-10 FM response criteria including improvement in pain, physical function, and fatigue or sleep [61], a long-term program like the one we used in this study inducing improvements in pain (38.3 %) more than $\geq$30 % and closer to $\geq$30 % in fatigue (29.8 %) as proposed [61] seems to be required.

Strengths and limitations of the study

The strength of the present study is the fact that to date, it is the only study that compares the effectiveness of interdisciplinary treatment approaches with a CG and also compares the effectiveness of long- and short-term interdisciplinary treatment approaches in groups with homogenous demographic features and pre-treatment assessments. Another important strength is the fact that in the CBT program, psychotherapy sessions were regularly conducted by the experienced clinical psychologist in an interactive way and supervised by the investigators.

Our study had several limitations that must also be considered. Firstly, the follow-up period of the study was not long enough to accurately determine the efficacy of the current treatment approaches in the long term. Secondly, the CBT sessions was conducted collectively with 22 patients, which is too many for an ideal CBT session. In addition, lack of any specific content in our intervention programs for improving sleep, mental aspects of HRQoL, and depressive symptoms was another limitation of the study. Finally, regarding patient follow-up, we did not know exactly how frequently the patients practiced the prescribed home exercises and relaxation techniques despite reinforcements on the maintenance of exercises at monthly visits and self-reported adherence by the majority of the participants in the intervention groups.

Conclusions

The findings in the present study indicate that both the long- and short-term interdisciplinary treatment approaches are effective for reducing pain intensity and tender point numbers, increasing pressure pain threshold, controlling disease activity and improving functional status in women with FM. Also, the long-term treatment program was effective in reducing fatigue severity and improving physical components of the HRQoL. Our interventions were not effective in reducing depressive symptoms or improving the quality of sleep or the mental aspects of the HRQoL. No obvious differences were found between the two treatment approaches when directly compared except for better effectiveness of the long-term program in reducing pain. It may be concluded that our short-term program well meets the needs of women with FM in relation to pain and important components of health status as measured using FIQ; however, a long-term program may be beneficial in reducing fatigue and improving physical function to a higher extent. Further studies with a larger number of patients and longer follow-up periods, including more comprehensive treatment programs that additionally target sleep quality and mental status are recommended.

Compliance with ethical standards

Conflict of interest All authors declare no conflict of interest. No grant or industry support was received for this study.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration Helsinki and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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