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Efficacy of Combined Cognitive-Behavioral Therapy for Insomnia and Pain in Patients with Fibromyalgia: A Randomized Controlled Trial

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Abstract This controlled trial aims to analyze the efficacy of cognitive-behavioral therapy for insomnia and pain (CBT-IP) compared to cognitive-behavioral therapy for pain (CBT-P) and usual medical care (UMC) at improving sleep and other clinical manifestations (pain, fatigue, impaired functioning, and emotional distress) in women with fibromyalgia (FM). One hundred and twenty-six patients with FM were randomly assigned to different treatment groups and 113 completed the treatments (38 in the CBT-IP group, 34 in the CBT-P group and 41 in the UMC group) and a number of self-reports at pre-treatment, post-treatment, and 3 months of follow-up. The CBT-IP group showed significant improvements at post-treatment in several sleep variables (i.e., subjective sleep quality, sleep latency, sleep efficiency, and use of sleeping medication) that were not observed in the

CBT-P and UMC groups. The CBT-IP and CBT-P groups reported significant improvements at post-treatment in FM impact and self-efficacy for coping with pain; the CBT-IP group reported improvements at follow-up in pain intensity, and the CBT-P reported improvements at post-treatment in pain catastrophizing and pain acceptance. Clinical improvements are also described. The findings revealed differential responses between groups regarding sleep and other adjustment parameters and the CBT-IP group exhibited the best clinical response pattern overall. More research in the area of FM treatment is needed to enhance the efficacy of the CBT and identify which patients are likely to benefit from each modality of CBT.

Keywords Fibromyalgia · Cognitive-behavioral therapy · Insomnia · Randomized controlled trial

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Introduction

Fibromyalgia (FM) is a rheumatic disease characterized by widespread pain in muscles and soft tissues for more than 3 months and tenderness in specific points of the body (Wolfe et al. 1990). Patients with FM also report other symptoms as chronic fatigue, cognitive dysfunctions, sleep disturbances with unrefreshing sleep, and somatic symptoms such as irritable bowel syndrome, morning stiffness, or temporomandibular disorder (Fitzcharles and Yunus 2012). The prevalence is about 2.9–4.7% in the general European population and more frequent in women than in men (Branco et al. 2010). Patients with FM experience substantial impairments in functional status and mental and physical health (Wolfe et al. 2014).

Recent studies have found that 88.75% of people diagnosed with FM report sleep difficulties (Wagner et al. 2012),

showing more insomnia and less restorative sleep than rheumatic patients and the general population (Belt et al. 2009). Previous reviews (Díaz-Piedra et al. 2015; Moldofsky 2009; Prados and Miró 2012) have described a reduction of total sleep time, a considerable decrease in the percentage of slow-wave sleep due to the intrusion of alpha waves, and increased arousal as common characteristics of sleep in FM. The American College of Rheumatology recognizes the importance of sleep problems as a diagnostic criterion (ACR; Wolfe et al. 2010), as well as widespread pain, cognitive symptoms, fatigue, and a number of somatic symptoms.

Several studies have explored the relationship between sleep abnormalities and the exacerbation of FM symptoms. Such studies have reported that sleep disturbances and poor sleep quality are associated with negative mood, more intense emotional reactions to negative events and pain (Hamilton et al. 2007), difficulty in identifying and describing feelings (Martínez et al. 2015), poorer physical function and depression (Canivet et al. 2008), impairment in alertness (Miró et al. 2011a), and greater pain, which can be interpreted as a vicious circle between poor sleep and pain (for a review, see Moldofsky 2010). It has been suggested that sleep disturbances play an important role in the etiology and maintenance of chronic pain and fatigue (Moldofsky 2009). Poor sleep is related to a disturbance of central pain-processing mechanisms, identified as a “diffuse hyperalgesia state” in patients with FM; it could be due to specific impairments such as loss of descending analgesic activity and central sensitization (Lee et al. 2011). From this perspective, given the two-way relationship between sleep and pain, it can be assumed that treatment aimed at regulating sleep disturbances and improving the restorative value of sleep is likely to have an impact on the main symptoms of FM (Thomas 2011). In a clinical context, sleep disturbances may play a key role as a transdiagnostic process and be the target of therapy across FM and mood or anxiety disorders comorbidity (Palagini et al. 2016).

The American Pain Society (APS) recommends a multidisciplinary approach to the treatment of chronic pain and particularly to the cognitive-behavioral therapy (CBT) over other psychotherapies (Häuser et al. 2010). The Spanish interdisciplinary consensus document for FM treatment (Alegre de Miquel et al. 2010) also recommends CBT as the best approach for patients with high levels of catastrophizing and depression. Due to insomnia is the most common sleep disorder in chronic pain patients (Belt et al. 2009) a psychological treatment based on cognitive-behavioral therapy focused on insomnia (CBT-I) was developed. Several studies have explored the efficacy of CBT-I in patients with chronic pain (Currie et al. 2000), older adults with osteoarthritis (Vitiello et al. 2009), patients with various medical conditions (Rybarczyk et al. 2005), and patients with other chronic non-malignant pain conditions (Jungquist et al. 2010). To

the best of our knowledge, Edinger et al. (2005) and our research group (Martínez et al. 2014a; Miró et al. 2011b; Sánchez et al. 2012) are the only ones that have explored the efficacy of CBT-I in patients with FM. Edinger et al. (2005) assessed insomnia, pain, mood, life quality, and various sleep parameters in patients with FM randomly assigned to CBT-I, sleep hygiene (SH), or usual care (UC) groups. Patients in the CBT-I group showed greater improvements in sleep parameters (i.e., total sleep time, total wake time, and sleep-onset latency), reduction of insomnia symptoms, and improvements in subjective mental well-being and mood, compared to patients in the SH and UC groups. Miró et al. (2011b), Sánchez et al. (2012), and Martínez et al. (2014a) observed significant improvements in patients with FM who underwent CBT-I compared to those who received SH in several parameters such as attentional functioning assessed by neuropsychological tasks, objective improvement in sleep quality evaluated by polysomnography, and better levels of daily functioning, psychological well-being and sleep quality evaluated by self-administered questionnaires.

Although CBT-I has proven to be helpful for many patients with chronic pain syndromes, including FM, it has also shown limitations in improving patients' ability to mitigate the severity of pain (Martínez et al. 2014b). It has been suggested to combining CBT-I along with procedures that contribute to a better management of pain (CBT-IP), and their efficacy have been analyzed in chronic pain patients. However, no studies to date have explored the clinical utility of this hybrid therapy in patients with FM. So far, three research groups have published the outcomes of CBT-IP, the studies conducted are characterized in general by small samples and methodological differences (McCurry et al. 2014; Pigeon et al. 2012; Tang et al. 2012; Vitiello et al. 2013). Pigeon et al. (2012) evaluated clinical changes in a small sample of patients with chronic pain ($n=21$) in CBT-P, CBT-IP, CBT-I and waiting list (WL) groups. Results showed the advantage of CBT-IP and CBT-I over CBT-P in improving sleep parameters, depression, and fatigue. The greatest improvements in pain intensity were observed after CBT-P, despite that this group did not exhibit better results than the WL group in other parameters. Tang et al. (2012) compared a group that underwent CBT-IP to a monitoring group without any intervention in a small and heterogeneous chronic pain sample ($n=20$). The CBT-IP group showed a greater reduction of pain interference, pain catastrophizing, fatigue, and depression, and considerable improvements in sleep parameters such as insomnia, sleep onset latency, wake after sleep onset, sleep efficiency, and total sleep time than the monitoring group. Studies conducted in a large sample of older adult patients with chronic pain ($n=367$) by Vitiello et al. (2013) and McCurry et al. (2014), explored the efficacy of CBT-IP, CBT-P, and an education intervention. Results revealed greater improvements in insomnia after CBT-IP

than after the mentioned intervention. Both, CBT-IP and CBT-P were associated with significantly greater improvements in sleep efficiency than in education intervention but the three groups did not exhibit any differences in pain intensity (Vitiello et al. 2013). The long-term (18 months) evaluation of a subgroup of patients with severe pain and insomnia revealed that the benefits gained in pain, insomnia severity and sleep efficiency were larger after CBT-IP than in CBT-P and the education intervention groups (McCurry et al. 2014). In a previous pilot study our research group (Prados et al. in review) compared CBT-P ($n = 15$) versus CBT-IP ($n = 17$) in FM women observing that CBT-IP achieves greater improvements in several polysomnography parameters than CBT-P, and these improvements were concordant with a positive change in self-reported sleep quality only in CBT-IP.

Although some previous studies (McCurry et al. 2014; Pigeon et al. 2012; Tang et al. 2012; Vitiello et al. 2013) have examined the efficacy of CBT-IP, all of them were focused on heterogeneous samples of chronic pain, so the potential utility of this therapeutic modality in FM patients is unknown. The present randomized controlled trial aims to cover this gap identifying the clinical benefits of CBT for management of insomnia and pain (CBT-IP) compared with the usual psychological treatment focused on pain (CBT-P) and the usual medical care (UMC) regarding sleep quality, pain and other troubling symptoms (evaluated via self-reports) in FM women. The hypotheses proposed were: (1) CBT-IP will produce greater improvements in sleep quality than CBT-P and UMC; and (2) CBT-IP and CBT-P will produce greater improvements in pain-related variables, fatigue, functioning, and emotional distress than UMC.

Method

Design and Participants

We followed the guidelines of the CONSORT statement for randomized trials (Moher et al. 2010). One hundred and twenty-six patients with FM were randomly assigned to one of the three conditions: CBT-P ($n = 42$), CBT-IP ($n = 42$), or UMC ($n = 42$). The research protocol had received ethical approval from the University of Granada Ethics Committee, and patients signed an informed consent form prior to their inclusion in the study. Patients were recruited from the Rheumatology Service and Pain Unit of Virgen de las Nieves University Hospital and from AGRAFIM (a FM association), both in Granada, Spain. The assessment and treatment sessions were conducted in the Psychology Clinic of the University of Granada.

The inclusion criteria were the following: (1) being a woman aged between 25 and 65; (2) having met the

diagnostic criteria for FM (ACR; Wolfe et al. 1990) for > 6 months (to avoid the first impact of the diagnosis); (3) being stable in regards to the intake of analgesics, antidepressants, or other drugs (sleep and pain) at least 1 month before the study and not being treated with another psychological therapy; and (4) meeting the diagnostic criteria for insomnia (DSM-IV-TR; American Psychiatric Association, APA, 2000). The exclusion criteria were: (1) having major concomitant medical conditions (e.g., inflammatory rheumatic disease, endocrine disturbances, neurological disorder, cancer, recent surgery) or pregnancy; (2) having mental disorders with severe symptoms (e.g., major depression with suicide ideation, schizophrenia, personality disorder) or other organic sleep disorder (i.e., apnea); (3) having a severe dependence of hypnotic drugs; and (4) having irregularities in circadian rhythms at the time of the study (i.e., by rotating work shifts).

The physicians of Virgen de las Nieves University Hospital and the coordinators of AGRAFIM proposed to the FM women to participate in the study. Patients were informed that a psychologist would contact them soon to give them detailed information, ask them a series of questions, and if they met the requirements of the study, to establish an appointment at the Psychology Clinic to start their participation in the protocol. After the consent of the patients, the Hospital and AGRAFIM give to the psychologists of the study the name and telephone contact of the patients. One hundred and eighty-five eligible women with FM were screened having a short telephone interview administered by a psychologist. Fifty-nine of the patients contacted, were excluded at this stage due to not meeting the inclusion criteria, and those who fulfilled the criteria ($n = 126$) were committed to an individual interview for a psychological assessment. A semi-structured interview was conducted in two sessions. Session 1 focused on the onset and course of FM and insomnia, patients' life history, lifestyle, work activity, family and social relationships, and psychological state. After the interview, patients were given several self-report questionnaires and a sleep diary to be complete at home. Session 2 was scheduled to obtain additional data about insomnia, collect questionnaires, and answer any questions related to the treatment. All patients completed the sleep diary for 2 weeks before treatment and during the intervention. In order to allocate patients randomly to the treatments (42 patients in each condition), a number generator was used by a researcher blinded to the implementation of the trial. After some patients dropped out for reasons unrelated to the trial (e.g., inability to attend meetings due to familiar or work circumstances), 34 patients in the CBT-P group, 38 patients in the CBT-IP group, and 41 patients in the UMC group completed the treatments and were included in the analyses (see Fig. 1). The criterion to consider a

Fig. 1 Flow diagram of participants through the phases of the trial

patient had completed the treatment was to attend at least seven of the nine sessions.

Measures

The assessments were performed at pre-treatment, post-treatment (1 week after the completion of the intervention), and follow-up (3 months later). The primary end point was post-treatment. Sleep quality, as assessed by the global scale of the *Pittsburgh Sleep Quality Index* (Buysse et al. 1989), was established as primary outcome measure, and the remaining clinical variables were considered as secondary outcome measures. A psychologist who was blinded to group assignment assessed the following measures:

Pittsburgh Sleep Quality Index (PSQI; Buysse et al. 1989)

The PSQI includes 19 items that explore subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The sum of the scores of the subscales (Sleep quality-Total) ranges from 0 to 21, and high scores show greater disturbances. The PSQI is considered a reliable and valid instrument to measure sleep quality in patients

with FM (Osorio et al. 2006) and is frequently used in clinical trials on pain treatment (Cole et al. 2007). The Spanish adaptation of the PSQI has shown adequate psychometric characteristics (Royuela and Macías 1997).

McGill Pain Questionnaire-Short Form (MPQ-SF; Melzack 1987)

His questionnaire assesses different dimensions of pain experience. The present study used the VAS to assess the intensity of pain. The Spanish version of the MPQ has shown adequate reliability and validity in several studies (e.g., Lázaro et al. 2001).

Multidimensional Fatigue Inventory (MFI; Smets et al. 1995; adaptation by; Fillion et al. 2003)

This inventory explores five facets of fatigue using 20 items: *general fatigue*, *physical and mental fatigue*, *reduced motivation*, and *reduced activity*. Items are assessed on a Likert scale ranging from 1 (disagree) to 5 (totally agree). The general fatigue subscale was used in this study. The MFI has shown adequate internal consistency, construct validity, and convergent validity (Smets et al. 1995).

Fibromyalgia Impact Questionnaire (FIQ; Burckhardt et al. 1991)

This self-report inventory is composed of ten items and evaluates the current health status of patients with FM by considering their functional impairment in daily life and their work and other symptoms. Item 1 assesses their ability to perform various activities of daily living, and items 2 and 3 ask patients to mark the number of days they felt well/unwell to work. Items 4 through 10 are scales that rate work difficulty, pain, fatigue, morning tiredness, stiffness, anxiety, and depression on a Likert scale from 0 to 10. The Spanish adaptation of the FIQ has shown adequate test–retest reliability, internal consistency, external validity, and sensitivity (Rivera and González 2004).

Chronic Pain Self-Efficacy Scale (CPSS; Anderson et al. 1995)

This scale measures efficacy expectations for coping with pain using 19 items that are assessed on a Likert scale ranging from 0 to 10. The CPSS includes three factors: self-efficacy for pain management, self-efficacy to cope with symptoms, and for physical function. In this study we used the sum of the scores of the three subscales as a total score. The Spanish adaptation of the CPSS has shown good construct validity and internal consistency (Martín-Aragón et al. 1999).

Symptoms Check List 90-Revised (SCL-90-R; Derogatis 2002)

The SCL-90-R assesses current subjective distress using 90 items that describe psychopathological characteristics. Items are rated from 0 (not at all) to 4 (very or extremely). The SCL-90-R consists of nine dimensions: *Somatization*, *Obsessive–compulsive*, *Interpersonal sensitivity*, *Depression*, *Anxiety*, *Hostility*, *Phobic anxiety*, *Paranoid ideation*, and *Psychoticism*. In this study, the depression and anxiety scales were selected. The Spanish adaptation of the SCL-90-R has shown adequate internal consistency and a factor structure similar to that of the original version.

Pain Catastrophizing Scale (PCS; Sullivan et al. 1995)

This instrument assesses catastrophic thoughts associated with pain via three subscales: rumination, magnification, and helplessness. It includes 13 items measured on a Likert scale ranging from 0 (not at all) to 4 (all the time). In this study, the total sum of the scores of the subscales was considered. The Spanish version of the PCS has shown adequate internal consistency, test–retest reliability, and sensitivity to change (García-Campayo et al. 2008).

Chronic Pain Acceptance Questionnaire (CPAQ; McCracken et al. 2004)

This 20-item self-report assesses two aspects of acceptance of pain: activity engagement and pain willingness. The total sum of the scores of both subscales was used in this study. Items are rated on a scale from 0 (never true) to 6 (always true). The Spanish version of the CPAQ has shown adequate test–retest reliability, internal consistency, and construct validity (Rodero et al. 2010).

Treatment Protocols

The protocol-based psychological treatments (CBT-P and CBT-PI) were provided by therapists (M.J.L., M.P.M., E.M., and A.I.S.) with a high level of professional training, and experience in the domain of chronic pain and sleep disorders. Ninety-minute sessions were conducted in a group format (5–7 participants) once a week for 9 weeks. During the study all participants were required to follow their usual medical care.

CBT-P and CBT-IP protocols consist of multicomponent packages that are structured and limited in time and emphasize the active role of the patient. CBT-P was performed based on the Fear-Avoidance Model of Chronic Pain (Leeuw et al. 2007; Vlaeyen and Linton 2012). It was aimed at modifying the reinforcement contingencies that maintain pain behaviors as well as dysfunctional attitudes and emotional reactions, considering previous therapeutic guidelines for chronic pain collected in various publications (e.g., Thieme et al. 2007; Turk et al. 2008; Van; Koulil et al. 2008). CBT-IP covers the above-mentioned objectives and extends them to a sleep approach through training in cognitive, affective, and behavioral skills for better management of sleep problems. CBT-IP was based on the recommendations of the American Academy of Sleep Medicine (Morgenthaler et al. 2006) and the therapeutic guidelines for insomnia provided by Morin (1998) and Harvey (2005) therapeutic guidelines for insomnia.

The contents of the CBT are shown on Table 1. In order to ensure the integrity of the CBT interventions, participants were given a therapy manual containing the necessary information and tasks involved in each session. Furthermore, there were regular clinical meetings between the therapists and the research group, and video recordings to monitor the implementation of the intervention.

Data Analysis

A per-protocol analysis was applied because the aim of the study was to identify the effect of the CBT-IP and CBT-P unaffected by non-adherence, given the high rates of dropout

Table 1 Contents of the CBT-P and CBT-IP programs

Session	CBT-P	CBT-IP
1	Information about FM syndrome and pain (acute and chronic pain). Psycho-education about psychological factors (e.g., coping style, emotional responses, cognitions) that increase or reduce pain experience	Information about FM syndrome and relationship between pain and sleep. Psycho-education about sleep problems and insomnia (e.g., sleep stages, sleep functions, effects of sleep deprivation on sleep-wake functioning)
2	Information on the treatment program structure and the active role of the participant in the process	
2	Relaxation: abdominal breathing and relaxation training (a combination of passive relaxation and imagery training)	Sleep hygiene rules: environmental factors and lifestyle and healthy habits regarding diet, exercise, consumption of stimulants, alcohol, and medication
3	Identifying unpleasant emotional states. Analyzing the relationship between emotions and pain. Training in self-instructions to manage emotions and fear of pain	Sleep restriction therapy combined with stimulus control instructions, in order to reinforce the relationship between sleep and bed
4	Planning activities. Regulation of cycles of activity and rest. Exposition therapy for progressive incorporation of activities avoided	Relaxation: abdominal breathing and relaxation training (passive relaxation and imagery training)
5	Communication and relationship with others. Assertive communication training	Planning activities. Regulation of cycles of activity and rest. Incorporation of pleasant activities for counteracts avoidance behaviors
6	Training in problem solving skills	Communication and relationship with others. Training in assertive communication and problem solving skills
7	Cognitive therapy I: Identification of dysfunctional thoughts/attitudes related to pain (e.g., catastrophic appraisal of pain, excessive focus over pain, and misconceptions about the controllability of pain)	Cognitive therapy I: identification of dysfunctional thoughts/attitudes related to sleep (e.g., causes and consequences of sleep, sleep habits) and pain
8	Cognitive therapy II: strategies to replace dysfunctional thoughts/attitudes for more adaptive ones. Cognitive restructuring	
9	Integration of treatment components. Maintenance of gains. Anticipation of possible relapses. Planning future evaluations	

in chronic pain patients (Kim 2011). This approach is usually used in explanatory trials that try to measure the effect of an intervention under ideal conditions instead of clinical practice (Sedgwick 2014); as an example with FM patients, it could be mentioned the study of Von Bülow et al. (2017).

Statistical analyses were performed using IBM SPSS Statistics 19 software. Probabilities < 0.05 were used as the level of significance. ANOVA, Kruskal-Wallis, and χ^2 tests were used to compare baseline measures between the CBT-P, CBT-IP, and UMC groups. After that, 3 (Group; CBT-P vs. CBT-IP vs. UMC) $\times$ 3 (Time; Pre-treatment-T1 vs. Post-treatment-T2 vs. Follow-up-T3). ANCOVAs were performed considering pre-treatment values as a covariate to verify whether groups differed in the outcome measures. Additionally, unpaired and paired samples Student's t tests were computed between all pairs. Effect sizes were calculated via the partial η^2 and Cohen's d . Cohen's guidelines (1988) were considered: $d = 0.2$ is a small effect, 0.5 is a medium effect, and 0.8 is a large effect, and $\eta^2 = 0.01$ is a small effect, 0.06 is a medium effect, and 0.14 is a large effect. Given an anticipated effect size of Cohen's $d = 0.667$ (see review by Martínez et al. 2014b), a p -value < 0.05 , and a desired statistical power of $1 - \beta = 80\%$, the minimum required sample size for the study was 111 patients ($n = 37$ subjects per group).

The clinical significance was estimated based on the Jacobson–Truax method (reliable change index, RCI; Jacobson and Truax 1991). Patients were classified into different categories according to this index (Salaberría et al. 1996): *same* (with no positive or negative changes), *deterioration* (negative change), *improvement without complete recuperation* (positive change but less than 1), *somewhat positive change* (> 1 but < 1.96), and *Very positive change* (> 1.96). The last three categories were taken together for this study and named “Improvement”.

Results

Characteristics of the FM Sample

Table 2 shows participants' characteristics as a total sample and in each group. Groups did not differ in any baseline measures (all $p > .10$), except in percentage of antidepressant and anxiolytic intake, which was higher in the CBT-IP group ($p < .05$). The mean age of the FM sample was 50.19 years ($SD = 8.24$). Most participants were married (83.2%) and had basic education (29.2%) or secondary education (32.7%). Almost half of the subjects had an inactive work situation (24.7% unemployed and 22.9% disabled) or currently employed (38.2%). The mean duration of FM diagnosis was 6.62 years ($SD = 5.31$) but the mean duration of

FM symptoms was 10.11 years ($SD = 9.08$), and the mean duration of the sleep problem was 10.89 years ($SD = 8.89$).

Changes in Sleep Quality After Treatments

The ANCOVA for sleep quality-total revealed a significant and medium effect of time, group and time $\times$ group (see Table 3). The interaction effect in the primary outcome (sleep quality-total) showed a $1 - \beta = 85\%$. Whereas the CBT-IP group showed significant improvements in Sleep quality-total at post-treatment, the CBT-P and UMC groups did not. Moreover, subjective sleep quality showed a significant and medium effect of Time. The CBT-IP group showed a significant improvement between pre- and post-treatment in this parameter but neither CBT-P nor the UMC did. The UMC group reported better subjective sleep quality at baseline than CBT-IP. In sleep latency, a close to significance and small effect of time was found and significant improvements were observed at post-treatment in the CBT-IP group. Significant and medium effect of time were observed in sleep duration and sleep efficiency. Sleep efficiency improved significantly after CBT-IP, shown by significant differences between pre- and post-treatment, but not after CBT-P or UMC. Sleep disturbances showed significant and medium effects of time, group, and time $\times$ group. In this variable, significant differences between CBT-P and UMC at follow-up were observed (the UMC group showed less sleep disturbances). Use of sleeping medication showed significant and medium effects of group and time $\times$ group. Patients reported a significant reduction of Use of sleeping medication after CBT-IP, but not after CBT-P or UMC. Regarding daytime functioning, a significant and medium effect of time was observed, as well as a significant pre-treatment difference between the CBT-IP and UMC groups mentioned earlier. These differences between CBT-IP and UMC and between CBT-P and UMC increased at follow-up.

According to the RCI, 46.4% of patients in the CBT-P group, 62.9% in the CBT-IP group and 11.1% in the UMC group exhibited significant clinical changes in Sleep quality-Total.

Changes in Clinical Features (i.e., Pain Intensity, Fatigue, Impaired Functioning, Self-Efficacy, Depression, Anxiety, Pain Catastrophizing, and Pain Acceptance) After Treatments

An ANCOVA was performed in order to identify the effects of time, group and time $\times$ group on several clinical variables (see Table 4). The ANCOVA revealed a significant and large effect of group on pain intensity. A reduction in pain intensity was observed in the CBT-IP group at follow-up. Significant and large effects of time, group and time $\times$ group were identified in general fatigue. A significant reduction of

Table 2 Demographic and clinical characteristics of the FM subjects who completed the treatments

Variables	Total sample (<i>n</i> = 113)	CBT-P (<i>n</i> = 34)	CBT-IP (<i>n</i> = 38)	UMC (<i>n</i> = 41)	CBT-P versus CBT-IP versus UMC	
					<i>F</i> / <i>H</i> / <i>X</i> ²	<i>p</i>
Age, <i>M</i> (<i>SD</i>)	50.19 (8.24)	49.35 (6.43)	49.66 (8.44)	51.37 (9.38)	0.67	0.51
Education (%)					2.50	0.29
Basic education	29.2	29.4	31.5	26.8		
High school	32.7	44.1	21.1	34.2		
Professional instruction	15	20.6	7.9	17.1		
University studies	23	5.9	39.5	22		
Marital status (%)					5.12	0.53
Married	83.2	91.2	81.6	78		
Single	7.1	0	10.5	9.8		
Divorced	5.3	5.9	5.3	4.9		
Widowed	4.4	2.9	2.6	7.3		
Work status (%)					15.49	0.11
Currently employed	38.2	44.1	37.8	32.3		
Retired	14.2	5.9	15.9	20.6		
Unemployed	24.7	26.5	21.6	27.2		
Disabled	22.9	23.6	24.7	19.9		
Duration of FM diagnosis (years), <i>M</i> (<i>SD</i>)	6.62 (5.31)	6.39 (5.60)	5.94 (4.84)	7.48 (5.51)	0.78	0.46
Duration of FM symptoms (years), <i>M</i> (<i>SD</i>)	10.11 (9.08)	10.10 (9.03)	8.47 (6.99)	11.57 (10.63)	1.04	0.36
Duration of sleep problem (years), <i>M</i> (<i>SD</i>)	10.89 (8.89)	10.40 (8.06)	13.42 (9.99)	8.10 (5.73)	2.29	0.51
Sleep latency (hours), <i>M</i> (<i>SD</i>)	0:50 (0.36)	0:46 (0.46)	0:48 (0:29)	0:38 (0:35)	0.22	0.81
Number of awakenings per night, <i>M</i> (<i>SD</i>)	2.92 (1.63)	2.86 (1.56)	2.67 (1.30)	3.47 (2.17)	1.19	0.31
Sleeping hours per night, <i>M</i> (<i>SD</i>)	5:06 (1.41)	4:45 (1.19)	5:25 (1:40)	5:20 (2:06)	0.57	0.57
Drug intake (%)						
Antidepressants	59.3	52.9	71.1	53.7	4.97	0.05
Anxiolytics	62.8	50	73.7	63.4	4.78	0.05
Anti-inflammatory drugs	76.1	82.4	78.4	68.3	4.51	0.10
Analgesics	77.9	79.4	84.2	70.7	4.31	0.17

fatigue after UMC was observed at post-treatment; however, this reduction tended to increase significantly at follow-up. At post-treatment, significant differences were observed in this parameter between UMC and CBT-P and CBT-IP (UMC was better at reducing the level of fatigue). In FM impact, participants exhibited a significant and medium time effect and a significant improvement after CBT-P and CBT-IP at post-treatment. In this variable, significant differences were identified at baseline between the CBT-P and UMC groups (the UMC group was less affected by the disease). In self-efficacy, participants showed a significant and medium effect of time. A significant increase in self-efficacy after CBT-P and CBT-IP was observed at post-treatment.

A close to significance and small effect of time was found in depression. At pre-treatment, it was observed that depression in UMC was significantly lower than in CBT-IP group. At post-treatment, significant differences between CBT-P and UMC were observed; at follow-up,

these differences remained. Regarding anxiety and pain catastrophizing, no significant effects of group, time or time $\times$ group were observed. But pain acceptance showed a significant and large effect of time. Significant improvements in both pain variables (catastrophizing and acceptance) after CBT-P were observed at post-treatment, but this trend was inverted at follow-up.

According to the RCI, Pain intensity improved in 50% of patients in both CBT-P and CBT-IP groups. In other clinical variables such as FM impact, self-efficacy, depression, anxiety, pain catastrophizing, and pain acceptance, the percentage of improvement shown ranged from 81.5 to 57% in patients who received CBT-P, and from 77 to 52% in patients who received CBT-IP. In all variables (excluding fatigue and anxiety), the percentage of improvement was considerably lower after UMC than after CBT-P or CBT-IP.

Table 3 Group and time effects on sleep quality (PSQI)

Variables	Groups	Pre-treatment M (SD) CBT-P (n = 34) CBT-IP (n = 38) UMC (n = 41)	Post-treatment M (SD) CBT-P (n = 28) CBT-IP (n = 27) UMC (n = 36)	Follow-up M (SD) CBT-P (n = 24) CBT-IP (n = 22) UMC (n = 26)	Time F (η^2)	Group F (η^2)	Time x Group F (η^2)	T1 vs. T2 <i>t</i> (<i>d</i>)	T2 vs. T3 <i>t</i> (<i>d</i>)
Total-Sleep quality	CBT-P	13.47 (4.45)	13.68 (4.61)	13.79 (4.22)	5.43** (0.08)	4.45* (0.12)	3.48** (0.10)	−0.18	−0.93
	CBT-IP	14.68 (3.70)	13.19 (4.31)	13.57 (3.64)				2.94** (.35)	−1.39
	UMC	12.88 (5.01)	13.08 (5.33)	11.88 (4.68)				−0.78	0.85
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	−1.25	0.81	0.19					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	0.54	0.47	1.51					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	1.79	0.41	1.35					
Subjective sleep quality	CBT-P	2.00 (0.78)	1.86 (0.85)	1.79 (0.78)	5.42** (0.08)	0.36	0.42	1.00	0.25
	CBT-IP	2.22 (0.58)	1.93 (0.87)	1.95 (0.78)				2.13* (0.46)	−0.37
	UMC	1.73 (0.74)	1.86 (0.76)	1.65 (0.69)				−1.67	1.44
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	−1.33	−0.30	−0.71					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	1.52	−0.02	0.66					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	3.18** (0.74)	0.31	1.41					
Sleep latency	CBT-P	1.97 (1.03)	1.71 (1.24)	1.83 (1.01)	3.03, <i>p</i> = .05 (0.05)	0.49	0.69	1.31	−1.32
	CBT-IP	2.03 (0.96)	1.74 (0.90)	1.91 (0.92)				2.81** (0.41)	−0.81
	UMC	1.94 (1.08)	2.00 (1.15)	1.77 (1.31)				−0.81	0.00
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	−0.24	−0.09	−0.27					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	−0.22	−0.95	0.19					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	0.01	−0.97	0.42					

Table 3 (continued)

Variables	Groups	Pre-treatment M (SD) CBT-P (n = 34) CBT-IP (n = 38) UMC (n = 41)	Post-treatment M (SD) CBT-P (n = 28) CBT-IP (n = 27) UMC (n = 36)	Follow-up M (SD) CBT-P (n = 24) CBT-IP (n = 22) UMC (n = 26)	Time F (η^2)	Group F (η^2)	Time x Group F (η^2)	T1 vs. T2 <i>t</i> (<i>d</i>)	T2 vs. T3 <i>t</i> (<i>d</i>)
Sleep duration	CBT-P	1.97 (0.87)	2.18 (0.90)	1.87 (0.90)	8.07** (0.11)	0.83	0.82	– 1.80	1.22
	CBT-IP	1.81 (0.99)	1.93 (0.83)	2.00 (0.89)				– 1.28	0.00
	UMC	1.90 (0.99)	1.86 (1.07)	1.81 (0.98)				0.37	0.44
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	0.72	1.08	– 0.47					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	0.31	1.26	0.25					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	– 0.41	0.26	0.69					
Sleep efficiency	CBT-P	1.68 (1.22)	1.61 (1.26)	1.67 (1.09)	7.86** (0.11)	1.42	0.95	0.14	– 0.89
	CBT-IP	1.78 (1.17)	1.64 (1.18)	1.86 (1.19)				2.24* (0.46)	– 1.32
	UMC	1.80 (1.25)	1.75 (1.18)	1.81 (1.06)				0.25	– 0.33
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	– 0.35	– 0.69	– 0.56					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	– 0.45	– 0.47	– 0.46					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	– 0.10	– 0.40	0.15					
Sleep disturbances	CBT-P	2.21 (0.69)	2.18 (0.61)	2.33 (0.64)	96.21*** (0.60)	3.45* (0.10)	2.77* (0.08)	0.00	– 1.28
	CBT-IP	2.35 (1.75)	2.07 (0.73)	2.00 (0.69)				1.03	0.57
	UMC	1.95 (0.70)	1.94 (0.79)	1.77 (0.76)				0.57	0.00
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	– 0.45	0.58	1.70					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	1.57	1.29	2.82** (0.80)					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	1.35	0.66	1.09					

Table 3 (continued)

Variables	Groups	Pre-treat- ment M (SD) CBT-P (n = 34) CBT-IP (n = 38) UMC (n = 41)	Post- treatment M (SD) CBT-P (n = 28) CBT-IP (n = 27) UMC (n = 36)	Follow-up M (SD) CBT-P (n = 24) CBT-IP (n = 22) UMC (n = 26)	Time F (η^2)	Group F (η^2)	Time x Group F (η^2)	T1 vs. T2 t (d)	T2 vs. T3 t (d)
Use of sleep- ing medi- cation	CBT-P	1.74 (1.38)	1.96 (1.34)	1.79 (1.41)	0.19	3.65* (0.10)	2.83* (0.08)	-0.49	0.96
	CBT-IP	2.30 (1.17)	1.89 (1.31)	1.91 (1.38)					
	UMC	1.76 (1.41)	1.89 (1.39)	1.58 (1.44)					
	CBT-P versus CBT-IP t (d)	-1.85	0.21	-0.28					
	CBT-P ver- sus UMC t (d)	-0.06	0.22	0.53					
	CBT-IP ver- sus UMC t (d)	1.83	0.00	0.81					
Daytime function- ing	CBT-P	2.12 (0.91)	2.21 (0.99)	2.46 (0.93)	7.62** (0.11)	2.11	1.34	0.00	-1.06
	CBT-IP	2.24 (0.98)	2.19 (0.88)	2.32 (0.78)					
	UMC	1.71 (1.25)	1.75 (1.20)	1.62 (1.23)					
	CBT-P versus CBT-IP t (d)	-0.56	0.11	0.55					
	CBT-P ver- sus UMC t (d)	1.59	1.65	2.70** (.77)					
	CBT-IP ver- sus UMC t (d)	2.09* (0.47)	1.59	2.31* (0.68)					

Italic indicates the level of significance

CBT-P Cognitive-behavioral therapy for pain, *CBT-IP* Cognitive-behavioral therapy for insomnia and pain, *UMC* Usual medical care, *T1* Pre-treatment, *T2* Post-treatment, *T3* Follow-up after 3 months

* $p < .05$; ** $p < .01$; *** $p < .001$

Discussion

The aim of this trial was to evaluate the effects of CBT-IP compared to CBT-P and UMC in patients with FM. The findings demonstrated differential responses among treatments. According to the first hypothesis of this study, CBT-IP was associated with significant improvements in sleep-related variables between pre- and post-treatment (total-sleep quality, subjective sleep efficacy, sleep latency, sleep efficiency, and use of sleeping medication), that were not observed in the CBT-P or UMC groups as expected. However, significant interactions time $\times$ group were identified in some of these sleep variables. Meanwhile, results regarding pain-related variables and other clinical parameters showed a significant improvement in pain intensity after CBT-IP and a significant

improvement in FM impact and Self-efficacy for coping with pain after CBT-IP and CBT-P, showing also CBT-P positive changes in regards to pain catastrophizing and pain acceptance (with a tendency towards a reduction of the improvements at follow-up). Such changes were not shown by the UMC group, as predicted by the second hypothesis. However, fatigue was improved neither after CBT-IP nor CBT-P but positive changes were observed after UMC, although such improvements were transitory and fatigue tended to return to pre-treatment levels at UMC's follow-up. Finally, emotional distress (i.e., anxiety and depression) did not change significantly in any of the three treatment groups. Depression showed differences at post-treatment (UMC vs. CBT-P) and at follow-up (UMC vs. CBT-P and UMC vs. CBT-IP), in favor of UMC. In these pain and emotional

Table 4 Group and time effects on clinical variables

Variables	Groups	Pre-treatment M (SD) CBT-P (n = 34) CBT- IP (n = 38) UMC (n = 41)	Post-treatment M (SD) CBT-P (n = 28) CBT- IP (n = 27) UMC (n = 36)	Follow-up M (SD) CBT-P (n = 24) CBT- IP (n = 22) UMC (n = 26)	Time F (η^2)	Group F (η^2)	Time x Group F (η^2)	T1 vs. T2 <i>t</i> (<i>d</i>)	T2 vs. T3 <i>t</i> (<i>d</i>)
Pain intensity- VAS (MPQ- SF)	CBT-P	7.58 (1.75)	7.35 (2.08)	7.21 (1.79)	1.13	3.67* (0.15)	2.24	0.66	1.57
	CBT-IP	7.44 (1.33)	7.29 (1.46)	6.62 (1.47)				0.54	2.84* (0.65)
	UMC	7.16 (1.27)	7.40 (1.29)	7.20 (1.58)				−0.56	0.56
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	0.36	0.10	1.14					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	1.16	−0.11	0.21					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	0.94	−0.28	−1.28					
General fatigue (MFI)	CBT-P	4.40 (0.72)	4.31 (0.68)	4.35 (0.72)	19.70*** (0.24)	7.12** (0.19)	8.41*** (0.21)	0.53	−0.34
	CBT-IP	4.31 (0.76)	4.31 (0.66)	4.05 (0.67)				0.00	1.32
	UMC	4.01 (0.96)	3.18 (1.04)	4.03 (0.77)				4.27*** (0.67)	−4.23*** (−.78)
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	0.56	0.01	1.40					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	1.85	4.97*** (1.29)	1.50					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	1.42	4.80*** (1.30)	0.12					
FM impact (FIQ)	CBT-P	65.53 (11.08)	57.93 (14.16)	53.33 (14.85)	4.72** (0.07)	1.05	0.88	4.09*** (0.82)	1.29
	CBT-IP	61.98 (11.14)	55.82 (14.52)	56.53 (13.97)				2.59* (0.42)	−0.47
	UMC	55.57 (18.14)	55.45 (16.79)	53.22 (16.59)				0.41	1.49
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	1.35	0.54	−0.76					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	2.79** (.66)	0.62	0.24					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	1.87	0.09	0.74					
Self-efficacy (CPSS)	CBT-P	72.85 (36.54)	87.14 (30.21)	78.36 (41.32)	9.00*** (0.12)	2.43	2.08	−3.39** (−.46)	1.87
	CBT-IP	76.38 (31.29)	85.52 (38.22)	90.41 (37.64)				−0.222* (−.52)	−0.25
	UMC	76.56 (30.16)	79.53 (25.66)	81.79 (38.82)				−1.33	−0.40
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	−0.43	0.17	−1.04					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	−0.99	1.09	−0.31					
	CBT-IP vers. UMC <i>t</i> (<i>d</i>)	−0.60	0.74	0.78					
Depression (SCL-90-R)	CBT-P	2.15 (0.88)	2.15 (0.78)	2.11 (0.90)	2.58, <i>p</i> = .08 (0.04)	0.49	0.43	0.05	0.71
	CBT-IP	2.20 (0.79)	2.03 (0.96)	2.02 (1.01)				1.21	0.31
	UMC	1.77 (0.95)	1.68 (0.98)	1.47 (0.78)				1.36	0.02
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	−0.29	0.50	0.33					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	1.72	2.05* (0.53)	2.69** (0.76)					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	2.13* (0.49)	1.40	2.10* (0.61)					

Table 4 (continued)

Variables	Groups	Pre-treatment M (SD) CBT-P (n = 34) CBT- IP (n = 38) UMC (n = 41)	Post-treatment M (SD) CBT-P (n = 28) CBT- IP (n = 27) UMC (n = 36)	Follow-up M (SD) CBT-P (n = 24) CBT- IP (n = 22) UMC (n = 26)	Time F (η^2)	Group F (η^2)	Time x Group F (η^2)	T1 vs. T2 <i>t</i> (<i>d</i>)	T2 vs. T3 <i>t</i> (<i>d</i>)
Anxiety (SCL-90-R)	CBT-P	1.63 (0.81)	1.71 (0.94)	1.60 (1.05)	1.47	2.04	1.60	– 1.31	1.17
	CBT-IP	1.78 (0.93)	1.68 (1.05)	1.62 (0.98)				0.49	0.45
	UMC	1.50 (0.93)	1.37 (0.91)	1.18 (0.69)				1.22	0.88
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	– 0.72	0.81	– 0.07					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	0.65	1.94	1.65					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	1.34	1.24	1.79					
Pain cata- strophizing (PCS)	CBT-P	24.91 (12.07)	20.00 (10.59)	22.84 (14.14)	0.51	1.13	1.37	3.75***(.72)	– 2.44*(.55)
	CBT-IP	26.03 (11.47)	24.44 (13.01)	24.05 (14.14)				1.47	0.91
	UMC	23.55 (12.81)	24.91 (12.41)	24.20 (11.78)				0.75	– 0.25
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	– 0.40	– 1.38	– 0.29					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	0.47	– 1.23	0.18					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	0.89	0.26	0.49					
Pain acceptance (CPAQ)	CBT-P	51.74 (17.72)	57.57 (13.62)	53.46 (19.12)	13.11*** (0.17)	0.84	1.43	– 4.20*** (.83)	2.38* (0.53)
	CBT-IP	52.16 (18.47)	53.48 (21.41)	53.68 (15.70)				– 1.33	– 0.96
	UMC	54.05 (22.94)	55.86 (21.48)	57.54 (21.85)				– 0.63	– 0.69
	CBT-P versus CBT-IP <i>t</i> (<i>d</i>)	– 0.09	0.85	– 0.04					
	CBT-P versus UMC <i>t</i> (<i>d</i>)	– 0.46	0.37	– 0.70					
	CBT-IP versus UMC <i>t</i> (<i>d</i>)	– 0.39	– 0.44	– 0.69					

Italic indicates the level of significance

CBT-P Cognitive-behavioural therapy for pain, CBT-IP Cognitive-behavioral therapy for insomnia and pain, UMC Usual medical care, T1 Pre-treatment, T2 Post-treatment, T3 Follow-up after 3 months

* $p < .05$; ** $p < .01$; *** $p < .001$

parameters only a significant interaction time $\times$ group was identified in fatigue.

Considering clinical improvements, our results showed that sleep quality improved in a larger percentage of patients after CBT-IP (62.9%) than after CBT-P (46.4%) or UMC (11.1%). Taking these findings all together, it can be stated that CBT-IP and CBT-P were better than UMC, and the combined version of CBT addressing pain and insomnia was able to improve more clinical parameters than CBT that focused on pain alone.

The present study is the first to explore the efficacy of CBT-IP in comorbid FM and insomnia compared with CBT-P and UMC at post-treatment and follow-up considering as a primary outcome sleep quality and as a secondary outcome a wide variety of self-reported measures of wellbeing. Our results are congruent with those reported by Tang et al. (2012), Pigeon et al. (2012), and Vitiello et al. (2013). Though the small sample size of the study conducted by

Pigeon et al. (2012) does not make it possible to reach firm conclusions, it revealed that CBT-IP was associated with better results in insomnia severity, total wake time, and sleepiness than CBT-P and a control condition. The study performed by Tang et al. (2012) compared a waiting list group and a CBT-IP group and showed significant improvements between pre- and post-CBT-IP in sleep diary data (e.g., latency, efficiency, and sleep time). The clinical trial performed by Vitiello et al. (2013) in a large sample of older adults showed a greater reduction in insomnia severity in a CBT-IP group than in a CBT-P group and an education intervention group. By contrast, no differences among the three treatment conditions in sleep variables were observed at 18 months of follow-up, though participants with higher levels of insomnia and pain at baseline showed greater (but not significant) improvements in insomnia severity and sleep efficiency in the CBT-IP group than in the education intervention group (McCurry et al. 2014).

Nevertheless, comparisons between the present study and previous reports (McCurry et al. 2014; Pigeon et al. 2012; Tang et al. 2012; Vitiello et al. 2013) should be analyzed with caution given the methodological differences between them, particularly in sample type and sample sizes, treatments conditions compared, and follow-up periods evaluated. Moreover, the measurements used in the present study are not the same as those used in previous research. The studies mentioned above evaluated several dimensions of sleep disturbances with self-report questionnaires, sleep diaries, and actigraphy. In contrast, we evaluated sleep quality only via a self-report questionnaire focused on sleep quality rather than insomnia.

Regarding pain-related variables, neither of the studies (Pigeon et al. 2012; Tang et al. 2012; Vitiello et al. 2013) nor the present displayed significant improvements in pain intensity after CBT-IP or CBT-P at post-treatment. Even though the relationship between sleep and the origin and maintenance of chronic pain is well-established (Prados and Miró 2012), the psychological process that CBT develops in patients with FM may require larger periods of follow-up until the clinical benefits over pain intensity become evident. In our trial, we observed a tendency of pain severity to decrease at CBT-IP follow-up. Similarly, McCurry et al. (2014) found that patients with a high severity of insomnia and pain at baseline showed greater improvements in pain after CBT-IP (compared to CBT-P) at 18 months of follow-up. In another study conducted by the same group (Vitiello et al. 2014) in which the three conditions were explored together (CBT-IP, CBT-P and education), patients exhibiting greater improvements in sleep at post-treatment also showed better improvements in pain and other symptoms at 9 and 18 months of follow-up.

In the latest review of CBT-IP in chronic pain patients (Finan et al. 2014), the authors reached the conclusion that the pain severity index may be a poor primary outcome because it fails to consider the complex variance between sleep and pain. These authors recommend including a pain diary, quantitative sensory testing with an algometer, and measures of daily functioning and disability related to chronic pain. This last one revealed at the present study, a significant decrease of FM impact after CBT-P and CBT-IP. Although no previous studies had used FM impact questionnaires, Tang et al. (2012) found significant improvements after CBT-IP in pain interference rather than in symptoms monitoring condition, and Pigeon et al. (2012) observed that CBT-P showed a larger effect on pain interference than CBT-I and CBT-IP. Our outcomes showed an improvement in self-efficacy in pain management after CBT-IP and CBT-P. Similar results are mentioned in review of studies with FM patients (Bernardy et al. 2010), showing clearly that the CBT approach provides a greater sense of control over the symptoms (Clauw 2014).

Likewise, participants showed significant improvements in pain catastrophizing after CBT-P but not after CBT-IP, despite the fact that both treatments address dysfunctional beliefs about pain. These results are in line with those obtained in a review by Glombiewski et al. (2010), which concluded that CBT is efficient in reducing pain catastrophizing in short term. The study by Tang et al. (2012) showed a greater reduction of pain catastrophizing in the CBT-IP group compared to the control group, though there were no comparisons with any other CBT approach. According to the influential fear-avoidance model of chronic pain (Leeuw et al. 2007; Vlaeyen and Linton 2012), pain catastrophizing is a crucial cognitive variable involved in emotional distress and impairment associated to pain experience. Smeets et al. (2006) revealed the catastrophizing of pain is a core-mediatory variable at the improvement of chronic pain patients functioning after both, CBT and active physical treatment, as well as combined. In our study, changes in pain catastrophizing, delivered by CBT-IP or CBT-P, were followed by improvements in impairment and self-efficacy, but positive changes in depression or anxiety were not observed after these treatments. Some recent studies have pointed out the relationship between parameters of cognitive appraisal about pain and sleep problems. In a sample of patients with chronic pain and comorbid insomnia, maladaptive thoughts, such as pain catastrophizing, predicted both insomnia severity and pain disability (Bryson et al. 2014). In patients with FM, Martínez et al. (2015) found that poorer sleep quality was associated with higher pain catastrophizing. The mechanisms through which negative appraisal of pain can exacerbate sleep problems are still an open issue that needs more research.

Moving forward, the present trial has some limitations. Although self-report measures are adequate to assess the perceived quality of sleep, they should be endorsed with objective data obtained from polysomnography. Furthermore, it would be advisable to include measures of progress and continuity during the treatment (e.g., electronic diaries). In addition, pain intensity measurement could be complemented with objective measures, such as a pressure algometer, which assesses pain threshold and tolerance. The CBT-IP includes a greater number of components, so this modality might require more sessions in order for the patient fully internalize the therapeutic tools. Given the explanatory approach of the trial, a per-protocol analysis was used. This inevitably left out the analysis of dropouts, so the comparison could not be fully guaranteed. The differences in the dropout amount in the treatments group could have affected the results; regrettably, the magnitude of this possible influence could not be measured. In this trial, data was analyzed considering only short-term changes, but as noted above it would be highly recommendable to conduct the evaluation with a longer follow-up (1 year or more). Including

comparisons with a CBT-I group and an attention condition (to control the nonspecific influences) would provide relevant information. The results obtained from the CBT-P and the CBT-IP reflected some relevant and modest positive changes.

Future research in this domain has a lot to offer to patients with FM. It would be interesting to evaluate the CBT-IP response of patients who do not meet the diagnostic criteria for insomnia but experience sleep disturbances, as well as the responses of men to treatment. This would help to identify which group of patients with FM would benefit the most of the different types of treatment. It would also be necessary to dismantle studies to identify which components of CBT-IP contribute the most to the efficacy of treatment and conduct sessions over longer periods in order to avoid training patients in a large number of skills in a short time. An alternative consideration of the data based on the intention to treat analysis should also be considered in future research.

In conclusion, reversing the negative interaction between sleep and pain in therapeutic contexts is difficult, and CBT focused on insomnia and pain does not achieve complete recovery of sleep in all patients. However, the relevant clinical benefits achieved by this therapy in key variables (e.g., sleep quality, self-efficacy for coping with pain, daily functioning), suggest that it can be a useful strategy to include in the multidisciplinary approach to patients with FM who have comorbid sleep disorders. However, more research is needed to enhance the therapeutic efficacy of this modality of CBT applied to these patients.

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Compliance with Ethical Standards

Conflict of Interest María J. Lami, M. Pilar Martínez, Elena Miró, Ana I. Sánchez, Germán Prados, Rafael Cáliz and Johan W. S. Vlaeyen declares that they have no conflict of interest.

Informed Consent All procedures performed in studies involving human participants were in accordance with the ethical standards of the University of Granada Ethics Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

Animal Rights Statement No animal studies were carried out by the authors for this article.

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