Effectiveness of a Psychoeducational Treatment Program Implemented in General Practice for Fibromyalgia Patients

A Randomized Controlled Trial

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Objectives: A recent meta-analysis concluded that multicomponent treatments are effective for some fibromyalgia (FM) symptoms. The objective of this study was to examine whether a psychoeducational intervention implemented in primary care is more effective than usual care for improving the functional status of patients with FM.

Methods: This study was based on a randomized controlled trial. The 484 patients with FM included in a database of the Viladecans Hospital (Barcelona, Spain) were eligible for screening. Finally, 108 patients were randomly assigned to the intervention and 108 patients were assigned to usual care. The intervention comprised nine 2-hour sessions (5 sessions of education and 4 sessions of autogenic relaxation). The patients were assessed before and after the intervention with a battery of instruments (measuring sociodemographic data, medical comorbidities, functional status, trait anxiety, and social desirability).

Results: The posttreatment drop-out rate was 9.7% (intervention: 6.5%; control: 13%). The intention-to-treat analyses showed significant differences between the groups at posttreatment: the intervention group improved in physical impairment, days not feeling well, pain, general fatigue, morning fatigue, stiffness, anxiety, and depression (medium effect size in most cases). The patients who responded to the intervention reported less trait anxiety at baseline than nonresponders. The absolute risk reduction with the intervention was 36.1% (95% confidence interval: 23.3-48.8) and the number needed to treat was 3 (95% confidence interval: 2.0-4.3).

Discussion: A 2-month psychoeducational intervention improves the functional status of FM patients to a greater extent than usual care, at least in the short-term. The social desirability bias did not explain the reported outcomes. Trait anxiety was associated with response to treatment.

Trial Registration: NCT00550966.

Key Words: fibromyalgia, randomized controlled trial, primary care, education, relaxation

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The American College of Rheumatology (ACR) defined 2 major diagnostic criteria for classifying fibromyalgia (FM) in adults[1]: a history of widespread pain for at least 3 months and patient report of tenderness in at least 11 of 18 defined tender points when digitally palpated with approximately 4 kg per unit area of force. The prevalence of FM in developed countries ranges approximately from 0.5% to 4% in the general population, women being 10 times more likely to meet the diagnostic criteria.[2] This debilitating condition affects approximately 2% or up to 6% of the patients seen by general practioners (GPs).[3]

Several medications have been used in the treatment of patients with FM. However, only a small number of these medications have shown effectiveness in randomized controlled trial (RCTs).[4,5] Multicomponent therapies (a combination of at least 2 nonpharmacologic therapies) have shown effectiveness in RCTs[6] and are recommended in evidence-based guidelines.[7] The 2 most common nonpharmacologic treatments are physical exercise and educational programs with varying contents.[8–12] For instance, Mannekorpi et al[11] examined patients' symptoms, health status, and physical functioning 6 and 24 months after the completion of an FM treatment program based on pool exercise therapy and education. Some of the Fibromyalgia Impact Questionnaire (FIQ) subscales showed improvements not only at 6-month follow-up compared with the baseline, but also at 24-month follow-up. More recently, Rooks et al[12] concluded that the benefits of exercise are enhanced when combined with targeted self-management education. These investigators evaluated and compared the effects of 4 common self-management interventions on measures of functional status, symptom severity, and self-efficacy in women with FM. In addition,

various relaxation techniques have also been used in the treatment of FM, showing effectiveness mainly in the relief of muscle tension and anxiety.[13] One of the main problems related to multimodal interventions is that their positive results might be the consequence of the special attention these patients receive in comparison with that received by controls[11,14]; that is, there might be a desire on the part of the patient who has received the intervention to "please" the researcher.[15]

In a recent meta-analysis[16] of all RCTs of pharmacologic and nonpharmacologic treatments available in standard general practice and secondary care settings, the investigators did not find significant differences in the efficacy of treatments according to the level of care. They compared the efficacy of the treatments for FM available in both settings using 3 outcome domains: pain, global function, and the FIQ. Sex and type of treatment (pharmacologic vs psychologic) were not related to outcome. Clauw and Crofford[2] suggest that given the high frequency of visits required and the attention that must be paid to the many psychosocial aspects of the fibromyalgic patient, GPs may be especially suited to caring for these patients.

The main aim of this study was to assess whether a psychoeducational intervention implemented by a multidisciplinary team situated in primary care, and based on education about the illness and autogenic relaxation training,[17] improves the functional status of patients with FM to a greater extent than the usual care provided by GPs. In addition, we examined within the intervention group whether there were any differences between responders and nonresponders in some clinical characteristics measured at baseline.

MATERIALS AND METHODS

Design

The study was based on a controlled trial with a random allocation of participants in 2 branches:

1. Intervention group: Usual care + psychoeducational program
2. Control group: Usual care.

A detailed description of the study protocol, approved by the Jordi Gol i Gorina Foundation (Barcelona, Spain) research ethics committee, has been provided elsewhere.[18] We have followed the guidelines of the revised Consolidated Standards of Reporting Trials statement.[19]

Settings and Participants

Three general practices voluntarily participated in this study: Viladecans-2, Gavà-1, and Gavà-2, situated in the province of Barcelona (Spain). The GPs at these centers refer those patients who are suspected of having FM to the Viladecans Hospital Rheumatology Unit. If the FM diagnosis is confirmed by a rheumatologist, the patient is included in a database. Subsequently, the patient is referred to the general practice to monitor the treatment. In this study, the sample pool comprised all patients included in this database between 2005 and 2008. With regard to the eligibility criteria, all patients aged between 18 and 75 years contactable by telephone, and who met the diagnostic criteria of FM established by the ACR were candidates for inclusion in the study. The exclusion criteria were (1) diagnosis of FM not based on the ACR criteria, (2) cognitive impairment, (3) presence of physical/psychiatric limitations that impeded participation in the study assessments, (4) life expectancy of less than 12 months, and (5) absence of schooling.

An a priori sample size calculation indicated that 108 patients would be required to complete each group to detect a statistically significant difference ($\alpha = 0.05$, $\beta = 0.80$, difference of 5 points in the FIQ total score based on an earlier study,[10,20] a standard error of 12, and a 15% drop-out rate).

Procedure

The potential participants were screened through an initial telephonic interview by some of the investigators (N.M., M.T.P., R.F., and M.E.B.), who provided a general overview of the study. Then the research assistant (N.M.) made an appointment with those patients who agreed to participate in the study. Finally, the research assistant, who was not involved with the treatment and was blind to group allocation, conducted all the face-to-face interviews once written consent was obtained. Data were collected at baseline and on completion of the intervention. The patients were randomly assigned to the intervention group or to the control group using a computer-generated randomization list drawn up by one of the investigators (M.T.P.).

Intervention Group

The patients received usual care from their GP and a psychoeducative program. The treatment program was based on a consensus document developed by an expert panel in 2005 and published in 2006 by the Catalan Health Department.[21] It consisted of nine 2-hour sessions delivered over a 2-month period (1 afternoon session per week). All sessions took place in the conference room of the general practice, Gava-2. The patients were allocated to groups with a maximum of 18 patients per group. Six separate intervention groups began the program between October 2007 and January 2009. Patient recruitment began 1 month before the start of the trial and continued until December 2008. All interventions were completed by March 2009.

The educative part of the program (5 sessions) included information about typical symptoms, usual course, comorbid medical conditions, potential causes of the illness, the influence of psychosocial factors on pain, current pharmacologic and nonpharmacologic treatments, the benefits of regular exercise, and the typical barriers to behavior change. The speakers included 4 GPs and 1 rheumatologist. The patients were encouraged to be active, to ask questions and to discuss issues with the speakers or with other participants. It was important that they shared their daily experience of the syndrome because it helps to illustrate the theoretical concepts addressed in the sessions. A summary of the contents of each educative session was provided earlier.[18]

The autogenic training (4 sessions), especially recommended for immediate physical and mental relaxation, pain relief, and stress reduction, was led by a clinical psychologist with the main objective of increasing the pain control of the patients. Other objectives were to create a space in which the conflictual emotional experiences manifested in the patients' bodies could be elaborated and to facilitate emotive exchange with other patients suffering from the same condition. The link between emotions and bodily reactions was often highlighted and the benefits of distracting attention from fibromyalgic pain. The psychologist emphasized the need to practice the relaxation techniques at home daily.

The educational sessions were intercalated with the autogenic training sessions until the 9 weeks were completed. After implementing the intervention, we considered that it was important to assess its usefulness (strengths and shortcomings) from the patients' perspective. For this reason, we carried out a brief qualitative assessment at the end of session 9, which also included the clarification of doubts concerning specific theoretical and practical aspects of the intervention.

The patients were informed that they could choose to drop out at any time with the guarantee that they would continue to receive the treatment considered most appropriate by their GP. To avoid conversations concerning the intervention between patients from different groups, they were not allowed to talk about the program with people who were not part of their group. Before baseline assessment, an explanatory note addressing this important issue was delivered.

Control Group

The patients in the control group received usual care. In general practice, the treatment provided is mainly pharmacologic and is adjusted to the symptomatic profile of the patient. In addition, counselling about aerobic exercise adjusted to patients' physical limitations is usually provided.

Instruments

Sociodemographic Questionnaire

This questionnaire collected information on the following variables: sex, date of birth, marital status, living arrangements, education level, and work status.

FIQ (Spanish Version)[22,23]

The self-administered instrument of functional status includes 10 questions. The first question contains 10 items related to the ability to carry out large muscle tasks—each question is rated on a 4-point (0 to 3) Likert-type scale. In the Spanish version, the physical function item contains 9 subitems instead of the original 10. Items 2 and 3 ask the patient to mark the number of days on which they felt well and the number of days on which they were unable to work because of FM symptoms. Items 4 to 10 are horizontal linear scales marked in 10 increments on which the patient rates work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression. Once the initial scoring has been completed, the resulting scores are subjected to a normalization procedure so that all scores are expressed in similar units. Each item has a maximum possible score of 10, which yields a maximum total score of 80 (excluding job-related items), with higher scores indicating greater impact. The Spanish adaptation of the FIQ[22] showed excellent internal consistency ($\alpha = 0.82$ for all items and $\alpha = 0.86$ for the physical function subitems) and is a sensitive index of change in FM-related symptomatology.

Chronic Medical Conditions Checklist

The presence of comorbid medical conditions, defined by the WHO[24] as "health problems that require ongoing management over a period of years or decades," was assessed using a yes-or-no checklist. It included questions about a wide range of chronic physical conditions including: arthritis, rheumatism, cervical pain, back pain, bronchitis or emphysema, asthma, diabetes, hypertension, heart arrhythmias, heart attack, stroke, gastric or duodenal ulcer, migraines or other chronic headaches, varicose veins, cancer, eyesight problems, and hearing problems. The respondents were asked whether they experienced in the last year any of the symptom-based conditions in the checklist.

The State Trait Anxiety Inventory (STAI; Spanish Version)[25]

This scale is a 40-item self-reported measure of general anxiety. In this study, we only assessed trait anxiety (STAI-T), or how the patient generally feels. The patients rate each item using a Likert-type scale from 0 (not at all) to 3 (very much so). Total scores on the STAI-T vary from 0 to 60, with higher scores indicating more trait anxiety. The internal consistency values of the Spanish adaptation in nonclinical and clinical samples are similar to those of the English version (ranging from 0.82 to 0.92), which also occurs in the test-retest values (between 0.70 and 0.80). The validity analyses confirmed its usefulness in clinical settings. Huber et al[26] reported an α value of 0.90 for the STAI trait scale in a sample of women with chronic multiregional musculoskeletal pain (41 of whom met the ACR criteria for FM).

The *Marlowe-Crowne Social Desirability Scale* (Spanish version[27,28]). It comprises 33 true-false items that assess the person's tendency to distort self-presentation toward a socially desirable bias. Total Marlowe-Crowne Social Desirability Scale scores range between 0 (low defensiveness) and 33 (high defensiveness). The Spanish adaptation[27] is 1-dimensional and has adequate internal consistency ($\alpha = 0.78$).

Statistical Analyses

All statistical analyses were carried out using the PASW 17.0.3 statistical package. First, we examined baseline differences in the sociodemographic and clinical characteristics between the intervention and control group, applying the Student *t*-test for continuous variables and the χ^2-test with continuity correction (or 2-sided Fisher exact test when appropriate) for categorical data.

Second, the treatment effect on functional status was analyzed with factorial analyses of variance (ANOVAs) (when the sphericity could not be assumed, the Huynh-Feldt correction was used). The 2×2 repeated measures ANOVAs were carried out with groups (Intervention and Control) as 1 factor and test occasion (pretreatment and posttreatment) as the repeated measures factor to examine differences in the FIQ total score (global functional status) and in each of the FIQ domains (physical impairment, days not feeling well, pain, general fatigue, morning fatigue, stiffness, anxiety, and depression). We conducted intention-to-treat analyses that included all patients who underwent random allocation, using the conservative approach of baseline values carried forward to replace missing values. Therefore, the patients were analyzed in the condition to which they were randomized irrespective of whether they adhered to their treatment. Planned comparisons (analyses of covariance comparing the 2 groups at posttreatment with baseline values as covariates) were subsequently computed if the group-by-period interaction was statistically significant.

Third, we dichotomized patients in the intervention group into responders ($\geq 20\%$ reduction on the FIQ total score from baseline to end of treatment) or nonresponders. Reductions in the FIQ total score of 20% or greater have been considered to be clinically important.[29] Student *t* tests were conducted to identify whether there were any clinical

differences at pretreatment between these 2 subgroups. No adjustments were made for multiple testing, as was recommended earlier.[30] The overall α level was set at 5%. The effect size in ANOVAs was based on η_p^2 (rule of thumb: 0.01 = small; 0.06 = medium; 0.14 = large), which can be interpreted as the proportion of variance in the dependent variable that is attributable to each effect.

RESULTS

Patient Flow

The flow of patients through the study is shown in Figure 1. Thirty-one patients were not evaluated at posttreatment; 21 of them were drop-outs (drop-outs = patients who explicitly refused to continue in the study). Therefore, the overall drop-out rate was 9.7%. The drop-out rate was 6.5% (n = 7) in the intervention group and 13% (n = 14) in the control group. The reasons for drop-out were: not interested in the study (n = 16), family burden (n = 2), not able to comply with the treatment schedule (n = 2), and relocation (n = 1).

Baseline Characteristics of the Groups

Table 1 displays the baseline characteristics of the groups. The sociodemographic variables that had more than 2 response categories were collapsed into dichotomous categories to ensure that the number of patients was appropriate for statistical analysis. The typical patient was a woman, approximately 55 years of age, married, lived with spouse/partner and/or offspring, with primary studies, and homemaker or unemployed. She had 4 comorbidities, a diagnosis of FM for approximately 15 years at the time of study enrolment, medium trait anxiety, and medium-to-high social desirability. There were no statistically significant differences between the intervention and the usual care group in any of the variables, indicating that random group assignment had been achieved.

Functional Status Outcomes

Means and standard deviations on the FIQ dimensions by group at pretreatment and posttreatment are presented in Table 2. The repeated-measures ANOVAs yielded significant group-by-period interactions in all

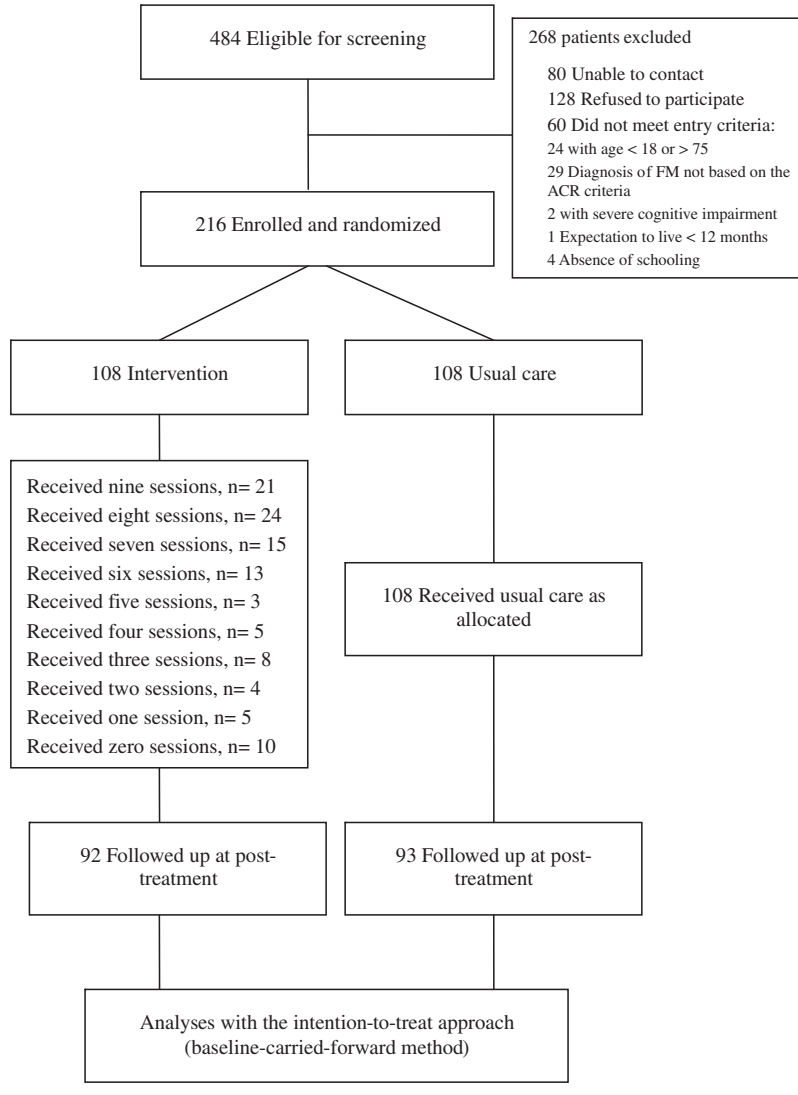

FIGURE 1. Flow diagram of the participants in the randomized controlled trial.

TABLE 1. Baseline Characteristics of Patients With Fibromyalgia by Treatment Group

Sociodemographic Variables	Intervention	Control	*P*
Sex (No. females, %)	105 (97.2%)	106 (98.1%)	1.00
Age, male (SD)	55.17 (8.58)	55.42 (8.63)	0.83
Marital status, n (%)*			0.12
Married/living with a partner	92 (85.2%)	82 (75.9%)	
Single	2 (1.9%)	6 (5.6%)	
Separated/divorced	7 (6.5%)	6 (5.6%)	
Widowed	7 (6.5%)	14 (13.0%)	
Living arrangement, n (%)*			0.62
Living alone	6 (5.6%)	16 (14.8%)	
Living with spouse/partner	44 (40.7%)	31 (28.7%)	
Living with spouse/partner and/or offspring	52 (48.1%)	53 (49.1%)	
Living with other relatives	1 (0.9%)	2 (1.9%)	
Living with friends	0 (0%)	1 (0.9%)	
Others	5 (4.6%)	5 (4.6%)	
Education level, n (%)*			0.10
Illiterate	1 (0.9%)	0 (0%)	
Did not graduate from primary school	23 (21.3%)	33 (30.6%)	
Primary school	52 (48.1%)	53 (49.1%)	
Secondary school	28 (25.9%)	15 (13.9%)	
University	2 (1.9%)	4 (3.7%)	
Others	2 (1.9%)	3 (2.8%)	
Employment status, n (%)*			0.77
Student	2 (1.9%)	0 (0%)	
Homemaker	35 (32.4%)	30 (27.8%)	
Unemployed	12 (11.2%)	16 (14.8%)	
Paid employment	28 (25.9%)	22 (20.4%)	
Paid employment but in sick leave	9 (8.3%)	10 (9.3%)	
Retired/pensioner	3 (2.8%)	10 (9.3%)	
Permanent disability	16 (14.8%)	10 (9.3%)	
Others	3 (2.8%)	10 (9.3%)	
Clinical variables, male (SD)			
No. comorbidities	4.55 (2.46)	4.38 (2.52)	0.62
No. medications	2.36 (1.34)	2.37 (1.41)	0.96
Years of diagnosis	15.20 (11.68)	14.33 (10.60)	0.63
STAI-T (0–60)	34.35 (10.94)	31.61 (10.12)	0.09
MCSDS (0–33)	20.01 (4.84)	20.24 (3.75)	0.73

*The response categories were collapsed into dichotomous categories for statistical analysis.
MCSDS indicates Marlowe-Crowne Social Desirability Scale; STAI-T, Trait Anxiety Inventory.

dimensions. Subsequently, we computed planned comparisons (analyses of covariance) that showed between-group differences at posttreatment. Compared with the control group, the intervention group reported better functional status (FIQtot) than the control group [$F(1, 213) = 39.72$, $P = 0.001$, $\eta_p^2 = 0.16$, 95% confidence interval (CI): 7.20-13.76], and less physical impairment [$F(1, 213) = 19.94$, $P = 0.001$, $\eta_p^2 = 0.09$, 95% CI: 0.66-1.70], days not feeling well [$F(1, 213) = 19.62$, $P = 0.001$, $\eta_p^2 = 0.08$, 95% CI: 0.97-2.53], pain [$F(1, 213) = 28.52$, $P = 0.001$, $\eta_p^2 = 0.12$, 95% CI: 0.86-1.86], general fatigue [$F(1, 213) = 8.21$, $P = 0.005$, $\eta_p^2 = 0.04$, 95% CI: 0.24-1.30], morning fatigue [$F(1, 213) = 10.77$, $P = 0.001$, $\eta_p^2 = 0.05$, 95% CI: 0.36-1.45], stiffness [$F(1, 213) = 7.35$, $p = 0.007$, $\eta_p^2 = 0.03$, 95% CI: 0.23-1.47], anxiety [$F(1, 213) = 19.41$, $P = 0.001$, $\eta_p^2 = 0.08$, 95% CI: 0.79-2.06], and depression [$F(1, 213) = 21.44$, $P = 0.001$, $\eta_p^2 = 0.09$, 95% CI: 0.93-2.31].

Although the effect size on functional status (FIQtot) represents a large effect, the magnitude of the effect size is not equally distributed among the different domains. As such, physical impairment, days not feeling well, pain, anxiety, and depression represent medium effects, whereas general fatigue, morning fatigue, and stiffness showed small effect sizes.[31] Finally, a partial correlation analysis (controlling for baseline FIQtot scores) indicated that higher attendance rate (number of sessions) was related to better functional status (FIQtot) at posttreatment ($r = -0.32$, $P = 0.001$).

Clinical Differences Between Responders and Nonresponders

Fifty-three percent and 17% of the patients in the intervention and control group, respectively (49/92 and 16/93 who completed pretreatment and posttreatment interviews) met the responder criterion at posttreatment (FIQtot reduction $\geq 20\%$). The difference in the distribution of responders and nonresponders between the conditions was statistically significant (Fisher exact test, $P < 0.001$).

The clinical characteristics of responders and nonresponders within the intervention group are shown in Table 3. With the exception of trait anxiety, there were no significant differences between responders and nonresponders in any other variable.

Number Needed to Treat

We had a binary outcome in both groups (responders and nonresponders), which allowed calculation of the number needed to treat.[32] This index refers to the "estimated number of patients who need to be treated

TABLE 2. Repeated Measures of ANOVA for Mean Scores on Functional Status (FIQ) by Treatment Group (Psychoeducative Intervention vs Control) for Baseline and Posttreatment (Intention-to-Treat Analysis)

			Group Period Effect		
	Intervention (n = 108)	Control (n = 108)	*F*	*P*	η_p^2
FIQ total score (0-80)			42.22	0.001	0.17
Baseline	58.90 (12.09)	55.97 (14.01)			
Posttreatment	46.87 (16.77)	54.72 (15.95)			
Physical impairment (0-10)*			22.74	0.001	0.10
Baseline	3.31 (2.27)	2.80 (2.40)			
Posttreatment	2.44 (2.51)	3.22 (2.79)			
Not feeling good (0-10)*			21.44	0.001	0.09
Baseline	8.73 (2.11)	8.28 (2.81)			
Posttreatment	6.53 (3.49)	8.04 (2.84)			
Pain (0-10)			23.92	0.001	0.10
Baseline	7.37 (1.86)	7.37 (2.10)			
Posttreatment	6.34 (2.35)	7.70 (2.03)			
General fatigue (0-10)			7.69	0.006	0.04
Baseline	8.18 (1.83)	8.13 (1.89)			
Posttreatment	7.06 (2.41)	7.80 (2.17)			
Morning fatigue (0-10)			13.14	0.001	0.06
Baseline	8.17 (2.09)	7.68 (2.55)			
Posttreatment	6.82 (2.56)	7.38 (2.68)			
Stiffness (0-10)			8.66	0.004	0.04
Baseline	7.80 (2.21)	7.44 (2.53)			
Posttreatment	6.37 (2.94)	6.99 (2.54)			
Anxiety (0-10)			21.89	0.001	0.09
Baseline	7.94 (2.22)	7.45 (2.42)			
Posttreatment	6.07 (3.19)	7.14 (2.61)			
Depression (0-10)			23.68	0.001	0.10
Baseline	7.42 (3.02)	6.82 (3.11)			
Posttreatment	5.24 (3.54)	6.45 (3.09)			

*Raw data were transformed into normalized scores ranging from 0 to 10, with higher scores indicating a worse condition.
ANOVA indicates analysis of variation.

with the new treatment rather than the standard treatment for one additional patient to benefit"[33] (p. 1309). In this case, with the psychoeducational intervention the absolute risk reduction was 36.1% (95% CI: 23.3-48.8) and the number needed to treat was 3 (95% CI: 2.04.3). In other words, 3 patients are needed to treat with usual care + psychoeducation rather the standard treatment (usual care only) for 1 additional patient to experience clinically significant improvement in functional status (FIQtot reduction $\geq$20%).

DISCUSSION

Summary of Key Findings

This is the first study that assesses the efficacy of a multicomponent treatment for FM at primary care level using a control group. These results can be summarized as follows: overall, usual care with psychoeducation produced greater increase in patients' functional status than usual care alone. Specific improvements were seen in physical function, days feeling well, pain, general fatigue, morning fatigue, stiffness, anxiety, and depression. Second, responders had less trait anxiety at baseline than nonresponders. Third, the multidisciplinary team should treat 3 FM patients with the new intervention rather than the standard treatment for 1 additional patient to benefit.

Consideration of Possible Mechanisms and Explanations

One mechanism that might have contributed to the outcomes of this study is the "Hawthorne phenomenon,"[34] conceptualized in this area as the patient's tendency to report a positive outcome because of the time and effort invested by the clinicians in the treatment. Although it is

TABLE 3. Baseline Clinical Characteristics of Patients From the Psychoeducational Intervention Group by Treatment Response (Responders vs Nonresponders)

Clinical Variables	Responders (n = 49)	Nonresponders (n = 43)	*P*
Attendance (0-9)	6.88 (2.10)	6.19 (2.89)	0.20
No. comorbidities	4.47 (2.46)	4.81 (2.57)	0.51
No. medications	2.12 (1.25)	2.37 (1.40)	0.37
Years of diagnosis	17.58 (12.23)	13.41 (11.21)	0.18
STAI-T (0-60)	31.70 (11.02)	37.03 (10.58)	0.03
MCSDS (0-33)	20.68 (5.05)	19.70 (4.18)	0.35

MCDS indicates Marlowe-Crowne Social Desirability Scale; STAI-T, Trait Anxiety Inventory.

not possible to completely avoid this bias in treatments such as that reported here, the absence of significant differences between responders and nonresponders in social desirability suggests that the "tendency to please" is not likely to be the main causal factor of the improvement. We suspect that patients' motivation, expectations, or other psychological variables such as catastrophizing[35] may have greater importance.

Several studies have pointed out that perception and adjustment to pain are significantly influenced by some anxiety-related constructs such as health anxiety, trait anxiety, pain-related anxiety, and anxiety sensitivity.[36] With regard to trait anxiety, Hallberg and Carlsson[37] reported that patients with back pain or FM, who have a high trait of anxiety, indicate elevated levels of catastrophizing and reduced pain control. In addition, some investigators have emphasized the link between anxiety and treatment response. For instance, Thorn et al[38] stated that "Patients who fail to significantly improve with treatment often share common personality characteristics, including neuroticism, anxiety, external locus of control, negative affectivity…" (p. 128). Our results add strong support to this conclusion. Those patients with higher trait anxiety were less prone to benefit from the psychoeducational intervention. From this point of view, trait anxiety represents an emotional vulnerability factor that should be assessed by clinicians when selecting FM patients for participation in nonpharmacologic treatment programs. In fact, comorbid anxiety has also emerged as one of the most important outcome predictors in medical illnesses.[39] In contrast, anxiety has been shown to have no influence on the outcome in FM for pharmacologictreatments.[40]

Comparison With Relevant Findings From Other Published Studies

Our findings indicate that an intervention including education and relaxation, made by an interdisciplinary team, is an effective treatment for FM, at least in the short term, as some investigators had suggested earlier.[41] In a recent meta-analysis,[6] there was strong evidence that multicomponent therapies reduce pain, fatigue, depressed mood, and limitations in health-related quality of life at posttreatment, and improve self-efficacy pain and physical fitness, compared with education-only, waiting list, and treatment as usual. Similarly, 2 of the 3 evidence-based guidelines for the management of FM,[7] assigned the highest level of recommendation to multicomponent treatment. The results obtained by Gowans et al[8] and by Hammond and Freeman[9] are in line with our findings, given that they showed the beneficial effects of education, especially when it is combined with physical exercise or psychological techniques. Gowans et al[8] developed a 6-week exercise and education program for patients with FM that produced significantly greater increases in well-being, self-efficacy for pain, improvement in the 6-minute walk test and significantly greater decreases in morning fatigue than the waiting-list condition. More recently, Hammond and Freeman[9] evaluated the short-term and long-term effects of a 10-week community intervention (education, exercise, and cognitive-behavioral therapy) on self-efficacy, health status, and healthcare use of FM patients, using a group relaxation program as a control condition. The intervention led to short-term significant benefits in self-efficacy for managing pain and other symptoms, a greater sense of controlling the condition, some health status benefits and a reduction in number of GP visits. However, most benefits were not sustained over the long-term.

The effectiveness of multimodal treatment programs is usually examined in secondary or tertiary care, whereas most patients suffering from FM are treated in primary care. Although this study is not the first to assess the effectiveness of a multimodal intervention implemented in the context of general practice, it is the first that includes a control group. In an earlier noncontrolled study,[42] the short-term effects of a self-management program for FM patients who included education sessions and physical therapy sessions was assessed. The patients reported improvement in pain, fatigue, stiffness, quality of life, catastrophizing, and on some physical tests.

Research focused on the effects of relaxation training on FM symptoms is scarce.[43–45] In the autogenic training, we emphasized the benefits of distracting attention from pain, taking into account the conclusions of Fors et al[44] who compared the effects of 2 different types of guided imageries on FM pain with a control group. Both interventions included music and relaxation. The investigators indicated that only those patients visualizing peaceful and beautiful scenery had a significant decline in their pain ratings.

Strengths and Limitations of This Study

The randomized design, participant selection, minimal exclusion criteria, large sample size in each branch of the study, use of a standard self-report instrument as primary outcome measure, a blind instrument administrator, and the intention-to-treat analysis, aspects that indicate considerable internal validity. Although RCTs have been criticized because of their generalizability problems,[46] the sociodemographic characteristics of the study sample were very similar to those of FM individuals from the general population in Spain,[47] which provides some external validity to our results.

Our results should be interpreted with caution because of the following limitations: first, the results in the follow-up assessments have not been reported; therefore, we cannot conclude that the intervention causes a permanent improvement in patients' functional status. The analysis of follow-up assessments will allow us to determine the direct and indirect costs derived from the intervention, a question of crucial importance for policymakers. Some common comorbid psychiatric disorders such as major depression or personality disorders were not assessed, so the distribution of these disorders may be different in both groups, influencing the results. Finally, future studies should determine which FM patient subgroup or profile[48] would most benefit from the intervention and maximize its therapeutic success.

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