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FIBROMYALGIA: EFFECT OF A COGNITIVE BEHAVIORAL TREATMENT WITH AND WITHOUT BIOFEEDBACK ON PSYCHOPATHOLOGICAL SYMPTOMS

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Abstract

The purpose of the study was to design two cognitive behavioral treatments (CBT) for people with fibromyalgia (FM): therapy with electromyographic biofeedback (T1) and therapy without biofeedback (T2); and to assess their effects on psychopathological symptoms. The study was carried out with 88 people diagnosed with FM, aged between 26 and 65 years; 33 received T1, 33 received T2, and 22 were assigned to a control group without treatment. An evaluation was performed before and after a treatment of 10 sessions with the "Symptom Checklist-90-Revised," the "State-Trait Anxiety Inventory," the "Beck Depression Inventory" and "State-Trait Anger Expression Inventory". The results showed that participants who had received a treatment decreased symptoms of hostility, state-anxiety, trait-anxiety, depression, trait-anger, and anger expression ($p< .05$). The effects of the two treatments were similar, and no significant group differences were found for any variable. The control group decreased less the symptoms, increasing anxiety and anger. This work provides an efficacious tool to reduce psychopathological symptoms and negative feelings in people with FM.
KEY WORDS: *fibromyalgia, cognitive behavioral therapy, psychopathological symptoms, anger, depression*.

Resumen

El estudio tuvo como objetivo diseñar dos tratamientos cognitivo conductuales (TCC) para personas con fibromialgia (FM), uno con biofeedback electromiográfico (T1) y otro sin biofeedback (T2), y evaluar sus efectos en síntomas psicopatológicos. El estudio se realizó con 88 personas con diagnóstico de FM, entre 26 y 65 años, 33 recibieron el T1, 33 el T2 y 22 fueron el grupo control sin tratamiento. Se realizó una evaluación antes y después del tratamiento de 10 sesiones con el "Listado de 90 síntomas-revisado", el "Inventario de ansiedad estado-rasgo", el "Inventario de depresión de Beck" y el "Inventario de expresión de ira estado-rasgo". Los resultados muestran que los pacientes que recibieron algún tratamiento disminuyeron en síntomas de hostilidad, ansiedad-estado, ansiedad-rasgo, depresión, ira-rasgo y expresión de sentimientos de ira ($p< 0,05$). Los efectos de ambos tratamientos fueron similares, no se hallaron

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diferencias significativas entre ellos en ninguna variable. El control disminuyó menos los síntomas, aumentando en ansiedad e ira. El trabajo aporta una herramienta eficaz para la reducción de síntomas psicopatológicos y sentimientos negativos en personas con FM.
PALABRAS CLAVE: *fibromialgia, tratamiento cognitivo conductual, síntomas psicopatológicos, ira, depresión*.

Introduction

Fibromyalgia (FM) is a chronic syndrome of unknown etiology, complex and variable evolution, provoking generalized pain that can become incapacitating. It affects the biological, psychological, and social spheres, decreasing the quality of life of the affected people (Del Río, García-Palacios, & Botella, 2014), and is an important health problem due to its prevalence, morbidity, high index of use and consumption of health resources (Collado et al*.,* 2002).

The diagnostic criteria of FM were established in 1990 by the American College of Rheumatology (ACR) (Wolfe et al*.,* 1990), and recently reviewed (Wolfe et al*.,* 2010), and it is described as the existence of generalized pain of more than three months' duration, absence of other causal pathology, and comorbidity with other syndromes and symptoms, such as chronic fatigue, nonremedial sleep, cognitive deficit, and numerous somatic and emotional symptoms, such as anxiety and depression (Miró et al*.,* 2011). In 1992, FM was recognized by the World Health Organization and typified in the International Classification of Diseases (CIE-10) with code M79.0 within rheumtological diseases. The prevalence of FM in developed countries is between 1 and 4%, and in Spanish population, it is 2.4%, with 4.2% in females and 0.2% in males (Mas, Carmona, Valverde, & Ribas, 2008).

More recent studies postulate that FM is a central sensitization syndrome, revealing the existence of a neuroendocrine-immune dysfunction in a terrain predisposed by genetic and environmental factors (Meeus, 2007; Woolf, 2011). This dysfunction is often associated with emotional distress, at least in a subgroup of the affected people (Giesecke et al*.,* 2004), particularly depression, anxiety, anger, and irritability (Banks & Kerns, 1996; Fernández & Turk, 1995). Some authors (Baer, 2006; Kratz, Davis, & Zautra, 2007) think that the lack of acceptance of pain seems to be related to the increase of negative emotions and anger. In addition, other studies (e.g., Camino, Jiménez, De Castro-Palomino, & Fábregas, 2009) indicate that anger, being a repeated emotion in the affected people, increases muscular tension. Therefore, the elaboration and acceptance of pain may decrease negative emotions. Emotional functioning, as reflected in emotional distress, is not intended to be synonymous with a psychiatric diagnosis or disorder, but is rather meant to refer to more generally distressed mood, so emotional functioning should be measured and treated in chronic pain patients (Dowrkin et al*.,* 2008; Turk et al*.,* 2003).

Given that FM is a multifaceted disorder, a multidisciplinary treatment with cognitive behavioral therapies (CBT) as the central axis is proposed (Lami, Martínez,

& Sánchez, 2013; Williams, 2003). CBT emphasizes the learning of adaptive behavioral responses to illness and in so doing, alters thinking styles, experiences, and emotional responses that can maintain or worsen the illness (Society of Clinical Psychology, American Psychological Association, 2014). CBT often includes three components: 1) education about FM, 2) symptom self-management skills (Janke, Spring & Weaver, 2011), and 3) life style change (Burckhardt et al*.,* 2005; González-Gutiérrez et al*.,* 2009; Velasco, Zautra, Peñacoba, López, & Bartola, 2010).

Numerous studies have shown the efficacy of CBT in FM for decreasing negative emotions such as anxiety (Bernardy, Füber, Köllher, & Häuser, 2010; Thieme & Turk, 2012), and that it is even more efficacious than pharmacological treatment (Glombiewski et al*.,* 2010; Gryfe Saperia, & Swartzman, 2012). Accordingly, Comeche et al*.* (2010), applying CBT, found a significant improvement in the depression index of the Beck Depression Inventory (BDI) and in anxiety. Similar results were obtained by De Felipe, Castel-Bernal and Vidal-Fuentes (2006) and Vázquez-Rivera et al*.* (2009), with a CBT group, applying the BDI and the State-Trait Anxiety Inventory (STAI). The positive effect of CBT on depression was also confirmed in the meta-analysis of Martínez, Miró and Sánchez (2016).

Biofeedback (BFB) is another intervention, either applied alone or within cognitive behavioral or multidisciplinary pain treatments. BFB is a procedure in which patients' bodily responses, such as muscle tension, heart rate, or skin temperature, are monitored and reported to the patient through an auditory or visual modality. Applied to FM, the function that has received the most attention is muscular tension, measured through the electromyographic feedback (EMG-FB) by electrodes applied to the forearm extensors and upper trapezius in 10 individual sessions. In EMG-FB, patients learn to control and to alleviate their muscle tension (Glombiewski, Bernardy, & Häuser, 2013).

Bucklew, Conway, and Parker (1998), applying EMG-FB training to patients with FM, observed improvement in depressive symptoms similar to that obtained in the education and physical exercise modality; the best results were obtained when combined therapies were administered. In a similar vein, Collado et al*.* (2001), applying EMG-FB combined with CBT in a multicomponent format, obtained significant improvements in depression and anxiety. Nevertheless other authors have obtained opposite results. Ferraccioli, Ghirelli, and Scita (1987) did not observe improvement in psychopathological symptoms such as depression. Van Santen et al*.* (2002), comparing EMG-FB with physical exercise, and Glombiewski et al*.* (2013) concluded that BFB significantly reduces pain, but not the emotional symptoms.

Hence, there is little and contradictory knowledge about this treatment option for FM, and it is not yet a part of regular FM patient care. Thus, one aim of the present study is to obtain evidence about the efficacy of EMG-FB for FM. Within this context, the present study had the goal of designing and assessing the effect of two CBTs, a group therapy combined with EMG-FB (T1) and a group therapy without EMG-FB (T2), comparing the change in patients receiving treatment with that of a control group without treatment. According to these goals and with reference to prior studies, the present investigation proposed two

hypotheses. Hypothesis 1 posits that people affected with FM who receive either treatment (T1 or T2) will experience a significant decrease in diverse psychopathological symptoms, as well as in the experience and expression of anger, when compared with control patients who receive no treatment. Given that, at T1, the main focus of BFB is learning to control muscle tension, which is a core symptom in anxiety (Glombiewski et al., 2013) and taking into account that different authors (Ferracoli et al., 1987; Van Santen et al., 2012) found no improvement in other psychopathological symptoms such as depression by applying BFB, hypothesis 2 posits that T1 (therapy with EMG-FB) will promote greater improvement in anxiety. In addition, taking into account that in CBT without EMG-FB, more time is dedicated to learning another variety of competences such as control of thoughts, emotional responses, and behavioral experiences, and coping with multiple symptoms (Glombiewski et al., 2013), in hypothesis 2, it is proposed that T2 (therapy without EMG-FB) will promote greater improvement in depressive symptoms and in feelings of anger, compared with T1.

Method

Participant

The study was carried out with 88 people with FM, distributed in 3 conditions: experimental group 1 (T1), made up of people who received CBT with EMG-FB (*n*= 33); experimental group 2 (T2), made up of people who received CBT without EMG-FB (*n*= 33); and a control group of participants who did not receive any treatment (*n*= 22). The sociodemographic characteristics of the sample are presented in Table 1, and, as can be observed, the participants of the three conditions were very homogeneous in sociodemographic variables such as sex, age, educational and socioeconomic level. To identify the clinical characteristics of the people with FM, we used the Questionnaire of Biographical and Medical-Psychological Data for those Affected by Fibromyalgia (*Cuestionario de datos biográficos y médico-psicológicos para afectados de fibromialgia*; Garaigordobil & Govillard, in press). The results can be seen in Table 2, and, as can be observed, among the trigger factors associated with the development of symptomatology are included: stress (81.4%) and the existence of an emotional shock (57.9%); 47% reported that age at onset was between 30 and 49 years; only 23.6% reported psychological or psychiatric symptoms prior to FM that led them to request consultation or treatment; they reported having different physical illnesses (among others, chronic fatigue syndrome, irritable colon syndrome, myofascial pain syndrome...); a high percentage had psychological symptoms such as anxiety, depression and sleep disorders (89.9, 74.1 and 95%, respectively); during the disease, they had undergone numerous pharmacological (46.4% between 4 and 6 treatments) and psychological treatments (44.3%). The questionnaire also requested information about their perceived quality of life on a Likert scale ranging from 1 to 10, with a moderately low mean score (*M*= 3.89, *SD*= 1.36). In addition, using the FM Impact Questionnaire (FIQ; Burckhardt, Clark, & Bennett, 1991, Spanish adaptation by Monterde, Salvat, Montull, & Fernández-Ballart, 2004), it

was confirmed that the people with FM of this sample had a very high level of functional impairment (scale 1-100) (*M*= 74.34, *SD*= 13.81), pain (scale 1-10) (*M*= 8.11, *SD*= 1.69) and exhaustion (scale 1-10) (*M*= 8.72, *SD*= 1.65).

In order to select the sample of people with FM, we offered treatment to all the members of the BIZI BIDE (a fibromyalgia association of Guipuzcoa) who were diagnosed with FM. All the people of the association were invited to participate in this study by mail and by phone. Out of all the members of the association (*N*= 160), 55% participated in the study (*n*= 88). They were informed about the characteristics of the intervention, and the only requirements were to come to at least 80% of the treatment sessions and to complete a battery of tests before and after treatment. Besides high participation in the treatment sessions (80%), they had to present the diagnostic medical certificate that accredited they had FM as an inclusion criterion. Initially, 95 persons were recruited. Of them, 3 were excluded for not fulfilling the inclusion criteria (their FM was secondary to another pathology). The FM patients were randomly assigned to T1 (CBT with EMG-FB), T2 (CBT), or to a control group (which was placed on a waiting-list to receive intervention after the study). During the treatment, 4 persons left treatment, 2 to be reincorporated in a labor activity, 1 due to change of residence, and 1 for not feeling satisfied with the treatment.

Table 1
Sociodemographic characteristics of the sample in all three conditions

Sociodemographic characteristics	T1 (*n*= 33)		T2 (*n*= 33)		Control (*n*= 22)		χ^2
	n	%	*n*	%	*n*	%	
Sex							3.33 ns
Men	1	3	0	0	2	9.1	
Women	32	97	33	100	20	90.9	
Age							3.87 ns
26-38 years	6	18.2	4	12.5	1	4.5	
39-48 years	8	24.2	11	34.4	6	27.3	
49-59 years	12	36.4	13	40.6	11	12.6	
60-65 years	7	21.2	4	12.5	4	18.2	
Educational Level							4.56 ns
No studies	3	9.1	2	6.1	0	0	
Primary studies	8	24.2	14	42.4	8	36.4	
Secondary studies	16	48.5	12	36.4	10	45.5	
High school-Vocational training	4	12.1	4	12.1	4	18.1	
University students	2	6.1	1	3.1	0	0	
Socio-economic Level							1.01 ns
Low	5	15.2	5	15.6	3	14.3	
Medium-low	5	15.2	7	21.9	3	14.3	
Medium	21	63.6	18	56.3	13	61.9	
Medium-high	2	6.1	2	6.3	2	9.5	
No reply	0	0	1	3.1	1	4.7	

Note: ns= nonsignificant.

Table 2
Clinical characteristics of the participants

Clinical characteristics	*n*	%
Trigger factors of symptomatology		
Stress	114	81.4
Emotional shock	81	57.9
Cervical whiplash	48	34.3
Age at symptom onset		
1-19 years	15	10.7
20-29 years	28	20
30-49 years	66	47.1
49-50 years	18	12.9
Psychological or psychiatric antecedents prior to the disease		
Yes	33	23.6
No	107	76.4
Diseases: comorbidity of FM with other diseases		
I have no other disease	5	3.5
Rheumatic arthritis	51	36.4
Chronic fatigue syndrome	99	70.7
Myofascial pain syndrome	70	50
Irritable bowel syndrome	86	61.3
Thyroidism	24	17.2
Irritable bladder	57	40.7
Sleep apnea	45	32.1
Rinaud's syndrome	8	5.7
Diabetes	6	4.2
Ulcerative colitis	4	0.8
Restless leg syndrome	77	55
Types of current psychological symptoms		
Anxiety	125	89.9
Depression	103	74.1
Sleep disorders	132	95
Number of traditional doctors consulted during the disease		
1-3	7	5
4-6	58	41.5
7-9	50	35.7
10-13	25	17.8
Number of pharmacological treatments received during the disease		
0-3	36	25.7
4-6	65	46.4
7-10	34	24.3
Psychological treatments received during the disease		
No	78	55.7
Yes	62	44.3

Instruments

a) *Symptom Checklist-90-Revised* (SCL-90-R; Derogatis, 1983) Spanish adaptation by González de Rivera, De las Cuevas, Rodríguez-Abuín, & Rodríguez-Pulido (2002). This self-report has 90 items distributed in 10 scales referring to psychopathological disorders: somatization, obsession-compulsion, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, psychoticism and additional scale (melancholic depression). Furthermore, the instrument permits the calculation of the global severity index (GSI), which is a measure of the intensity of global mental and psychosomatic suffering, the positive symptom total (PST) which is the number of symptoms present, and the positive symptom distress index (PSDI). People report the frequency with which they have experienced these symptoms during the last month. The results of studies conducted with Spanish samples (González de Rivera et al*.,* 2002) suggest good reliability of the instrument, being consistent with those carried out by the author. Alpha coefficient values range from .81 to .90. Reliability analysis with the sample of this study showed high internal consistency (GSI α= .90). Temporal stability (between .78 and .90) with a test-retest interval of one week showed score stability. Other studies that have strengthened claims of the instrument's validity have shown the relationship between the profile of symptomatic dimensions and the diagnostic group of the clinical sample. Thus, for example, scores are significantly higher in psychiatric samples than in non-clinical samples. The author's original studies with American samples show the construct validity (Derogatis & Cleary, 1977) and the convergent validity, given the high correlations of symptomatic dimensions with MMPI in psychiatric patients (Derogatis, Rickels, & Rock, 1976).

b) *State-Trait Anxiety Inventory* (STAI; Spielberger, Gorsuch, & Lushene, 1970). This assesses two concepts of anxiety: State-Anxiety (SA) (a transitory emotional condition, at the time of assessment) and Trait-Anxiety (TA) (a relatively stable anxiety proneness, in general, in most situations). STAI is a self-applied scale with 40 items. Item scores range between 0 and 3, with the following operational criteria as a function of the intensity (0= *not at all*; 1= *somewhat*; 2= *moderately so*; 3= *very much so*) or presentation frequency (0= *almost never*; 1= *sometimes*; 2= *often*; 3= *almost always*). The test has good internal consistency (between .90 and .93 in SA; between .84 and .87 in TA). The results with the sample of the present study confirm its consistency (SA α= .75; TA α= .89). Concurrent validity of the STAI is shown through its correlations with the measure of anxiety of the 16PF Personality Questionnaire (Spielberger et al*.,* 1970).

c) *Beck Depression Inventory* (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961). This scale has 21 items that assess clinical symptoms of melancholy and intrusive thoughts present in depression. There is a high percentage of cognitive items in the scale, which is consistent with Beck's cognitive theory of depression. Another distinctive element is the absence of motor or anxiety symptoms. This test presents a series of statements, and respondents should

choose the response that best describes the degree of intensity of their symptoms (0= *not at all* to 3= *very much*). A final total score of depression is obtained (maximum= 63). Data from psychometric studies support internal consistency (α= .83) and temporal stability (test-retest between .60 and .72) of the inventory. The results obtained with the present sample study confirm the consistency (α= .88). The convergent validity indexes of the inventory with regard to Zung's self-applied Depression Scale are also high, with correlations ranging between .68 and .89 (Beck et al*.,* 1961). In addition, other studies (Salkind, 1969) have confirmed the criterial validity of the instrument and provide cut-off points for the interpretation of the BDI (No depression: 0-10 points; Mild depression: 11-17 points; Moderate depression 18-23 points; Severe depression: 24-63 points).

d) *State-Trait Anger Expression Inventory* (STAXI-2; Spielberger, 2000) Spanish adaptation by Miguel-Tobal, Casado, Cano-Vindel, & Spielberger (2001). This inventory measures State-Anger (SA) (intensity of the experience of anger as an emotional state, intensity of feelings of anger at certain times), Trait-Anger (TA) (frequency with which a person feels angry over time, anger-proneness as a personality trait, stable personality proclivity towards feelings of anger), and the Anger Expression Index (AEI) (a general measure of anger expression and control in anger-provoking situations). State-Anger is explored with 15 statements with which individuals report whether they have these feelings at the time, responding on a scale ranging from 1 (*not at all*) to 4 (*very much*). Trait-Anger has 10 statements describing feelings, and participants report whether they habitually have those feelings, ranging from 1 (*almost never*) to 4 (*almost always*). The Anger Expression Index (AEI) includes 24 statements with which individuals rate the way they react when they get angry or furious, responding on a scale ranging from 1 (*almost* never) to 4 (*almost always*). STAXI-2 has been shown to have adequate levels of reliability (test-retest AEI *r*= .62) and internal consistency (AEI α= .69). Reliability analysis with the sample of this study showed high internal consistency (SA α= .83; TA α= .85; IEI α= .75). Validation studies have found correlations of Trait-Anger with other measures of anger-hostility (Novaco, 1975).

Procedure

At pretest, after participants had given informed consent, we administered four assessment instruments to measure the dependent variables. The assessment was performed by members of the research team, graduate in Psychology, who had been trained to administer the assessment in a standardized way. The administration and scoring of the questionnaires was blind. Subsequently, participants were randomly assigned to one of the three conditions: T1, T2, and control group. Treatment duration was three months, that is, 10 weekly sessions. Session duration was 1:15 hours. The groups were comprised of a minimum of 5 people with FM and a maximum of 10. The intervention in the two conditions (T1 and T2) was performed by a Psychology graduate, with extensive clinical

experience with patients with FM. With regard to the intervention, in both treatments, the same modules were administered: 1) Information/education about FM, 2) Sleep hygiene, 3) Concept-function of anxiety, 4) Relaxation or anxiety reduction (breathing, Jacobson's progressive relaxation, Schultz's autogenic relaxation, and visualization), 5) Coping strategies for the disease (cognitive control, behavioral habits, and social skills), 6) Self-esteem (concept and promotion), and 7) Acceptance of negative emotions (elaboration of negative emotions, for example, anxiety, depression and anger). In both cases, the techniques applied were cognitive behavioral (e.g., relaxation, cognitive restructuring, modeling, role-playing). The main difference between the two treatments was the use of EMG-FB for the relaxation and anxiety reduction techniques in T1, and no EMG-FB in T2. In T1, EMG-FB electrodes were applied to the forearm extensors and upper trapezius (neck), for 10 sessions during 25 minutes, and participants learned, with help from visual and auditory FB, to relax these muscles with cognitive and progressive muscle relaxation, and in every session, measures of muscular tension were registered. Thus, T1 dedicated more time to learning to control muscle tension and to relax using EMG-FB, whereas in T2, more attention was paid to coping strategies for the disease (cognitive control, behavioral habits, and social skills), self-esteem (concept and promotion), and acceptance of negative emotions. Upon treatment completion, posttreatment assessment was carried out, and the same instruments as at pretest were administered.

Data analysis

Firstly, to confirm possible pretest differences in the target variables of the study between participants who had received some treatment (T1 or T2) and the control participants, we performed a multivariate analysis of variance (MANOVA) with the total pretest scores of the target variables. Subsequently, we calculated the means and standard deviations, and performed an analysis of variance (ANOVAs) with regard to each variable.

Having confirmed a priori group homogeneity, secondly, to determine whether the change was significantly different in participants who had received treatment (experimental) versus control participants, we carried out a multivariate analysis of covariance (MANCOVA) of the pretest-posttest differences for all the target variables of the study. Subsequently, we conducted descriptive (means and standard deviations) and inferential analyses of the pretest-posttest differences in each one of the variables (ANCOVAs) in the experimental and control participants.

Thirdly, taking as the definition of clinical change the transition in the psychopathological variables from high or very high percentile scores (76-99th percentile) to average or low scores (1-75th percentile), we calculated a reliable change index (Jacobson & Truax, 1991) based on the percentage of treated people who improved with the treatment. Specifically, we also explored the percentage of participants at pretest and posttest who obtained high or very high percentile scores in the variables in which the analysis of variance confirmed significant differences between the experimental and control groups. For this purpose, using

the norms of the manuals of the assessment instruments, the raw scores of the participants in both assessment phases were recoded in five ranges or percentile levels.

Finally, to confirm whether the change was significantly different in participants who had received T1 or T2, we carried out a multivariate analysis of covariance (MANCOVA) with the pretest-posttest differences for all the target variables of the study. Subsequently, we conducted descriptive (means and standard deviations) and inferential (ANCOVAs) analyses of the pretest-posttest differences in each one of the variables in the experimental participants who received T1 or T2.

Results

Effects of the treatment on psychopathological symptoms: pretest-posttest changes in the participants with and without treatment

The results of the pretest MANOVA revealed no statistically significant differences among the three groups or conditions before the intervention, Wilks' Lambda, Λ= .587, $F(36, 136)$= 1.15, p= .277, with a medium effect size (η^2= .234, r= .48). The ANOVA results (see Table 3) showed that the experimental and control participants were very similar before the intervention because, except for the variable state-anxiety, where group differences were found, no significant differences were observed in the remaining variables. Bonferroni's group comparison only yielded evidence about the control group, with a higher score than T2 in anxiety, and than T1 in PST, state-trait anxiety, and trait-anger, thus confirming a high level of homogeneity between T1 and T2 before treatment.

The participants' pretest level of psychopathological symptoms was high. After transforming the total scores obtained in all the variables to percentile scores (using the norms of the test manuals) (Table 3), it was observed that, compared to the standardized sample of the test in nonclinical population, people with FM obtained very high percentiles in all the psychopathological symptoms, ranging between percentile 85 and 99. In anxiety, the percentiles corresponding to pretest scores exceeded 85, that is, high, but in anger, the percentiles were within average (between percentiles 40 and 65).

The results of the pretest-posttest MANCOVA (covariate the pretest scores) revealed significant differences between the two conditions (with and without treatment), Wilks' Lambda, Λ= .617, $F(19, 66)$= 2.16, p= .011, with a medium-high effect size (η^2= .383, r= .61). As can be observed, the results of the ANCOVAs confirm that the experimental participants significantly decreased their symptoms of hostility, levels of state- and trait-anxiety, depressive symptoms, trait-anger, and anger expression in anger-provoking situations (Table 4). The effect size of the treatments was moderate for symptoms of hostility, and large for state-trait anxiety and depression, as well as for the experience and expression of anger. Moreover, the experimental participants decreased (p<.06) their global symptomatology index (GSI).

Table 3
Means, standard deviations, and analysis of variance at pretest in the experimental group T1 (CBT with EMG-FB), the experimental group T2 (CBT without EMG-FB), and the control group (without treatment)

Variables	T1 (*n*= 33)		T2 (*n*= 33)		Control (*n*= 22)		*F* (2,85)	*p*	*Post hoc*
	M	*SD*	*M*	*SD*	*M*	*SD*			
SCL-90-R									
Somatization	30.66	7.47	30.48	9.21	28.93	5.31	0.25	.772	-
Obsession-compulsion	25.14	8.68	23.65	7.96	24.47	9.18	0.23	.793	-
Interpersonal sensitivity	14.07	6.90	14.32	6.53	14.07	6.80	0.01	.987	-
Depression	31.79	10.50	31.35	11.30	29.40	13.90	0.22	.802	-
Anxiety	16.83	7.47	20.26	11.44	15.00	11.23	1.64	.200	T2>C
Hostility	7.62	4.96	7.68	5.98	6.13	5.37	0.45	.634	-
Phobic anxiety	6.17	5.23	7.39	7.87	3.00	5.39	2.31	.106	-
Paranoid ideation	6.48	4.19	6.71	5.00	6.07	5.10	0.09	.911	-
Psychoticism	8.59	6.21	8.84	8.59	7.33	7.99	0.20	.815	-
Additional	13.93	4.48	15.71	5.67	14.40	5.26	0.93	.397	-
GSI	1.64	0.53	1.67	0.60	1.49	0.61	0.50	.607	-
PST	65.41	12.50	67.16	13.21	57.60	16.29	2.58	.082	T1,T2>C
PSDI	2.22	0.47	2.23	0.60	2.30	0.50	0.11	.895	-
STAI									
State-Anxiety	34.62	9.91	30.32	11.74	24.80	11.91	3.93	.024	T1>C
Trait-Anxiety	37.10	8.81	34.52	9.45	31.60	11.08	1.68	.192	T1>C
BDI									
Depression	21.66	7.64	20.71	10.46	19.00	10.84	0.38	.684	-
STAXI-2									
State-Anger	25.52	9.17	23.23	11.73	18.67	8.51	2.22	.115	-
Trait-Anger	22.38	5.59	20.81	6.68	18.87	6.76	1.57	.215	T1>C
Anger Expression Index	34.17	9.93	31.32	13.01	28.53	10.58	1.26	.289	-

Note: SCL-90-R= Symptom Checklist-90-Revised; GSI= Global Severity Index; PST= positive symptom total; PSDI= positive symptom distress index; STAI= State-Trait Anxiety Inventory; BDI= Beck Depression Inventory; STAXI-2= State-Trait Anger Expression Inventory; *Post hoc* = Bonferroni's group comparison.

Table 4
Means, standard deviations, pretest-posttest analysis of covariance, and effect size (Cohen's *d*) in participants with and without treatment

Variables	With Treatment (*n*= 66)		Without Treatment (*n*= 22)		*F*(2, 85)	*p*	*d*
	M	*SD*	*M*	*SD*			
SCL-90-R							
Somatization	-2.08	6.98	0.00	4.63	1.83	.179	-.35
Obsession-compulsion	-2.39	7.07	-2.14	5.21	0.02	.878	-.04
Interpersonal sensitivity	-2.59	5.70	0.00	6.72	3.08	.083	-.41
Depression	-5.37	11.64	-0.82	9.72	2.71	.103	-.42
Anxiety	-3.25	8.81	0.00	5.16	2.66	.106	-.45
Hostility	-2.06	4.75	0.23	2.79	4.53	.036	-.58
Phobic anxiety	-0.79	5.53	1.18	3.80	2.39	.125	-.41
Paranoid ideation	0.33	4.27	-1.82	3.86	4.32	.041	.52
Psychoticism	-2.12	6.23	-1.32	5.04	0.30	.585	-.60
Additional	-1.66	4.16	-2.45	4.18	0.60	.441	.18
GSI	-0.24	0.45	-0.06	0.20	3.46	.066	-.51
PST	-5.61	14.40	0.18	7.34	3.24	.075	-.50
PSDI	-0.07	1.03	-0.09	0.83	0.00	.929	.02
STAI							
State-Anxiety	-5.30	11.57	4.14	7.16	12.86	.001	-.97
Trait-Anxiety	-3.23	7.85	2.50	4.31	10.71	.002	-.90
BDI							
Depression	-4.63	7.35	-0.27	3.75	8.68	.004	-.74
STAXI-2							
State-Anger	-3.69	9.41	0.32	4.96	3.61	.061	-.53
Trait-Anger	-2.03	5.27	0.77	3.63	5.28	.024	-.61
Anger Expression Index	-3.50	8.87	1.91	5.19	7.28	.008	-.74

Note: SCL-90-R= Symptom Checklist-90-Revised; GSI= Global Severity Index; PST= positive symptom total; PSDI= positive symptom distress index; STAI= State-Trait Anxiety Inventory; BDI= Beck Depression Inventory; STAXI-2= State-Trait Anger Expression Inventory.

Reliable change index: clinical interpretation of the data

Table 5 shows the frequency and percentage of participants of the two conditions (with and without treatment) who were in each percentile range in the pretest and posttest phases (reliable change index).

As can be observed in Table 5, many participants who received treatment went from percentiles that indicated a high or very high level (76-99) at pretest to an average or low level (75-1) at posttest. Of them, 4.4% decreased the Global Severity Index (GSI) (which integrates the score of all the psychopathological scales of the SCL-90-R); 7.5% decreased the number of positive symptoms (PST); 13.7% decreased trait-anxiety; 10.6% decreased trait-anger, 10.6% decreased anger expression, and, in depression (BDI), 21.2% went from severe depression to moderate depression, and 12.1% went from having some level of depression to absence of depression. In contrast, the participants of the control group worsened:

Table 5
Participants in each range of percentile scores of the target variables of the study (Reliable Change Index) at the pretest and posttest phases

Variables & Percentiles	With Treatment (*n*= 66)				Without Treatment (*n*= 22)			
	Pretest		Posttest		Pretest		Posttest	
	n	%	*n*	%	*n*	%	*n*	%
SCL-90-R. Global Severity Index								
99-95	41	62.1	32	48.5	9	40.9	8	36.4
94-85	21	31.8	24	36.4	9	40.9	9	40.9
84-76	2	3	5	7.6	0	0	2	9.1
75-25	1	1.5	4	6.1	4	18.2	3	13.6
24-1	1	1.5	1	1.5	0	0	0	0
SCL-90-R. Positive Symptom Total								
99-95	56	84.8	43	65.2	13	59.1	13	59.1
94-85	7	10.6	16	24.2	5	22.7	3	13.6
84-76	2	3	1	1.5	1	4.5	4	18.2
75-25	1	1.5	5	7.6	3	13.6	2	9.1
24-1	0	0	1	1.5	0	0	0	0
BDI. Depression								
Severe depression	29	43.9	15	22.7	6	27.3	6	27.3
Mild depression	15	22.7	19	28.8	4	18.2	3	13.6
Moderate depression	15	21.2	16	24.2	6	27.3	7	31.8
No depression	8	12.1	16	24.2	6	27.3	6	27.3
STAI. Trait-Anxiety								
99-95	17	25.8	11	16.7	3	13.6	4	18.2
94-85	18	27.3	14	21.2	3	13.6	3	13.6
84-76	10	15.2	11	16.7	4	18.2	4	18.2
75-25	20	30.3	27	40.9	10	45.5	10	45.5
24-1	1	1.5	3	4.5	2	9.1	1	4.5
STAXI2. Trait-Anger								
99-95	5	7.6	1	1.5	1	4.5	2	9.1
94-85	7	10.6	10	15.2	1	4.5	1	4.5
84-76	9	13.6	3	4.5	1	4.5	2	9.1
75-25	29	43.9	23	34.8	7	31.8	6	27.3
24-1	16	24.2	29	43.9	12	54.4	11	50
STAXI2. Anger Expression Index								
99-95	7	10.6	2	3	1	4.5	1	4.5
94-85	8	12.1	5	7.6	1	4.5	1	4.5
84-76	1	1.5	2	3	0	0	0	0
75-25	36	54.5	37	56.1	9	40.9	14	63.6
24-1	14	21.2	20	30.3	11	50	6	27.3

Note: SCL-90-R= Symptom Checklist-90-Revised; STAI= State-Trait Anxiety Inventory; BDI= Beck Depression Inventory; STAXI-2= State-Trait Anger Expression Inventory.

4.6% of those who had average or low percentile levels (1-75) at pretest in GSI, PST, and trait-anxiety increased at posttest to high or very high levels (76-99); 9.2% increased trait-anger, and there was no pretest-posttest change in anger expression and depression (BDI) in the percentage of participants that had

obtained high or very high percentiles. These results confirm the clinical significance of the effects of the CBT treatment with or without EMG-FB, as an important percentage of participants improved significantly in all the psychopathological variables.

Differential effects of the two treatments: pretest-posttest changes in therapy with EMG-FB (T1) and therapy without EMG-FB (T2)

The results of the pretest-posttest MANCOVA (covariate the pretest scores) indicated no significant differences in the change undergone in both treatments, Wilks' Lambda, Λ= .658, F(19, 44)= 1.20, p= .298, with a moderate effect size (η^2= .342, r= .58). Results of the descriptive (means and standard deviations) and inferential (ANCOVAs) analyses of the pretest-posttest differences in each one of the variables in the experimental participants who received T1 or T2 can be seen in Table 6.

Table 6
Means, standard deviations, pretest-posttest analysis of covariance, and effect size (Cohen's *d*) in T1 (CBT with EMG-FB), and T2 (CBT without EMG-FB)

Variables	T1 (n= 66)		T2 (n= 22)		F(2, 85)	p	d
	M	*SD*	*M*	*SD*			
SCL-90-R							
Somatization	-2.00	5.51	-2.16	8.28	0.00	.930	.02
Obsession-compulsion	-2.94	6.56	-1.84	7.61	0.37	.540	-.15
Interpersonal sensitivity	-1.72	5.26	-3.47	6.07	1.51	.223	.30
Depression	-3.63	10.07	-7.13	12.95	1.45	.232	.30
Anxiety	-1.84	7.27	-4.66	10.03	1.64	.204	.74
Hostility	-1.62	4.19	-2.50	5.29	0.53	.466	.86
Phobic anxiety	0.26	4.05	-1.84	6.60	2.35	.130	.38
Paranoid ideation	1.19	4.41	-0.53	4.01	2.65	.108	.40
Psychoticism	-0.88	5.33	-3.38	6.88	2.63	.109	.69
Additional	-0.78	4.07	-2.53	4.13	2.91	.093	.42
GSI	-0.15	0.40	-0.34	0.48	2.96	.090	.43
PST	-3.59	13.91	-7.63	14.81	1.25	.266	.28
PSDI	0.09	1.33	-0.22	0.57	1.39	.241	.30
STAI							
State-Anxiety	-6.63	11.19	-3.97	11.97	0.84	.363	-.22
Trait-Anxiety	-2.66	8.72	-3.81	6.98	0.34	.560	.14
BDI							
Depression	-4.25	7.79	-5.00	6.99	0.16	.687	.10
STAXI-2							
State-Anger	-4.88	8.89	-2.50	9.90	1.01	.317	-.25
Trait-Anger	-1.31	4.55	-2.75	5.93	1.18	.281	.27
Anger Expression Index	-3.75	8.83	-3.25	9.04	0.05	.824	-.05

Note: SCL-90-R= Symptom Checklist-90-Revised; GSI= Global Severity Index; PST= positive symptom total; PSDI= positive symptom distress index; STAI= State-Trait Anxiety Inventory; BDI= Beck Depression Inventory; STAXI-2= State-Trait Anger Expression Inventory.

The results revealed the absence of statistically significant differences in the effects of both treatments (see Table 6) for the variables assessed. Nevertheless, the patients of T2 decreased their psychopathological symptoms (except for obsessive-compulsive symptoms and paranoid ideation), as well as their trait-anxiety, trait-anger, and depression to a greater extent.

Discussion

The purpose of the study was to assess the effect of two CBTs in people with FM. The analyses of variance confirmed that the experimental participants significantly decreased their symptoms of hostility (thoughts, feelings, and behaviors that are characteristic of states of aggressiveness, anger, irritability, rage, and resentment), their level of state-anxiety (anxiety at the time of assessment), trait-anxiety (tendency of high levels of anxiety on most occasions, tendency toward an anxious personality), their depressive symptoms (clinical symptoms of melancholy, intrusive thoughts present in depression), trait-anger (frequency with which they feel anger), and expression of anger in anger-provoking situations. In addition, the experimental participants with FM who received treatment displayed a greater decrease of their symptoms of interpersonal sensitivity (feelings of shyness and shame, tendency to feel inferior to others, hypersensitivity to others' opinions and attitudes, discomfort and inhibition in interpersonal relations), their GSI, as well as the PST.

Therefore, hypothesis 1 is confirmed practically in its entirety, as the treatments were efficacious because they stimulated a significant decrease of diverse psychopathological symptoms (e.g., hostility, depression), reducing the level of anxiety, as well as the feelings and expression of anger in anger-provoking situations. The results point in the same direction as other studies that have decreased symptoms of depression (Collado et al*.,* 2001; Comeche et al*.,* 2010; De Felipe et al*.,* 2006; Vázquez-Rivera et al*.,* 2009), anxiety (Comeche et al*.,* 2010), and diverse psychopathological symptoms using CBT. In CBT, we also stressed the emotional elaboration of the disease until achieving its acceptance, which may explain the decrease of negative emotions such as anxiety, depression, and feelings of anger, which has also been noted in other studies (Baer, 2006; Kratz et al*.,* 2007).

Secondly, the results reveal the absence of statistically significant differences in the effects of the two treatments. Therefore, no differential effect of the treatment including EMG-FB was revealed. Thus, hypothesis 2 is rejected. Nevertheless, patients from T2 decreased their psychopathological symptoms (somatization, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, psychoticism, GSI, PST, PSDI), trait-anxiety, trait-anger, and depressive symptoms to a greater extent, although the differences between the two treatments were not statistically significant. The fact that the differences between the two treatments were nonsignificant for anxiety suggests an equivalent efficacy of the relaxation technique through EMG-FB and the group relaxation techniques (breathing, Jacobson's progressive muscular relaxation, Schultz's autogenic relaxation, visualization), which involve a lower economic cost. Therefore, in view

of these results, we suggest the development of group CBT without EMG-FB because it is more efficient from the viewpoint of an analysis of cost/benefits.

As a limitation of the study, we note the difficulty to isolate the results of the psychological treatments from the effect of other variables, such as the numerous pharmacological modifications undergone by people with FM, changes in their work situation due to sick leave versus return to work, or the impact of the judicial procedures in which many people with FM are involved, all of which reveals the complexity of this type of study. Moreover, the study does not assess the long-term maintenance of the effects, so we recommend performing posttreatment assessments at 6 and 12 months.

The study contributes an efficacious, evidence-based proposal of CBT, to reduce the psychopathological symptoms and negative feelings frequently suffered by many people with FM, and which combines various modalities and psychotherapeutic intervention techniques (e.g., information-education, relaxation techniques).

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