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Diseños de Investigación y Aplicaciones en Psicología y Salud

## TESIS DOCTORAL

# EFICACIA DE LA TERAPIA COGNITIVO-CONDUCTUAL FRENTE AL TRATAMIENTO MÉDICO ESTÁNDAR EN MUJERES CON FIBROMIALGIA

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# RESUMEN

La fibromialgia (FM) es un síndrome de etiología desconocida caracterizado por dolor músculo-esquelético crónico y generalizado, que afecta significativamente la calidad de vida de las personas que lo padecen, y para el cual no existe en la actualidad un tratamiento totalmente eficaz. Desde que en 1990 se la reconoce en su diagnóstico como una enfermedad reumática multidimensional, ha aumentado el interés en avanzar en su estudio desde distintas disciplinas. Muchos de los pacientes con FM han debido de sobrellevar la enfermedad de manera estigmatizante y en ocasiones con incomprensión, tanto del sistema de salud como de su contexto cercano. La FM se caracteriza principalmente por dolor generalizado en los músculos y articulaciones, no obstante, en los nuevos y revisados criterios para su diagnóstico se ha observado la necesidad de tener en cuenta otros síntomas manifestados por los pacientes, como la fatiga, los problemas de sueño, las disfunciones cognitivas, las alteraciones emocionales, y diversos síntomas somáticos, que producen significativo malestar; y en el caso de los problemas de sueño o sueño no reparador que caracteriza a estas personas, configura un factor de mantenimiento y cronicidad importante en el dolor crónico. Este síndrome constituye el tercer diagnóstico más común dentro de las enfermedades reumáticas, siendo su prevalencia mucho mayor en mujeres que en hombres. Diversos han sido los resultados de los estudios que han procurado analizar los mecanismos subyacentes a esta afección, teniendo en cuenta factores biológicos y psicosociales. La bibliografía actual no refleja acuerdos sobre la manifestación clínica divergente de la FM entre hombres y en mujeres.

Desde su área de especialidad, la psicología ha intentado arrojar conocimiento acerca de las variables cognitivas, afectivas, motivacionales, psicopatológicas y de personalidad que podrían afectar al impacto de la FM sobre el bienestar y la calidad de vida de los pacientes. A partir de los estudios empíricos y los desarrollos de modelos

explicativos, se ha podido conocer que existen factores cognitivo-afectivos y comportamentales que exacerban las manifestaciones clínicas de este síndrome e impiden a las personas recuperar su estado de funcionamiento óptimo. A partir de estudios sobre el efecto de la privación del sueño en la salud mental, se ha establecido que existe una relación recíproca entre una mala calidad de sueño y la hipersensibilidad a los estímulos dolorosos (hiperalgesia) en pacientes con dolor crónico. La investigación del sueño en pacientes con FM es un área innovadora, la cual ha permitido, a través del examen con medidas objetivas de sueño (polisomnografía), revelar la existencia de disfunciones y alteraciones estructurales en el sueño de los pacientes con FM.

Aún con el cúmulo de conocimientos recabado hasta la actualidad, la FM continúa siendo un problema importante de salud pública, debido a que no se ha logrado establecer un tratamiento eficaz. La terapia cognitivo-conductual (TCC) ha sido el enfoque psicoterapéutico con mayor desarrollo y ha demostrado tener considerable éxito en el abordaje de los aspectos cognitivo-afectivos intervinientes en la vivencia del dolor y en los síntomas asociados. Es importante poder analizar cuáles de los componentes terapéuticos resulta de mayor relevancia para generar cambios en estos pacientes, dado que ha habido propuestas clínicas con diferentes énfasis, como la TCC orientada al dolor, la TCC orientada al sueño, o la opción combinada.

La presente tesis se realizó con el objetivo de analizar la eficacia del tratamiento psicológico desde un enfoque cognitivo-conductual, en sus distintas modalidades, sobre la disminución de los principales síntomas de la FM y la mejora de la calidad de vida de estas personas. Para ello, fue necesario conocer previamente el papel que juegan los factores de personalidad y los aspectos cognitivo-afectivos en la modulación del impacto de la FM y los síntomas psicológicos, principalmente ansiedad y depresión. A

partir de este objetivo general se postularon los siguientes objetivos específicos: 1) Evaluar las propiedades psicométricas de la versión española del instrumento de medición de la Vigilancia y Conciencia del Dolor (PVAQ) en una muestra de pacientes diagnosticadas con FM; 2) Analizar el efecto modulador de la alexitimia, como factor de personalidad, en la relación entre la valoración cognitivo-afectiva del dolor y el malestar emocional en la FM; 3) Clarificar la función mediadora de la catastrofización del dolor, la aceptación del dolor y de los diferentes estilos de afrontamiento en la relación entre la intensidad del dolor y los síntomas de ansiedad, depresión e impacto de la FM; 4) Realizar un análisis sistemático y descripción de los tratamientos psicológicos empleados en los últimos años en el abordaje de la FM; 5) Evaluar de manera preliminar la eficacia de la TCC para el insomnio en la FM y comparar la eficacia diferencial entre mujeres y hombres; y 6) Examinar la eficacia de la TCC en sus modalidades de TCC para el dolor, y TCC para el dolor y el insomnio en mujeres con FM.

El primer objetivo se pudo cumplir a través de un estudio instrumental que permitió evaluar las propiedades psicométricas del PVAQ, en su versión corta de 9 ítems, en un grupo de 242 mujeres españolas con diagnóstico de FM. Los datos obtenidos en este estudio permitieron demostrar, a través de un análisis confirmatorio, la bondad de ajuste en esta muestra en dos subescalas (vigilancia activa y conciencia pasiva). Asimismo, se observaron adecuados niveles de consistencia interna, validez convergente y discriminante. Este estudio logró establecer un punto de corte para identificar pacientes con peor funcionamiento diario. La posibilidad de evaluar la variable hipervigilancia del dolor, utilizando esta herramienta redunda en beneficios a nivel clínico y de investigación.

El segundo objetivo se puso a prueba a través de la evaluación de la alexitimia, la percepción de dolor y el malestar emocional, entre otras variables, en 97 pacientes con FM y 100 mujeres sanas con medidas de auto-informe. Los resultados revelaron que las pacientes con FM manifiestan mayores dificultades en identificar y expresar emociones, se observaron correlaciones significativas entre las subescales mencionadas y manifestaciones clínicas relevantes en la FM (pobre calidad de sueño, mayor ansiedad y depresión y mayores niveles de catastrofización y miedo al dolor). La alexitimia, en su dimensión de identificación de las emociones, moderó la relación entre la ansiedad y la catastrofización del dolor. La dimensión dificultad para la expresión emocional, se identificó como moderador de la relación entre la ansiedad y el miedo al dolor.

Para cumplimentar el tercer objetivo, se evaluaron tres de las variables, que según la literatura existente, cumplen un rol preponderante en la cronicidad del dolor: la catastrofización del dolor, la aceptación al dolor y las estrategias de afrontamiento; con el fin de identificar su rol como mediador entre la intensidad del dolor y el malestar emocional y el impacto de a FM; en una muestra de 92 pacientes con FM (80 mujeres y 12 varones). Los resultados indicaron que las variables mencionadas correlacionaron de manera significativa con los síntomas de depresión y ansiedad, y el impacto funcional en la FM, pero sólo la catastrofización del dolor medió de manera significativa la relación entre la intensidad del dolor y el malestar psicológico.

El cuarto objetivo se desarrolló a través de la revisión sistemática de 568 artículos inicialmente identificados sobre el tratamiento psicológico de la FM desde la publicación de sus criterios diagnósticos en 1990 hasta el año 2012. El análisis de los resultados finalmente llevó a la revisión profunda de 58 artículos originales, que incluyeron como mínimo el 60% del tiempo en intervención psicológica. Se observó que entre todas las modalidades de abordaje, la terapia cognitiva-conductual es la que

mayor desarrollo e investigación ha recibido. Esta revisión permitió un análisis y descripción global de los abordajes implementados con el objetivo disminuir el impacto de los síntomas de la FM. Habiendo explorado la influencia de algunas de las variables psicológicas sobre la vivencia del malestar asociado a la FM, y reconocido la importancia del tratamiento psicológico para aliviar dicho malestar y mejorar la calidad de vida de los pacientes; se establecieron como objetivos evaluar la eficacia del tratamiento cognitivo-conductual orientado al dolor y al sueño en la FM. El quinto objetivo se llevó a cabo con muestra de mujeres y hombres que recibieron TCC-I, evaluando los cambios con medidas de auto-informes de los principales síntomas de la FM antes y después de la intervención y con un seguimiento a los 3 meses. Los resultados revelaron mejoras significativas en ambos grupos sobre la calidad del sueño y los principales síntomas. En relación a las divergencias entre hombres y mujeres, este estudio no reveló diferencias significativas en las variables evaluadas; sin embargo los hombres y las mujeres mostraron respuestas dispares al tratamiento. Por último, el sexto objetivo se alcanzó a través de un estudio clínico controlado en una muestra de mujeres, que evaluó la eficacia del TCC orientado al dolor (TCC-D) y el TCC orientado al dolor y el insomnio (TCC-ID), comparando éstos con el tratamiento médico estándar (TME). Como se esperaba, el TCC-ID reveló mejoras significativas en las variables relacionadas a la calidad del sueño en el postratamiento, y mejoras en la intensidad del dolor en el seguimiento, que no se observaron en los otros grupos. Tanto el grupo de pacientes que recibieron TCC-D como TCC-ID evidenciaron mejoras en el impacto de la FM y la auto-eficacia para el manejo del dolor. El abordaje específico para el dolor, mostró disminución de la catastrofización y aumento de la aceptación del dolor. También se observaron importantes mejoras a nivel clínico después de TCC-ID y TCC-D.

Para finalizar, los estudios realizados en la presente tesis permiten concluir que resulta imprescindible la inclusión de la evaluación y el tratamiento psicológico cuando existe un diagnóstico de FM. Asimismo, la visión multidisciplinar contribuye a la comprensión integral sobre el impacto funcional que los síntomas asociados a la FM generan. La TCC tanto para el sueño como para el dolor, demuestra mayor eficacia que el actual tratamiento médico estándar que las pacientes reciben, ya que les permite manifestar un rol activo en su tratamiento. El objetivo del tratamiento desde esta perspectiva es acompañar a estos pacientes a convivir con el síndrome mejorando su calidad de vida.

# Abstract

Fibromyalgia (FM) is a syndrome of unknown etiology characterized by chronic and generalized musculoskeletal pain, which significantly affects the patient´s quality of life, and for which there is not a fully effective treatment at the present moment. Since in 1990, it is recognized by diagnosis as a multidimensional rheumatic disease, has increased the interest in advancing their study from different disciplines. Most of patients with FM have had to cope with the stigma of the disease and sometimes with the misunderstanding from both the health system and its immediate context. The FM is characterized mainly by generalized pain in muscles and joints, however, in the new and revised criteria for diagnosis, have been taking into account other symptoms manifested by patients, as fatigue, sleep disorders, cognitive dysfunctions, emotional distress, and various somatic symptoms; and in terms of sleep disturbances or a not restorative sleep characteristic in these individuals, sets up an important maintenance and chronicity factor in chronic pain problems. This syndrome is the third most common diagnosis in the rheumatic diseases, being the prevalence higher in women than in men. The studies developed in order to analyses the mechanisms underlying this issue revealed divergent results, having considered biological and psychosocial factors. The current literature does not reflect agreements about the divergences of clinical manifestation of FM between men and women.

From psychology´s area of expertise, it has being trying to bring light about cognitive, affective, motivational, psychopathological and personality variables that may be affect at FM impact to wellbeing and life´s quality of these patients. From the empirical studies, and the developed of explicative models, it has been known that there are cognitive-affective and behavioral factors that exacerbate the clinical manifestations of this syndrome and prevent people regain their state of functioning. Studies regarding

the consequences of sleep deprivation into mental health, allowed determining a relationship between a poor sleep quality and hypersensitivity to painful stimuli (hyperalgesia) in patients with chronic pain. The investigation of sleep in patients with FM is an innovative area, which has generated, through examination with objective measures of sleep (polysomnography), the finding of the existence of structural dysfunctions and sleep disturbances in patients with FM.

Even with the body of knowledge gathered to date, the FM remains an important public health problem because it has not succeeded in establishing an effective treatment. The cognitive-behavioural therapy (CBT) has been the most developed psychotherapeutic approach and has demonstrated considerable success in addressing the cognitive-affective aspects involved in the experience of pain and the associated symptoms of FM. It is important to evaluate which of the therapeutic components results of greater relevance to bring about change in these patients, since there have been clinical proposal with different highlighted components, as CBT for pain, CBT for insomnia, or the hybrid approach.

This thesis was conducted in order to analyse the efficacy of psychological treatment from a cognitive-behavioral approach, with different forms, in reducing the main symptoms of FM and improving the patient´s quality of life. For that purpose, it was needed to understand the role of personality factors and cognitive-affective aspects in modulating the impact of FM and psychological symptoms, particularly anxiety and depression. Beginning with this general objective, the following specific objectives are formulated: 1) Evaluate the psychometric properties of the Spanish version of the measuring instrument of Vigilance and Awareness of Pain (PVAQ) in a sample of patients diagnosed with FM; 2) Analyse the moderating effect of alexithymia, as personality factor in the relationship between the cognitive-affective assessment of pain

and emotional distress in FM; 3) Clarify the mediating function of pain catastrophizing, acceptance of pain and different coping styles in the relationship between pain intensity and symptoms of anxiety, depression and impact of FM; 4) Analyse and describe systematically the psychological treatments used in recent years in addressing FM; 5) Preliminarily evaluate the efficacy of CBT for insomnia in FM and compare the differential response between women and men; 6) To examine the efficacy of CBT in different forms, CBT for pain, and CBT for pain and insomnia in women with FM.

The first goal could be met through an instrumental study allowed us to evaluate the psychometric properties of PVAQ, in its short version with 9 items in a group of 242 Spanish women diagnosed with FM. The data obtained in this study demonstrated in the confirmatory analysis the goodness of fit in this sample into two subscales (active vigilance and passive awareness). Also, adequate levels of internal consistency, convergent and discriminant validity were observed. This study succeeded in establishing a cutoff point for identifying patients with worse daily functioning. The ability to evaluate the variable pain hypervigilance using this tool, results in benefits to the clinical and research level.

The second objective was tested by the evaluation of alexithymia, pain experience and emotional distress, and others variables, in a sample of 97 FM patients and 100 healthy women with self-report measures. The results show that patients with FM report more difficulty in identifying and expressing emotions, significant correlations between subscales mentioned and relevant clinical manifestations were observed in FM (poor sleep quality, more anxiety and depression, higher levels of pain catastrophization and fear of pain). The aspect of identifying emotions of the alexithymia moderated the relationship between anxiety and pain catastrophizing. The difficulty of emotional

expression dimension was identified as a moderator of the relationship between anxiety and fear of pain.

For the achievement of the third objective, three of the variables, which according to the literature, play a major role in chronic pain were evaluated: pain catastrophizing, acceptance of pain and coping strategies; in order to identify its role as mediator between the intensity of pain and emotional distress and FM impact; in a sample composed by 92 patients with FM (80 women and 12 men). The results indicate that these variables significantly correlated with depression and anxiety´s symptoms, and functional impact on FM, but only pain catastrophizing significantly mediated the relationship between pain intensity and distress.

The fourth aim was developed through a systematic review of 568 articles initially identified about psychological treatment of FM since the publication of its diagnostic criteria in 1990 to 2012. The analysis of the results finally reached the depth review of 58 original articles, which included at least 60% of the time in psychological intervention. It was noted that among all forms of approach, cognitive-behavioral therapy has received further development and research. This review analysed and described comprehensively the approaches implemented in order to reduce the impact of FM symptoms. Having explored the influence of some of the psychological variables on the distress associated to FM, and recognized the importance of psychological treatment to relieve this discomfort and improve the quality of life of patients, as targets were established to evaluate the efficacy of cognitive-behavioral treatment for pain and sleep in FM. The fifth objective was carried out with a sample of women and men who received CBT-I, assessing changes by self-report measures of the main symptoms of FM before and after the intervention and after 3 months follow-up. The results showed significant improvements in both groups in sleep quality and the main symptoms of FM.

Regarding the differences between men and women, this study revealed no significant differences in the variables evaluated; however men and women showed differences in responses at treatment. Finally, the sixth aim was achieved through a controlled clinical trial in a women sample that evaluated the efficacy of CBT for pain (CBT-P) and the CBT facing pain and insomnia (CBT-IP), comparing them with the usual medical care (UMC). As expected, the CBT-IP showed significant improvements in variables related to sleep quality in the post-treatment, and improvement in pain intensity at follow-up, while were not observed in the other groups. Both group of patients who received CBT-P and CBT-IP evidenced improvements in FM impact and self-efficacy for pain management. The pain oriented approach showed a decrease of pain catastrophizing and an improvement in acceptance of pain. Clinically significant improvement after CBT-P and CBT-IP were also observed.

Finally, studies in this thesis can be concluded that it is essential to include psychological evaluation and treatment when there are patients with FM diagnosis. Also, the multidisciplinary perspective contributes to the overall understanding of the functional impact generated by FM symptoms. Either CBT for sleep as for pain proves greater efficacy than the current standard medical care that patients receive, since it allows them to develop an active role in their treatment. The goal of treatment from this perspective is to accompany these patients to live with the syndrome and come to the aid of improve their quality of life.

# INTRODUCCIÓN

## 1. Definición, diagnóstico y epidemiologia de la Fibromialgia

La Fibromialgia (FM) es una afección reumatológica crónica, no progresiva y de etiología desconocida. En 1990 el Colegio Americano de Reumatología (*American College of Rheumaology, ACR*) estableció los siguientes criterios para su diagnóstico: 1) dolor músculo-esquelético generalizado, que se manifiesta en el hemi-cuerpo izquierdo y derecho y en la parte superior e inferior del mismo, durante un periodo mayor a tres meses; y 2) la presencia de dolor en puntos específicos del cuerpo denominados "puntos gatillo" (*tender points*) ante la palpación del clínico con su mano o mediante un aparato de medida (algómetro) con una presión aproximada de 4 kg. Los puntos se encuentran en nueve localizaciones bilaterales (ver Figura 1), y es necesario que el paciente manifieste dolor en al menos 11 de los 18 puntos gatillo (Wolfe et al., 1990).

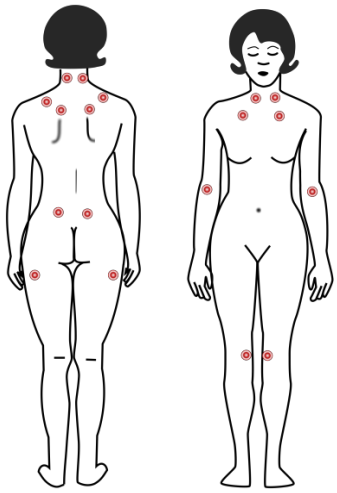

**Figura 1**. Localización de "puntos gatillos" como criterio diagnóstico de la FM.

A pesar de que el dolor crónico es el principal síntoma de la FM, su definición y criterios diagnósticos han sido revisados desde su primera denominación en 1904 (Gowers, 1904). El primer término con el que se conoció la enfermedad fue

“fibrositosis”, atribuyéndole un origen inflamatorio. En la actualidad se la reconoce como un síndrome multidimensional sin base anatomopatológica, en la que además del dolor, se identifican otros síntomas como pautas diagnósticas y de severidad. En un esfuerzo por determinar con mayor precisión el diagnostico de FM, la ACR ha establecido nuevos criterios necesarios adicionales al dolor, como la fatiga, el sueño no reparador, las alteraciones cognitivas (dificultades en la atención, concentración y memoria), síntomas psicológicos (ansiedad y depresión) así como síntomas somáticos (p. ej., debilidad muscular, parestesias en las extremidades, rigidez matutina, dolores de cabeza, hinchazón en las manos, sensación de frío, cambios en los hábitos intestinales, sudores nocturnos, sequedad de ojos, tensión mandíbular, etc.) (Wolfe et al., 2010). De esta manera, los síntomas mencionados cobran mayor relevancia en la evaluación diagnóstica de la FM. Estos nuevos criterios surgen como alternativa a la evaluación de los “puntos gatillo” logrando una mejor conceptualización de la enfermedad y permitiendo diagnosticar a un mayor número de hombres que con los anteriores criterios quedaban sin diagnóstico de FM, por no responder a la sensibilidad de los 11 puntos dolorosos (Clauw et al., 2014, 2015).

A diferencia de otras enfermedades reumatológicas, los pacientes con FM no manifiestan alteración anatomofisiologica evidente, sin embargo, la FM afecta significativamente la calidad de vida y el funcionamiento diario de las personas que la padecen. Estudios epidemiológicos informan que existe una prevalencia del 2,9% en la población general europea (Branco et al., 2010), y del 10,2% al 15,7% en las consultas de reumatología (Neumann y Buskila, 2003), siendo la enfermedad reumática más común después de la lumbalgia y la osteoartritis (Lawrence et al., 2008). Aun así, estudios recientes revelan que el 73% de los pacientes con FM, no reciben tal diagnóstico, sino que se ven erróneamente incluidos en otras enfermedades reumáticas

(Walitt, Nahin, Katz, Bergman, y Wolfe, 2015). Se ha identificado una prevalencia preponderante en mujeres de edades comprendidas entre 20 y 55 años (Branco et al., 2010). En población española, la proporción del diagnóstico de FM es de un 4,2% de mujeres, en contraposición a un 0,2% en hombres (Mas, Carmona, Valverde, y Ribas, 2008). Asimismo, Weir et al. (2006) destacan que las mujeres con FM muestran mayor probabilidad (ratio hombre/mujer: 2,14/7,05) de manifestar al menos un trastorno comórbido incluyendo depresión, ansiedad, lupus eritematoso sistémico y artritis reumatoide. Esta diferencia entre género es compleja y algunos estudios han evaluado la existencia de diferentes aspectos involucrados en el diagnóstico diferencial según se trate de hombres o mujeres. Podría existir un sesgo por parte de los especialistas encargados del diagnóstico, así como una dificultad para que los hombres expresen libremente los síntomas dada las expectativas en base al género y los estereotipos que intervienen en la FM entendida como "una enfermedad de mujeres". A pesar de que algunos estudios destacan las influencias sociales, más que psico-biológicas de la afección (Hooten, Townsend, y Decker, 2007), los estudios actuales revelan discrepancias sobre esta cuestión. Asimismo, existe discrepancia en los valores de prevalencia debido a variabilidad de los criterios empleados para la evaluación de la FM, así como aspectos metodológicos de los estudios. No obstante, diferentes estudios compararon los síntomas informados por mujeres y hombres y refieren que las pacientes revelan mayores niveles de dolor, malestar emocional relacionado al dolor, y mayor sensibilidad al dolor experimental (Paller, Campbell, Edwards, y Dobs, 2009). En los estudios realizados por nuestro grupo de investigación, se observó que el dolor en los hombres se relaciona negativamente con la autoeficacia para el manejo del dolor y la calidad de sueño; en cambio en las mujeres con FM, el dolor correlaciona con el miedo, hipervigilancia y catastrofización del dolor (Miró, Diener, Martínez, Sánchez, y

Valenza, 2012). Por otra parte, son escasos los estudios realizados que analizan las diferencias entre hombres y mujeres en respuesta al tratamiento no-farmacológico para el dolor crónico y sus resultados son dispares (véase Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, y Riley, 2009 para una revisión). Sin embargo, se observan ciertos procesos diferentes entre los géneros relacionados con aspectos del "rol de género", como la expectativa de que los hombres manifiesten mayor tolerancia al dolor y la mujer considere el dolor como parte de la vida y exprese el dolor con mayor facilidad (Myers, Riley, y Robinson, 2003).

La FM ha sido identificada como un problema de salud pública de primera magnitud dada la prevalencia, el impacto en la calidad de vida y la salud, y la cantidad de profesionales sanitarios que intervienen en su diagnóstico y tratamiento. El deterioro funcional producido por esta enfermedad lleva aparejado importantes costos socio-sanitarios directos e indirectos. En España un paciente con FM genera un gasto aproximado de 10.000 euros al año (Rivera et al., 2009), siendo tres veces mayor el gasto en materia de salud de las personas con este síndrome en comparación con las personas sanas (Berger, Dukes, Martin, Edelsberg, y Oster, 2007). De este monto, el 33% se derivan del uso de recursos sanitarios, es decir consumo de fármacos, consultas médicas, fisioterapia o intervenciones quirúrgicas, y el 66% se dirigen a costes indirectos relacionados a bajas laborales, incapacidad o reducción de horas de trabajo, entre otros, dado que la FM afecta a las personas principalmente en edad laboral (Rivera et al., 2009).

## 2. Etiopatogenia de la Fibromialgia

En relación a la etiología de la FM, las investigaciones desde diferentes disciplinas no han podido establecer su patogénesis de manera definitiva. No obstante,

hay cierto consenso respecto a la existencia de factores disfuncionales a nivel neurofisiológico, inmunológico, neuroendocrino y autonómico involucrados en el inicio y mantenimiento de la FM, así como aspectos psicológicos cognitivos, afectivos y conductuales que desempeñan un papel significativo en la modulación de la vivencia y respuesta ante el dolor (Clauw, 2015). Algunas investigaciones se han centrado en la búsqueda de bio-marcadores objetivos para determinar el diagnóstico, pronóstico y la posibilidad de predecir la evolución en el tratamiento (Mease et al., 2007; Clauw, 2015), con el objetivo de monitorizar su progreso y adecuarlo para la mejora de la calidad de vida de estos pacientes. De esta manera, se han descrito una serie de factores de tipo biológico que conciernen al sistema inmunológico y a la acción de las citoquinas (Buskila, Atzeni, y Sarzi-Puttini, 2008) como mecanismo central en la etiología y la magnitud de los principales síntomas de la FM (Menzies y Lyon, 2010). Las citoquinas son proteínas inmunomoduladoras que poseen diferentes acciones biológicas, estas pueden ser pro-inflamatorias o anti-inflamatorias. Las citoquinas afectan al funcionamiento del Sistema Nervioso Central (SNC) modulando la respuesta inflamatoria (Webster, Tonelli, y Sternberg, 2002), dando lugar a la "conducta de enfermedad" ("*sickness behaviour").* El comportamiento de enfermedad se refiere a la constelación de síntomas no específicos que acompañan la infección y la activación del sistema inmunológico que incluye fatiga, mayor sensibilidad al dolor, cambios en los patrones del sueño y síntomas ansiosos-depresivos (Kelley et al., 2003). Dado el solapamiento de estos síntomas con los observados en la FM, Bazzichi et al. (2007) han llevado a cabo un estudio con el objetivo de analizar los niveles de citoquina (IL) en pacientes con FM, observando que existe una activación del sistema de respuesta inflamatoria, manifestado por mayores niveles de IL-10 e IL-8 en pacientes con FM comparados con controles sanos. Sin embargo, dados los resultados divergentes,

finalmente no existe acuerdo acerca de la relación entre aumento o disminución de algunas citoquinas y los síntomas de la FM (Menzies y Lyon, 2010).

Otros estudios han apelado a alteraciones en la fisiología del SNC, señalando la existencia de una disfunción en los mecanismos centrales de modulación del dolor generando hipersensibilidad difusa al dolor. Los pacientes con dolor crónico presentarán *hiperalgesia* (incremento de la respuesta de dolor ante estímulos dolorosos normales) y *alodinia* (percepción dolorosa de un estímulo habitualmente indoloro) (Lee, Nassikas, y Clauw, 2011). Estas características también fueron encontradas en pacientes con FM, presentando umbrales de dolor más bajos (Geisser et al., 2003). En la FM, se ha observado que existen alteraciones en el procesamiento de la respuesta del dolor a nivel central, y no una disfunción periférica, como en el dolor agudo o inflamatorio (Dadabhay y Clauw, 2006). Estas particularidades en la modulación del dolor en estos pacientes, se encuentra explicada parcialmente por deficiencias funcionales, como disminución de la acción analgésica y una sensibilización central (para una revisión véase Lee et al., 2011).

Existe una estrecha relación entre los sistemas mencionados como posibles factores asociados a la etiología de la FM, y el sistema de respuesta al estrés. Algunos autores (ver Stisi et al., 2008 para una revisión) mencionan el importante papel que juega el estrés en la FM. Se observan en pacientes con FM alteraciones en el eje hipotálamo-hipofiso-suprarrenal (HHP) derivadas de la exposición a eventos traumáticos agudos o situaciones negativas prolongadas en la infancia o adultez. La relación entre el dolor y el estrés ha sido estudiada en los últimos 20 años (Melzack, 1999; Van Houdenhove y Egle, 2004) habiéndose constatado que mientras que el estrés agudo, a través de la libración de la hormona corticotrofina, genera una respuesta analgésica funcional, el estrés crónico produciría un fenómeno inverso. Algunos

hallazgos refieren que en la FM se produciría dicho fenómeno, considerado como una sobrecarga del sistema de respuesta al estrés, generando hipofuncionalidad e hiperalgesia traducido en un déficit de la respuesta adecuada ante situaciones estresantes de la vida actual (Van Houdenhove y Egle, 2004) (véase Figura 2).

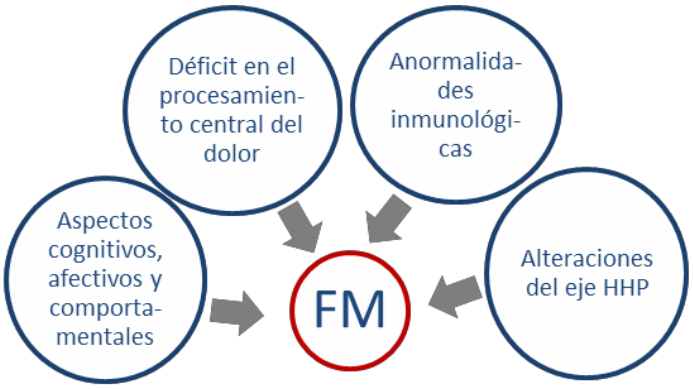


**Figura 2.** Factores relacionados con la etiopatogenia y mantenimiento de la FM.

## 3. Aspectos psicológicos en la FM y su relación con otras variables

La Asociación Internacional para el Estudio del Dolor (1979) definió al dolor como *"una sensación desagradable en una parte o partes del cuerpo asociada a un daño tisular actual o petencial".* Sin embargo, esta misma Asociación en 1986 añade a la mencionada definición: *"pero también se trata siempre de una experiencia perceptiva y subjetiva desagradable y, por tanto, emocional, resultante de un amplio número de factores: biológicos, psicológicos y sociales"* (p. 211). Esta conceptualización desde un modelo biopsicosocial, reconoce la experiencia del dolor como algo complejo y multidimensional.

El principal modelo que asume la influencia de los aspectos psicológicos en la vivencia de malestar asociado al dolor es la Teoría de la Puerta de Control del Dolor (*Gate Control Theory*). Melzack y Wall (1965), que plantea que existen ciertos

mecanismos de modulación del dolor que están situados en la medula espinal y que tienen la capacidad de enviar o no enviar los mensajes de estímulos dolorosos al cerebro (Pross y Martín, 2009), destacando el importante papel que cumplen los mecanismos cognitivo-evaluativos y motivacionales-afectivos en la comunicación entre SNC y periférico. La teoría de la Puerta de Control del Dolor, destaca la implicación de tres sistemas moduladores del dolor que participan inter-relacionalmente en la experiencia dolorosa: 1) sistema sensorial discriminativo, encargado de la información nocioceptiva y de la identificación de la localización, duración e intensidad del estímulo doloroso; 2) sistema motivacional-afectivo, regulado por el sistema límbico que percibe al dolor como un estímulo desagradable y aversivo, lo que genera el alejamiento o huida; y 3) sistema cognitivo-evaluativo, regulado por la corteza frontal, que integra y modula los sistemas anteriores a través de creencias, pensamientos, contexto, experiencias previas, etc. La Puerta del Dolor, puede abrirse o cerrarse en estos tres niveles, esto explicaría las diferencias individuales de la percepción del dolor y da lugar a una mirada multidimensional de la experiencia del dolor, donde los aspectos psicólogos desempeñan un importante papel modulador.

Algunas de las variables psicológicas han demostrado su influencia en la percepción del dolor, así como en el desajuste funcional de los pacientes con FM (Raphael, Janal, Kayak, Schwartz, y Gallagher, 2006). Estudios de revisión sobre la influencia de los aspectos psicológicos sobre el dolor crónico (Keefe, Rumbre, Scipio, Giordano, y Perri, 2004), destacan el papel de efectos moduladores de la adaptación al dolor persistente. Entre estos factores asociados el incremento del dolor y a un mayor desajuste funcional figuran la catastrofización del dolor (Quartana, Campbell, y Edwards, 2009), el miedo y ansiedad ante el dolor (Turk, Robinson, y Burwinkle, 2004), y la indefensión y la hipervigilancia al dolor (Crombez, Eccleston, Van den

Broeck, Goubert, y Van Houdenhove, 2004). Por otro lado, se ha observado que existen factores cognitivo-afectivos que reducen el impacto de la intensidad del dolor y mejoran la adaptación al dolor crónico (Keefe et al., 2004), entre los que figuran las expectativas de auto-eficacia sobre el manejo del dolor (Sánchez, Martínez, Miró, y Medina, 2011), ciertos tipos de estrategias de afrontamiento (Amir et al, 2000), y la disposición al cambio y la aceptación del dolor (McCracken y Eccleston 2006).

Estos factores han sido considerados en el *Modelo de Miedo-Evitación del Dolor* (ver Figura 3) (Leeuw et al., 2007), modelo que integra teóricamente y con sólida evidencia empírica, las mencionadas variables y los aspectos de la personalidad (Martínez, Sánchez, Miró, Medina, y Lami, 2011) como factores que afectan negativamente la experiencia de dolor, el malestar emocional y el funcionamiento diario en pacientes con dolor crónico (Vlaeyen y Linton, 2000, 2012). Este modelo sugiere que ante la percepción de un estímulo doloroso, independientemente de la severidad de éste, en algunas personas se dispara una respuesta de miedo y ansiedad, caracterizada por la percepción de amenaza del dolor y su correlativa reacción psicofisiológica (reacciones de ansiedad), conductual (tendencia al escape o la evitación), y cognitiva (valoración de la experiencia). El precursor del miedo al dolor sería la catastrofización del dolor, que se refiere a la dimensión cognitiva del miedo al dolor (Leeuw et al., 2007) y se describe como una tendencia a una interpretación negativa y magnificada de la severidad del dolor y de sus consecuencias (Quartana et al., 2009). Dicha reacción de miedo, llevaría al paciente a desarrollar y enfocar de manera excesiva su atención a posibles sensaciones dolorosas y a un permanente escaneo corporal en forma de chequeo de sensaciones displacenteras, y esto es lo que se identifica como hipervigilancia al dolor. A su vez, la hipervigilancia al dolor, llevaría a la activación psicofisiológica de miedo cuando se identifica una sensación dolorosa como peligrosa

(Crombez, Van Damme, y Eccleston, 2005). Asimismo, vendrían asociadas reacciones de escape y evitación como conductas de excesivo cuidado ante posibles daños, discapacidad o dificultades en la ejecución de actividades de la vida diaria (Boersma y Linton, 2005), así como el llamado "síndrome de desuso", caracterizado por un deterioro gradual del sistema muscular y la aptitud física de la persona, que repercute a nivel fisiológico y psicológico (Verbunt et al., 2003). Estas reacciones cognitivas, emocionales y conductuales producen un espiral disfuncional a largo plazo y disminuyen las actividades valoradas por la persona como el trabajo, ocio, contacto social, etc., lo que provoca consecuencias negativas en el estado de ánimo (Vlaeyen y Crombez, 2007). Es importante destacar, que además de las variables mencionadas en el *Modelo de Miedo-Evitación del Dolor*, existen numerosos estudios que se han centrado en cada eslabón del proceso. Es así como se ha identificado que un estilo de afrontamiento centrado en la solución del problema, está relacionado con una mejor adaptación psicológica al dolor (Peres y Lucchetti, 2010) y un afrontamiento centrado en la emoción se asocia a una peor salud mental en las mujeres (Boehm, Eisenberg, y Lampel, 2011). La aceptación del dolor, entendida como la disposición para abrirse a experimentar y sentir las sensaciones dolorosas sin juzgarlas y aun así manteniendo el compromiso de la persona en participar en actividades significativas de la vida, ha sido relacionada en el dolor crónico con un mejor funcionamiento diario, menor sintomatología ansiosa y depresiva, y menos catastrofización del dolor (Boer, Steinhagen, Versteegen, Struys, y Sanderman, 2014; Esteve, Ramírez-Maestre, y López-Martínez, 2007).

Asimismo, el *Modelo de Miedo-Evitación del Dolor* contempla la influencia de las variables de personalidad asociadas, dado que en pacientes con FM se ha constatado un perfil de personalidad clínico orientado a la manifestación de una amplia variedad de

síntomas somáticos, problemas de salud y mal funcionamiento físico (Pérez-Pareja, Sesé, González-Ordi, y Palmer, 2010). El neuroticismo, característico en estos pacientes (Malt, Olafsson, Lund, y Ursin, 2002), es un predictor significativo de las manifestaciones conductuales desadaptativas ante el dolor (Lauver y Johnson, 1997). La alexitimia, como rasgo de personalidad, también se ha visto asociada de manera indirecta a una mayor intensidad del dolor (Lumley et al., 2011), así como otros síntomas de la FM. Asimismo, se ha observado que los pacientes con FM presentan mayores limitaciones en la experiencia y conexión con estados afectivos, así como en reconocimiento de emociones en sí mismos y en los demás (habilidades de cognición social) (Di Tella et al., 2015).

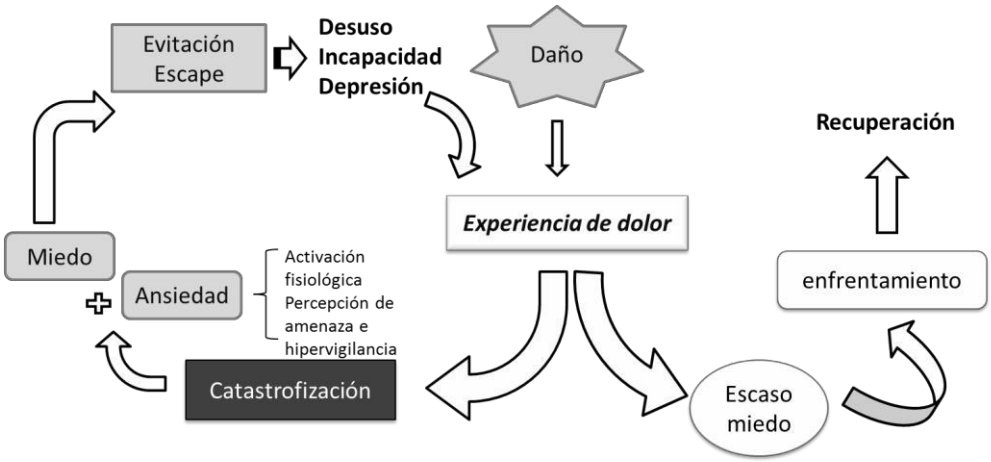


**Figura 3**. Modelo de Miedo-Evitación del Dolor Crónico. Adaptado de Vlaeyen y Linton (2000) y Leeuw et al. (2007).

### 3.1 Relación entre el sueño y el dolor en la FM

Uno de los criterios diagnósticos actuales más importantes en la FM hace referencia a las dificultades del sueño (Wolfe et al., 2010), representando una de las

manifestaciones clínicas más frecuentemente informadas por los pacientes (Wagner, DiBonaventura, Chandran, y Cappelleri, 2012). Estudios recientes han hallado que del 88,75% al 96% de los pacientes con FM manifiestan problemas de sueño o refieren tener un sueño poco reparador (Bigatti, Hernandez, Cronan, y Rand, 2008). Asimismo, se ha observado que los criterios diagnósticos para el insomnio se presentan en una frecuencia cinco veces mayor en pacientes con FM que en pacientes con artritis reumatoide (Belt, Kronholm, y Kauppi, 2009). Diferentes estudios han analizado la relación entre las perturbaciones en el sueño y la exacerbación de los síntomas de la FM, informando que la pobre calidad de sueño está relacionada con el estado de ánimo negativo, mayores y más intensas reacciones emocionales a eventos negativos (Hamilton, Catley, y Karlson, 2007), así como el subyacente estado de hiperalgesia (hipersensibilidad corporal) y fatiga observado en estos pacientes (Moldofsky, 2008, 2009), produciendo una relación cíclica entre patrones anormales del sueño y dolor (Moldofsky, 2010). Existe una relación bidireccional entre el sueño y el dolor que contribuye a la cronificación del cuadro clínico, donde consecuente a una noche de sueño no reparador se observa un aumento de dolor durante el día, y a un día con dolor, le sigue una noche con pobre calidad de sueño (O'Brien et al., 2011) (véase Figura 4). Los primeros estudios en relacionar la influencia de las perturbaciones del sueño y el dolor observaron que la disrupción experimental del sueño de ondas lentas (*Slow Wave Sleep*, SWS) en sujetos sanos inducía dolor músculo-esquelético y fatiga (Moldofsky, Scarisbrick, England, y Smythe, 1975). Recientes revisiones en pacientes con FM, han destacado la presencia de alteraciones en la microestructura del sueño, una reducción del tiempo total de sueño, un incremento en las latencias del sueño y de microarousal (despertares) generando una fragmentación del sueño de ondas lentas (SWS) y una reducción del tiempo de sueño REM (*Rapid Eyes Movement*) (Diaz-Piedra, Si Stiasi,

Baldwin, Buela-Casal, y Catena, 2015; Prados y Miró, 2012). En el análisis polisomnográfico de los pacientes con FM se ha observado una superposición anómala de ondas alfa en el SWS, lo que se denomina ritmo alfa-delta (Roizenblatt, Moldofsky, Benedito-Silva, y Tufik, 2001). Esta característica en la neurofisiología del sueño es la que generaría un hiperarousal fisiológico que perjudica la continuidad y arquitectura normal del sueño y explicaría el dolor músculo-esquelético y la fatiga de estos pacientes (Branco, Atalaia, y Paiva, 1994), dado que durante la fase lenta del sueño se genera la hormona del crecimiento y su mediador, ambos encargados de la reparación y homeostasis celular del músculo (Bradley, 2009). Otro patrón característico en el electroencefalograma (EEG) observado en el sueño de las pacientes con FM, es una recurrencia de ondas complejo K-alfa (*K-complex)* caracterizado por "patrón cíclico alternante" de arousal y actividad de frecuencia baja en el EEG, que estarían asociadas a la percepción del sueño poco reparador y una menor eficiencia del sueño (MacFarlane, Shahal, Mously, y Moldofsky, 1996; Rizzi et al., 2004). Por otro lado, también se ha observado una baja dominancia de la actividad parasimpática del sistema nervioso autónomo (SNA), generando una variabilidad de la tasa cardíaca durante el sueño en estos pacientes (Martinez-Lavin, Hermosillo, Rosas, y Soto, 1998). Dicha desregulación del SNA está relacionada con el dolor y el sueño, síntomas característicos en la FM (Lerma et al., 2011).

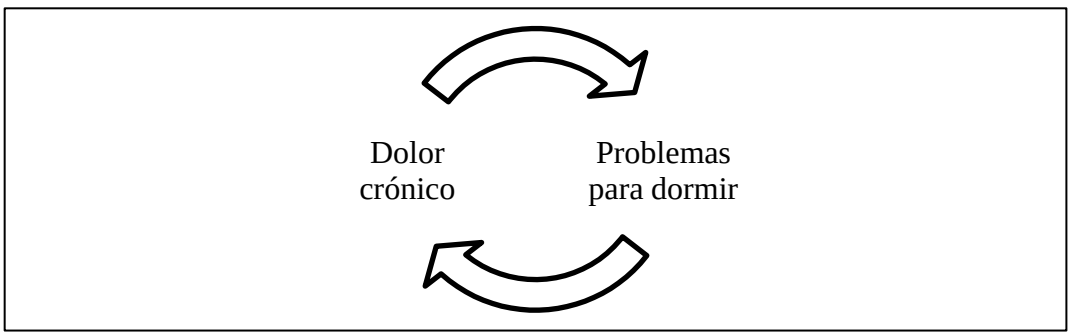


**Figura 4.** Relación recíproca entre perturbaciones en el sueño y el dolor crónico.

En lo referido a las investigaciones sobre la calidad del sueño, también se han utilizado medidas de auto-informe de manera válida, dado que se ha descripto la importancia de revelar la percepción subjetiva desde el punto de vista del paciente (Aletaha et al., 2008). En este sentido, ya se ha mencionado la relación bidireccional y potenciadora entre las dificultades en el sueño, dolor y otras manifestaciones clínicas en la FM (Prados y Miró, 2012). Aunque la investigación en esta área, está todavía en desarrollo, algunos estudios han demostrado la relación secuencial que existe entre una mala calidad de sueño y la exacerbación de síntomas asociados a la FM. Affleck et al. (1996), Bigatti et al. (2008) y Nicassio et al. (2002) realizaron estudios longitudinales evaluando la calidad de sueño en pacientes con FM y observaron que una pobre calidad de sueño conlleva una mayor intensidad de dolor, fatiga e impacto funcional, lo que afecta negativamente al sueño de manera cíclica. Otros estudios han revelado que el sueño media las relaciones entre el estrés y las emociones negativas y entre el dolor y las emociones en general (Hamilton, Catley, y Karlson, 2007).

Estas investigaciones han sido tenidas en cuenta para la elaboración de tratamientos psicológicos con el objetivo de mejorar la calidad de vida de los pacientes diagnosticados con FM.

## 4. Tratamientos psicológicos en la FM

Tanto la Asociación Americana del Dolor (APS, *American Pain Society*) (Burckhardt et al., 2005), como el Documento de Consenso Interdisciplinario Español (Alegre de Miquel et al., 2010**)** recomiendan el tratamiento multidisciplinar para el abordaje de las pacientes con FM, enfatizando la superioridad de las intervenciones psicológicas basadas en la terapia cognitivo-conductual (TCC) (Häuser, Thieme, y Turk, 2010), especialmente para aquellos pacientes con tendencia a la catastrofización

del dolor y con síntomas depresivos. En la actualidad, existen numerosos estudios sobre la eficacia de distintas aproximaciones al tratamiento de la FM, considerando de mayor eficacia los programas multimodales que incluyen tratamientos farmacológicos, ejercicio físico y fisioterapia, psicoeducación y tratamiento psicológico (Hasset y Gevirtz, 2009). En lo que respecta al tratamiento psicológico desde una perspectiva biopsicosocial, recientes revisiones refieren que los tratamientos de base cognitivo-conductual son eficaces para reducir la intensidad del dolor, los síntomas depresivos (Glombiewsky et al., 2010), para mejorar las estrategias de afrontamiento, y para el aumento de la autoeficacia y la reducción de conductas de dolor (Bernardy, Fueber, Koellner, y Häuser, 2010; Bernardy, Klose, Busch, Choy, y Häuser, 2013).

Con anterioridad se ha establecido la concomitancia y la relación recíproca existente entre los problemas de sueño, la intensidad del dolor y los demás síntomas característicos en la FM. Dado que estudios previos han establecido que la privación del sueño produce disminución del umbral del dolor (Moldofsky, 2010) y a su vez, el dolor no permite una óptima calidad del sueño, cabe presuponer que la intervención en el sueño pueda revertir positivamente en las manifestaciones clínicas anteriores. Por ello, los investigadores han evaluado y desarrollado intervenciones para pacientes con FM y otros síndromes de dolor crónico destinadas a la mejora del sueño-insomnio (TCC-I) (véase Martínez, Miró, y Sánchez, 2014 para una revisión), así como han recomendado abordajes híbridos orientados al sueño y al dolor (TCC-ID) (Tang, 2009). Las intervenciones cognitivo-conductuales centradas en el insomnio incluyen como ejes fundamentales la higiene del sueño, la terapia de control de estímulos y la restricción del sueño. La higiene del sueño posee un enfásis educacional orientado a dar a conocer los componentes ambientales y de estilo de vida que afectan a la calidad de sueño. Los demás componentes son de carácter conductual y consisten en controlar los estímulos

que se han condicionado con conductas incompatibles al dormir (Buela-Casal y Sánchez, 2002), y buscar la reducción del tiempo en cama con el objetivo de modificar los hábitos de sueño incorrectos que agravan el problema de insomnio (Morin, 1998).

Aunque la evidencia es todavía incipiente se ha analizado esta cuestión en diversos síndromes de dolor utilizando TCC-I (Currie, Wilson, Pontefract, y deLaplante, 2000; Vitiello, Rybarczyk, Von Korff, y Stepanski, 2009; Jungquist et al., 2010; Rybarczyk et al., 2005), y sólo el estudio de Edinger, Wohlgemuth, Krystal, y Rice (2005) y nuestro grupo de investigación han evaluado la eficacia de la TCC-I en pacientes con FM. Aún son escasos los estudios como para aseverar la eficacia de los tratamientos orientados al dolor y al sueño en pacientes con FM, sin embargo los datos actuales en pacientes con dolor crónico, refieren prometedores resultados en esta área. Las revisiones indican que la modalidad combinada (TCC-ID) permite obtener beneficios clínicos destacados en diversas condiciones de dolor crónico (Finan, Buenaver, Runko, y Smith, 2014), sobre parámetros como latencia de inicio del sueño, eficiencia del sueño, insomnio, creencias disfuncionales sobre el sueño, arousal cognitivo pre-sueño, y ansiedad relacionada con el sueño.

Finalmente, se puede asegurar que es necesaria más investigación para determinar la eficacia de los abordajes con base cognitivo-conductual orientados al sueño y al dolor para determinar los beneficios que redundan en la mejora de la calidad de vida de los pacientes con FM, siendo un síndrome crónico y notablemente incapacitante.

Los presentes seis trabajos de investigación enmarcados en la tesis doctoral titulada "Eficacia de la terapia cognitivo-conductual frente al tratamiento médico estándar en mujeres con fibromialgia", se han planteado con el propósito de obtener una mayor compresión sobre las variables psicológicas intervinientes en el impacto del síndrome

de la FM y sus principales síntomas, así como la capacidad del tratamiento psicológico basado en la terapia cognitiva-conductual en sus diferentes modalidades, para ayudar a estos pacientes y contribuir al actual tratamiento médico estándar de este síndrome de dolor.

En el primer estudio se realizó un análisis de las propiedades psicométricas de la Escala de Vigilancia y Conciencia del Dolor (PVAQ) versión española, en una muestra de pacientes con FM. Teniendo en cuenta que la hipervigilancia al dolor constituye una variable cognitivo-afectiva que contribuye a la experiencia de dolor, resulta sustancial contar con un instrumento fiable para ser aplicado en nuestro contexto. De este modo, el presente estudio posibilitó conocer los valores de fiabilidad y validez de una versión corta (9 ítems) del instrumento, así como los puntos de corte en población española. El presente trabajo constituye el primer estudio de las propiedades psicométricas del PVAQ en muestra de mujeres españolas con diagnóstico de FM.

El segundo estudio incluye dos investigaciones empíricas que permitieron evaluar a través de auto-informes las relaciones entre las principales variables que integran el Modelo de Miedo-Evitación del Dolor y los síntomas que afectan a las pacientes con FM. El primer trabajo se planteó como objetivo examinar el rol moderador de la alexitimia en la relación entre la valoración cognitivo-afectiva del dolor y el malestar emocional. El segundo trabajo indagó sobre el efecto mediador de la catastrofización del dolor, las estrategias de afrontamiento y la aceptación del dolor crónico entre la percepción del dolor y síntomas de depresión, ansiedad y el impacto de la FM.

El tercer estudio consistió en una revisión teórica narrativa, con el objetivo de analizar estudios empíricos sobre los tratamientos psicológicos de la FM, realizados entre los años 1990 y 2012. Esta revisión permitió obtener información del estado de

arte de los desarrollos con base en distintos modelos teóricos psicológicos para el abordaje de la FM. Los tratamientos psicológicos con mayor desarrollo continúan siendo los que incluyen técnicas con apoyo en los principios cognitivo-conductuales, e incluyen reestructuración cognitiva, entrenamiento en relajación, habilidades de comunicación asertiva y resolución de problemas, así como la inclusión de actividades agradables, encontrando el equilibrio entre la actividad y el descanso, entre otras herramientas de cambio. Todas éstas orientadas a la modificación de variables cognitivo-afectivas de dolor y otros síntomas asociados al cuadro clínico, y evaluadas a través de autoinformes, entrevistas e instrumentos objetivos.

El estudio cuarto estuvo compuesto por dos investigaciones destinadas a evaluar la eficacia de la TCC enfocada al dolor (TCC-D), enfocada al insomnio (TCC-I) y combinando el abordaje centrado en el dolor y el insomnio (TCC-ID). El primero se trata de un estudio preliminar con el objetivo de evaluar la eficacia diferencial entre hombres y mujeres tras haber recibido TCC-I. Este estudio analizó las diferencias entre los valores pre-tratamiento, post-tratamiento, y seguimiento en grupos de mujeres y hombres, en las manifestaciones sintomáticas asociadas a la FM. En este estudio preliminar, se observó que los hombres manifestaron mejorías en ciertas variables en las que las mujeres no manifestaron cambios y viceversa; concluyendo en la necesidad de mayor investigación en este ámbito para dar respuesta a necesidades diferentes entre los géneros. El segundo trabajo constituyó un ensayo aleatorio y controlado donde se estableció como objetivo evaluar la eficacia de la TCC-I en comparación con la TCC-ID y el tratamiento médico estándar sobre los paramétros del sueño y las manifestaciones clínicas de las mujeres con FM. Se observaron importantes cambios positivos en distintas variables que afectan al bienestar de estas pacientes. Estas mejorías se exhibieron de manera diferencial entre los grupos que recibieron las distintas

modalidades de TCC. Estos resultados permitieron una discusión profunda y exhaustiva de las implicaciones de la terapia psicológica con orientación cognitivo-conductual para lograr una disminución de la sintomatología asociada a la FM y mejorar la calidad de vida de estos pacientes.

# PRIMER ESTUDIO

*Artículo 1*

# Spanish Version of the Pain Vigilance and Awareness Questionnaire: Psychometric Properties in a Sample of Women with Fibromyalgia

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# Spanish Version of the Pain Vigilance and Awareness Questionnaire: Psychometric Properties in a Sample of Women with Fibromyalgia

**Abstract.** Excessive attention to pain is a common psychological characteristic among people who suffer from chronic pain. The Pain Vigilance and Awareness Questionnaire (PVAQ) is an internationally accepted tool to assess this feature, although there is no validated version of this measure for Spanish people with fibromyalgia. Since this pain syndrome mainly affects women, the aim of this study was to determine the psychometric properties of the PVAQ in Spanish women with fibromyalgia. A group of 242 women diagnosed with fibromyalgia aged between 20 and 66 years participated in the study. The goodness of fit of several structures of the PVAQ reported in previous studies was compared via confirmatory factor analysis. A two-factor solution (active vigilance and passive awareness) of the 9-item shortened version (PVAQ-9) was identified as the most appropriate (RMSEA = .08, NNFI = .96, CFI = .97, GFI = .87). It showed good reliability (internal consistency $\alpha$ = .82), convergent validity and divergent validity ($p < .01$). The optimal cutoff point for identifying fibromyalgia women with worse daily functioning was a score of 24.5, with a sensitivity of .71 and a specificity of .75. The relevance of vigilance to pain for clinical research in fibromyalgia is discussed.

**Keywords:** pain, fibromyalgia, vigilance, reliability, validity.

Fibromyalgia (FM) is characterized by widespread musculoskeletal pain for at least three months and pain on pressure in at least 11 of the 18 tender points (Wolfe et al., 1990). In addition to pain, FM patients experience other disturbing symptoms such as fatigue/tiredness, insomnia, muscle weakness, irritable bowel syndrome, nervousness, depression, and thinking/remembering problems (Wolfe et al., 2010). In Spain, FM has a prevalence of 2.3–4% (Branco et al., 2010) and the mean annual direct ambulatory cost per patient is higher in the FM group (908.67€) than in the reference medical group (555.58€) (Sicras-Mainar, Blanca-Tamayo, Navarro-Artieda, & Rejas-Gutiérrez, 2009).

Pain hypervigilance (i.e., excessive attention to pain and constant scanning of the body for annoying sensations) is a cognitive feature that intensifies pain perception and maladaptive responses to chronic musculoskeletal pain. Pain hypervigilance is an automatic and efficient process that emerges when painful sensations are appraised as dangerous, the fear system is activated, and the current goal is related to avoidance of/escape from pain (Crombez, Van Damme, & Eccleston 2005). Attentional processing of pain stimuli is a dynamic process that is modulated by competing demands, and pain may be given less priority when other competing and highly valued goals are present (Van Damme, Legrain, Vogt, & Crombez, 2010). In patients with chronic pain, the level of attention to pain has been associated with pain-related anxiety, depression, pain severity, physical and psychosocial disability, and number of physical visits due to pain (McCracken, 1997), pain severity, pain catastrophizing, and fear of movement/(re)injury (Goubert, Crombez, & Van Damme, 2004), and pain catastrophizing and pain anxiety (Martínez, Sánchez, Miró, Medina, & Lami, 2011). In the influential fear-avoidance model of chronic pain (Leeuw et al., 2007; Vlaeyen &

Linton, 2000), pain hypervigilance is considered to explain the exacerbation of pain experience in musculoskeletal pain. According to this model, individuals who interpret pain catastrophically tend to experience fear of and anxiety about pain. This leads them to pay excessive attention to bodily signals and to show avoidance/escape behaviors toward activities that they believe increase the pain. These processes lead to deterioration of the muscular system and the ability to function and to the development of depressive symptoms. All this exacerbates the pain experience, contributing to a spiral that increases fear and avoidance. There is important empirical evidence supporting the validity of this model (for a review, see Leeuw et al., 2007; Pincus, Smeets, Simmonds, & Sullivan, 2010).

One of the main instruments used to assess pain hypervigilance is the Pain Vigilance and Awareness Questionnaire (PVAQ), a 16-item self-report measure developed by McCracken (1997). In 80 American patients with low back pain, the PVAQ showed adequate internal consistency, test-retest reliability, construct validity, and criterion validity (McCracken, 1997). An exploratory factor analysis (EFA) conducted with 256 Canadian university students revealed a hierarchical model with three lower-order factors (awareness of change, intrusion, and monitoring) and a single higher-order pain vigilance and awareness factor; the scale was found to have acceptable internal consistency and criterion validity (McWilliams & Asmundson, 2001). In 271 Dutch college students, an EFA showed a two-factor structure (attention to pain and attention to changes in pain), suitable internal consistency, test-retest reliability, and convergent and divergent validity (Roelofs, Peters, Muris, & Vlaeyen, 2002). In that study, a confirmatory factor analysis (CFA) conducted with 207 Dutch college students indicated good fit of the two and three-factor models; yet, the intrusion factor showed low internal consistency in the three-factor model. An EFA performed

with 200 Dutch FM patients replicated the two-factor solution with 14 items (PVAQ-14), and a CFA conducted with 276 American patients with various chronic pain syndromes and 201 Dutch FM patients showed good fit of the two and three-factor solutions; however, the intrusion and monitoring subscales (i.e., three-factor model) were highly intercorrelated, suggesting that they represent the same construct (Roelofs, Peters, McCracken, & Vlaeyen, 2003). In that study, the PVAQ-14 showed adequate internal consistency and convergent validity in Dutch patients. In 227 American patients with chronic pain, an EFA revealed a two-factor structure (active vigilance and passive awareness) with 13 items (PVAQ-13), and this scale showed adequate internal consistency (McCracken, 2007). In 242 Chinese patients with chronic pain, a CFA and a comparison between different factor solutions (i.e., two- and three-factor, hierarchical and non-hierarchical) identified the two-factor structure proposed by McCracken (2007) as having the best data-model fit, and this scale showed acceptable internal consistency and construct and predictive validity (Wong, McCracken, & Fielding, 2011). Finally, in 468 Spanish patients with chronic low back pain, a comparison of various structures (i.e., single-, two-, and three-factor structures) via CFA identified the two-factor structure proposed by Roelofs et al. (2003) as the most suitable (Esteve, Ramírez-Maestre, & López-Martínez, 2013). In that study five items were excluded in order to optimize model fit, resulting in a 9-item version (PVAQ-9) with active vigilance and passive awareness factors, and this scale showed adequate internal consistency and convergent validity.

Previous research has shown that the PVAQ is a valid and reliable measure and that the two-factor model is the most replicated structure. However, no psychometric studies of the PVAQ have been conducted with Spanish patients with FM. The only study with a Spanish population was conducted with subjects with low back pain, a pain

condition that greatly differs from FM. Since FM is more prevalent in women than in men (Branco et al., 2010) and women suffer from greater clinical pain and pain-related distress than men (Paller, Campbell, Edwards, & Dobs, 2009), it may be important to develop a Spanish version of the PVAQ for use in FM women. Therefore, this study included FM women and was aimed at analyzing the following:

a. The goodness of fit of several two-factor structures of the PVAQ identified in previous studies. The proposed hypothesis was that the PVAQ-9 would show the best fit.

b. The reliability (i.e., internal consistency) and construct validity (i.e., convergent, divergent, and predictive validity) of the most appropriate PVAQ structure. The proposed hypothesis was that the PVAQ would show high correlations with pain-related cognitive-affective variables (i.e., pain catastrophizing and pain anxiety) and moderate correlations with pain intensity, impairment, and emotional distress (i.e., anxiety and depression).

## Method

### *Participants and Procedure*

The sample was composed of 242 FM women recruited through consecutive sampling from the Pain Unit and Rheumatology Service of Hospital Universitario Virgen de las Nieves in Granada, Spain, and several associations of FM patients in Andalusia, Spain. Inclusion criteria were: (a) being a woman aged between 18 and 67 years, (b) having adequate reading comprehension, and (c) having been diagnosed with FM according to the criteria of the American College of Rheumatology (ACR, Wolfe et al., 1990). Exclusion criteria were: (a) presence of other chronic pain conditions, (b) presence of serious medical illness, (c) presence of a major depressive disorder with severe symptoms or suicide ideation or other major Axis I disorders of the DSM-IV-TR

(APA, 2000), and (d) a history of alcohol or drug abuse. Patients were administered a semi-structured interview collecting socio-demographic and clinical data (i.e., onset and course of FM symptoms, life history, lifestyle, work, personal relationships, the family and the patient‟s attitudes about illness, and psychological status). In this interview, the possible presence of psychological problems was assessed through a shortened and adapted screening test derived from the structured clinical interview for DSM-IV Axis I disorders (SCID-I) (First, Spitzer, Gibbon, & Williams, 1999). After that, they were given several questionnaires to complete at home and deliver within a week.

A total of 325 FM women from the hospital and the FM associations were invited to participate in a study about the relationships between perceived health status and pain-related behaviours and attitudes. As 46 subjects did not meet the criteria to participate in the study, 21 subjects refused to participate in the study, and 16 subjects did not return the questionnaires, the final sample was composed of 242 subjects.

The mean age of participants was 48.29 years (*SD* = 8.23). Most of them were married (81%) and had secondary studies (38.4%), elementary studies (33.8%) or university studies (27.9%). As regards labor status, 41.3% were active workers, 24.6% were off work on disability, 20.4% were unemployed, and 13.8% were retired/students. Mean time since FM diagnosis was 5.43 years (*SD* = 4.41). Most participants (88.54%) were receiving drug treatment. All patients signed informed consent to participate in the research. The study was approved by the Ethics Committee of the University of Granada.

***Instruments***

The McGill Pain Questionnaire-Short Form (MPQ-SF, Melzack, 1987) assesses the pain experience via 15 verbal descriptors of pain, an index of current pain intensity,

and a visual analog scale to assess pain intensity during the last week (from 1 = no pain to 10 = extreme pain). Several studies (e.g., Lázaro et al., 2001) have reported the reliability and validity of the Spanish version of the MPQ.

The Fibromyalgia Impact Questionnaire (FIQ, Burckhardt, Clark, & Bennett, 1991) consists of 10 items assessing health status in FM patients. Item 1 explores daily functioning ability (scored from 0 to 3), items 2 and 3 evaluate the days per week that the subject feels well/unable to work, and items 4 through 10 assess physical and emotional symptoms (scored from 0 to 10). The Spanish version has shown adequate reliability, validity and sensitivity to change (Rivera & González, 2004).

The Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983) assesses symptoms of anxiety and depression in non-psychiatric hospital settings with 14 items (scored from 0 to 3). It includes two subscales: Anxiety and Depression. The Spanish version has shown appropriate internal consistency in chronic pain patients (Vallejo, Rivera, Esteve-Vives, Rodríguez-Muñoz, & ICAF Group, 2012).

The Pain Vigilance and Awareness Questionnaire (PVAQ, McCracken, 1997) evaluates awareness, consciousness, vigilance, and observation of pain through 16 items measured on a Likert scale from 0 (never) to 5 (always). The PVAQ has shown acceptable reliability and validity (see the Introduction section).

The Pain Anxiety Symptoms Scale (PASS-20, McCracken & Dhingra, 2002) explores fear, escape/avoidance, physiological anxiety, and cognitive anxiety. It includes 20 items scored from 0 (never) to 5 (always) on a Likert scale. The PASS-20 has shown good internal consistency, reliability, and predictive and construct validity (McCracken & Dhingra, 2002).

The Pain Catastrophizing Scale (PCS, Sullivan, Bishop, & Pivik, 1995) consists of 13 items assessing rumination, magnification, and helplessness scored from 0 (not at

all) to 4 (all the time) on a Likert scale. The Spanish version has shown adequate internal consistency, test-retest reliability, and sensitivity to change (García-Campayo et al., 2008).

The PVAQ was translated into Spanish, and then translated back into English in order to ensure semantic equivalence. Only small semantic differences between both translations were identified in several items and these differences were reconciled by a professional English translator.

***Data Analysis***

Considering the subject:item ratio (10:1) recommended for factor analysis (Thorndike, 1982), and since the PVAQ includes 16 items, a minimum sample size of 160 subjects was required, so the sample recruited (242 FM women) was adequate. Data were computed with SPSS 20.0 and LISREL 8.80. Significance levels < .05 were considered. In order to identify the most suitable factor model of the PVAQ, a CFA with the Robust ML method was applied. The following indexes were computed: Satorra-Bentler $\chi^2$ statistic, Root Mean Square Error of Approximation (RMSEA), Non-Normed Fit Index (NNFI), Comparative Fit Index (CFI), Goodness of Fit Index (GFI) and Expected Cross Validation Index (ECVI). Values < .08 in the RMSEA (Thompson, 2004), and > .90 in the NNFI, CFI and GFI (Stevens, 2002) indicated acceptable model fit.

Reliability (internal consistency) of the PVAQ was examined with Cronbach‟s alpha, considered as suitable minimum values between .70 and .80 (Nunnally & Bernstein, 1995). The standard error of measurement was also estimated. The convergent and divergent validity of the PVAQ was determined by the magnitude of the relationship with other variables using the Pearson correlation coefficient. Correlations

were considered low (from .10 to .29), medium (from .30 to .49), or high (.50 or higher) (Cohen, 1988). An ROC curve was obtained to examine the predictive validity of the PVAQ in identifying FM patients with clinical/high levels of pain, FM impact, anxiety, and depression. For the instrument to be predictive, the area under the curve must be > .50. The cutoff score with the best sensitivity and specificity was identified.

## Results

### *Descriptive Statistics*

As expected, pain intensity in the last week ($M$ = 7.48, $SD$ = 1.56) was relatively high in FM patients. FM impact ($M$ = 61.05, $SD$ = 14.70) was severe (score ≥ 59) (Bennett, Bushmakin, Cappelleri, Zlateva, & Sadosky, 2009). Anxiety ($M$ = 11.03, $SD$ = 4.48) indicated clinical range (score ≥ 11), and depression ($M$ = 9.93, $SD$ = 4.69) was indicative of a doubtful clinical problem (score between 8 and 10) (Zigmond & Snaith, 1983). Pain vigilance ($M$ = 45.32, $SD$ = 12.64), pain catastrophizing ($M$ = 25.79, $SD$ = 12.48), and pain anxiety ($M$ = 48.64, $SD$ = 20.31) were similar to those reported in previous studies (e.g., Roelofs et al., 2003). Table 1 shows the descriptive statistics for each item of the PVAQ.

**Table 1**. Mean (M), Standard Deviations (SD), Item-Total Correlation ($r_{tot}$) and Internal Consistency (α) if the Item is Deleted of the PVAQ

| Items | *M* | *DT* | $r_{tot}$ | $\alpha$ |
|---|---|---|---|---|
| 1. I am very sensitive to pain | 2.87 | 1.48 | .48 | .79 |
| 2. I am aware of sudden or temporary changes in pain | 3.89 | 1.29 | .54 | .79 |
| 3. I am quick to notice changes in pain intensity | 3.91 | 1.25 | .55 | .79 |
| 4. I am quick to notice effects of medication on pain | 2.34 | 1.50 | .27 | .81 |
| 5. I am quick to notice changes in localization or extent of pain | 3.67 | 1.24 | .50 | .79 |
| 6. I focus on sensations of pain | 2.12 | 1.49 | .56 | .79 |
| 7. I notice pain even if I am busy with another activity | 3.82 | 1.41 | .38 | .80 |
| 8. I find it easy to ignore pain | 2.55 | 1.73 | −.01 | .83 |
| 9. I know inmediately when pain starts or increases | 3.68 | 1.50 | .59 | .79 |
| 10. When I do somethig that increases pain, the first thing I do is check to see how much pain was increased | 1.70 | 1.65 | .47 | .80 |
| 11. I konw inmediately when pain decreases | 3.29 | 1.59 | .43 | .80 |
| 12. I seem to be more conscious of pain than others | 2.14 | 1.75 | .45 | .80 |
| 13. I pay close attention to pain | 1.85 | 1.46 | .58 | .79 |
| 14. I keep track of my pain level | 2.20 | 1.54 | .53 | .79 |
| 15. I become preoccupied with pain | 2.76 | 1.60 | .47 | .79 |
| 16. I do not dwell on pain | 2.45 | 1.51 | −.02 | .83 |

***Confirmatory Factor Analysis***

As a previous step to the CFA, multivariate normality was examined and atypical observations in the PVAQ were identified. Missing values (0.36%) were imputed with the expected maximization method. Seven cases were excluded due to outliers, so the final sample was composed of 235 subjects. The multivariate normality test showed non-normal values for both asymmetry ($z = 17.97$, $p < .001$) and kurtosis ($z = 10.52$, $p < .001$), so a CFA with the Robust ML method was computed.

Table 2 shows the CFAs corresponding to the two-factor models proposed in previous research. Results showed good fit of the three models based on NNFI and CFI indexes, while GFI and RMSEA indexes were not adequate. The PVAQ-9 was identified as the best structure, with slightly better indexes than the others. The standardized factor loadings of the PVAQ-9 items were significant ($p < .05$) (see Figure 1). The remaining analyses were conducted using the structure of the PVAQ-9.

**Table 2.** Goodness of Fit Indexes of the Structural Models Proposed for the PVAQ

| Model | *Satorra-Bentler* $\chi^2$ | *df* | *RMSEA* | *ECVI* | *NNFI* | *CFI* | *GFI* |
|---|---|---|---|---|---|---|---|
| Two-factors model, PVAQ-14 (Roelofs et al., 2003) | 216.21 | 76 | .08 | 1.17 | .94 | .95 | .80 |
| Two-factors model, PVAQ-13 (Wong et al., 2011) | 160.01 | 64 | .08 | 0.91 | .95 | .96 | .83 |
| Two-factors model, PVAQ-9 (Esteve et al., 2013) | 69.83 | 26 | .08 | 0.46 | .96 | .97 | .87 |

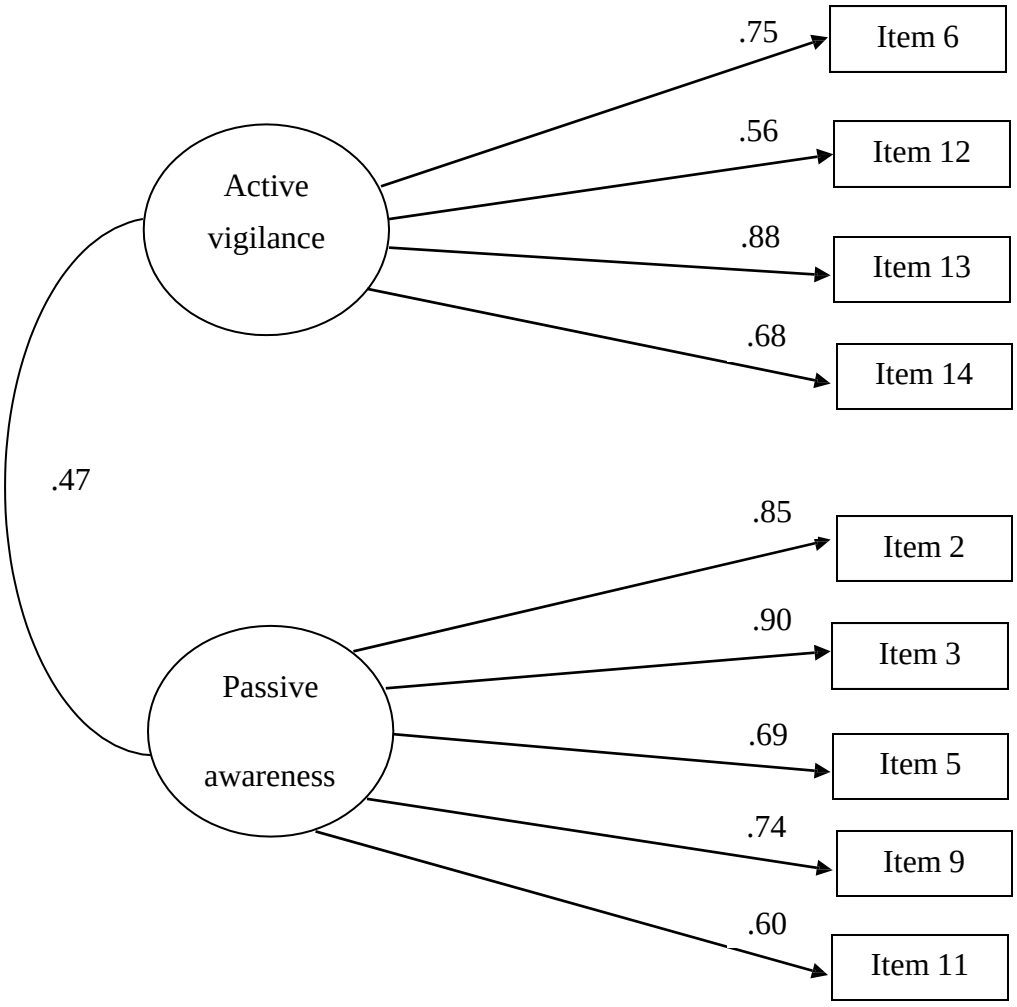


*Figure 1.* Standardized solution for the two-factor model of the PVAQ-9 (Esteve et al., 2013).

***Reliability and Validity***

The reliability (internal consistency) of the PVAQ-9 was adequate in the total scale ($\alpha$ = .82) and subscales (active vigilance, $\alpha$ = .76, and passive awareness, $\alpha$ = .82). In the PVAQ-9, the standard error of measurement was 3.64. The PVAQ-9 showed significant and low correlations with anxiety ($r$ = .22, $p$ < .01) and depression ($r$ = .20, $p$ < .01), indicating divergent validity, and significant and high correlations with pain anxiety ($r$ = .55, $p$ < .01) and pain catastrophizing ($r$ = .53, $p$ < .01), indicating convergent validity. The PVAQ-9

showed significant and moderate correlations with pain intensity in the last week ($r$ = .30, $p$ < .01) and FM impact ($r$ = 0.36, $p$ < .01).

An ROC curve was used to study the predictive validity of the PVAQ-9 and several groups were established to examine this psychometric characteristic. Two groups were created based on current pain intensity (MPQ-SF): patients who estimated pain as low (absent, mild, or uncomfortable) ($n$ = 103) and patients who estimated pain as high (intense, terrible, or unbearable) ($n$ = 123). Based on the cutoff points of < 39 (mild impact) and ≥ 59 (severe impact) in the FIQ (Bennett et al., 2009), 101 women with severe FM impact and 12 women with mild FM impact were identified. Considering a cutoff score of ≥ 11 in the HADS as an indicator of a clinical problem (Zigmond & Snaith, 1983), 129 patients with a clinical problem of anxiety and 106 without this problem, and 98 patients with a clinical problem of depression and 137 without such problem were identified. Table 3 shows the best cutoff points of the PVAQ-9 to classify these groups. The score that reflected acceptable sensitivity and sensitivity was 24.5; it correctly classified 71% of cases of severe FM impact (and 75% of cases of mild FM impact).

**Table 3**. Area Under the Curve, Better Cutoff, Sensitivity and Specificity of the PVAQ-9 (Esteve et al., 2013)

| | | | 95% CI | | | | |
|---|---|---|---|---|---|---|---|
| | *Area* | *p* | Lower limit | Upper limit | Better cutoff | Sensitivity | Specificity |
| High pain intensity (positive) | .60 | .007 | .53 | .67 | 25.5 | .63 | .54 |
| High impact of fibromyalgia (positive) | .70 | .021 | .54 | .86 | 24.5 | .71 | .75 |
| Clinical anxiety (positive) | .63 | .001 | .56 | .70 | 25.5 | .63 | .55 |
| Clinical depression (positive) | .59 | .012 | .52 | .66 | 26.5 | .60 | .55 |

## Discussion

In this study we examined the reliability and validity of the Spanish version of the PVAQ. This is the first instrumental study of this questionnaire in Spanish women with FM. The findings support the psychometric suitability of the 9-item short form (PVAQ-9; Esteve et al., 2013) in this clinical population. The PVAQ-9 showed appropriate internal consistency, convergent validity, divergent validity, and predictive validity, which means that it is a good instrument to measure attention to and awareness of painful sensations. It is relevant to have a validated Spanish version of this self-report for use in our community context, especially considering the relationship between pain hypervigilance and pain experience, emotional distress, and disability in chronic pain patients (Goubert et al., 2004; McCracken, 1997).

CFAs were conducted to examine the goodness of fit of several two-factor structures of the PVAQ identified in previous studies with chronic pain patients (Esteve et al., 2013; Roelofs et al., 2003; Wong et al., 2011). Results revealed that all models (PVAQ-14, PVAQ-13 and PVAQ-9) represented the data well according to several fit indexes (NNFI and CFI), with the PVAQ-9 model (Esteve et al., 2013) showing the best fit. The PVAQ-9 had good internal consistency in both the total scale and the active vigilance and passive awareness subscales.

The PVAQ-9 showed satisfactory convergent validity, as indicated by the high correlations between this measure and other cognitive-affective constructs of pain such as pain anxiety and pain catastrophizing. These findings are in line with previous studies (Esteve et al., 2013; Goubert et al., 2004; Martínez et al., 2011; Roelofs et al., 2003). The PVAQ-9 was associated with other clinical measures considered, although we found moderate correlations with pain intensity and FM impact and low correlations with anxiety and depression, suggesting adequate divergent validity. These results are consistent with those

reported in previous studies (McCracken, 1997, 2007; Wong et al., 2011). Regarding predictive validity, the PVAQ-9 was found to be useful in identifying cases with severe FM impact. A cutoff score of 24.5 reflected higher sensitivity (71%) and specificity (75%). There are no studies with which to compare these results.

The present study has some limitations. Participants were Spanish FM women, so it may not be possible to generalize its results to FM men, other cultural/ethnic groups, or other chronic pain syndromes. Using a pressure algometer to assess the pain tolerance threshold and the Stroop task to examine selective attention to pain-related stimuli would have enriched the data collected. It would also have been relevant to include measures of self-efficacy beliefs and coping strategies, given their important contribution to the pain experience (Ramírez-Maestre, Esteve, & López, 2012; Sánchez, Martínez, Miró, & Medina, 2011). No other psychometric properties such as test-retest reliability and sensitivity to change were explored.

This study shows that the PVAQ-9 has satisfactory psychometric properties in Spanish FM women. This instrument is suitable for use in clinical settings, given its simplicity and reduced application time. The PVAQ-9 makes it possible to determine the attention level that FM patients direct to their painful sensations, which may be indicative of higher affective suffering and impaired functioning. This self-report may also be useful as an index of improvement, reflecting the degree to which individuals with chronic pain can live without cognitively focusing on pain and prioritizing it over other valuable life goals.

Several studies have provided evidence that psychological treatments aimed at promoting changes in vigilance and awareness of pain are beneficial for patients with chronic pain. Cognitive-behavioral treatment (i.e., education about pain, graduated exercises, applied relaxation training, training in pacing and goal setting, problem solving, and cognitive restructuring) can increase pain self-efficacy and reduce pain severity, catastrophizing, fear of

re-injury, depression, stress, and attentional bias towards sensory pain words in chronic pain conditions (Dehghani, Sharpe, & Nicholas, 2004). Attention management strategies (via attention diversion, imagery, and mindfulness exercises) are useful for reducing pain-related anxiety, hypervigilance, and interference of pain in chronic pain patients (Elomaa, Williams, & Kalso, 2009). Attentional bias modification (a modified version of the dot-probe task to implicitly train subjects to attend away from pain-related stimuli) has been found to reduce anxiety sensitivity, fear of pain, and pain severity in patients with FM (Carleton, Richter, & Asmundson, 2011). Mindfulness-based treatment (aimed at helping patients to become aware of their present-moment experience without judging it, accepting it as it is through meditative body scan, meditation focused on breathing, and mindful yoga) facilitates a more flexible use of attention. Mindfulness training enhances attention modulation of 7–14Hz alpha rhythms that play an important role in filtering inputs to the primary sensory neocortex, and such training in chronic pain may work by "debiasing" the sensory attentional system and freeing up resources to attend to other demands (Kerr, Sacchet, Lazar, Moore, & Jones, 2013). In this regard, a recent study has shown that a multimodal mindfulness-oriented intervention including complementary aspects of mindfulness training, cognitive-behavioral therapy, and techniques used in positive psychology was able to reduce selective attention to pain-related stimuli, increase perceived control over pain, and attenuate reactivity to distressing thoughts and emotions in patients with chronic pain (Garland & Howard, 2013). Considering these therapeutic approaches, a good self-report instrument such as the PVAQ-9 can be helpful to estimate clinical improvements regarding excessive attention to pain in FM patients.

In conclusion, the Spanish version of the PVAQ seems to be an adequate instrument to identify FM patients who show an increased tendency to observe, monitor, and focus on pain, which contributes to a maladaptive response to disease.

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# SEGUNDO ESTUDIO

*Artículo 2*

# Relationships Between Physical Symptoms, Emotional Distress, and Pain Appraisal in Fibromyalgia: The Moderator Effect of Alexithymia

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# Relationships between Physical Symptoms, Emotional Distress, and Pain Appraisal in Fibromyalgia: The Moderator Effect of Alexithymia


## Abstract

Alexithymia is a personality construct that is frequently identified in fibromyalgia (FM). Previous studies have explored the relationship between alexithymia and emotional distress in this disease. Yet, the additional link with factors of pain appraisal is unknown. This study examined the moderating effect of alexithymia in the relationship between emotional distress and pain appraisal in 97 FM women. A control group of 100 healthy women also participated in the study. All participants completed several self-reports about pain experience, sleep quality, impairment, emotional distress, pain appraisal and alexithymia. FM women showed significantly more difficulty in identifying and describing feelings, but less externally oriented thinking than healthy women. In the clinical group, difficulty in identifying feelings and difficulty in describing feelings significantly correlated with lower sleep quality, higher anxiety and depression, and increased pain catastrophizing and fear of pain. Difficulty in describing feelings significantly correlated with higher pain experience and vigilance to pain. Externally oriented thinking was not correlated with any of the clinical variables. Difficulty in identifying feelings moderated the relationship

between anxiety and pain catastrophizing, and difficulty in describing feelings moderated the relationship between anxiety and fear of pain. Implications of the findings for the optimization of care of FM patients are discussed.

***Keywords**:* alexithymia, emotional distress, fear of pain, fibromyalgia, pain catastrophizing.

According to the American College of Rheumatology (ACR; Wolfe et al., 1990), fibromyalgia (FM) is a syndrome characterized by widespread musculoskeletal pain for at least three months and pain on digital palpation in at least 11 of the 18 sensitive points. In Europe, this syndrome affects 2.9–4.7% of the general population, with a higher prevalence in females than males (Branco et al., 2010). In the United States, annual mean healthcare costs are three times higher for FM patients ($ 9,573) than for control group patients without any healthcare encounters for FM ($ 3,291) (Berger, Dukes, Martin, Edelsberg, & Oster, 2007).

The clinical understanding of FM has evolved over the last twenty years to consider symptoms beyond pain as an integral part of this condition (Fitzcharles & Yunus, 2012). In fact, FM patients report a wide range of symptoms including, among others, morning stiffness, fatigue, non-restorative sleep, forgetfulness, poor concentration, difficulty falling asleep, muscle spasms, anxiety, and depression (Bennett, Jones, Turk, Russell, & Matallana, 2007). Several reports have shown a high prevalence of mood and anxiety disorders and emotional distress in this pain condition. FM patients have shown higher levels of mental distress including depression and anxiety than healthy controls (Gormsen, Rosenberg, Bach, & Jensen, 2010). In FM patients, the prevalence of mood disorders is 29–34.8% and that of anxiety disorders is 22.3–32.2% (Epstein et al., 1999; Thieme Turk, & Flor, 2004; Uguz et al., 2010).

Previous research in several chronic pain conditions including FM has documented the negative influence of affective distress in the pain experience. In FM patients, anxiety and depression scores have been associated with a poorer subjective rating of general health (Jensen et al., 2010), higher pain intensity, poor sleep quality, and worse functioning (Miró, Martínez, Sánchez, Prados, & Medina, 2011). FM patients with comorbid anxiety disorders show the highest number of physical symptoms, the highest level of pain intensity and

interference, and frequent solicitous behaviors of significant others and avoidance behaviors (Thieme et al., 2004). FM patients with depressive symptoms show more sleep disturbances, sexual dysfunctions, and loss of physical function, and poorer quality of life than FM patients without depressive symptoms (Lange & Petermann, 2010).

Several factors of pain appraisal contribute to the pain experience. The most outstanding ones are pain catastrophizing, fear of pain, and vigilance to pain. In FM patients, pain catastrophizing has been associated with pain intensity and impairment (Martínez, Sánchez, Miró, Medina, & Lami, 2011), fear of pain has been associated with increased pain and tender point sensitivity as well as decreased tolerance for physical performance and speed of cognitive performance (de Gier, Peters, & Vlaeyen, 2003), and vigilance to pain has been related to pain intensity and negative affectivity (Crombez, Eccleston, van den Broeck, Goubert, & van Houdenhove, 2004). These factors are considered in the fear–avoidance model of chronic pain (Leeuw et al., 2007; Vlaeyen & Linton, 2000, 2012), the most influential model of chronic pain from a biopsychosocial perspective. According to this model, catastrophic appraisal of pain is a potential precursor of pain-related fear, which triggers a hypervigilance to possible somatic signals of threat and avoidance and escape behaviors. These reactions lead to detrimental changes in the musculoskeletal system, disability, and depression. All this ultimately intensifies the pain experience, contributing to a vicious circle of fear and avoidance. The fear–avoidance model has inspired a number of experimental, prospective and clinical studies on the changes in the aforementioned variables and relationships between them; it is a process model with a natural flow from diagnostic information to treatment that is easy to adopt as a framework from multidisciplinary clinical practice and has been considered as credible by patients (Crombez, Eccleston, van Damme, Vlaeyen, & Karoly, 2012). There is wide scientific evidence supporting the validity of the

fear–avoidance model in several chronic pain conditions (for a review see Leeuw et al., 2007; Pincus, Smeets, Simmonds, & Sullivan, 2010). This conceptual framework is open to additional refinements and extensions that may strengthen its clinical value. In the context of the refinement of this model, for example, scholars have explored the links between pain catastrophizing, pain-related fear and vigilance to pain and personality traits such as neuroticism (Goubert, Crombez, & Van Damme, 2004; Martínez et al., 2011).

Psychological research has proven that greater pain is associated with emotional distress and limited emotional awareness, expression, and processing (for a review see Lumley et al., 2011). Alexithymia is a personality construct that denotes a deficit in cognitive processing of emotional experience and emotional regulation (Taylor, Bagby, & Parker, 1997) and is frequently associated with chronic diseases (Baiardini, Abba, Ballaurí, Vuillermoz, & Braido, 2011). Alexithymia is characterized by difficulties in identifying and communicating feelings, problems distinguishing between emotions and physical sensations, restricted imaginal capacity, and a concrete, externally oriented way of thinking (Sifneos, 1996). These psychological characteristics contribute to heightened physiological arousal, certain types of unhealthy behavior, and a biased perception and reporting of somatic sensations and symptoms (for a review see Lumley, Neely, & Burger, 2007; Lumley, Stettner, & Wehmer, 1996). Alexithymia may influence illness behavior via cognitive mechanisms as follows (Lumley et al., 1996): alexithymic individuals are likely to have high body awareness that makes them notice benign somatic sensations and focus on them, magnifying them and generating a feedback loop; as a result, they may experience these sensations as physical illness because they attribute these sensations to biological causes rather than psychological ones.

Deficit in the ability to regulate one‟s affective states is frequent in FM. Patients with FM have shown higher levels of alexithymia than healthy controls (Brosschot & Aarsse, 2001; Sayar, Gulec, & Topbas, 2004; Tuzer et al., 2011; van Middendorp et al., 2008) and chronic low back pain patients (Tuzer et al., 2011). When pain severity or depression was controlled, FM patients showed higher levels of alexithymia than rheumatoid arthritis patients (Sayar et al., 2004). However, Malt, Olafsson, Lund, and Ursin (2002) reported no differences in alexithymia between FM and control groups. Moreover, it has been reported that 39.2–44% of FM patients are alexithymic (Evren, Evren, & Guler, 2006; Steinweg, Dallas, & Rea, 2011). This rate is significantly higher than that of general medicine patients (8%) and rheumatoid arthritis patients (21%) (Steinweg et al., 2011). Several studies have identified alexithymia as an important factor involved in the pain experience of FM patients. In these patients, alexithymia has been related to general distress, anxiety and depression (Malt et al., 2002), pain intensity (Sayar et al., 2004), and current general psychiatric symptoms, as well as severity of depression and anxiety (Evren et al., 2006). In FM patients, difficulty in identifying feelings has been significantly correlated with mental distress, pain, and fatigue; however, difficulty in describing feelings has only shown significant associations with mental distress, and this component of alexithymia has been found to moderate the relationship between pain and affect intensity (van Middendorp et al., 2008). In these patients, difficulty in identifying feelings was related to higher affective ongoing pain and lower cold pressor pain tolerance, but this alexithymic factor ceased to predict affective ongoing pain when psychological distress or illness behavior was controlled (Huber, Suman, Biasi, & Carli, 2009). However, in FM patients, alexithymia (or some of its facets) was not related to impairment (Sayar et al., 2004), pain severity (Evren et al., 2006), sensory ongoing pain, or experimental pain thresholds (Huber et al., 2009).

Most studies on FM have focused on the relationship between alexithymia and emotional distress. Yet, no studies have further explored the links with pain appraisal factors (pain catastrophizing, fear of pain, and vigilance to pain) outlined in the fear–avoidance model of chronic pain. To the best of our knowledge, only three studies have explored this topic but only included non-fibromialgic pain conditions or non-clinical samples. In a sample of 80 patients with chronic myofascial pain, Lumley, Smith, and Longo (2002) found that alexithymia was related with greater catastrophizing and was a significant predictor of affective pain severity (but not of physical impairment) while controlling for catastrophizing. In a group of 67 healthy subjects, Katz, Martin, Pagé, and Calleri (2009) used a magnitude estimation procedure and found that sex, fear of pain, and alexithymia (difficulty in identifying feelings and difficulty in describing feelings) were significant predictors of average heat pain intensity. In a group of 128 patients with chronic pain, Makino et al. (2012) found that alexithymia was associated with pain interference (influence of pain on patient functioning) and catastrophizing, however, alexithymia was not a significant predictor of these clinical variables when demographic variables and negative affectivity were controlled.

The present study is the first to explore the relationship between alexithymia, emotional distress, and pain appraisal components of the fear–avoidance model of chronic pain in FM patients. Determining how deficits in affective regulation are related to pain appraisal may contribute to a better understanding of psychological factors that exacerbate FM. Considering this assumption and the previous findings, the objectives of this cross-sectional study with FM women and healthy women were the following:

1. Determine the differences between both groups regarding alexithymia, physical symptoms (pain experience and sleep quality), impairment, emotional distress (anxiety and

depression), and variables of pain appraisal (pain catastrophizing, fear of pain, and vigilance to pain).

2. Analyze the relationship between alexithymia and these clinical variables in FM women.

3. Assess whether alexithymia makes a unique contribution to physical symptoms and impairment of these patients beyond the effect of emotional distress and pain appraisal.

4. Explore the moderator role of alexithymia in the relationship between emotional distress and pain appraisal in this clinical group.

## Method

*Subjects and Procedure*

Ninety-seven women with FM with a mean age of 47.64 years (*SD* = 8.03) participated in the study. Patients were recruited from the Rheumatology Service and Pain and Palliative Care Unit of Virgen de las Nieves University Hospital and AGRAFIM, a FM association, both in Granada, Spain. According to several reports women experience greater clinical pain, pain-related distress, and sensitivity to experimentally induced pain than men (Paller, Campbell, Edwards, & Dobs, 2009), and FM is more frequent in women than in men (Branco et al., 2010). For these reasons, socio–demographic variables were controlled and only women were selected for this study. Inclusion criteria to participate in the study were: (a) being a woman aged between 18 and 65 years, (b) having been diagnosed with FM according to the criteria of the ACR (Wolfe et al., 1990), and (c) having adequate reading comprehension. Exclusion criteria were as follows: (a) having a history of alcoholism or drug addiction, (b) having concomitant major medical conditions, and (c) having a major

depressive disorder with severe symptoms, schizophrenia, borderline personality disorder, or other major Axis I/Axis II diagnoses of the DSM-IV-TR (APA, 2000).

Female patients diagnosed with FM from the hospital and the FM association were contacted by telephone and invited to cooperate in the study. Considering the abovementioned criteria, 97 participants were selected as the clinical group. The psychological assessment included a semi-structured interview and several self-report questionnaires. The interview lasted approximately one hour and focused on onset and course of symptoms, life history, lifestyle, work, personal relations, family and participant‟s attitudes about her illness, and psychological status. After the interview, participants were given a set of questionnaires to be completed at home and returned within a week.

Most FM patients were married (78.1%), had elementary or secondary education (65.3%), and were not employed at the time (60.5%). Mean duration of the diagnosed disease was 5.98 years (*SD* = 5.52). Among participants, 95.9% were receiving current pharmacological treatment (e.g., analgesics, anti-inflammatory drugs, anxiolytics, and antidepressants), and 96.6% of them were also following other treatments (e.g., physical exercise, psychological therapy, acupuncture).

One hundred healthy women with a mean age of 48.39 years (*SD* = 7.53 years) participated in the study. This group was recruited from non-clinical community settings (e.g., by friends and family of college students and associations of housewives or trade workers), and was matched to FM women in the main socio–demographic variables. Inclusion criteria for the healthy group were: (a) being a woman aged between 18 and 65 years, (b) being free of pain conditions and other important medical or psychological diseases, and (c) having adequate reading comprehension. Exclusion criteria were the same as those of the clinical group. Most healthy participants were married (88.8%), had elementary or secondary

education (76.2%), and were employed at the time (64.4%). This group completed the same set of questionnaires as the clinical group.

All subjects received detailed information about the study and gave their written informed consent. The study received ethical approval from the Ethics Committee of the University of Granada.

*Measurements*

Short-Form McGill Pain Questionnaire (SF-MPQ; Melzack, 1987). This instrument assesses pain experience using 15 verbal (sensory and affective) pain descriptors rated on a scale from 0 (no) to 3 (severe), a current pain intensity index, and a visual analogue scale to assess pain intensity in the last week. Previous studies have reported the reliability (internal consistency = .74) (Masedo & Esteve, 2000) and validity of the Spanish version of the MPQ (Lázaro et al., 2001). In the present study, the sensory–affective scale of pain was used.

Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupher, 1989). This index includes 19 items that assess several dimensions of sleep quality: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. In the present study the total score (from 0 "absence of perturbation" to 21 "severe perturbation") was used. The Spanish adaptation of the PSQI has acceptable internal consistency (between .67 and .81), sensitivity and specificity (Royuela & Macías, 1997).

Impairment and Functioning Inventory (IFI; Ramírez-Maestre & Valdivia, 2003). This instrument is composed of 19 items that evaluate the level of functioning and impairment of patients with chronic pain in several areas of life (household activity, independent functioning, social activities, and leisure activities). The IFI has adequate reliability (.76 in the

functioning scale and .72 in the impairment scale) and a four-factor structure (Ramírez-Maestre & Valdivia, 2003). In the present study the level of impairment as the number of activities affected was considered.

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). This scale explores anxiety and depression symptoms in non-psychiatric hospital contexts using 14 items that are rated on a scale ranging from 0 to 3. The HADS includes two subscales: Anxiety and Depression. The Spanish version of this instrument has good internal consistency (.85 in the Anxiety scale and .84 in the Depression scale) and external validity and favorable sensitivity and specificity (Herrero et al., 2003).

Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995). This scale assesses the rumination, magnification, and helplessness associated with pain. This instrument includes 13 items measured on a Likert scale ranging from 0 (not at all) to 4 (all the time). The Spanish version of the PCS has shown good internal consistency (.79), test-retest reliability and sensitivity to change (García-Campayo et al., 2008).

Pain Anxiety Symptoms Scale-20 (PASS-20; McCracken & Dhingra, 2002). This instrument assesses the fear, cognitive anxiety, escape and avoidance behavior, and physiological anxiety associated with pain. This scale includes 20 items that are evaluated using a Likert scale ranging from 0 (never) to 5 (always). The PASS-20 has shown good convergent validity and reliability (internal consistency ranging from .91 to .92) (Roelofs et al., 2004).

Pain Vigilance and Awareness Questionnaire (PVAQ; McCracken, 1997). This instrument consists of 16 items that evaluate the awareness, consciousness, vigilance and observation of pain using a Likert scale ranging from 0 (never) to 5 (always). The PVAQ has

shown adequate convergent validity and internal consistency (.87) (Roelofs, Peters, McCracken, & Vlaeyen, 2003).

Toronto Alexithymia Scale (TAS-20; Bagby, Parker, & Taylor, 1994). The TAS-20 is the most widely and frequently used measure of alexithymia (Bagby, Taylor, Quilty, & Parker, 2007). This scale includes 20 items that assess different aspects of alexithymia: difficulty in identifying feelings, difficulty in describing feelings, and externally oriented thinking. The Spanish adaptation has adequate internal consistency (.82), temporal reliability, and validity and a three-factor structure that is similar to that of the original version (Moral & Retamales, 2000). In this adaptation, the items are rated on a Likert scale ranging from -3 (totally disagree) to +3 (totally agree).

*Data Analyses*

Statistical analyses were performed with IBM SPSS Statistics 19 software (SPSS Inc.), a program that graphically displays moderating effects (ModGraph-I; www.victoria.ac.nz/psyc/staff/paul-jose-files/modgraph/modgraph.php), and an effect size calculator (Statistics Calculators, version 3.0 beta; www.danielsoper.com/statcalc3/default.aspx). All analyses were two-tailed and probabilities less than or equal to .05 were taken as the level of significance.

The reliability (internal consistency) of the measures was examined and Cronbach‟s alpha values greater than .70 were considered acceptable (Nunnally & Bernstein, 1994). The clinical and healthy groups were compared for demographic and psychological variables using Student‟ *t* and $\chi^2$ tests. Cohen‟s d was computed to assess effect sizes. The relationship between physical symptoms (pain experience and sleep quality), impairment, emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing, fear of pain and

vigilance to pain), and alexithymia in the FM group was analyzed using Pearson‟s correlation coefficient. Several hierarchical regression analyses were conducted to test alexithymia as a predictor of physical symptoms or emotional distress. The guidelines provided by Frazier, Tix, and Barron (2004) for testing moderation effects were followed. The moderating role of alexithymia was analyzed using the criteria proposed by Baron and Kenny (1986): in predicting emotional distress (dependent variable, DV), the model considers the impact of physical symptoms and pain appraisal factors (predictors), the impact of alexithymia (moderator), and the interaction of both (predictor x moderator); the moderating role is supported if the interaction is significant. Following the recommendations of Aiken and West (1991) to reduce multicollinearity, the predictor and moderator variables were centered (this was accomplished by subtracting the sample mean from all individual scores). Later, the interaction term was obtained by multiplying the centered scales. As a post-hoc analysis of the moderator effect, several simple slopes were computed for low, medium, and high levels of alexithymia.

## Results

*Differences between FM and Healthy Groups in Demographic and Clinical Variables*

The Cronbach‟s alpha of the measures administered in both the clinical and control groups was adequate (higher than .70) with only two exceptions (see Table 1): it was slightly low in the Depression scale for the control group, and markedly low in the Externally oriented thinking scale for both groups, but similar to the indices reported in previous studies of the TAS-20 (Bagby et al., 1994).

No significant differences were found between FM and healthy groups in age ($t_{187}$ = −0.66, $p$ = .508) or education level ($x^2_3$ = 2.90, $p$ = .406). However, as expected, significant

differences were found in employment status ($x^2_4$ = 29.92, $p$ < .001). In the FM group, compared to the control group, a higher proportion of participants had an inactive employment status (mainly due to sick leave).

Table 1 shows the comparisons between FM women and healthy women in self-reports. Pain experience and impairment were significantly higher and sleep quality was significantly lower in the clinical group than in the control group. This is consistent with the expected scores of patients with persistent pain.

Anxiety and depression were significantly higher in FM patients than in healthy participants. Given the cut-off scores in the HADS (Zigmond & Snaith, 1983), the scores of the FM group identified anxiety as a clinical problem (score of 11 or higher) and depression as a problem that was not necessarily clinical. At an individual level, 55.7% and 37.1% of FM patients had scores above the cut-off indicative of clinical problem on the anxiety and depression scales, respectively. Pain experience, pain catastrophizing, fear of pain, difficulty in identifying feelings and difficulty in describing feelings were significantly higher and sleep quality was significantly lower in patients with clinical level of anxiety than in patients with nonclinical level of anxiety (between $t_{94}$ = 2.82, $p$ < .01, and $t_{94}$ = 4.60, $p$ < .001), however the groups did not differ in impairment ($t_{82}$ = 1.87, $p$ = .06), vigilance to pain ($t_{95}$ = 0.37, $p$ = .70) and externally oriented thinking ($t_{93}$ = −0.38, $p$ = .69). Pain experience, impairment, pain catastrophizing and fear of pain were significantly higher and sleep quality was significantly lower in patients with clinical level of depression than in patients with nonclinical level of depression (between $t_{87}$ = 2.24, $p$ < .05, and $t_{93}$ = 3.63, $p$ < .001), however the groups did no differ in vigilance to pain ($t_{95}$ = 0.89, $p$ = .37) and subescales of alexithymia (between $t_{93}$ = −0.49, $p$ = .62, and $t_{94}$ = 1.71, $p$ = .09).

Pain catastrophizing, fear of pain, and vigilance to pain were significantly higher in FM women than in healthy women. Difficulty in identifying feelings and difficulty in describing feelings were significantly higher in FM participants than in control subjects. However, externally oriented thinking was significantly lower in the clinical group than in the healthy group.

**Table 1.** Internal Consistency of the Scales and Comparison between Fibromyalgia Women and Healthy Women in Clinical Variables

| | Fibromyalgia women | | Healthy women | | | |
|---|---|---|---|---|---|---|
| Variable | $\alpha$ | *M* (*SD*) | $\alpha$ | *M* (*SD*) | *t* | *d* |
| Pain experience-SF-MPQ | .87 | 23.66 (10.31) | .86 | 4.45 (6.60) | 14.74** | 2.21 |
| Sleep quality-PSQI | .77 | 14.43 (4.46) | .77 | 6.33 (3.58) | 13.78** | 2.00 |
| Impairment-IFI | .76 | 4.15 (3.30) | .78 | 1.58 (1.96) | 6.07** | 0.94 |
| Anxiety-HADS | .82 | 11.14 (4.62) | .80 | 5.93 (3.84) | 8.59** | 1.22 |
| Depression-HADS | .86 | 9.36 (4.82) | .69 | 3.03 (2.70) | 11.30** | 1.62 |
| Pain catastrophizing-PCS | .94 | 24.10 (12.05) | .94 | 15.88 (11.00) | 4.97** | 0.71 |
| Fear of pain-PASS-20 | .91 | 49.72 (19.09) | .94 | 29.88 (20.69) | 6.93** | 0.99 |
| Vigilance to pain-PVAQ | .82 | 47.31 (12.11) | .89 | 36.70 (15.14) | 5.40** | 0.77 |
| Difficulty in identifying feelings-TAS-20 | .87 | 3.88 (11.01) | .85 | −6.68 (10.46) | 6.84** | 0.98 |
| Difficulty in describing feelings-TAS-20 | .74 | 0.32 (5.77) | .72 | −1.28 (5.93) | 1.90* | 0.27 |
| Externally oriented thinking TAS-20 | .61 | 4.53 (5.78) | .63 | 6.29 (6.75) | −1.94* | 0.28 |

*Note*. *d* of .20, .50, and .80 represents small, medium and large effect size, respectively.
*$p \leq .05$ . **$p \leq .01$.

*Association between Clinical Measures in the FM Group*

Table 2 shows the Pearson correlations between the clinical measures. The main results were the following: (a) greater pain experience was related to higher anxiety, depression, pain catastrophizing, fear of pain, vigilance to pain, and difficulty in describing

feelings; (b) poorer sleep quality was related to higher anxiety, depression, pain catastrophizing, fear of pain, difficulty in identifying feelings, and difficulty in describing feelings; (c) greater impairment was related to higher depression and pain catastrophizing; (d) greater anxiety was related to higher pain catastrophizing, fear of pain, difficulty in identifying feelings, and difficulty in describing feelings; and (e) greater depression was related to higher pain catastrophizing, fear of pain, vigilance to pain, difficulty in identifying feelings, and difficulty in describing feelings. Externally oriented thinking did not correlate with any variable.

In the following regression analysis, only measures significantly correlated with the dependent variable, DV (pain experience, sleep quality, and anxiety), were included as predictors. Impairment was not considered as a DV in the prediction analysis because it did not correlate significantly with the alexithymia measures. Depression was not considered as a DV in the moderation analysis because it was not identified as a clinical problem according to the cut-off scores in the HADS, and differences were not found in alexithymia between patients with clinical level of depression and patients with nonclinical level of depression. Vigilance to pain was not included as an independent variable in the moderation analysis because it did not correlate significantly with anxiety. Externally oriented thinking was not analyzed as a potential moderator because it did not correlate significantly with anxiety.

**Table 2**. Intercorrelation between Clinical Variables in Fibromyalgia Women

| Variable | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. Pain experience-SF-MPQ | | | | | | | | | | |
| 2. Sleep quality-PSQI | .37** | | | | | | | | | |
| 3. Impairment-IFI | .29** | .12 | | | | | | | | |
| 4. Anxiety-HADS | .46** | .40** | .20 | | | | | | | |
| 5. Depression-HADS | .35** | .48** | .40** | .66** | | | | | | |
| 6. Pain catastrophizing-PCS | .54** | .38** | .22* | .49** | .44** | | | | | |
| 7. Fear of pain-PASS-20 | .56** | .43** | .16 | .54** | .47** | .76** | | | | |
| 8. Vigilance to pain-PVAQ | .33** | .17 | .11 | .15 | .22* | .58** | .48** | | | |
| 9. Difficulty in identifying feelings-TAS-20 | .18 | .26* | .01 | .42** | .32** | .37** | .42** | .18 | | |
| 10. Difficulty in describing feelings-TAS-20 | .23* | .21* | .00 | .33** | .27** | .36** | .24* | .27** | .43** | |
| 11. Externally oriented thinking-TAS-20 | .03 | −.04 | .06 | −.04 | −.14 | .08 | .06 | .16 | .22* | .21* |

*Note.* *$p \leq .05$. **$p \leq .01$.

*Alexithymia as a Predictor of Physical Symptoms (Pain Experience and Sleep Quality) in the FM Group*

Table 3 shows the hierarchical model of prediction of pain experience from emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing, fear of pain, and vigilance to pain), and alexithymia (difficulty in describing feelings). In Step 1, only anxiety made a significant contribution. The predictive effect was maintained when pain appraisal factors were included in Step 2, but none of these factors proved to be significant predictors. In Step 3, which also included difficulty in describing feelings, anxiety remained significant, but this alexithymia measure was not identified as a significant predictor.

**Table 3**. Hierarchical Models Predicting Pain Experience in Fibromyalgia Women

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Anxiety-HADS | 0.93 | .41 | 3.21** | .21 | .21 | 11.32** |
| Depression-HADS | 0.13 | .06 | 0.49 | | | |
| Step 2 | | | | | | |
| Anxiety-HADS | 0.59 | .26 | 1.98* | | | |
| Depression-HADS | −0.18 | −.08 | −0.69 | | | |
| Pain catastrophizing-PCS | 0.16 | .18 | 1.26 | .37 | .16 | 9.65** |
| Fear of pain-PASS-20 | 0.15 | .27 | 1.85 | | | |
| Vigilance to pain-PVAQ | 0.09 | .10 | 0.92 | | | |
| Step 3 | | | | | | |
| Anxiety- HADS | 0.60 | .27 | 1.98* | | | |
| Depression- HADS | −0.18 | − .08 | −0.70 | | | |
| Pain catastrophizing-PCS | 0.16 | .18 | 1.27 | .37 | .00 | 7.96** |
| Fear of pain-PASS-20 | 0.15 | .26 | 1.83 | | | |
| Vigilance to pain-PVAQ | 0.09 | .10 | 0.94 | | | |
| Difficulty in describing feelings-TAS-20 | −0.04 | −.02 | −0.24 | | | |

*Note*. *$p \leq .05$. **$p \leq .01$.

Table 4 shows the hierarchical model of prediction of sleep quality from emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing and fear of pain), and alexithymia (difficulty in identifying feeling and difficulty in describing feelings). In Step 1, only depression made a significant contribution. This predictive effect was maintained when pain appraisal factors were considered in Step 2, but none of these factors made a significant contribution. In Step 3, which also included difficulty in identifying feelings and difficulty in describing feelings, depresion remained significant but none of these alexithymia measures had a significant predictor effect.

**Table 4**. Hierarchical Models Predicting Sleep Quality in Fibromyalgia Women

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Anxiety-HADS | 0.12 | .13 | 1.05 | .23 | .23 | 13.44** |
| Depression-HADS | 0.35 | .38 | 3.11** | | | |
| Step 2 | | | | | | |
| Anxiety- HADS | 0.01 | .01 | 0.11 | .28 | .05 | 8.57** |
| Depression- HADS | 0.30 | .32 | 2.67** | | | |
| Pain catastrophizing-PCS | 0.00 | .01 | 0.11 | | | |
| Fear of pain-PASS-20 | 0.06 | .26 | 1.73 | | | |
| Step 3 | | | | | | |
| Anxiety-HADS | −0.00 | −.00 | −0.02 | .28 | .00 | 5.66** |
| Depression-HADS | 0.30 | .32 | 2.62** | | | |
| Pain catastrophizing-PCS | 0.00 | .00 | 0.01 | | | |
| Fear of pain-PASS-20 | 0.05 | .25 | 1.67 | | | |
| Difficulty in identifying feelings-TAS-20 | 0.01 | .04 | 0.41 | | | |
| Difficulty in describing feelings-TAS-20 | 0.02 | .02 | 0.24 | | | |

*Note*. **$p \leq .01$.

*Alexithymia as a Moderator between Anxiety and Pain Appraisal (Pain Catastrophizing and Fear of Pain) in the FM Group*

Moderation analyses were performed separately for each potential moderator (difficulty in identifying feelings and difficulty in describing feelings).

Two moderation analyses tested whether the pain catastrophizing x difficulty in identifying feelings interaction and the pain catastrophizing x difficulty in describing feelings interaction were significant predictors of anxiety after controlling the influence of physical symptoms, pain catastrophizing, and difficulty in identifying feelings (or difficulty in describing feelings) (see Table 5). In Step 1, pain experience and sleep quality were identified as significant predictors. In Step 2, the effects of sleep quality disappeared when pain catastrophizing was included, and pain experience and pain catastrophizing were significant predictors. In Step 3a, the contribution of pain experience and pain catastrophizing remained significant when difficulty in identifying feelings was included, and this measure of alexithymia was also a significant predictor. In Step 3b, pain experience and difficulty in identifying feelings remained significant, and a significant effect was observed in the pain catastrophizing x difficulty in identifying feelings interaction; this revealed that the relationship between anxiety and pain catastrophizing is moderated by this facet of alexithymia. In Step 4a, pain experience and pain catastrophizing were significant predictors, and in Step 4b, the contribution of both variables was retained and difficulty in describing feelings was an additional significant predictor.

**Table 5.** Alexithymia as a Moderator between Anxiety and Pain Catastrophizing in Fibromyalgia Women

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Pain experience-SF-MPQ | 0.17 | .37 | 3.72** | .26 | .26 | 14.96** |
| Sleep quality-PSQ | 0.25 | .23 | 2.33* | | | |
| Step 2 | | | | | | |
| Pain experience-SF-MPQ | 0.10 | .23 | 2.12* | .32 | .06 | 13.46** |
| Sleep quality-PSQI | 0.19 | .18 | 1.82 | | | |
| Pain catastrophizing-PCS | 0.12 | .30 | 2.82** | | | |
| Step 3a | | | | | | |
| Pain experience-SF-MPQ | 0.11 | .24 | 2.32* | .39 | .06 | 13.39** |
| Sleep quality-PSQI | 0.14 | .13 | 1.39 | | | |
| Pain catastrophizing-PCS | 0.08 | .21 | 2.03* | | | |
| Difficulty in identifying feelings-TAS-20 | 0.11 | .28 | 3.03** | | | |
| Step 3b | | | | | | |
| Pain experience-SF-MPQ | 0.13 | .28 | 2.84** | .45 | .06 | 13.66** |
| Sleep quality-PSQI | 0.06 | .05 | 0.60 | | | |
| Pain catastrophizing-PCS | 0.06 | .16 | 1.57 | | | |
| Difficulty in identifying feelings-TAS-20 | 0.12 | .29 | 3.30** | | | |
| Pain catastrophizing X Difficulty in identifying feelings | −0.00 | −.26 | −3.05** | | | |
| Step 4a | | | | | | |
| Pain experience-SF-MPQ | 0.10 | .22 | 2.11* | .35 | .02 | 11.03** |
| Sleep quality-PSQI | 0.17 | .16 | 1.64 | | | |
| Pain catastrophizing-PCS | 0.10 | .25 | 2.31* | | | |
| Difficulty in describing feelings-TAS-20 | 0.13 | .16 | 1.69 | | | |
| Step 4b | | | | | | |
| Pain experience-SF-MPQ | 0.11 | .25 | 2.32* | .36 | .01 | 9.48** |
| Sleep quality-PSQI | 0.13 | .12 | 1.20 | | | |
| Pain catastrophizing-PCS | 0.10 | .26 | 2.38* | | | |
| Difficulty in describing feelings-TAS-20 | 0.15 | .18 | 1.96* | | | |
| Pain catastrophizing X Difficulty in describing feelings | −0.00 | −.14 | −1.57 | | | |

*Note*. *$p \leq .05$. **$p \leq .01$.

Figure 1 shows the pain catastrophizing x difficulty in identifying feelings interaction. Low, medium, and high levels (for both terms) were computed using the mean as the medium value and considering 1 *SD* below the mean as the low level and 1 *SD* above the mean as the high level (Aiken & West, 1991). Simple slope in the line showing low difficulty identifying feelings ($t_{93}$ = 3.08, $p$ < .01) was significant. Patients with different levels of difficulty in identifying feelings did not differ in anxiety under conditions of high pain catastrophizing. By contrast, differences were observed under conditions of medium-low pain catastrophizing: subjects reporting high difficulty in identifying feelings scored significantly higher in anxiety than subjects reporting low difficulty in identifying feelings.

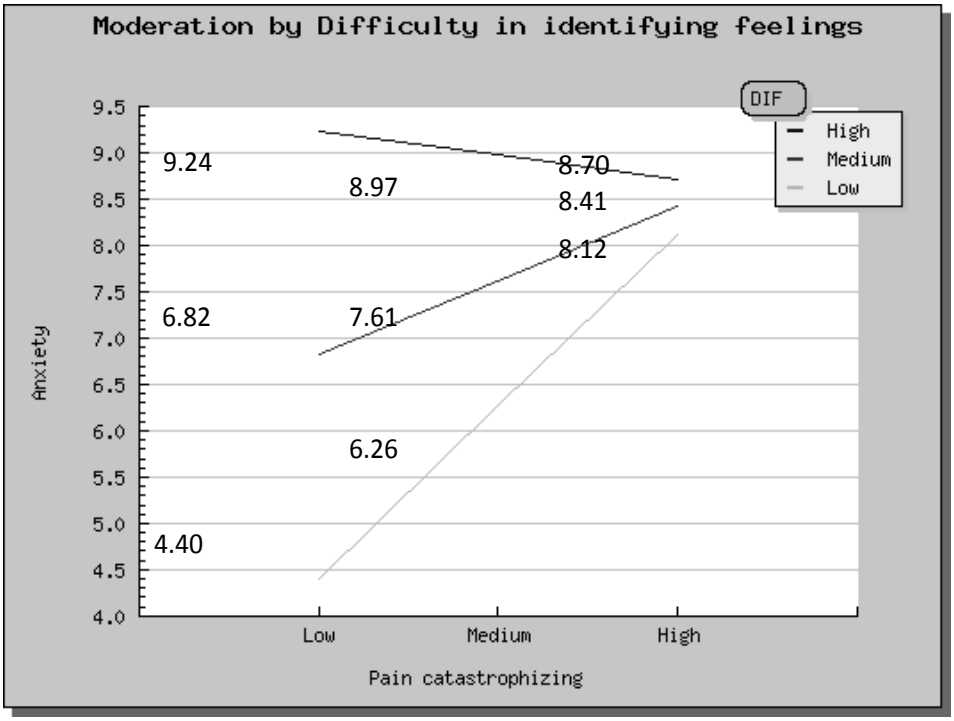


*Figure 1.* Moderating role of alexithymia (difficulty in identifying feelings, DIF) in the relationship between anxiety and pain catastrophizing.

Two moderation analyses tested whether the fear of pain x difficulty in identifying feelings interaction and the fear of pain x difficulty in describing feelings interaction were

significant predictors of anxiety after controlling the effect of physical symptoms, fear of pain and difficulty in identifying feelings (or difficulty in describing feelings) (see Table 6). In Step 1, pain experience and sleep quality were identified as significant predictors. In Step 2, the effects of these predictors disappeared when fear of pain was included and fear of pain was identified as a significant predictor. In Step 3a, the contribution of fear of pain remained significant when difficulty in identifying feelings was included, and this measure of alexithymia was also a significant predictor. In Step 3b, fear of pain and difficulty in identifying feelings were retained as significant predictors. In Step 4a, only fear of pain was identified as a significant predictor. In Step 4b, fear of pain and difficulty in describing feelings were significant predictors and a significant effect was observed in the fear of pain x difficulty in describing feelings interaction; this indicated that the relationship between anxiety and fear of pain is moderated by this facet of alexithymia.

**Table 6.** Alexithymia as a Moderator between Anxiety and Fear of Pain in Fibromyalgia Women

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Pain experience-SF-MPQ | 0.16 | .37 | 3.63** | .24 | .24 | 13.43** |
| Sleep quality-PSQ | 0.23 | .22 | 2.15* | | | |
| Step 2 | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .14 | 1.31 | .37 | .12 | 16.14** |
| Sleep quality-PSQI | 0.14 | .13 | 1.35 | | | |
| Fear of pain-PASS-20 | 0.11 | .44 | 4.06** | | | |
| Step 3a | | | | | | |
| Pain experience-SF-MPQ | 0.07 | .16 | 1.60 | .43 | .05 | 15.27** |
| Sleep quality-PSQI | 0.09 | .08 | 0.95 | | | |
| Fear of pain-PASS-20 | 0.08 | .33 | 2.98** | | | |
| Difficulty in identifying feelings-TAS-20 | 0.11 | .27 | 2.88** | | | |
| Step 3b | | | | | | |
| Pain experience-SF-MPQ | 0.07 | .15 | 1.52 | .45 | .02 | 13.24** |

| | | | | | | |
|---|---|---|---|---|---|---|
| Sleep quality-PSQI | 0.08 | .08 | 0.87 | | | |
| Fear of pain-PASS-20 | 0.08 | .32 | 2.95** | | | |
| Difficulty in identifying feelings-TAS-20 | 0.10 | .26 | 2.85** | | | |
| Fear of pain X Difficulty in identifying feelings | −0.00 | −.15 | −1.83 | | | |
| Step 4a | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .13 | 1.27 | .39 | .01 | 12.93** |
| Sleep quality-PSQI | 0.12 | .11 | 1.21 | | | |
| Fear of pain-PASS-20 | 0.10 | .41 | 3.73** | | | |
| Difficulty in describing feelings-TAS-20 | 0.11 | .14 | 1.56 | | | |
| Step 4b | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .14 | 1.37 | .42 | .03 | 11.69** |
| Sleep quality-PSQI | 0.09 | .08 | 0.91 | | | |
| Fear of pain-PASS-20 | 0.10 | .41 | 3.81** | | | |
| Difficulty in describing feelings-TAS-20 | 0.14 | .17 | 1.91* | | | |
| Fear of pain X Difficulty in describing feelings | −0.00 | −.18 | −2.12* | | | |

*Note*. *$p \leq .05$. **$p \leq .01$.

Figure 2 shows the fear of pain x difficulty in describing feelings interaction. Simple slope in the line showing medium ($t_{93} = 3.28$, $p < .01$) and low difficulty in describing feelings ($t_{93} = 3.98$, $p < .001$) were significant. Under conditions of medium-low fear of pain, subjects reporting high difficulty in describing feelings scored significantly higher in anxiety than subjects reporting low difficulty in describing feelings.

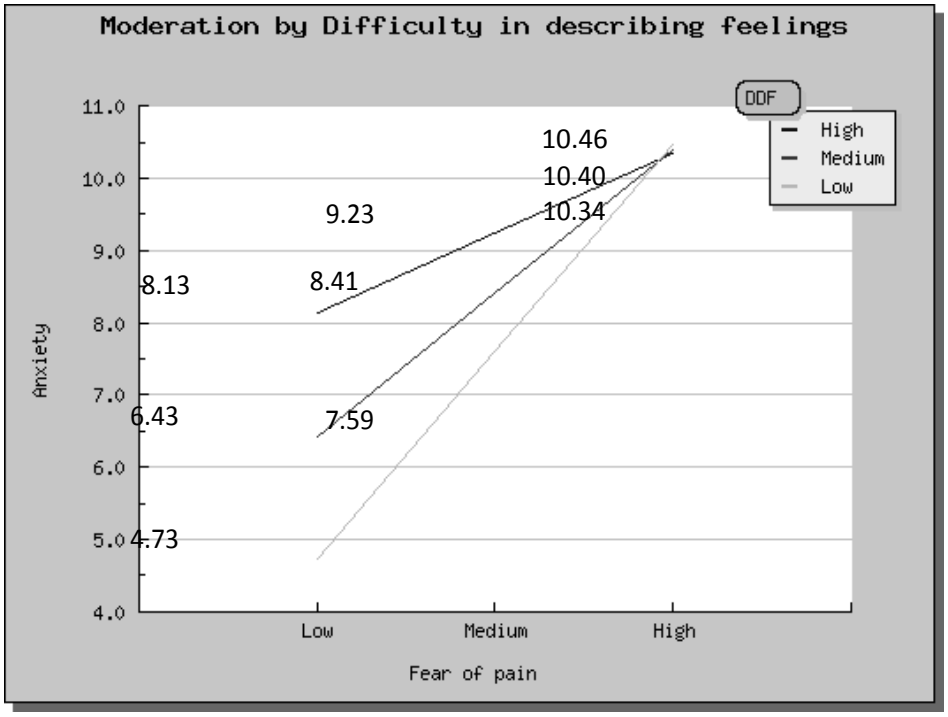


*Figure 2.* Moderating role of alexithymia (difficulty in describing feelings, DDF) in the relationship between anxiety and fear of pain.

**Discussion**

In the current psychological approach to medical illness, personality characteristics are considered as moderators or mediators that influence illness from risk and vulnerability factors to maintenance of symptoms and recovery (Porcelli & McGrath, 2007). The present study falls within this perspective, analyzing the moderating role of alexithymia in the relationship between emotional distress and pain appraisal variables in FM.

First, FM women and healthy women were compared regarding various components of alexithymia. Women in the clinical group showed more limitations in connecting with their affective states and recognizing the type of emotion they experience, and they also had greater difficulty in expressing their affective states and communicating them to others than those in the control group. These results are consistent with previous studies indicating that FM patients are more alexithymic than healthy controls (Brosschot & Aarsse, 2001; Sayar et al.,

2004; Tuzer et al., 2011; van Middendorp et al., 2008). The present study identified a large effect size in difficulty in identifying feelings and small effect sizes in the other alexithymia scales, in line with previous evidence (van Middendorp et al., 2008). In the present study, healthy women showed higher levels of externally oriented thinking than FM women. This is consistent with the consideration that this cognitive component may be less representative of alexithymia than emotional components.

Second, the relationship between alexithymia and clinical measures in FM women was explored. Difficulty in identifying feelings and difficulty in describing feelings were significantly correlated with lower sleep quality, higher anxiety and depression symptoms, and increased tendency to make a catastrophic appraisal of pain and experience fear associated with pain. Yet, none of these components of alexithymia were significantly associated with impairment in daily functioning. Difficulty in describing feelings – but not difficulty in identifying feelings – was significantly correlated with higher pain experience (sensory–affective aspects) and increased vigilance to and observance of pain. By contrast, externally oriented thinking was not correlated with any of the clinical variables. These findings are similar to those reported in previous studies that have shown strong links between alexithymia and emotional distress (Evren et al., 2006; Malt et al., 2002; van Middendorp et al., 2008) and catastrophizing (Lumley et al., 2002; Makino et al., 2012), but no relationship between alexithymia and disability (Sayar et al., 2004) or pain severity (Evren et al., 2006). These results partially differ from those of the study by Huber et al. (2009), which showed that alexithymia was associated with affective pain and pain tolerance but not with sensory pain. One might expect the affective dimension of pain (the closest one to emotions) to be more strongly associated with alexithymia; however, the current study shows that the three dimensions of pain (i.e., sensory, affective, and evaluative) are related to this personality

characteristic. It should be noted that this study used the combined sensory–affective scale of pain, which included mainly sensory items. Previous studies have suggested that alexithymia may result from disrupted brain structures involved in emotional processing. Healthy subjects identified as alexithymic have shown higher activation of the pregenual anterior cingulate cortex, right insula, and midbrain (Kano, Hamaguchi, Itoh, Yanai, & Fukudo, 2007). Considering previous neuroimaging studies, Kano and Fukudo (2013) have proposed that deficient development of emotional neural structures may lead to hypersensitivity to bodily sensations and unhealthy behaviors, and this may be a mechanism underlying the link between alexithymia and psychosomatic disorders. Further research is needed to determine the facet of pain most influenced by alexithymia and the neuropsychological substrate of this process.

Third, the contribution of alexithymia to physical symptoms was analyzed. Alexithymia was not a significant predictor of pain experience or sleep quality when the effect of emotional distress and pain appraisal factors was considered. The best predictor of pain experience was anxiety and the best predictor of sleep quality was depression. This result can be explained considering alexithymia as a personality characteristic and catastrophizing, fear, and vigilance to pain as pain appraisal characteristics of vulnerability, both types of characteristics may be acting as precursors to emotional distress, whether expressed as manifestations of depression or anxiety; in turn, this emotional distress may ultimately intensify pain and disrupted sleep. The findings differ partially from those of Lumley et al. (2002), who found that alexithymia and catastrophizing were significant predictors of pain; however, when depression was considered along with alexithymia, only depression significantly predicted pain. The findings also differ from those of Katz et al. (2009), who identified sex, fear of pain, and alexithymia as significant predictors of pain. Such findings

are not directly comparable to the present study. Lumley et al. did not examine anxiety, fear of pain, and vigilance to pain as predictors and included patients with chronic myofascial pain; Katz et al. did not examine vigilance to pain as predictor and included healthy subjects, and neither of these studies analyzed the variables that contribute to sleep quality.

The differential role of negative emotions in the manifestations of FM shown in the present study is consistent with the accumulating evidence. Several reports have shown that anxiety and depression were independently associated with severity of pain and fatigue in FM (Kurtze, Gundersen, & Svebak, 1998), that anxiety – but not depression – was a significant predictor of physical functioning (Epstein et al., 1999), that, in comorbidity patients, fatigue was associated with depression whereas pain was associated with anxiety (Kurtze & Svebak, 2001), and that dysfunctional patients mainly reported anxiety disorders and interpersonally distressed patients mainly reported mood disorders (Thieme et al., 2004). It has been hypothesized that stress and depression contribute to deregulating neuroendocrine, immune, and central pain mechanisms in FM (see van Houdenhove & Luyten, 2006, for a review), yet, the specific mechanisms through which each negative emotional state exerts its influence are unknown.

Last, the moderating role of alexithymia in the relationship between anxiety and pain appraisal factors (pain catastrophizing and fear of pain) was explored. Difficulty in identifying feelings moderated the link between anxiety and pain catastrophizing. This finding reveals that the tendency to evaluate pain as threatening can have greater impact on secondary emotions (such as anxiety) when the patient shows a deficit in recognizing emotions and in differentiating between emotions and bodily sensations. It was also observed that difficulty in describing feelings moderated the relationship between anxiety and fear of pain. This suggests that the effect of primary emotions (such as pain-related fear) upon secondary emotions (such

as anxiety) is stronger when the patient finds it difficult to express and communicate the emotions experienced. In a previous study, van Middendorp et al. (2008) found that difficulty in describing feelings moderated the relationship between pain and affect intensity. The current study extends these findings, suggesting that inadequate affective regulation has a considerable influence on the transition process from negative pain appraisal to the development of maladaptive secondary emotions. In other words, individuals who have the ability to properly handle negative thoughts about pain and fear of pain are likely to show lower levels of anxiety.

In summary, our findings suggest that FM patients have difficulties identifying their affective states, differentiating them from other emotions or physical complaints, and expressing and communicating their feelings. These facets of alexithymia in interaction with negative pain appraisal (pain catastrophizing and fear of pain) may contribute to the development of emotional distress (anxiety), which in turn is associated with more severe symptoms (increased pain experience and poorer sleep quality). Therefore, interventions that guide patients to acquire an adequate knowledge of their emotional experiences may improve their clinical condition.

The present research has some weaknesses. Physical symptoms were only evaluated using self-report questionnaires. Assessing pain with a pressure algometer and sleep with polysomnography would have provided objective measures that might have shown a different relationship with alexithymia. A self-report was used to assess alexithymia; adding a clinical interview and measures estimated by significant others may have allowed a better assessment of this construct. It was not possible to report the validity of the measures applied in the clinical and control groups. In addition, including a control group of non-fibromyalgic chronic pain patients would have contributed clarifying the specific alexithymic characteristics of FM

patients. The effect of other personality traits such as neuroticism, which may share some variance with alexithymia, was not controlled. Only Spanish women with FM were considered, so results may not be applicable to other demographic or cultural groups. Last, the cross-sectional design of the study does not allow establishing causal relationships.

This study has practical implications. Since alexithymia can play an important role in the manifestations of FM, the whole therapeutic approach should consider patients‟ style of affective processing and regulation. Techniques aimed at reducing emotional avoidance and promoting emotional expression may be helpful. For example, helping patients with FM identify their emotional experiences (e.g., fear of pain) as being distinct from other emotions or bodily sensations and express these emotional experiences, may contribute to reducing dysphoric affective states such as anxiety. Several controlled trials have shown that interventions focused on written emotional disclosure (Broderick, Junghaenel, & Schwartz, 2005; Gillis, Lumley, Mosley-Williams, Leisen, & Roehrs, 2006) and affective self-awareness (Hsu et al., 2010) were associated with clinical improvements in FM. Recently, Geenen, van Ooijen-van der Linden, Lumley, Bijlsma, and van Middendorp (2012) have suggested that adjustment in FM depends on the specific combinations of emotion processing style and emotion regulation strategies. They found that, in patients high in affect intensity, emotion expression – but not cognitive reappraisal – was associated with less impairment; yet, they did not find cognitive reappraisal to be more adaptive than emotion expression in alexithymic patients. Therefore, we consider it would be advisable to apply a treatment that combines both strategies according to the clinical profile of the FM patient. The intervention should aim to reduce emotional distress or alexithymia depending on the type of emotion. Experiencing and communicating secondary emotions (e.g., anxiety, depression) may increase pain and interventions focused on reducing these emotions are recommended, by

contrast, awareness and expression of primary adaptive emotions (e.g., fear, sadness) may reduce pain and therapies such as emotional disclosure may be beneficial (Lumley et al., 2011). The recent study by Woolfolk, Allen, and Apter (2012) has shown that affective–cognitive–behavioral therapy including, among others, facilitation of emotional awareness and cognitive restructuring resulted in substantial improvements in pain and functioning in FM patients.

In conclusion, alexithymia is a personality trait that is notably involved in the clinical manifestations of FM. Difficulty in identifying emotions and difficulty in describing emotions in interaction with dysfunctional pain appraisal (pain catastrophizing and fear of pain) may contribute to a clinical problem of anxiety. Assessing the level of alexithymia in FM patients is important not only to identify inadequate emotional regulation that may affect the disease, but also to choose the most appropriate psychological intervention strategies.

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*Artículo 3*

# Relationship Between Pain and Emotional Distress and Disability in Fibromyalgia: The Mediating Role of Catastrophizing, Acceptance and Coping

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(en revisión)

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# Relationship between pain and emotional distress and disability in fibromyalgia: The mediating role of catastrophizing, acceptance and coping.

***Background and Objectives:*** Catastrophizing, acceptance and coping have an important predictive value in chronic pain, however, it is not known which of these variables plays the greatest contribution in fibromyalgia (FM). This study explored the mediating role of catastrophizing, acceptance, and coping in the relationship between pain and emotional distress/disability in FM sample. ***Design and methods:*** Ninety two FM patients and 51 healthy subject controls were evaluated on pain and psychological related variables. ***Results:*** Catastrophizing, acceptance, behavioral coping, and emotional coping were significantly correlated with emotional distress and/or disability. Catastrophizing had a significant effect as a mediator on the relationship between pain and depression/anxiety. ***Conclusions:*** The current management of FM could improve by including cognitive techniques aimed at modifying the negative appraisal of pain.

**Key words**: Fibromyalgia, pain, catastrophizing, acceptance, coping.

## Introduction

The American College of Rheumatology (ACR) defines Fibromyalgia (FM) as a condition characterized by widespread musculoskeletal pain for at least three months and pain on pressure in at least 11 of the 18 tender points (Wolfe et al., 1990). In addition to pain, FM patients also experience other disturbing symptoms such as fatigue, unrefreshed sleep, muscle weakness, irritable bowel syndrome, nervousness, depression, and thinking/remembering problems (Wolfe et al., 2010). FM has a negative impact on patients‟ quality of life (Pereira and Vázquez, 2012) and is associated with higher levels of work productivity loss (McDonalds, Di Bonaventura and Ullman, 2011). The prevalence of FM is estimate 2–5% of the population and predominantly among women (Serber, Cronan, & Walen, 2003).

Although the etiology of FM is still unknown, evidence suggests that genetic, biological, and environmental factors are involved in its development and maintenance (see Stisi et al., 2008, for a review). It is widely accepted that cognitive, affective, and behavioral variables are related to adjustment and well-being in several chronic musculoskeletal conditions, including FM (Keefe et al., 2004; Leeuw et al., 2007; Vlaeyen and Linton, 2012). For instance, Keefe et al. (2004) highlighted the relevance of factors that increase pain, psychological distress, and physical impairment (e.g., catastrophizing, pain-related anxiety/fear, and helplessness) and factors that decrease them (e.g., coping strategies, self-efficacy, readiness to change, and acceptance). Numerous experimental and clinical studies have shown the contribution of variables such as pain catastrophizing, pain acceptance, and coping style in the experience of chronic pain (for a review, see Peres and Luchetti, 2010; Quartana, Campbell and Edwards, 2009; and Thompson and McCracken, 2011, respectively).

Pain-related catastrophizing is characterized as an exaggerated and negative mental schema brought to bear during actual or anticipated painful experiences (Sullivan et al.,

2001). Although this construct shares variance with negative affectivity and cognitive-affective variables related to pain, the influence of catastrophizing on the pain experience is widely recognized (Quartana et al., 2009). In several chronic pain syndromes, catastrophizing has been related with disability (Picavet, Vlaeyen and Schouten, 2002), negative mood (Grant, Long and Willms, 2002), pain severity, affective distress, pain-related disability, and poor outcome of treatment (Edwards et al., 2006a), less self-efficacy for physical function and for coping with symptoms (Sánchez et al., 2011), and even increased risk of suicide ideation (Edwards et al., 2006b).

Acceptance of pain is defined as a willingness to live with pain with no need to reduce, avoid or try to change it (McCracken, 1999). This construct includes two aspects: activity engagement, that is, continuing life activities regardless of pain, and pain willingness, defined as experiencing pain without efforts to avoid or control it (McCracken, Vowles and Eccleston, 2004). Acceptance has been associated with less pain, disability, depression, and pain-related anxiety (McCracken and Eccleston, 2003), less prone to pain catastrophizing (Boer, Steinhagen, Versteegen, Struys, Sanderman, 2014), better functioning (Esteve, Ramírez-Maestre and López-Martínez, 2007), more activity (Gyurcsik et al., 2011), increased positive affect, and reduced negative affect (Kranz, Bollinger and Nilges, 2010) and greater success at living according to personal values (McCracken and Yang, 2006) in several musculoskeletal pain conditions.

Coping strategies are the cognitive and behavioral efforts of individuals to achieve control and manage the situation that has been evaluated as a physical or emotional threat (Folkman et al., 1986). Chronic pain patients have shown a greater tendency to avoid or escape pain as a way of coping compared to healthy controls (Ablin et al., 2008; Amir et al., 2000). Studies on these patients have identified passive behavioral coping as a predictor of

disability and passive cognitive coping as a predictor of depression (Samwel et al., 2006), avoidance-oriented coping has been found to have a negative impact on pain intensity (Cui et al., 2009). Regarding emotional-focused coping have been found different results, has observed to contribute negatively to mental and general health and functioning (Boehm, Eisenberg and Lampel, 2011) and associated with better health general status (Cronan, Serber and Walen, 2002); however coping variables seems to be context specific (Smith and Wallston, 1996).

To date, few studies have simultaneously analyzed the role of these psychological variables in chronic pain; conducted on non-fibromyalgia pain samples. Some studies have compared the influence of catastrophizing and acceptance on the pain experience. Nicholas and Asghari (2006) found that, in patients with persistent pain, catastrophizing was a significant predictor of pain intensity and depression and activity engagement was a significant predictor of physical disability and depression; this component of pain acceptance played a significant contribution to depression when the effects of age, pain intensity, physical disability, fear of movement/(re)injury, and catastrophizing were controlled. In chronic pain patients, Esteve et al. (2007) observed that pain acceptance significantly determined functional status and functional impairment, coping had a significant influence on emotional distress and catastrophizing significantly affected pain intensity and anxiety. In patients who completed an interdisciplinary pain treatment, Vowles, McCracken and Eccleston (2007) found that, after controlling for changes in pain intensity, changes in catastrophizing and acceptance played a similar contribution to the improvement observed during intervention. In patients with chronic pain, Vowles, McCracken and Eccleston (2008) showed that acceptance partially mediated the effects of catastrophizing across depression, pain-related fear, and disability. In a study of experimentally-induced ischemic pain in

patients with chronic back pain, Richardson et al. (2009) observed that catastrophizing, but not acceptance, was a significant predictor of depressive symptoms and sensory and present pain intensity ratings of ischemic pain after controlling for the contribution of age, education, pain duration, and baseline chronic pain intensity. Later, Richardson et al. (2010) reported that catastrophizing and pain willingness were significant predictors of self-reported pain interference, but only pain willingness significantly predicted task interference during induced pain, when demographic and pain variables were controlled.

Some studies have also compared the impact of acceptance and coping on the pain experience. McCracken and Eccleston (2006) studied chronic pain patients and found that acceptance variables were stronger predictors of distress and disability than coping variables. In patients with chronic pain, McCracken, Vowles and Gauntlett-Gilbert (2007) observed that pain control-oriented coping significantly contributed to disability, depression, pain, avoidance, and sit-to-stand performance; by contrast, activity persistence was a significant predictor of uptime, pain-related anxiety, and avoidance. In FM patients, Rodero et al. (2011) found that several components of coping and acceptance were significant predictors of emotional distress and functioning but acceptance accounted for more variance than coping.

Although these studies represent an important contribution to the analysis of these psychological responses (catastrophizing, acceptance, and coping), there is disagreement about which one has a greater weight in adjustment/maladjustment to chronic pain. None of the previous studies jointly examined the value of these psychological responses (except Esteve et al., 2007) and all of them included mixed samples of patients with chronic pain or pain conditions other than FM (except Rodero et al., 2011).

To the best of our knowledge, the current study is the first to explore the predictive value of these psychological variables considered together in affective distress and

functioning of FM patients. To broaden previous research, this cross-sectional study was designed with the following objectives: (1) explore the differences between FM patients and healthy subjects regarding pain, depression, anxiety, pain catastrophizing, pain acceptance, and coping styles; (2) analyze the relationships between these variables in the FM group; and (3) assess and compare the mediator role of catastrophizing, acceptance, and coping in the relationship between pain and emotional distress and disability in FM patients.

## Method

*Participants and design*

Ninety-two FM patients (80 women and 12 men) and 51 healthy subject controls (39 women and 12 men) participated in this study. The clinical group was recruited from the FM associations in Malaga, Seville and Granada and from the Rheumatology Service and the Pain Unit of Virgen de las Nieves University Hospital in Granada, Spain. The inclusion criteria were: 1) being aged from 18 to 65 years old; 2) having been diagnosed with FM according to the ACR criteria (Wolfe et al., 1990); 3) being free of any severe psychological disorders; and 4) being free of other significant medical diseases. Two semi-structured one-hour individual interviews were conducted with each FM participant to obtain socio-demographic data and clinical information. After the interviews, participants were given a booklet of questionnaires that had to be completed individually at home and delivered in a week at the latest. It took about one hour to fill in the booklet.

FM patients had a mean age of 50.21 years (SD=8.15) and most of them were married (81.7%). Twenty-nine of these participants had elementary education, 23.7% had secondary education and 36.6% had professional training or university education. More than half of the patients were not working at the time (24.7% unemployed, 15.1% retired and 22.6% on sick

leave). The average time from FM diagnosis was 6.58 years (SD=5.22) but the mean duration of symptoms reported was 10.5 years (SD=9.55). In this group, 53.6% of subjects rated their health as being poor or bad. Eighty-nine percent of patients were receiving pharmacological treatment, but none of them were undergoing structured psychological therapy for this problem.

The healthy control group was recruited from non-healthcare community settings (e.g., students‟ families, associations of housewives or trades workers) and matched to the FM patient group in the main socio-demographic variables. The inclusion criteria for this group were being between 18 and 65 years old and being free of pain conditions and other important medical or psychological diseases. This group completed the same set of questionnaires as the clinical group. Healthy participants had a mean age of 48.12 (SD=8.97) and most of them were married (70.6%), had professional training or university education (52.8%) and had an active job status (84.3%). In this group, 67.5% of the subjects reported good health status.

No significant differences were found between the FM and control groups in age or level of education ($t_{141}$=1.42 and $x_5^2$=16.14 respectively, $p$>.06), but significant differences were found in labor status ($x_4^2$=31.07, $p$<.01). All participants signed informed consent for their questionnaire data to be used for research purposes. The study was approved by the Ethics Committee for Human Research of the University of Granada.

*Measures*

*Short-form McGill Pain Questionnaire* (*SF-MPQ*; Melzack, 1987). This questionnaire assesses pain experience with 15 descriptive items (sensory and affective) rated on a scale from 0 (no) to 3 (severe), pain intensity during the previous week with a visual analogue scale, and pain intensity at the time of the test. The Spanish version has shown adequate

concurrent validity (Lázaro et al., 2001) and internal consistency (Masedo and Esteve, 2000). In the present study, the sensory-affective scale of pain experience was used.

*Pain Catastrophizing Scale* (*PCS*; Sullivan, Bishop and Pivik, 1995). This 13-item self-report evaluates three aspects of catastrophic appraisal: magnification, rumination, and helplessness. The items are rated on a scale from 0 (not at all) to 4 (all the time). The Spanish version has shown good 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 items are rated on a scale from 0 (never true) to 6 (always true). The Spanish version has shown adequate test-retest reliability, internal consistency, and construct validity (Rodero et al., 2010).

*COPE-Dispositional Questionnaire* (Carver, Scheier and Weintraub, 1989). This is a 60-item questionnaire that assesses coping style. The Spanish adaptation (Crespo and Cruzado, 1997) includes 6 subscales: behavioral problem-focused coping, cognitive problem-focused coping, coping of emotions, behavioral avoidance, cognitive avoidance, and alcohol/drug use. The items are rated on a scale from 1 (never or almost never) to 4 (very usually). This instrument has shown good internal consistency and test-retest reliability in most subscales (Crespo and Cruzado, 1997).

*Hospital Anxiety and Depression Scale* (*HADS;* Zigmond and Snaith, 1983). The HADS is a 14-item inventory designed to screen depression and anxiety symptoms in non-psychiatric hospital contexts. The items are rated on a scale from 0 to 3. The Spanish version has shown good internal consistency and external validity with adequate sensitivity and specificity (Herrero et al., 2003).

*Fibromyalgia Impact Questionnaire* (*FIQ*; Burckhardt, Clark and Bennett, 1991). This 10-item self-report evaluates the current health status of FM patients based on functional capacity for daily living, days they felt well/unable to work, and other clinical manifestations. The Spanish version has shown good test-retest correlations, internal consistency, validity, and sensitivity to change (Rivera and González, 2004).

*Data analyses*

All statistical analyses were performed with SPSS 18.0 software (SPSS Inc., Chicago, IL, USA), and SPSS macro for multiple mediation (www.quantpsy.org). An alpha level of .05 was taken as the critical level of significance.

Student t-tests were computed to identify differences between FM and control groups. Cohen‟s d was used to examine effect sizes. Pearson‟s correlation coefficients were performed to analyze the relationships between variables. A multiple mediation model was tested with catastrophizing, acceptance, and coping as mediators of the effect of pain on depression, anxiety, and FM impact. Mediation processes consider the direct effect, the indirect effect, and the total effect (Preacher and Hayes, 2008). We calculated the direct effect of the *X* variable on the *Y* variable (*c´* path) and the specific indirect effects of *X* on *Y* through each *M* mediator (*ab* paths). Path *a* represents the effect of *X* on the proposed mediator, whereas path *b* is the effect of *M* on *Y* partialling out the effect of *X*. Lastly, we determined the total effect of *X* on *Y* (*c* path), which is the sum of the direct and indirect effects. The paths were quantified with unstandardized regression coefficients (B). To test the significance of the indirect effects, percentile-based, bias-corrected (BC), and bias-corrected and accelerated (BCa) bootstrap confidence intervals (CIs) were computed following the procedures

recommended by Preacher and Hayes (2008). The bootstrap estimates were based on 5000 bootstrap samples and a 95% CI was considered.

## Results

*Comparative analysis*

No significant differences were found between men and women in the FM group ($t_{86}$ between -2.14 and 0.44, $p$>.10) or in the control group ($t_{48}$ between -1.93 and 0.48, $p$>.09) among the variables evaluated. The only exception was the scale of alcohol/drug use, in which men in the FM and control groups had higher scores than women ($t_{91}$=4.46 and $t_{48}$=2.97, $p$<.01). Thus, women and men were analyzed together in the control and FM groups.

Table 1 shows the comparisons between FM patients and healthy subjects in the self-reports. The FM group reported significantly higher scores in pain than the control group. This was consistent with expected scores in patients with persistent pain. The FM group showed significantly higher levels of depression and anxiety than the control group. Given the cut-off scores in the HADS (Zigmond and Snaith, 1983), the scores of the FM group indicated a doubtful clinical problem. Results in FM impact showed considerable levels of impairment, slightly higher than those reported by Rivera and González (2004). The FM group showed significantly higher mean scores in pain catastrophizing and significantly lower mean scores in pain acceptance than the control group. No differences were found between both groups in all the subscales of coping styles, except in alcohol/drug use, where FM patients obtained lower mean scores than control subjects.

**Table 1**. Comparative analysis between FM and healthy groups in the clinical variables.

| Variables | FM group (n=92) | Healthy group (n=51) | t | d |
|---|---|---|---|---|

| | M (SD) | M (SD) | | |
|---|---|---|---|---|
| SF-MPQ (Pain) | 19.55 (9.30) | 2.82 (5.25) | 11.18** | 2.29 |
| HADS (Emotional distress) | | | | |
| Depression | 9.87 (4.48) | 3.66 (3.46) | 8.50** | 1.66 |
| Anxiety | 10.45 (4.21) | 5.90 (4.05) | 6.17** | 1.09 |
| FIQ (FM impact) | 58.86 (16.32) | -- | -- | |
| PCS (Pain catastrophizing) | | | | |
| Rumination | 8.04 (4.33) | 5.61 (4.58) | 3.11** | .54 |
| Magnification | 4.72 (2.89) | 2.90 (2.99) | 3.43** | .62 |
| Helplessness | 11.00 (6.01) | 4.88 (4.75) | 6.18** | 1.14 |
| PCS-total | 23.75 (12.34) | 13.47 (11.33) | 4.84** | .87 |
| CPAQ (Pain acceptance) | | | | |
| Activity engagement | 30.12 (15.71) | 38.33 (12.65) | -2.91** | -.58 |
| Pain willingness | 23.97 (10.32) | 29.29 (14.39) | -2.41* | -.43 |
| CPAQ-total | 53.04 (20.49) | 65.15 (19.92) | -3.13** | -.60 |
| COPE (Coping style) | | | | |
| Behavioural coping | 29.38 (7.73) | 31.22 (5.61) | -1.82 | |
| Cognitive coping | 33.85 (6.78) | 33.61 (7.12) | .20 | |
| Emotional coping | 28.90 (7.73) | 28.94 (8.57) | -.03 | |
| Behavioural avoidance | 18.71 (2.69) | 18.86 (3.61) | -.27 | |
| Cognitive avoidance | 20.01 (5.02) | 19.32 (5.41) | .93 | |
| Alcohol/drugs use | 4.11 (.74) | 4.55 (1.53) | -2.31* | -.39 |

Note: *$p$<.05,**$p$<.01.

*Correlation analysis*

Correlation analyses were calculated for depression, anxiety, and FM impact across measures of pain catastrophizing, pain acceptance, and coping styles (see Table 2). Significant correlations were observed between pain and depression, anxiety, and FM impact. Likewise, pain was significantly correlated with catastrophizing, however, no significant correlations were found between pain and acceptance or between pain and coping styles. Depression,

anxiety, and FM impact showed significant positive correlations with catastrophizing, and significant negative correlations with acceptance. Regarding coping styles, only significant correlations were observed between depression and behavioral coping and between anxiety and emotional coping and behavioral coping.

**Table 2.** Correlations between the variables included in the study for the FM group.

| Variables | SF-MPQ Pain | HADS Depression | HADS Anxiety | FIQ Impact |
|---|---|---|---|---|
| SF-MPQ (Pain) | | .33** | .29** | .42** |
| PCS (Pain catastrophizing) | | | | |
| Rumination | .25* | .46** | .44** | .26* |
| Helplessness | .32** | .55** | .49** | .34** |
| Magnification | .26** | .46** | .53** | .29** |
| PCS-Total | .30** | .54** | .52** | .32** |
| CPAQ (Pain acceptance) | | | | |
| Pain willingness | -.11 | -.38** | -.34** | -.25* |
| Activity engagement | -.17 | -.31** | -.36** | -.36** |
| CPAQ-Total | -.19 | -.44** | -.44** | -.37** |
| COPE (Coping style) | | | | |
| Behavioural coping | -.04 | -.37** | -.23* | -.11 |
| Cognitive coping | .11 | -.17 | -.16 | -.01 |
| Emotional coping | .18 | .20 | .31** | .17 |
| Behavioural avoidance | -.20 | -.02 | .03 | -.15 |
| Cognitive avoidance | .01 | -.02 | .07 | -.12 |
| Alcohol/drugs use | -.06 | -.01 | .14 | -.20 |

Note: *$p$<.05,**$p$<.01.

Considering the correlations with the independent/dependent variables of the mediation models, pain catastrophizing (total), pain acceptance (total), behavioral coping, and emotional

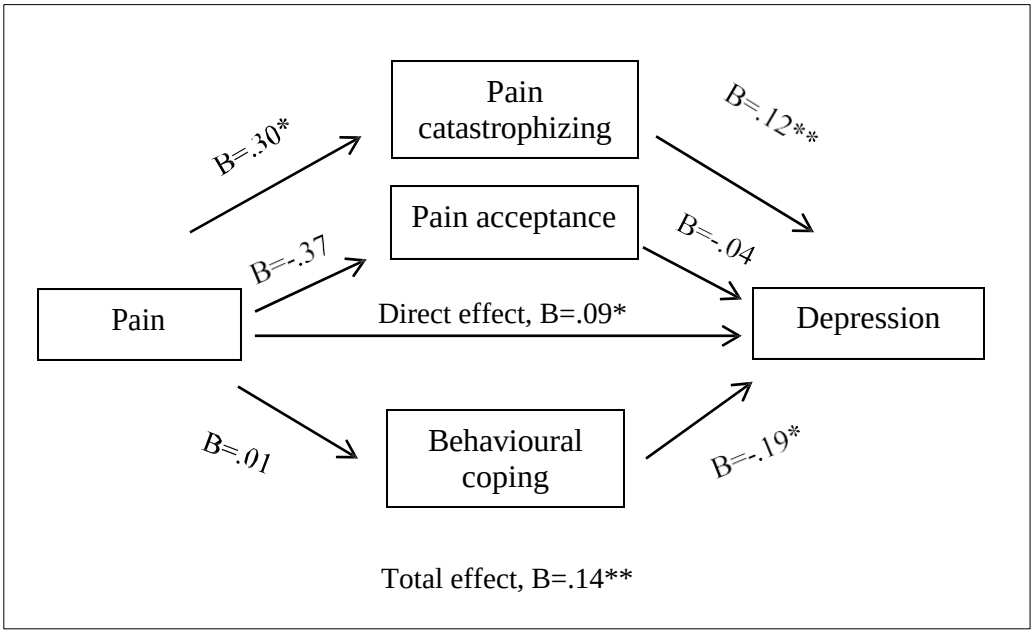
coping were included as proposed mediators in the relationship between pain and emotional distress/FM impact.

*Mediators in the relationship between pain and depression*

Figure 1 shows the effect of pain on depression through pain catastrophizing, pain acceptance and behavioral coping as proposed mediators. Significant total and direct effects of pain on depression were found ($t$=2.64, $p$<.01 and 2.05, $p$<.05, respectively). A significant effect of pain on catastrophizing ($t$=2.03, $p$<.05) was also observed, although the effect of pain on acceptance or behavioral coping was not significant ($t$=-1.43 and .19, $p$>.15, respectively). The effects of the proposed mediators catastrophizing and behavioral coping on depression were significant ($t$=2.95, $p$<.01 and -2.81, $p$<.05, respectively), but the effect of acceptance on depression was not significant ($t$=-1.64, $p$=.10). The model explained 36.12% of the variance in depression ($F_{4,76}$=12.31, $p$<.01). Table 3 summarizes the point estimate and 95% CIs (percentile, BC, and BCa) values. When the 95% CI for the estimates of the mediation effect does not include zero, the mediation effect is considered significant at the .05 level. The 95% CIs showed the significance of the indirect effect of pain on depression via the mediator catastrophizing (see Table 3).

These results revealed that the impact of pain on depression was mediated by catastrophizing but not by acceptance or behavioral coping.

*Figure 1*. Multiple mediation model of the relationship between pain and depression.




Note: *$p$<.05,**$p$<.01.

**Table 3**. Mediations of the effect of pain on depression, anxiety and FM impact.

| | | Bootstrapping | | | | | |
|---|---|---|---|---|---|---|---|
| | Point estimate | Percentile 95% CI | | BC 95% CI | | BCa 95% CI | |
| | | Lower | Upper | Lower | Upper | Lower | Upper |
| Mediators between pain and depression | | | | | | | |
| *Indirect effects* | | | | | | | |
| Total | .49 | -.01 | .12 | -.01 | .13 | -.01 | .12 |
| Pain catastrophizing | .04 | .01 | .09 | .01 | .09 | .01 | .09 |
| Pain acceptance | .01 | -.01 | .05 | -.01 | .05 | -.01 | .05 |
| Behavioural coping | -.01 | -.03 | .03 | -.04 | .02 | -.04 | .02 |
| Mediators between pain and anxiety | | | | | | | |
| *Indirect effects* | | | | | | | |
| Total | .06 | .01 | .12 | .01 | .13 | .01 | .12 |
| Pain Catastrophizing | .03 | -.01 | .09 | .01 | .09 | .01 | .09 |
| Pain acceptance | .02 | -.01 | .05 | -.01 | .06 | -.01 | .06 |
| Emotional coping | .01 | -.01 | .04 | -.01 | .05 | -.01 | .05 |

| Mediators between pain and FM impact | | | | | | | |
|---|---|---|---|---|---|---|---|
| *Indirect effects* | | | | | | | |
| Total | .13 | -.01 | .29 | -.01 | .30 | .01 | .29 |
| Pain catastrophizing | .04 | -.08 | .20 | -.06 | .24 | -.06 | .24 |
| Pain acceptance | .09 | -.01 | .28 | -.01 | .31 | -.01 | .29 |

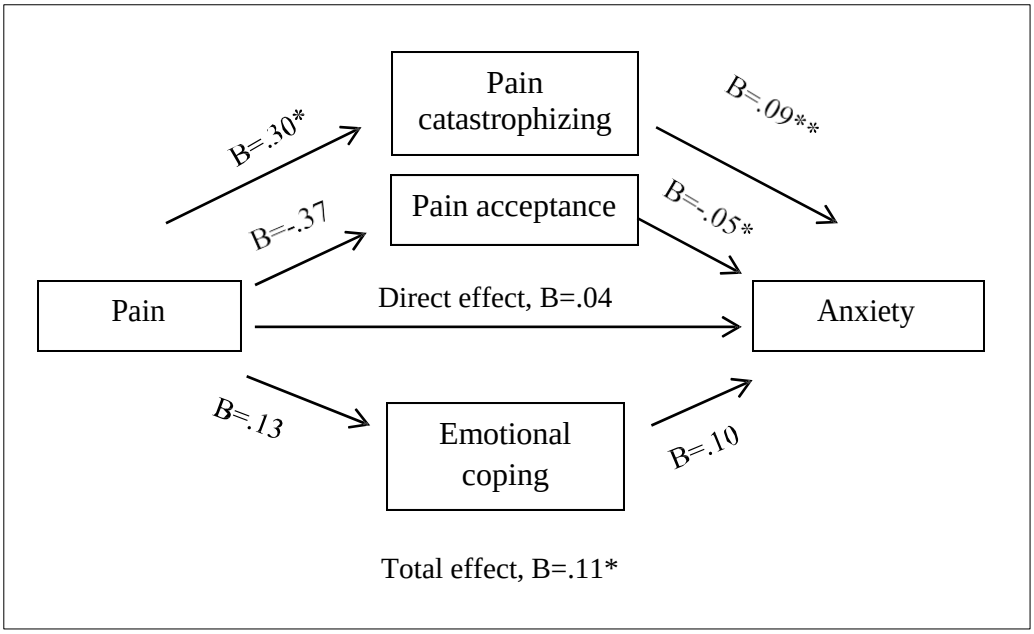
Note: The point estimate is the indirect effect calculated in the original samples; CI, confidence interval; BC, bias corrected; BCa, bias corrected and accelerated.

*Mediators in the relationship between pain and anxiety*

The mediator role of pain catastrophizing, pain acceptance, and emotional coping in the relationship between pain and anxiety was examined (see Figure 2). The total effect of pain on anxiety was significant ($t$=2.10, $p$<.05). A significant contribution of pain on catastrophizing ($t$=2.03, $p$<.05) and catastrophizing on anxiety ($t$=2.26, $p$<.01) was observed. No significant effects of pain on acceptance or emotional coping ($t$=-1.43 and 1.45, $p$>.15, respectively) were found. Finally, significant effects of acceptance on anxiety ($t$=-2.09, $p$<.05) and non-significant effects of emotional coping on anxiety ($t$=1.85, $p$=.07) were found. In this model, the direct effect of pain on anxiety was not significant ($t$=1.05, $p$=.29), so the total effect was mainly due to the influence of catastrophizing as a mediator. The model accounted for 28.12% of the variance in anxiety ($F_{4,76}$=8.82, $p$<.01). According to the 95% CIs, the indirect effect of pain on anxiety with catastrophizing as a mediator was significant (see Table 3).

The findings showed that catastrophizing mediated the influence of pain on anxiety. By contrast, neither acceptance nor emotional coping showed significant mediator effects.

*Figure 2***.** Multiple mediation model of the relationship between pain and anxiety.



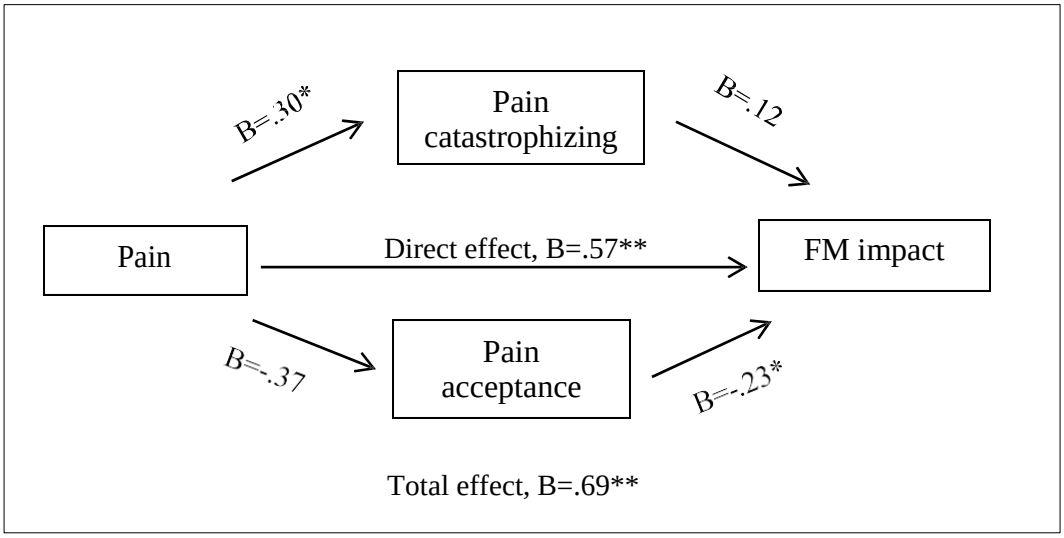

Note: *$p$<.05,**$p$<.01.

*Mediators in the relationship between pain and FM impact*

Pain catastrophizing and pain acceptance were evaluated as mediators of the effect of pain on FM impact (see Figure 3). The total and direct effects of pain on FM impact were significant ($t$=3.68 and 3.14, $p$<.01, respectively). The effect of pain on catastrophizing was significant ($t$=2.03, $p$<.05) but the effect of catastrophizing on FM impact was not ($t$=.79, $p$=.43). Moreover, the effect of pain on acceptance was not significant ($t$=-1.43, $p$=.15) but the effect of pain acceptance on FM impact was significant ($t$=-2.58, $p$<.05). The model explained 24.62% of the variance in FM impact ($F_{3,77}$=9.71, $p$<.01). Taking into account the 95% CIs, none of the indirect effects analyzed were significant (see Table 3).

Results showed that neither catastrophizing nor acceptance were significant mediators of the effect of pain on FM impact.

*Figure 3*. Multiple mediation model of the relationship between pain and FM impact.




Note:*$p$<.05,**$p$<.01.

**Discussion**

Although pain catastrophizing, pain acceptance, and coping style have an important role in the pain experience, is not known which of these variables plays the greatest contribution to adjustment to pain in FM. The aim of this study was to explore the relationship between pain, affective distress, and impairment in FM patients, considering the potential mediating role of catastrophizing, acceptance, and coping.

Firstly, patients with FM and healthy control subjects were compared in the various self-reported measures included in the study. As expected, FM patients showed significantly higher levels of pain, depression, anxiety, and pain catastrophizing than control subjects. However, the clinical group reported significantly lower levels of acceptance of pain than the healthy group. These results are consistent with previous research (Geisser et al., 2003; Gormsen, Rosenberg, Bach and Jensen, 2010). Regarding coping strategies, results revealed differences between both groups in the alcohol/drug use subscale but not in behavioral, cognitive, and emotional coping or behavioral and cognitive avoidance. These results are similar to those obtained by Raak Hurtig and Wahren (2003), who did not find differences in

coping strategies between FM patients and healthy controls, however, they differ from other studies (Ablin et al., 2008; Amir et al., 2000) that support an avoidant coping style of these patients. Differences in this variable may depend on the construct of coping assessed by the instrument (COPE) used in the present study.

Secondly, the relationships between clinical measures in the FM group were examined. Strong correlations were found between pain and anxiety, depression, and FM impact. In addition, the tendency to catastrophically appraise painful experiences was associated to higher level of pain, emotional distress, and disability, findings that are widely recognized in chronic pain patients (Grant et al., 2002; Keefe et al., 2004; Picavent et al., 2002; Quartana et al., 2009). Additionally, results revealed that acceptance of living with pain without reducing, avoiding or trying to change it was associated with less depression, anxiety, and impairment. These findings are similar to those reported in previous research (Keefe et al., 2004; Kranz et al., 2010; McCracken and Eccleston, 2003; Thompson and McCracken, 2011). It should be noted that pain did not significantly correlate with pain acceptance (pain willingness or activity engagement). This result is consistent with other studies (Esteve et al., 2007; Nicholas and Asghari, 2006; Richardson et al., 2009) that have not shown acceptance to be a significant predictor of pain intensity. In addition, the present study found that behavioral coping was associated with a lower level of depression and anxiety while emotional coping was associated with a higher level of anxiety. By contrast, none of the coping styles were related to pain experience or disability. These findings are consistent with previous reports that have shown that problem-focused coping is related to better psychological functioning (Peres and Lucchetti, 2010) and emotional-focused coping is related to worse mental health (Boehm et al., 2011).

Lastly, several mediator models were applied to explore how pain affects emotional distress and functioning of FM patients through specific mediators. The first model considered the relationship between pain and depression via catastrophizing, acceptance, and behavioral coping as mediators. Higher catastrophizing and lower coping behavior significantly contributed to depression, however, only catastrophizing was identified as a significant mediator between pain and depression. The second model examined the relationship between pain and anxiety with catastrophizing, acceptance, and emotional coping as mediators. Higher catastrophizing and lower acceptance significantly contributed to anxiety, but only catastrophizing played a significant mediator role between pain and anxiety. This model did not show a significant direct effect of pain on anxiety. Therefore, the impact of the pain experience on this negative emotion is due to the mediators, particularly catastrophizing. The third model considered the relationship between pain and FM impact via catastrophizing and acceptance as mediators. Acceptance but not catastrophizing had a significant influence on disability. However, none of these variables were significant mediators in the relationship between pain and FM impact.

In short, the findings show that pain leads to depression directly and via the mediator catastrophizing, and pain does not have a direct effect on anxiety and its impact is produced through the mediator catastrophizing. Acceptance and coping did not play a mediator role in the relationships analyzed.

The only previous research that has compared the influence of pain-related cognitions, acceptance, and coping on adjustment to chronic pain is the study by Esteve et al. (2007). These authors found that pain acceptance significantly influenced functional status and functional impairment, coping had a significant effect on emotional distress, and catastrophizing significantly determined pain intensity and anxiety. They also found that

catastrophizing had indirect effects on depression and functional impairment due to the mediating role of pain intensity. Our results partially agree with these findings. However, the present study differs from that of Esteve et al. in some methodological aspects. The latter was performed with a mixed sample of chronic pain patients, structural equation modeling, and different self-report measures.

The mediating role of pain catastrophizing between pain experience and emotional distress identified in the current study reveals that appraisal of pain as threatening is more important than pain *per se*. The findings also suggest that catastrophizing has a greater weight than other psychological variables such as acceptance or behavioral/emotional coping. Catastrophizing is a key construct in several theoretical approaches to chronic pain, such as the fear-avoidance model of chronic musculoskeletal pain (Leeuw et al., 2007; Vlaeyen and Linton, 2012). Our findings are consistent with this model and support the idea of pain catastrophizing as a mediator in the relationship between pain experience and emotional distress. The current study provides additional evidence of the validity of this model (Cook, Brawer and Vowles, 2006; Kamper et al., 2012; Martínez et al., 2011) and underlines the crucial role played by catastrophizing as a precursor of the dysfunctional responses to painful stimuli. Several studies have also shown that catastrophizing affects the neurophysiological pathways compromised in the pain experience by amplifying the pain-related cortical activation, interfering with the optimal functioning of the endogenous opioid pain-control system and activating systemic inflammatory processes (see the review by Campbell and Edwards, 2009). Although the influence of catastrophizing on pain experience is well accepted, more research is needed on the weight of this variable compared to others such as self-efficacy and sleep quality that have been shown to play a mediating role in the relationship between pain and several manifestations of FM (Miró et al., 2011).

The present study has some practical implications. Firstly, it highlights the importance of considering catastrophizing appraisal and promoting more functional cognitions about pain to reduce emotional suffering in FM patients, and the need to include cognitive restructuring techniques. Secondly, it highlights the complementary effect of an attitudinal change focused on the willingness to live with pain without trying to reduce, avoid or change it, and the appropriateness of considering acceptance-based strategies.

Although there are different approaches to catastrophizing and acceptance as complementary or antagonistic constructs, it seems to be a theoretical rather than an empirical issue. FM patients are likely to benefit from interventions that address both psychological variables. For example, it has been suggested that intervention could focus on decreasing or mindfulness/accepting emotional distress depending on the type of affective experience. Experiencing and expressing secondary emotions such as depression or anxiety may exacerbate pain and therapies aimed at reducing them are preferred, however, the awareness and expression of primary adaptive emotions such as sadness or fear may reduce pain and interventions like mindfulness may be advisable (Lumley et al., 2011). In this sense, cognitive-behavioral therapy (CBT), mindfulness, and acceptance and commitment therapy (ACT) may be compatible strategies in the management of FM patients. Recent studies (Veehof et al., 2011; Wetherell et al., 2011) have shown that both interventions have similar benefits in chronic pain patients. Therefore, a comprehensive therapeutic approach than combines CBT and ACT according to the clinical profile of patients may be a desirable option.

The present study has some limitations. The data were based on a cross-sectional design, so it is not possible to establish causal attributions in the relationship between the variables. Pain experience was evaluated via a self-report and it would have been preferable to

complete these data with objective measures such as a pressure algometer. FM patients were recruited from different care settings. The influence of other potential mediators such as neuroticism, self-efficacy beliefs and sleep disturbances was not explored.

In conclusion, the present research provides greater understanding of the connections between psychological parameters involved in the experience of FM patients. The findings revealed that pain catastrophizing mediates the relationship between pain and depression/anxiety and that although neither pain acceptance nor coping style play a mediator role in these relationships, both contribute to emotional distress or disability. Future research analyzing alternative paths and mediators is needed to improve our understanding of FM.

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# TERCER ESTUDIO

*Artículo 4*

# Systematic Review of Psychological Treatment in Fibromyalgia

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# Systematic review of psychological treatment in fibromyalgia

**Abstract**

Fibromyalgia (FM) is a debilitating rheumatic disorder characterized mainly by the presence of continual and widespread musculoskeletal pain, besides other disturbing symptoms. There is inconsistent evidence about the effectiveness of the treatments developed so far, making FM a chronic disease that is difficult to treat. The aim of this literature review was to analyze the empirical studies about psychological treatment of FM that have been published over the last twenty years. We conducted a literature search of studies published between 1990 and 2012 using Medline and PsycINFO in the Ovid and ProQuest platforms and hand searching. In total, 58 original studies were identified. The present review presents a comprehensive analysis of the main characteristics of these studies and a description of the interventions developed in order to improve FM symptoms. The most used intervention modality was group treatment with a cognitive-behavioral approach. We also found intensive and remote treatments as well as multimodal therapy, hypnosis, cognitive-behavioral therapy for insomnia, behavioral therapies, mind-body based techniques, and biofeedback components. Finally, we discuss the clinical relevance of addressing the symptoms of patients with FM and its scientific validation.

**Key words:** Literature review, fibromyalgia, psychological treatment, multimodal approach, cognitive-behavioral therapy, mind-body techniques

## Introduction

According to the American College of Rheumatology (ACR), fibromyalgia (FM) is a debilitating disorder characterized by the presence of continual and widespread musculoskeletal pain for three months or longer and tenderness in at least 11 of 18 specific points of the body (Wolfe et al., 1990). In addition to pain, patients with FM report fatigue, sleep disturbance (Lineberger, Means & Edinger, 2007), anxiety and depression, cognitive deficits in attention, concentration and memory, and other symptoms such as irritable bowel syndrome, morning stiffness, headaches, or cramps (Gormsen, Rosenberg, Bach & Jensen, 2010; Miró, Martínez, Sánchez, Prados & Medina, 2011), with significant negative consequences for patients‟ quality of life and daily functioning (Rivera et al., 2006; Sánchez, Martinez, Miró, & Medina, 2011). In the latest diagnostic criteria review, Wolfe et al. (2010) emphasized the clinical approach and proposed pain, sleep disturbance, cognitive dysfunction, and physical symptoms as the most important diagnostic variables. In Europe, FM affects 2.9%-4.7% of the general population (Branco et al., 2010), mostly middle-aged women, generating considerable economic, social, and personal costs. It is estimated that people with FM spend almost twice as much on health services in four years people than people of the same age and gender (Thompson et al., 2011).

Due to the complex pathophysiological mechanisms involved in the genesis and maintenance of FM and considering a psychobiological model in order to fully understand the pain experience, current treatments involve multidisciplinary approaches. Evidence-based treatment guidelines developed by the American Pain Society (APS) (Burckhardt et al., 2005) the European League Against Rheumatism (EULAR) (Carville et al., 2008), and the Association of Scientific Medical Societies in Germany (AWMF, 2001) mostly recommend multimodal approaches that include pharmacological treatment, physical exercise, and

psychological intervention, specifically cognitive-behavioral treatment (CBT). The EULAR essentially recommends pharmacological treatment and highlights the common use of mixed serotonin and norepinephrine reuptake inhibitors (SNRIs) such as milnacipran and duloxetine, and anticonvulsants such as pregabalin (Burckhardt et al., 2005; Traynor, Thiessen, & Traynor, 2011). These drugs decrease pain intensity, reduce sleep disturbance and fatigue and thereby improve patients‟ quality of life. However, controlled pharmacological trials show that treatments are effective only in the short term (approximately 6 months after the beginning of use) (Abeles, Solitar, Pillinger, & Abeles, 2008) or are usually abandoned by patients because of their side effects (Marcus, 2011).

Multicomponent treatments including at least two non-pharmacological interventions are recommended by the APS (Burckhardt et al., 2005) and the AWMF (2001). In this area, previous meta-analytic reviews highlighted the positive results of treatments including physiotherapy and physical exercise (Busch et al., 2011), complementary and alternative medicine (Baranowsky, Klose, Musial, Haeuser, Dobos, & Langhorst, 2009), psycho-educational programs (Buckhart, Clark, & Bennett, 2005; Luciano et al., 2011), and psychotherapy for groups, families, couples, and individuals (Glombiewsky, Sawyer, Gutermann, Koenig, Rief, & Hofman, 2010) as well as combined and comprehensive treatments (Kurtais, Kutlay, & Ergin, 2006). It should be noted that the recommendations of the AWMF are based not only on empirical evidence but also on other issues such as consistency of study results, clinical relevance and effect size, cost-benefit relationship, ethical obligations, patient preferences, and practicability (AWMF, 2001).

There is currently a controversy about the effectiveness and positive results of psychological treatments in FM as well as their long-term maintenance. Recent systematic reviews have reached different conclusions. Glombiewsky et al. (2010) analyzed 23 studies

and found that psychotherapy significantly reduced pain intensity and depressive symptoms and that interventions based on relaxation/biofeedback were especially effective for sleep disturbance. Other meta-analytic studies have recognized the effectiveness of CBT at improving coping strategies, self-efficacy, and pain behavior (Bennett & Nelson, 2006; Bernardy, Fueber, Koellner, & Haeuser, 2010; Rossy et al., 1999), observing that such positive effects persist after the end of treatment (Goldenberg, Burckhardt & Crofford, 2004). At the same time, Bernardy et al. (2010) conducted a review of CBT in FM and did not identify any significant effects after treatment regarding pain intensity, fatigue, and subjective sleep disturbance. Sim and Adam (2002) and Bennett and Nelson (2006) compared different kinds of non-pharmacological treatments for FM patients and concluded that there was not enough evidence to highlight any intervention over the others. Nevertheless, most of these reviews have limitations due to heterogeneity of the studies and potential methodological biases (Glombiewsky, 2010).

Having observed the inconsistent evidence obtained so far, it is useful to analyze the characteristics of treatments applied in FM in order to identify the psychological proposals that may be of greater clinical utility.

The aim of the present study was to systematically and qualitatively review psychological treatments developed for FM over the last twenty years. In this regard, we described and integrated the contributions provided, analyzed the techniques and strategies used, reviewed the potential inconsistencies in the different approaches or explanatory models underlying the interventions, and examined the context in which treatments were delivered. Finally, we propose future directions to obtain the maximum benefit in the management of FM.

## Method

This systematic review was performed according to the recommendations of PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) (Urrútia & Bonfill, 2010). Studies were identified through an exhaustive bibliographic search in Medline and PsycINFO in the Ovid and ProQuest platforms. The terms used were *treatment* OR *therapy* OR *intervention* AND *fibromyalgia*. The literature search applied to the period from 1990 – the year of publication of FM diagnostic criteria (Wolfe et al., 1990) – to August 2012.

The following inclusion criteria were set to select the studies: 1) empirical articles (experimental, quasi-experimental, or single-case design studies) published in scientific journals; 2) written in English or Spanish; 3) including psychological treatment (at least 60% of total intervention time); and 4) adult samples (18 years or over) with FM diagnosis according to the ACR criteria.

The search identified 568 articles. After eliminating duplicates, 526 papers were selected for more detailed analysis. All titles and abstracts were reviewed against the inclusion criteria, which led to excluding 466 articles (Figure 1). Subsequently, 60 articles were fully analyzed. Four of them were excluded due to non-compliance with some of the criteria: two of them were secondary analyses of treatment results and did not assess psychological variables, one was not a scientific publication, and one was a study protocol. After a manual analysis of reviews and empirical articles, we included two additional papers that were not in the previous list. Finally, a total of 58 original articles were included in the present review.

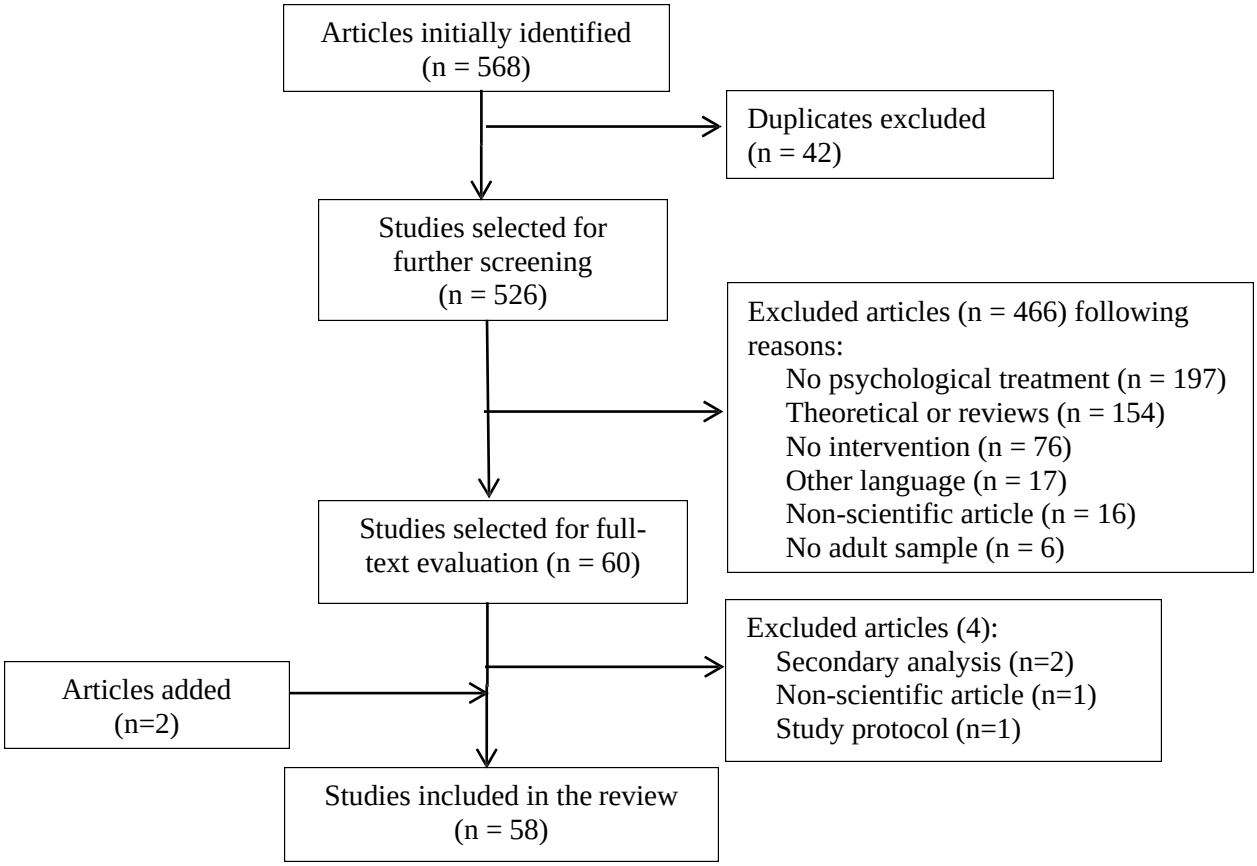


*Figure 1*. Flowchart of the study selection process

Qualitative data were collected using a table developed specifically for the study to collect information about substantive characteristics (i.e., participants, context, treatment variables), methodological characteristics (i.e., design and instruments), and external characteristics (i.e., publication bias, year of publication). Studies were analyzed and described following the recommendations of Sánchez-Meca and Botella (2010) for conducting systematic reviews of psychological interventions. We also used the quantitative procedure developed by Yates, Morley, Eccleston, and Williams (2005) for assessing psychological treatments for pain.

## Results and discussion

Table 1 shows the 58 articles analyzed in the present review. The studies are listed in alphabetical order under the name of the first author, including a brief abstract with relevant information about each article.

**Table 1.** Abstract of the treatment studies included in the review

| Study | Sex<br>Age | Type of treatment | Sessions/frecuency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT+MD |
|---|---|---|---|---|---|---|---|---|
| Alda et al. (2011) | Mixed<br>46.35 | **CBT:** cognitive restructuring of automatic thoughts and dysfunctional beliefs about pain (ruminations y catastrophizing). Training in coping and assertiviness. | 10/weekly/15 | Group | None | 1.TAU[a]<br>2.PHT[b] | Catastrophizing (PCS), depression (HAM-D), anxiety (HARS), pain (VAS), impact (FIQ) and acceptance (CPAQ). | 7+22 |
| Ang et al. (2010) | Woman<br>49 | **CBT:** cognitive restructuring, pleasant activity scheduling, time-contingent activity pacing, relaxation-stress. | 6/weekly/3,5 | Telephone/ virtual | TAU | TAU | Nociceptive flexion reflex , impact (FIQ), depression (PHQ-8). | 5+17 |
| Astin et al. (2003) | Woman<br>47.7 | **Mindfulness/mind-body:** mindfulness training, attention to the present moment, without judgment personal experiences. | 8/weekly/20 | Group | Qigong | Educative/ support | Pain (SF-36), impact (FIQ), depression (BDI) | 7+20 |
| Buckhardt et al. (2005) | Woman<br>43.5 | **Psycho-education:** education about FM, stress management, exercise program and support group for patients and family. | 6/weekly/NA | Group | PE[c] | TAU | Impact (FIQ), depression (BDI), Quality of life (QoLS) | NA |
| Buckelew et al. (1998) | Mixed<br>NR | **Biofeedback:** relaxation training and biofeedback + physical exercise. | 6/weekly/NA | Individual | PE | 1.Relaxation<br>2.PE | NR[d] | 6+17 |
| Carbonel-Baeza et al. (2011) | Woman<br>51.4 | **ACT:** education about FM, vital values clarification, acceptance of private events, awareness of avoidance, assertiveness and problem solving. | 12/intensive/45 | Group | PE | TAU | Impact (FIQ), depression and anxiety (HADS), coping (VPMI), self-steem (RSES) | 6+18 |
| Caro et al. (2011) | Mixed<br>66.7 | **Biofeedback**: Neuro-biofeedback training (Neurocybernetics® software package) | 40/NA[d]/≈ 17,33 | Individual | None | TAU | Atention (TOVA®), pain, fatigue and emotional distress (VAS) | 7+14 |
| Castel et al. (2009) | Mixed<br>44.2 | **Hypnosis:** self-hypnosis with analgesic suggestion + CBT (information, cognitive restructuring, behavioral activation and problem solving) | 12/weekly/18 | Group | None | 1.TAU<br>2.CBT | Pain (MPQ), impact (FIQ) | 6+13 |
| Cedraschi et al. (2004) | Mixed<br>48.9 | **Multimodal**: Physical exercise, relaxation, diary activity scheduling (occupational therapy), education and support group. | 12/intensive/18 | Group | PE + OT[d] | Wating list | Psychological well-being (PGWB), general health (SF-36), pain (RPS), impact (FIQ). | 6+21 |
| Comeche-Moreno et al. (2010) | Mixed<br>46 | **CBT:** education about FM and active coping (cognitive restructuring), pleasant activities, relaxation, sleep hygiene, sexual relations, assertiveness, improved attention and memory problems. | 10/weekly/20 | Group | None | No | Depression (BDI and HADS), self-efficacy (SES), catastrophizing (PCS), pain (VAS). | 6+15 |
| de Voogd et al. (1993) | Mixed<br>NR | **Behavioral:** psychomotor techniques for relaxation, assertiveness and learning in recognition of their symptoms. | NA | Group | Couple therapy | Waiting list | Symptoms (SCL-90-R). | |
| Edinger et al. (2005) | Mixed<br>48.6 | **CBT for insomnia:** information about sleep, circadian rhythms and sleep disturbances. Stimulus control techniques and sleep restriction. | 6/weekly/≈3 | Individual | None | 1. Sleep hygiene<br>2.TAU | Sleep (polysomnography, actigraphy and sleep logs), pain (MPQ and BPI), mood (PME), general health (SF-36). | 7+20 |
| Gillis et al. (2006) | Mixed<br>50.3 | **Other:** disclosure and expression of traumatic events through writing. | 4/intensive/≈1 | Individual | None | Placebo | Negative mood (PANAS-X), impact (FIQ), pain (AIMS2), fatigue, sleep quality (VAS). | 5+18 |
| Goldenberg et al. (1994) | Mixed<br>NR | **CBT:** stress reduction oriented | 10/weekly/20 | Group | None | TAU | Pain and sleep (VAS), impact (FIQ), symptoms (SCL-90-R). | |
| González-Ramírez et al. (2012) | Woman<br>45.7 | **CBT:** Information, goal setting, relaxation/hypnosis, cognitive restructuring, assertiveness and self-esteem. | 12/weekly/NA | Telephone/ virtual | None | No | Stress (PSS), impact (FIQ), memory (PMRQ-S), negative thoughts (ATQ), catastrophizing (PCS). | 6+12 |

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|---|---|---|---|---|---|---|---|---|
| Grossman et al. (2007) | Woman 54.4 | **Mindfulness/mind-body:** for stress reduction. Includes relaxation, stretching and social support. | 8/weekly/20 | Group | None | Educative/ Support | Quality of life (QoLS), anxiety and depression (HADS), pain (PRSS and IPR). | 7+21 |
| Gunther et al. (1994) | Mixed 45.2 | **Relaxation:** Jacobson's progressive muscle relaxation. | 4/intensive/NA | Individual | None | Hidrogalvanic therapy | Pain (MPQ) | 4+16 |
| Haanen et al. (1991) | Mixed 44.6 | **Hypnosis:** oriented to pain management, muscle relaxation and improving sleep problems. | 8/Weekly/8 | Individual | None | PE | Pain (dolorimeter), fatigue and sleep (VAS), symptoms (HSCL-90). | 4+15 |
| Jensen et al. (2012) | Women 45.6 | **CBT:** based on ACT, exposure to activities and emotions or thought that have been avoided. | 12/weekly/18 | Group | None | Waiting list | Pain (VAS), depression (BDI), anxiety (STAI), global change (PGIC), neuroimaging | 7+19 |
| Kayiran et al. (2010) | Woman 31.78 | **Biofeedback:** Neurofeedback program. Conditioning for modifying the amplitude/frequency of the neurophysiologic dynamic. | 20/Intensive/10 | Individual | None | PHT | Pain (vas), FIQ, depression (BDI), anxiety (BAI) general health (SF-36) and diagnostic (SCID-I) | 7+19 |
| Keel et al. (1998) | Mixed 49 | **Multimodal:** information, relaxation, cognitive restructuring, self-management strategies and training in self-efficacy. | 15/weekly/30 | Group | PE | Relaxation (autogenic) | Pain and sleep (VAS), medication intake. | 7+15 |
| Kravitz et al. (2007) | Mixed 46.9 | **Biofeedback**: Neurofeedback flexy neurotheraphy system®. | 22/Intensive/NA | Individual | None | Placebo | Pain (dolorimeter), fatigue, memory and depression, symtoms (SCL-90-R) and FIQ. | 7+19 |
| Kroese et al. (2009) | Mixed 44.2 | **Multimodal:** information, rational emotive therapy, problem solving, relaxation, coping, life goals, activity-rest balance. | 36/intensive/54 | Group | PE + socio + art therapy. | No | Quality of life (EuroQoL-5D) and impact (FIQ). | 7+14 |
| Lera et al. (2009) | Woman 50.2 | **Multimodal:** education, sleep hygiene, pleasant activities, cognitive restructuring, coping, assertiveness and psychosocial support | 15/weekly/22,5 | Group | PE + TF | PE + PHT | Symptoms (SCL-90-R), general health (SF-36), impact (FIQ). | 6+19 |
| Luciano et al. (2011) | Mixed 55.17 | **Psycho-education:** symptoms and course of FM, psychological factor/pain and autogenic relaxation. | 9/intensive/18 | Group | TAU | TAU | Health (cheklist), anxiety (STAI) and impact (FIQ). | 7+20 |
| Luedtke et al. (2005) | Mixed NR | **Multimodal:** education, relaxation, social skills and time schedule. | 1/intensive/5,5 | Group | PE + OT | No | Estado de salud (HSQ) and FIQ. | 4+13 |
| Lumley et al. (2005) | Woman 56 | **Other:** emotional disclosure and expression by writing traumatic events. | 10/weekly/10 | Individual | None | No | Pain (MPQ), FIQ, life satisfaction (SWLS), Impact of the event (IES-R). | 5+12 |
| Lundervold et al. (2008) | Woman 44 | **Behavioral:** behavioral activation for pain (BAT-P) education, relaxation-activity cycles (feedback) and valued activities. | 14/weekly/NA | Individual | None | No | Pain (VAS), depression (GDS-15), pain anxiety (PASS). | 6+NA |
| Martínez-Valero et al. (2008) | Woman 44.3 | **Hypnosis**: Hypnosis for pain, self-esteem or insomnia +CBT (information, cognitive restructuring, behavioral activation and problem solving). | 10/weekly/10 | Individual | TAU | 1.TAU<br>2.CBT (without hypnosis) | Pain (PBPI), impact (FIQ), sleep and fatigue (VAS). | 7+13 |
| Mason et al. (1998) | Woman 46.2 | **Multimodal**: exercise/physical therapy + CBT (sleep education, depression and pain maladaptive behaviors, cognitive restructuring and relaxation). | 24/intensive/144 | Group | PE + TF | TAU | Pain (dolorimeter and VAS), coping (CSQ), FIQ, depression (BDI) | 7+12 |
| Miró et al. (2011) | Woman 46.45 | **CBT for insomnia:** sleep hygiene, sleep restriction and stimulus control, relaxation, cognitive restructuring and assertiveness. | 6/weekly/9 | Group | TAU | TAU + sleep hygiene | Pain (MPQ), sleep (PSQI), anxiety and depression (HADS), FIQ. | 7+17 |
| Mueller et al. (2001) | Mixed 50.7 | **Biofeedback:** electroencephalographic activity modulation by stimulation. | 52/intensive/52 | Individual | PE | No | Pain (VAS), impact (FIQ) and symptoms (SCL-90-R) | 7+12 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Nelson et al. (2006) | Mixed 44 | **Psycho-education:** info about pain, coping strategies, catastrophizing, relaxation and personal goals with patients and families. | 1/NA/2 | Group | None | No | Catastrophizing. | 5+5 |
| Nicassio et al. (2007) | NR | **Behavioral:** training in coping strategies**.** | 10/weekly/15 | Group | None | Educative/ Support | Pain, depression, disability and pain behaviors (NR) | NA |
| Nielson et al. (1997) | Mixed 44.9 | **Multimodal:** CBT (cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education) + physical and occupational therapy | 16/Intensive/96 | Group | PE + OT | No | Pain (MPQ and tender points), impact (FIQ). | NA |
| Nielson et al. (1992) | Mixed NR | **CBT**: cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education. | Not available | | None | No | NR | 6+15 |
| Oh et al. (2010) | Mixed 48.3 | **Multimodal**: education + CBT (relaxation, social skills, stress management, daily planning) + physical and occupational therapy. | 1/intensive/5,5 | Group | PE+OT | No | Impact (FIQ) and general health (SF-36) | 7+13 |
| Pfeiffer et al. (2003) | Mixed 44.7 | **Multimodal:** education + CBT (relaxation, social skills, stress management, daily planning). | 1/intensive/5,5 | Group | PE + OT | No | Impact (FIQ) and depression (CES-D) | 7+12 |
| Redondo et al. (2004) | Woman NR | **CBT:** info about FM/pain and emotional factors, relaxation, coping, daily activities, assertiveness, sleep / rest, problem solving. | 8/weekly/20 | Group | TAU | PE | Pain (tender points), FIQ, general health (SF-36), anxiety (BAI), depression (BDI), self-efficacy (CPSS) and coping (CPCI). | 7+12 |
| Rodero et al. (2008) | Mixed 50.5 | **CBT:** info about stress/pain, cognitive restructuring, emotional exposure by writing and assertiveness. | 11/weekly/≈16,5 | Group | None | No | Pain (VAS), FIQ, anxiety (HADS) and catastrophizing (PCS). | 9+13 |
| Sánchez, et al. (2012) | Women 46.79 | **CBT for insomnia**: info about sleep/FM, sleep restriction therapy, stimulus control, relaxation and cognitive therapy for insomnia dysfunctional beliefs. | 6/weekly/9 | Group | None | Sleep hygiene | Polysomnography | 7+17 |
| Sales et al. (2008) | Woman 44.88 | **CBT:** diaphragmatic breathing and relaxation, cognitive restructuring and stress management. | 10/weekly/NA | Group | None | TAU | Pain (VAS), FIQ, general health (SF-36), anxiety (STAI), depression (BDI) | 5+18 |
| Singh e al. (1999) | Woman NR | **Mindfulness:** education on mind-body connection, relaxation / mindfulness + Qigong. | 8/weekly/20 | Group | None | No | Depression (BDI), FIQ, coping (CSQ) and general health (SF-36). | |
| Smyth et al. (2006) | Woman 45.75 | **Other:** emotional expression by writing, cognitive reappraisal and relaxation. | 8/intensive/8 | Individual | None | Placebo | Quality of life, sleep, pain and mood (PANAS) | 5+9 |
| Suman et al. (2009) | Woman 44.8 | **Multimodal:** education, cognitive restructuring, adaptation to pain and self-efficacy. | 15/intensive/25 | Individual | PE | No | Pain (VAS), depression (CES-D), coping (BPCI). | 6+11 |
| Thieme et al. (2008) | Woman 49.13 | **CBT:** catastrophic cognitions restructuring, problem solving, coping and relaxation. **Operant Conditioning:** reinforcement of incompatible with pain behaviors. | 15/weekly/30 | Group | None | Educative/ support | Pain (MPI), FIQ, health service utilization | 7+22 |
| Thieme et al. (2003) | Woman 46.6 | **Behavioral:** reinforcement of incompatible with pain behaviors. | 25/intensive/75 | Group | None | PE | Pain (MPI), pain behaviors | 6+15 |
| Toussanint et al. (2011) | Mixed 48 | **Mind-body:** based on amygdala retraining program combined with CBT and graded exercise therapy**.** | 1/intensive/2,5 | Group | TAU | TAU | General health (SF-36), fatigue (MFI), sleep (ESS), impact (FIQ). | 6+16 |
| Turk et al. (1998) | Mixed NR | **Multimodal:** psychotherapy, occupational and physical therapy. | NA | | NA | NA | Pain, distress, depression, anxiety, disability and fatigue. | NA |
| van Koulil et al. (2008) | Woman 47 | **CBT:** Education and planning. Changing cognitive-behavioral patterns (avoidant or persistent patterns). Assertiveness and education to couples. | 16/intensive/32 | Individual | PE | No | Pain, anxiety, depression, impact (FIQ), coping (CSQ) and fatigue. | 8+NA |
| | Woman 40 | | 16/intensive/32 | Individual | PE | No | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| van Koulil et al. (2010) | Mixed 41.7 | **CBT:** Changing cognitive-behavioral patterns adjusted to patient profile. | 16/intensive/32 | Group | PE | Waiting list | Impact (FIQ). | 9+22 |
| van Santen et al. (2002) | Woman NR | **Biofeedback** | NA | Group | None | PE | Pain (VAS and dolorimeter), symtoms (SCL-90-R), fatigue (VAS). | NA |
| Vázquez-Rivera et al. (2009) | Woman 51.9 | **CBT:** education, sleep hygiene, cognitive-affective factors, adaptive coping strategies. | 5/weekly/10 | Group | None | TAU | Depression (BDI), anxiety (STAI), coping (CPCI), impact (FIQ). | 7+20 |
| Vlaeyen et al. (1996) | Mixed 44 | **CBT:** education, self-efficacy and self-control, relaxation / biofeedback. | 12/intensive/20 | Group | PE | TAU | Pain (MPQ), Catastrophizing, coping (CSQ) | 8+16 |
| White et al. (1995) | NR | **CBT:** cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education. | NA | Group | PE+OT | NA | Pain/control behaviors | NA |
| Wigers et al. (1996) | Mixed NR | **Relaxation/biofeedback:** stress management oriented. | 14/weekly/NA | Group | None | TAU | Pain, fatigue, sleep and depression (dolorimeter and VAS), | NA |
| Williams et al. (2002) | Mixed 47.7 | **CBT:** psychological education, relaxation, increasing of activity, assertiveness, cognitive restructuring, and problem solving. | 6/intensive/6 | Group | TAU | TAU | Pain (MPQ), general health (SF-36) | 6+NA |
| Woolfolk et al.(2012) | Mixed 47.79 | **CBT:** based on affective approach. Cognitive restructuring, activity regulation, relaxation and interpersonal communication training. | 10/weekly/NA | Individual | TAU | TAU | Pain (VAS), general health (SF-36), self-efficacy (CPSE), depression (BDI), and anxiety (BAI). | 7+20 |

*Notes*: [a]TAU= Treatment-as-usual; [b]PHT= Pharmacological treatment; [c]PE= Physical exercise; [d]NA= Not available; [e]OT = occupational therapy.

*Abbreviation of instruments used:* AIMS-2= Arthritis Impact Measurement Scale-2; ATQ= Automatic Thoughts Questionnaire; BAI= Beck Anxiety Inventory; BDI= Beck Depression Inventory; BPCI= Brief Pain Coping Inventory; BPI= Brief Pain Inventory; CES-D= Center of Epidemiologic Studies Depression Scale; CPAQ= Chronic Pain Acceptance Questionnaire; CPCI= Chronic Pain Coping Inventory; CPSE= Chronic Pain Self-efficacy Scale; CSQ= Coping strategies Questionnaire; EuroQol-5D= European Quality of Life Scale-5D; ESS= Epworth Sleepiness Scale; FIQ= Fibromyalgia Impact Questionnaire; GDS-15= Geriatric Depression Scale 15; HAM-D= Hamilton Rating Scale for Depression; HARS= Hamilton Anxiety Rating Scale; HSCL-90= Hopkins Symptom Check-list; HSQ= Health Status Questionnaire; IES-R= Impact of Event Scale-Revised; IPR= Inventory of Pain Regulation; ISQ= Insomnia Symptom Questionnaire; MFI= Multi-Dimensional Fatigue Inventory; MPQ= McGill Pain Questionnaire; PANAS-X= Positive and Negative Affect Schedule; PASS= Pain Anxiety Symptom Scale; PBPI= Pain and Belief Perception Inventory; PCS= Pain Catastrophizing Scale; PGWB= Psychological General Well-Being Index; PHQ-8= Patients Health Questionnaire 8-ítems Depression Scale; PME= Profile of Mood States; PMRQ-S= Prospective and Retrospective Memory Questionnaire; PRSS= Pain Related Self-Statements Scale; PSS= Perceived Stress Scale; QoLS= Quality of Life Scale; RPS= Regional Pain Score; RSES= Rosenberg Self-esteem Scale; SES= Self-efficacy Scale; SF-36= Short-form Health Survey; SCID-I= The Structured Clinical Interview for DSM-IV Axis I Disorders; SCL-90-R= Symptom Checklist-90-Revised; SWLS= Satisfaction with Life Scale; VAS= Visual Analogue Scale; VPMI= Vaderbilt Pain Management Inventory.

*Study quality analysis*

The analysis of the studies included in this review was conducted using a scale to assess experimental design studies of psychological treatments for pain (Sánchez-Meca & Botella, 2010). Given that the review included experimental, quasi-experimental, and single-case design studies, high score variability was expected. In some cases it was not possible to complete all the data because of the methodological design of the main study (e.g., single-case design) or lack of information.

The scale had two parts, the first of which assessed the quality of the treatment performed in the study and was scored from 0 to 9. The issues considered in the assessment were a clear rationale of the treatment applied, an appropriate description of its contents, information about duration and number of sessions, treatment manual development and adherence to it, adequate professional training, and participants‟ commitment to the activities prescribed. None of the reviewed studies obtained a score below 5, which indicates a good quality of treatment.

The second part of the scale assessed the quality of the design and methodology used and was scored from 0 to 26. Although we observed a higher variability in scores, the aim of this review was not to perform a quantitative analysis. This part evaluated the criteria used to select the sample, evidence of validity of such criteria, a detailed description of dropouts and the total sample, equivalence between control and experimental groups, randomization of subjects, methodology for the assessment of subjects, equivalence in the expectation of treatment, justification of the outcome variables assessed, validity and reliability of the instruments used, follow-up measurement, adequacy and quality of the control groups, and statistical strategies used.

*Analysis of substantive characteristics*

A total of 5,876 participants received intervention in control or experimental groups. In the studies reviewed, 41.38% of studies included mixed groups composed of men and women, although women were more prevalent, and 58.62% of studies included only women. We did not find any group treatments or single-case design studies including only men. The mean age of participants was 38.3 years (SD=5.13). Most studies included participants from 18 to 65 years old, except for one, in which the age limit was 45 years (Kayiran, Dursun, Dursun, Ermutlu, & Karamursel, 2010). All participants referred widespread pain for long periods. The average time from the onset of the first symptoms or a diagnosis by a rheumatologist to the time of evaluation was 8.24 years (SD=5.21) (see Table 1). In total, 37.93% of studies did not mention the time from diagnosis.

Table 1 includes a brief description of each intervention. Most interventions involved group treatment (n=38, 65.52%), compared to 27.58% (n=16) of interventions, which involved individual treatment. We also identified an intervention conducted by telephone following a treatment protocol manual (Ang, Chakr, Mazzuca, France, Steiner, & Stump, 2010) and three studies in which the therapist sent all the information and treatment contents by e-mail (González-Ramírez & Landero-Hernández, 2010) or regular mail (Gillis, Lumley, Mosley-Williams, Leisen, & Roehrs, 2006; Smyth & Nazarian, 2006) and treatment was applied by participant themselves, with general guidelines but flexibility regarding intensity and duration. We found evidence of the efficacy of CBT in groups (Williams, 2003), although there were difficulties regarding costs and transfer of patients to the place of treatment because of the distance or the disability generated by FM. Distance intervention was useful to overcome such difficulties, but poor adherence was observed when treatments lacked a protocol or a system to ensure adherence to the treatment manual by the therapist (Gillis et al.,

2006; Smyth & Nazarian, 2006) or in the absence of a tutor/psychologist (González-Ramírez & Landero-Hernández, 2010). In this regard, the study by Ang et al. (2010) combined distance treatment with a protocol manual and a psychologist who monitored treatment by telephone, although treatment was not applied in groups. In some cases, this could be a suitable alternative.

Other studies attempted to overcome the difficulties related to treatment attendance by scheduling an intensive group program for one (Nelson & Tucker, 2006) or two days (Cedraschi et al., 2004; Luedtke, Thompson, Postier, Neubauer, Drach, & Newell, 2005; Oh et al., 2010; Pfeiffer et al., 2003; Toussaint, Whipple, Abboud, Vincent, & Wahner-Roedler, 2012). Nelson and Tucker (2006) developed an intervention conducted by trained nurses in the primary care framework and included a two-hour educational session aimed at modifying catastrophizing. This study included FM patients and their families and analyzed the impact of knowledge about the syndrome on pain and related psychological variables. Studies by Luedtke et al. (2005), Oh et al. (2010), and Pfeiffer et al. (2003) referred to the same one-and-a-half-day interdisciplinary program that included components such as pain education and FM, an interactive self-management session based on CBT, one hour for discussion on the benefits of physical activity and the display of graded exercise training, and occupational therapy. The last of these short treatments by Toussaint et al. (2012) also included a mind-body technique known as „amygdala retraining", applied in a two-and-a-half-hour program. This technique was aimed at deconditioning certain emotional responses such as fear that are mediated through the amygdala in order to decrease FM symptoms. Patients were encouraged to continue applying what they had learned, and results showed that improvements in both the impact of disease and quality of life were maintained at 6- and 12-month follow-up (Pfeiffer et al., 2003). Improvements after amygdala retraining were significant in pain, physical

health, and distress (Toussaint et al., 2012), compared with standard short treatment. However, an important limitation of this type of intervention is that there is no assurance that the results are not due to uncontrolled external variables. This is because, among other issues such as lack of a control group, there is no guarantee of patients‟ adherence to the techniques learned after the end of treatment. Therefore, treatment modalities that are continuous in time seem to be more common.

In this review, 55.17% of studies included interventions performed in weekly sessions that varied from 4 to 52 sessions. In total, 63% of studies included interventions with 4 to 12 sessions, which amounted to total treatment duration of one week to three months. Table 1 shows the number and frequency of sessions („intensive‟ refers to more than once a week). Mean total intervention time was 24.61 hours (SD=27.26). As expected, multimodal programs required more hours of treatment, as they included two or more specialties in different areas of health, and therefore demanded more time and effort.

We found 11 multimodal interventions (Cedraschi et al., 2004; Luedtke et al., 2005; Oh et al., 2010; Pfeiffer et al., 2003) that included mainly physical exercise, information about the illness, relaxation, CBT (except for one intervention, which involved rational emotive therapy instead (Kroese, Schulpen, Bessems, Nijhuis, Severens, Landewe, 2009), occupational therapy (Cedraschi et al., 2004; Luedtke et al., 2005; Nielson, Harth, Bell, 2009; Oh et al., 2010; Pfeiffer et al., 2003) and art therapy (Kroese et al., 2009). It is worth mentioning that the type of intervention somewhat determined the number and intensity of sessions and total treatment time, which probably explained the high variability in the number of sessions.

*Types of intervention*

Out of the 59 groups/cases of treatment conditions analyzed, eleven involved a multimodal approach (Cedraschi et al., 2004; Keel et al., 1998; Kroese et al., 2009; Lera et al., 2009; Luedtke et al., 2005; Mason et al., 1998; Nielsn et al., 1997; Oh et al., 2010; Pfeiffer et al., 2003; Suman et al., 2009; Turk et al., 1998; Toussaint et al., 2011), eight were based on relaxation or neuro/biofeedback (Buckelew et al., 1998; Caro & Winter, 2011; Gunther et al., 1994; Kravitz et al., 2007; Pfeiffer et al., 2003; van Santen et al., 2002; Wigers et al., 1996), four had a behavioral orientation, such as operant conditioning with reinforcement of healthy behaviors and behavioral activation (de Voogd et al., 1993; Lundervold, Talley & Buermann, 2008; Nicassio et al., 1997; Thieme, Gromnica-Ihle, Flor, 2003), three provided psycho-education (Buckhart et al., 2005; Luciano et al., 2011; Nelson & Tucker, 2006), three worked with hypnosis (Castel, Salvat, Sala & Rull, 2008; Haanen et al., 1991; Martínez-Valero et al., 2008), and four were based on mindfulness or mind-body intervention (Astin et al., 2003; Grossman et al., 2007; Singh et al., 1999; Toussaint et al., 2011). Most treatments implemented were cognitive-behavioral based (Ang et al., 2010; Alda et al., 2011; Carbonell-Baeza et al., 2011; Comeche-Moreno et al., 2010; Edinger et al., 2005; González-Ramirez et al., 2010; Goldenber et al., 1994; Jensen et al., 2012; Miró et al., 2011; Nielson, Walker, & Mccain, 1992; Redondo et al., 2004; Rodero el at., 2008; Sánchez et al., 2012; Sales, Feldman, & Natour, 2008; Thieme, Flor, & Turk, 2008; van Koulil et al., 2010; Vázquez-Rivera et al., 2009; Vlaeyen et al., 1996; White & Nielson, 1995; Williams et al., 2002; Woolfolk, Allen, & Apter, 2012), with some modifications in their components. The remaining studies (Gillis et al., 2006; Lumley et al., 2008; Smyth et al., 2006) referred to the same intervention based on written emotional disclosure and exposure of traumatic success especially oriented to FM patients with symptoms of post-traumatic stress disorder.

An important issue in previous reviews of CBT in FM and chronic pain in general is which components are effective and for whom (Morris, Bowen, & Morris, 2005). Some components such as psycho-education are common to almost all treatment programs. The aim of psycho-education is to provide information to the patient about the psychological process that may be maintaining or exacerbating pain problems. In the present review, however, the contents of this information were not clearly explained in some studies. In most cases, the first hours of treatment were devoted to providing information about the characteristics of the syndrome (e.g., main symptoms, differences between chronic and acute pain, progress and evolution, common comorbidities, benefits of a healthy diet and exercise, pharmacologic and non-pharmacologic treatments available) (Buckhart, Clark & Bennett, 2005; Luciano et al., 2011). These topics were usually dealt with by a well-prepared health professional. In the intervention carried out by Luciano et al. (2011), the educational sessions were performed by a rheumatologist; in the study by Nelson and Tucker (2006), the information was provided by nurses and was based on catastrophizing. Nevertheless, none of these studies evaluated whether information in itself led to improvements in participants, although it is an essential component in the start of any treatment.

Educational components such as an introduction to CBT are particularly interesting. It is useful to explain the psychological factors that affect pain experience based on a bio-psychosocial model. It is worth highlighting that the aim of CBT is not to eliminate pain but rather to train patients in the skills necessary to manage the symptoms in order to learn to live with it. Thus, Williams et al. (2002) refer to the *gate control theory of pain*, according to which pain perception is modulated by certain emotional, cognitive, and social aspects (Mezlack, 1964), and Van Koulil et al. (2008; 2010) apply the *fear-avoidance model of pain,* which postulates that mechanisms such as anxiety, fear of pain, and catastrophizing generate

avoidance behavior and hypervigilance to pain that increase the complications and disabilities associated to it (Leeuw et al., 2007). In both studies, Van Koulil et al. adapted the treatments according to patient profile, which could be characterized by avoidance of pain (passive patients) or persistence in pain and non-acceptance of the limits imposed by chronic pain and fatigue (active patients). The intervention was applied to FM patients with high scores in negative mood and anxiety, considered high-risk patients. The authors found a considerable proportion of high-risk patients with clinically significant improvements in pain intensity, fatigue, daily functioning, anxiety, and negative mood, compared to the control groups on the waiting list (van Koulil et al., 2010). These results agree with the systematic review conducted by Lohnberg (2007), which demonstrated the success of CBT aimed at reducing fear and avoidance of pain in patients with chronic pain. In general, CBT-based treatments seek to modify dysfunctional thoughts and behaviors through cognitive techniques (i.e., restructuring) or behavioral activation techniques (Lundervold, Talley, & Buermann, 2007) that include planning daily activities that are consistent with personal values and operant conditioning addressed to increase healthy behaviors that are incompatible with pain (Thieme, Gromnica-Ihle, & Flor, 2003; van Koulil et al., 2010). In this behavioral approach, de Voogd et al. (1996) included training sessions for couples with the aim of modifying the contingencies of behaviors associated with pain.

Most interventions examined in this review involved social skills training, relaxation through various techniques (e.g., guided imagery, controlled and deep breathing, progressive relaxation), assertiveness training, problem-solving strategies, and coping skills training in order to increase self-efficacy expectations. The inclusion of these components is justified by the existence of evidence about the mediator or modulator role of these psychological factors in exacerbation of discomfort and disability. Three studies applied CBT focused on insomnia

(CBT-I) (Edinger et al., 2005; Miró et al., 2011; Sánchez et al., 2012), based upon recent evidence of the relationship between poor sleep quality and pain increase and negative moods Smith et al., 2007). Evidence of clinical experimental studies suggested that disorders characterized by a disruption of deep sleep (slow waves) generate hypersensitivity to noxious stimuli and increase musculoskeletal pain symptoms (Moldofsky, 2010). The interventions included information about normal and pathological sleep processes, circadian rhythms, and their relation with pain, and proposed specific techniques to overcome insomnia such as sleep hygiene, sleep restriction, and stimulus control, and cognitive therapy in order to change misconceptions about sleep (Miró et al., 2011; Sánchez et al., 2012). Major instructions in the sessions were to wake up almost at the same time every day, to exit bed during more than 15 minutes of awakenings, to use the bedroom only for sleep and sex, and to avoid long naps (Edinger et al., 2005). These studies showed significant improvements in subjective variables of sleep quality compared to control groups that only received sleep hygiene information (Edinger et al., 2005; Miró et al., 2011), significant improvements in objective measures of sleep using actigraphy Edinger et al., 2005) and polysomnography (Sánchez et al., 2012), and significant improvements in neuropsychological measures (Miró et al., 2011). A recent review in chronic pain patients concluded that CBT-I obtained significant improvements in sleep and consequently in mood, subjective well-being, and confidence in pain management. Surprisingly, these improvements in sleep were not followed by reductions in pain severity, perhaps because modifications in polysomnographic parameters are not sufficient to recover normal sleep patterns (Moldofsky et al., 2010).

Efforts were also made to improve sleep quality using other techniques such as hypnosis. Three studies were based on hypnosis Castel et al., 2009; Hannen et al., 1991; Marínez-Valero et al., 2008), a technique that requires patients‟ active participation in order to

achieve greater self-control (Capafons, 2004). Cognitive hypnotherapy has been used in a variety of chronic pain diseases (e.g., cancer, low back pain, arthritis, temporomandibular disorder) and disability-related chronic pain with beneficial results. However, due to the methodological limitations of the studies, it is only recommended as a complementary intervention for FM patients (Elkins, Johnson, & Fisher, 2012). In the studies conducted by Castel et al. (2009) and Martínez-Valero et al. (2008), hypnosis was combined with CBT and led to significant improvements in the affective dimension of pain and overall functioning, although results were not significantly better than those of CBT without hypnosis. A recent publication analyzed the six-month follow-up data of the intervention performed by Castel et al. and showed significantly better results in psychological distress after CBT plus hypnosis than standard pharmacological treatment, although with no statistically significant differences compared to CBT alone (Castel et al., 2012).

The present review also identified other approaches aimed at achieving objective changes in biomarkers, as illustrated by seven studies characterized by biofeedback or neuro-biofeedback (EGG-BF) (Buckelew et al., 1998; Caro & Winter, 2011; Gunther et al., 1994; Kayiran et al., 2010; Kravitz et al., 2007; Mueller et al., 2001; van Santen et al., 2002; Wigers, Stiles, Vogel, 1996). In these cases, the intervention involved using specific software aimed at correcting of EEG rhythm abnormalities in patients with FM through reinforcement of desired frequencies or non-reinforcement (inhibition) of the unwanted amplitude. This technique was applied to patients non-invasively and interactively as feedback in order to change their EEG patterns (Mueller et al., 2001; Wigers, Stiles, Vogel, 1996). These studies varied in the number of sessions received by participants (20 to 52 sessions), time spent on each session (15 to 30 minutes) and total treatment time, with an average of 26.41 hours (SD = 22.38).

Alternative approaches that have recently received wide acceptance are mindfulness or mind-body interventions. Four studies included mindfulness-based interventions, one of them assesed a mindfulness-based stress-reduction program (MBSR) (Grossman et al., 2007), one study provided CBT based on mind-body connection (Singh et al., 1999), one study was exclusively based on mindfulness training (Astin et al., 2003), and another study provided specific amygdala retraining based on mind-body notions (Toussaint et al., 2012). These treatment programs include meditation exercises, yoga, and *qigong* (or *chi kung,* a Chinese technique that integrates physical postures, breathing, and focused intentions and accomplishment), in addition to training in the ability to be fully aware of the present moment, without judging or reacting either to internal experiences (feelings, thoughts, and emotions) or external stimuli (Astin et al., 2003). Intensity, frequency, and total treatment time were comparable to CBT. Results of these studies showed improvements in pain, depression, anxiety, and quality of life in FM patients. Positive outcomes were also revealed in a recent review of mindfulness treatments for FM (Veehof et al., 2011). However, both Veehof et al. (2011), in a review of 22 studies of acceptance-based interventions in chronic pain and Kozasa et al., (2012), after reviewing 13 meditation-based studies, concluded that such interventions cannot be considered more favorable than CBT and mentioned the lack of methodological quality of the studies. Nevertheless, approaches based on acceptance and commitment therapy alone or combined with CBT may be a useful alternative in some patients, but more controlled research is needed.

*Analysis of methodological characteristics.* Regarding the qualitative analysis of the methodological characteristics of the studies included in this review, 46.4% of studies used an experimental design with random assignment of subjects to experimental or control groups and 44.6% of the studies applied a quasi-experimental design, according to the classification

proposed by Montero and León (2007). Two of the studies were defined as single-case design studies (van Koulil et al., 2008; Lumley et al., 2008). Almost all studies (98%) included pre-post evaluation, 13% included only one assessment at the end of treatment but did not evaluate follow-up, 28% included 6-month follow-up, and 18% included follow-up after one year, with a mean follow-up of 9.22 months (SD = 16.74).

We found that 70.7% of the studies comprised a control group and only four studies included a passive waiting list control group (Cedraschi et al., 2004; de Voogd et al., 1993; Jensen et al., 2012; van Koulil et al., 2010), although many of them did not describe the protocol used in the control groups in detail. Most control groups received pharmacological treatment as usual (32.75%), although we also observed other types of control, including educational components or support groups (6.89%), physical exercise (10.34%), placebo treatment (5.17%), relaxation activities (3.44%), sleep hygiene (5.17%), or hydrogalvanic therapy (1.72%).

Concerning the source of the sample, all the studies adequately described the procedures and inclusion criteria. However, a significant proportion of interventions were conducted in specific contexts such as specialized pain units in clinics or hospitals (41.1%), the primary care setting (3.6%), patient associations (3.6%), or the general public (3.6%), with a strict medical control in order to ensure compliance with the inclusion criteria and FM diagnosis according to the ACR criteria. Level of care is relevant because of the high economic cost that FM represents for the health system (Thompson et al., 2011). This is the reason why it is important to determine the differential effect of treatment in primary or specialized care. Nevertheless, a recent meta-analysis compared treatments by level of care and found no significant differences in the results evaluated (García-Campayo et al., 2008),

concluding that the treatment of FM in specialized care has no advantage over treatment in primary care.

*Analysis of external characteristics*

External characteristics include those that are not directly related to the scientific process of research but may affect the results. We found growing interest in this topic from 2006, when six articles were published (see Fig. 2). The most productive year was 2008, with seven publications.

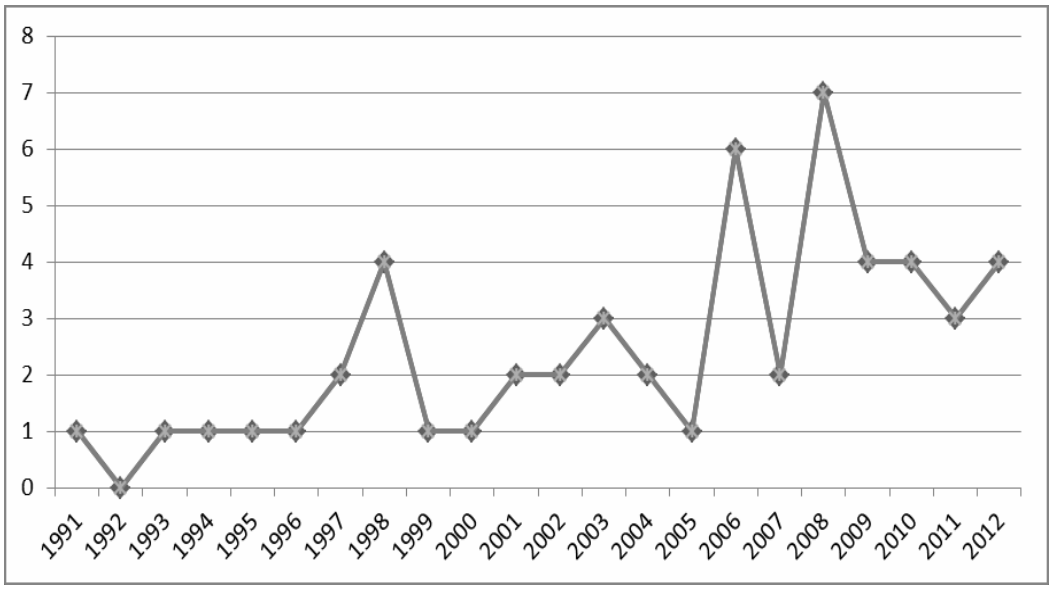


*Figure 2***.** Frequency per year of published articles included in the review

In the analysis of publications by countries, the United States stands out with 22 publications, Spain with 13 and Germany with 8. Yet, it should be noted that the language in which the scientific articles were written may have led to a certain bias. We excluded 18 studies from the analysis because they were written in German, Chinese, French, or other languages. In this review, most publications were in English and only two were in Spanish.

### *Study limitations*

Besides the language issues mentioned above, another limitation of the study is the exclusion of the term „fibrositis", which was previously used to refer to the syndrome currently known as FM. The term „fibrositis" was popularized in the 1970s but gradually fell into disuse and is now fully replaced by the term „fibromyalgia". Regarding the aims of this review, with the intention of including as many published types of treatments developed for FM, the search may not have considered databases such as the Cochrane Library, which may have limited the number of items included for review.

## Conclusions

Psychological treatment of FM has developed to improve various aspects of symptoms referred by patients. Most interventions described in this review focused on direct symptoms of the disease, particularly pain and fatigue, although some specifically focused on sleep disturbances. We found treatments based on CBT, CBT-I, and multimodal treatments. Studies also included other treatments aimed at improving symptoms associated with distress, such as depression, anxiety, general psychopathology symptoms, or impact of disease. When such treatments were delivered, better results were obtained when combined with treatments such as relaxation, mind-body techniques, and CBT and/or CBT-I. In addition, variables such as pain catastrophizing, self-efficacy, pain anxiety, and pain coping styles were poorly evaluated in most studies.

It is important to emphasize that the instruments used in the assessment were heterogeneous. Many studies used the Visual Analogue Scale (VAS) for pain, fatigue, and sleep, although the data obtained with such instruments were sometimes incomplete. A useful tool to measure the impact of patients with FM included in many studies was the

Fibromyalgia Impact Questionnaire (Burckhardt, Clark & Bennet, 1991), but it had the disadvantage of not being recommended for making comparisons with healthy individuals or individuals with other diseases.

**Clinical and scientific implications**

This work highlights the different modalities that have been developed over the last twenty years to address FM, a complex and chronic syndrome. Psychology is a discipline where multiple paradigms coexist, which contributes to the existence of various treatments for FM. Among them, cognitive-behavioral approaches have been well developed.

Although CBT has proven to be partially effective (Bernardy et al., 2010), the evidence argues that CBT components should be complemented by pharmacotherapy and physical exercise, as recommended by clinical practice guidelines (Burckhardt et al., 2005; AWMF, 2001). Moreover, treatment goals should be set by professionals in clinical practice, taking into account the specific circumstances of the patient and the variety of symptoms associated with fibromyalgia (i.e., level functioning, sleep problems, mood disorder, coping strategies, tendency to pain catastrophizing). It is important to note that changes and improvements are possible with these treatments, although they are not immediate and require perseverance and effort.

In a context of public health systems, it is crucial to evaluate the cost-benefit of treatment. Therefore, there is a need for more controlled studies of treatment effectiveness that meet the standard methodological requirements (Moher et al., 2010), with three objectives: 1) evaluate and compare the effectiveness of all types of treatment; 2) define specific treatment components that reflect the best results; and 3) identify patient characteristics that predict therapeutic success. As highlighted by Vlaeyen et al. (2005), more

research is needed to identify moderating and mediating variables that lead to a suitable match between the psychological characteristics of patients and treatment.

Finally, knowledge of psychological intervention strategies that improve the quality of life of FM patients is an area of growing interest and useful practical application that future research should continue to examine.

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# CUARTO ESTUDIO

*Artículo 5*

# Gender differences in Patients with Fibromyalgia undergoing Cogntive-Behavioral Therapy for Insomnia: Preliminar Data

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# Gender differences in patients with fibromyalgia undergoing cognitive-behavioral therapy for insomnia: Preliminary data


***Abstract***

Fibromyalgia (FM) is a chronic musculoskeletal pain syndrome that significantly affects patients‟ quality of life. Its main symptoms are pain, fatigue, and sleep disturbances. Aim: The aim of this study was to assess the efficacy of cognitive-behavioral therapy for insomnia (CBT-I) in men and women with FM, and compare sleep and clinical features between both genders.

**Methods**: Fifteen women and 13 men were selected to participate in nine weekly CBT-I sessions that involved completing several self-reported questionnaires at pre-treatment, post-treatment and follow-up. Patients were recruited from the Rheumatology Service and Pain Unit of Hospital and a fibromyalgia association. Group psychotherapy was performed at clinical unit of the Faculty of Psychology.

**Results**: Both groups showed significant clinical and statistical improvements in sleep quality and the main symptoms associated with FM (i.e., pain intensity, fatigue, anxiety, pain catastrophizing, and pain-related anxiety). Differential treatment responsiveness between sexes was observed. Male group exhibited significant changes at post-treatment in sleep disturbances and pain-related anxiety and catastrophizing. The female group showed post-

treatment improvements in sleep latency, general fatigue, and depression, which persisted at follow-up.

**Conclusions:** Differential responses to treatment between men and women were observed in some sleep and pain-related variables. Outcomes show the needed to design different treatments for men and women with FM is discussed.

**Key words**: Fibromyalgia – gender differences – cognitive-behavioral therapy – insomnia.

## Introduction

Fibromyalgia (FM) is a chronic syndrome characterized by widespread musculoskeletal pain persisting for more than three months and tenderness at specific points of the body (Wolfe et al., 1993). This disorder prevails between the 2% and 5% of the population and is more common to be found in women than in men (9:1 ratio) (Mas, Carrmona Valverde, & Ribas, 2008) FM causes a significant decrease in patients‟ life quality (Spaeth & Briley, 2009). A recent study has revealed that almost all FM patients show substantial impairments in functional status as well as in mental and physical health (Wolfe et al., 2014). In fact, treatments focused on alleviating pain have failed to yield effective treatment outcomes over time, which implies considerable health-related and social costs (Thompson et al., 2011). Given the evidence, expert recommendations establish integrative pharmacological and non-pharmacological treatments. Non-pharmacological therapies include education, exercise as well as cognitive behavioral therapy, and focus on return to function, while engaging patients as an active role in the improvement process (Clauw, 2014).

Although pain is considered to be the main symptom of FM, 96-99% of patients with FM are also affected by fatigue, sleep dysfunction, and unrefreshing sleep (Lineberger, Means, Edinger, 2007), moreover, insomnia is a common sleep disorder in these patients (Prados & Miró, 2012). The sleep abnormalities reported in FM patients mainly include a reduction of total sleep time, particularly a decrease in the percentage of slow-wave sleep and increased awakenings or arousal (Rizzi et al., 2004). Studies of the microstructure of sleep in FM patients have shown an anomalous intrusion of the alpha rhythm in the slow delta activity which characterizes deeper sleep stages (Lineberger et al., 2007), and a larger number of oxygen desaturations per hour of sleep have also been observed (Rizzi et al., 2004). It has been argued that sleep disorders may play a significant role in the vulnerability of the sensory

inhibition area of central nervous system responsible for the perception of noxious stimuli, leading to a state of hyperalgesia (Moldofsky, 2008a, 2008b). Furthermore, the Sleep and Pain Diathesis Model suggests that sleeping problems may play an important role in the etiology of FM and the persistence of many of the symptoms of this disease (Hamilton et a., 2012). Several studies have shown the existence of a relationship and reciprocal influence between sleep disorders and the pain threshold (Moldfsky, 2010), increased widespread pain(Mork & Nilsen, 2012), more fatigue and negative mood (Hamilton et al., 2008; Miró, Diener, Martínez, Sánchez & Valenza, 2012). Research has shown the efficacy of psychological treatments improving several clinical manifestations of pain (Marin et al., 2014; Glombiesky et al., 2010). Several intervention programs have been developed for the simultaneous treatment for insomnia and pain, these have shown positive results in sleep quality, pain interference, fatigue, and depression (Pigeon et al., 2012; Tang, Goodchild, & Salkovskis, 2012). Four studies have been found, which include specific interventions for FM patients with sleeping problems (Edinger, Wohlgemuth, Krystal, Rice, 2005; Martínez et al., 2014; Miró et al., 2011; Sánchez et al., 2012). Patients who underwent cognitive-behavioral therapy for insomnia (CBT-I) exhibited positive outcomes. Edinger et al. observed improvements in subjective variables of sleep quality, mood and life quality. Miró et al. and Sánchez et al. demonstrated improvements on attentional functioning and changes in sleep architecture as well as sleep efficiency applying neuropsychological tests and polysomnography respectively. Finally, Martínez et al. revealed increases in sleep quality, daily functioning, and psychological well-being adopting self-administered questionnaires.

In addition, the high prevalence of FM in women compared to that in men (Mas et al., 2008) has led some authors to analyze differences between both genders in symptom manifestation and psychological functioning. According to some reviews, gender determines

differences in pain perception and experience (Paller, Campbell, Edwards, & Dobs, 2009); moreover, laboratory studies have shown such differences in the pain threshold, one of them being the significantly higher threshold evidenced in healthy men compared to that in women (Moore, Eccleston, & Keogh, 2013). Several hypotheses have been proposed to explain the higher prevalence of chronic pain in women: 1) women are more willing to report pain, 2) women may be more exposed to biopsychosocial risk factors, which is likely to make them more vulnerable to developing chronic pain by responding differently to such risk factors, and 3) it is more likely for health effectors to diagnose women with FM (Wijnhhoven, de Vet & Picavet, 2006). Regarding psychological factors, some of them have been shown to vary in function of sex, as catastrophization of pain, coping style, and abuse history in childhood (Paller, Cambpell, Edwards Y Dods, 2009). The review by Paller et al. highlight that catastrophization is more common in women, and it is associated with enhanced sensitivity to experimental pain. As well, men are more likely to show an active coping style, while women rely on social support and positive self-statements. At last, young women are more exposed to suffer abuse, and childhood abuse is associated with chronic pain in adulthood (Paller et al. 2009).

However, the differential response to pain according to gender is far from being clear. Miró et al. observed that poor sleep quality in men and pain catastrophizing in women were significant predictors of pain experience. Other studies have not found significant differences between men and women in pain experience or physical activity (Sánchez et al., 2013; Yunus, Celiker, & Aldag, 2004). So far, inconclusive data has been obtained regarding diversity between men and women with FM in clinical symptoms and responses to pain (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams, & Riley, 2009). To the best of our knowledge, only Hooten, Townsend and Decker (2007), and Castro-Sánchez et al. (2013) have explored

psychological outcomes after treatment in FM patients according to gender. The authors of the first study (Hooten, Townsend & Decker, 2007) evaluated the effects of a multidisciplinary pain rehabilitation program based on the cognitive-behavioral model that included physical reconditioning, biofeedback, relaxation, and physical and occupational therapy. Men have shown at pre-treatment outcomes greater difficulties related to health perception and physical problems, while women have shown greater pain interference in life; such differences persisted despite post-treatment improvements. On the other hand, Castro-Sánchez et al. analyzed the effects of a manual therapy protocol administered by a physiotherapist. Results demonstrated that women exhibited a greater reduction in both pain and FM impact, but men reported a greater diminution in depressive symptoms and pressure hypersensitivity.

A recent review on psychological treatments for FM patients did not identify any group treatment or single case studies composed exclusively of men (Lami, Martínez & Sánchez 2012). Although there is evidence on the effectiveness of CBT-I for sleep improvement and other clinical manifestations of FM, these studies have been carried out with samples composed mostly of women (Edinger et al., 2005, Martínez et al., 2014; Miró et al., 2011; Sánchez et al., 2012). As a result, it has not been determined whether the therapeutic benefits observed in women also apply to men with FM. Considering this, the aim of the present study was to collect evidence on the efficacy of CBT-I to treat insomnia in men with FM and explore potential gender differences in clinical changes associated with CBT-I in women and men. We expect both men and women to show significant clinical and statistical improvements in pain and sleep-related variables after CBT-I; in addition, we expect women to show greater improvements in general distress (i.e., depression, anxiety) and FM impact.

## Methods

### *Procedure and participants*

Twenty-eight patients with FM (15 women and 13 men) participated in the study. Patients were recruited from the Rheumatology Service and Pain Unit of Virgen de las Nieves University Hospital and AGRAFIM, a fibromyalgia association, both in Granada, Spain. They were referred to the Clinical Psychology Unit of the University of Granada, where the psychological assessment and treatment sessions were conducted. The inclusion criteria for participating in the study were: (1) being aged between 25 and 60 years old; (2) having been diagnosed with FM according to the 1990 criteria[1] of the American College of Rheumatology (ACR) for more than six months so that the impact of the diagnosis had been assimilated; (3) meeting the diagnostic criteria for insomnia according to DSM-IV-TR[2], (American Psychiatric Association) with no sleep-disruptive comorbidities or apnea-hypopnea index or periodic limb movement-related arousal index of 15 or more per hour of sleep; (4) being free of major medical diseases (e.g., inflammatory rheumatic disease, endocrine disturbances, neurological disorder, cancer, recent surgery) and mental disorders with severe symptoms (e.g., major depression, schizophrenia, personality disorder); (5) not being dependent on hypnotic drugs or having irregularities in circadian rhythm (e.g., working at night) and having regularly used prescribed medication for at least one month; and (6) not being treated with any other psychological or physical therapy at the time of the study.

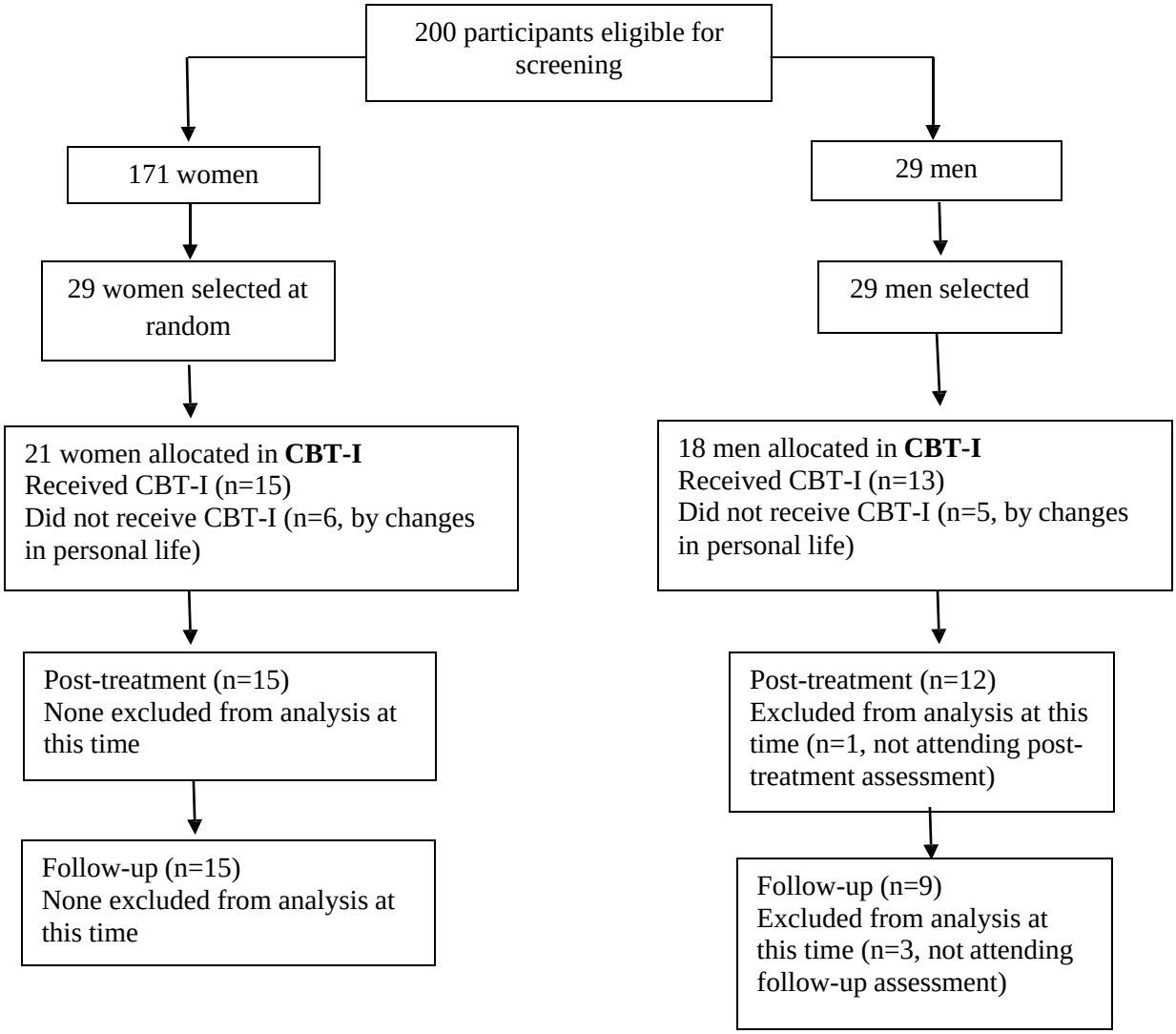
Two hundred patients were considered eligible for screening. This included 29 men (all of them were selected) and 171 women (a subgroup of 29 potential women were

[1] At the time of the participants‟ selection for the study, the 1990 criteria of the American College of Rheumatology was the ones adopted as the standard evaluation for FM diagnosis in the Rheumatology Service and Pain Unit of Virgen de las Nieves University Hospital.

[2] At the time of the participants‟ selection for the study, the DSM-IV-TR criteria for psychopathologic diagnosis were the ones adopted as standard evaluation in the Clinical Psychology Unit of the University of Granada.

randomly selected). All selected patients were contacted by telephone for a brief screening interview. Those who met the inclusion criteria were invited to participate in the study and were scheduled for a detailed assessment by a psychologist with experience in pain and sleep. Participants were evaluated in two individual interviews to ensure they met the inclusion criteria and collect relevant clinical data (e.g., onset and course of symptoms, lifestyle, work, personal relations, attitudes about the illness, and psychological status). In addition, participants were evaluated with several questionnaires, algometry, polysomnography, and a neuropsychological test (the last three measures were assessed as part of other studies). Of the selected patients, 21 women and 18 men with FM fulfilled the inclusion criteria, completed the assessments, and were allocated to CBT-I. Fifteen women and 13 men completed the treatment and were included in the analyses (see Figure 1 for the flowchart). All participants gave their informed consent prior to their inclusion in the study. The study was approved by the University of Granada Ethics Committee.

*Figure 1*. Flow of participants throughout the study.




*Measures*

The following measures were applied at pre-treatment, post-treatment, and follow-up performed 3 months after the intervention. Sleep quality was considered as the primary outcome measure; pain intensity, fatigue, functioning, emotional distress (anxiety and depression), pain anxiety, and pain catastrophizing were considered as secondary outcome measures.

*Short-Form McGill Pain Questionnaire* (MPQ-SF) (Melzack, 1987). This questionnaire consists of 15 descriptors of the pain experience (11 sensory and 4 affective descriptors) and a

visual analogue scale ranging from 1 (*no pain*) to 10 (*extreme pain*) to quantify pain intensity during the past week. Adequate reliability (internal consistency=.74) (Masedo & Esteve, 2000) and validity of the Spanish version of the MPQ (Lázaro et al., 2001) have been reported.

*Multidimensional Fatigue Inventory* (MFI) (Smets, Garssen, Bonke, & Haes, 1995; Fillion, Simard, Savard, & Gaqnon, 2003). This inventory includes 20 items that assess various aspects of fatigue (i.e., gener al fatigue, physical fatigue, mental fatigue, motivation reduction, and activity reduction). Items are assessed on a Likert scale ranging from 1 (*disagree*) to 5 (*totally agree*). All subscales were computed in this study. The MFI has shown adequate internal consistency (.84), construct validity, and convergent validity (Smets et al., 1995).

*Pittsburgh Sleep Quality Index* (PSQI) (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). This questionnaire includes 19 items that asses several dimensions of sleep quality: subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleeping medication, and daytime functioning. The Spanish version of the PSQI has shown acceptable internal consistency (ranging between .67 and .81), sensitivity and specificity (Royuela & Macías, 1999).

*Fibromyalgia Impact Questionnaire* (FIQ) (Burckhardt, Clark & Bennet, 1991). This self-report inventory evaluates the current health status of patients with FM by assessing their functional impairment in daily life, disability to work, and other symptoms such as pain intensity in the past week, depression, fatigue, anxiety, and unrefreshed sleep with a Likert scale from 0 to 10. In Spanish FM samples, the FIQ has shown adequate psychometric properties including test-retest reliability, internal consistency (.82), external validity, and sensitivity (Rivera & González, 2004).

*Hospital Anxiety and Depression Scale* (HADS) (Zigmond & Snaith, 1987). The HADS measures symptoms associated with depression (7 items) and anxiety (7 items) with four response options. It is useful for screening depression and anxiety symptoms in non-psychiatric contexts. In a Spanish sample, the HADS has shown good internal consistency (.84 for the depression scale and .85 for the anxiety scale) and external validity as well as adequate sensitivity and specificity (Herrero, Ramírez-Maestre & González, 2008).

*Pain Catastrophizing Scale* (PCS) (Sullivan, Bishop & Pivik, 1995). The PCS assesses pain catastrophizing cognitions using three subscales: rumination, magnification, and helplessness. It includes 13 items measured on a 5-point Likert scale ranging from 0 -*not at all*- to 4 -*all the time*-. The Spanish version has shown adequate internal consistency (.79), test-retest reliability, and sensitivity to change (García-Campayo, Rodero, Alda, Sobradiel, Montero, & Moreno).

*Pain Anxiety Symptoms Scale-20* (PASS-20) (McCracken & Dhingra, 2002). The PASS-20 evaluates four components of pain-related anxiety: cognitive anxiety, fear of pain, escape/avoidance behaviors, and physiological symptoms of anxiety. It is a 20-item scale in which subjects respond to a 6-point Likert scale ranging from 0 –*never*- to 5 –*always*-. The PASS-20 has shown good internal consistency (.91) and predictive and construct validity (McCracken & Dhingra, 2002).

*Intervention*

Male patients were administered CBT-I by a male psychologist (F.N.D.) and female patients were administered the CBT-I by three female psychologists (M.P.M., E.M., and A.I.S), one per group. Sessions were conducted in groups (5-7 participants) once a week for nine weeks and lasted about 90 minutes. Participants received a protocol-based manual that

included psychoeducational information, exercises and topics to discuss during the session and homework. The manual was designed based on cognitive-behavioral therapy for insomnia (Morin, 1988) and the recommendations of the American Academy of Sleep Medicine (Morgenthaler et al., 2006). The contents of the CBT-I are shown on Table 1. Patients continued with their usual medical care. They were receiving stable pharmacological treatment during their participation in the study and agreed not to initiate other treatments at that time. The potential bias regarding the fact that treatments were carried out by different psychologists and different gender, were controlled ensuring that all therapists developed the same intervention content and interactive style. The quality of the CBT-I protocol was guaranteed by the high level of professional training and experience of the therapist engaged, the therapy manual containing the full information and tasks involved in each sessions, and regular clinical meetings with the research group to monitor the implementation of the intervention.

**Table 1.** Contents of the CBT-I program

| **Session** | **Contents** |
|---|---|
| 1- Justification and introduction of the program | Information about FM syndrome and pain and its relationship with sleep. Identification of sleep problems and insomnia. Information on the treatment program structure and the active role of the participant in the process. |
| 2- Basic information on sleep and sleep hygiene rules I | Information about sleep (e.g., sleep stages, sleep functions, effects of sleep deprivation on sleep-wake functioning). Sleep hygiene rules focused on environmental factors: noise, temperature, light and furniture. |
| 3- Sleep hygiene rules II (health and quality of life) | Training in sleep hygiene in order to include changes in lifestyle and healthy habits regarding diet, exercise, consumption of stimulants, alcohol, and medication. |
| 4- Sleep restriction and stimulus control | Sleep restriction therapy combined with stimulus control instructions. Discussion about the difficulties of these techniques. |
| 5- Relaxation techniques | Abdominal breathing and relaxation training (a combination of passive relaxation and imagery training). |
| 6- Cognitive therapy I | Relationship between thoughts, emotions and behaviors. Role of negative thoughts on insomnia. Identification of dysfunctional thoughts related to sleep. |

| | |
|---|---|
| 7- Cognitive therapy II | Strategies to replace dysfunctional thoughts with more adaptive thoughts. Cognitive restructuring of dysfunctional thoughts about causes and consequences of insomnia. |
| 8- Cognitive therapy III | Cognitive restructuring of dysfunctional thoughts about sleep expectations, lack of control over sleep, and sleep habits. Planning of behavioral experiments. |
| 9- Maintenance of achievements and relapse prevention | Integration of treatment components. Maintenance of gains. Anticipation of possible relapses. Planning future evaluations. |

*Data analysis*

The analyses were performed with the SPSS-23 statistical package. Student‟s *t* test and the $\chi^2$ test were used to compare demographic and clinical variables between men and women at pre-treatment. In order to explore therapeutic changes in the outcome variables, 2 (Group: Men vs. Women) x 3 (Time: Pre-treatment vs. Post-treatment vs. Follow-up) ANCOVAs were performed considering pre-treatment values as covariables. Mauchly‟s test of sphericity and the Greenhouse-Geiser correction were computed. Student‟s *t* test was calculated to compare differences in unpaired (groups) and paired two samples (times). To test the significance of Student´s *t* test, bootstrap (confidence intervals at 95%) were computed based on 1000 bootstrap samples. In significant results, effect sizes were computed using $\eta^2$ and Cohen‟s *d* to determine small effects ($\eta^2$ =.01 or *d* =.2), medium effects ($\eta^2$ =.06 or *d* =.5) or large effects ($\eta^2$ =.14 or *d*=.8) (Cohen, 1988).

Also, is estimated the clinical significance of changes throughout the treatment. The Reliable Change Index (RCI), developed by Jacobson and Truax (Jacobson & Truax, 1991), was calculated and patients were classified into categories according to this index[53]: *Same*, no positive or negative change; *Deterioration*, negative change; *Improvement without complete recovery*, positive change but less than 1; *Somewhat positive change*, positive change higher than 1 but less than 1.96; or *Very positive change*, positive change higher than 1.96 (in the present study, the latter three categories were computed together as *Positive change*).

## Results

*Characteristics of the sample*

The selected participants (15 women and 13 men) had a mean age of 46.29 years (SD = 7.76). Most of them were married (64.3%) or single (25%), had elementary or secondary education (50%), or university education (39.3%). As regard their labor status, 57.1% were active and 42.8% were unemployed or inactive. Mean time from diagnosis of the disease was 4.85 years (SD = 3.01), but the mean duration of symptoms reported was 10.73 (SD = 7.74). The main demographic and clinical characteristics of FM men and FM women are shown on Table 2. There were no significant differences between groups in any of the variables evaluated at pre-treatment (all $p > .15$), except for intake of anti-inflammatory drugs – women reported significantly higher intake than men ($\chi^2 = 60.5$, $p = .04$).

**Table 2.** Characteristics of FM women and FM men at pre-treatment.

| **Variable** | **Women** *n=15* | **Men** *n=13* | **Women vs. Men** **t/** $\chi^2$ | p |
|---|---|---|---|---|
| Age, M (SD) | 45.2 (6.85) | 47.54 (8.82) | .79 | .44 |
| Marital status (%) | | | 78.50 | .38 |
| Married | 73.3 | 57.1 | | |
| Single | 13.3 | 38.5 | | |
| Divorced | 6.7 | 0 | | |
| Widowed | 6.7 | 7.7 | | |
| Education level (%) | | | 71.00 | .15 |
| Primary education | 13.3 | 15.4 | | |
| Secondary education | 33.3 | 23.1 | | |
| Professional instruction | 20 | 15.4 | | |
| University education | 33.3 | 46.2 | | |
| Work situation (%) | | | 93.00 | .82 |
| Active | 60 | 53.8 | | |
| Retired | 6.7 | 15.4 | | |
| Unemployed | 13.3 | 7.7 | | |
| Sick leave | 20 | 23.1 | | |
| Duration of FM diagnosis (years), M (SD) | 4.71 (3.33) | 5.00 (2.77) | .24 | .81 |
| Duration of FM symptoms (years), M (SD) | 12.76 (9.46) | 7.89 (6.44) | -1.40 | .17 |
| Drug intake (%) | | | | |
| Antidepressant | 46.7 | 61.5 | 76.5 | .26 |
| Anxiolytics | 20 | 30.8 | 94.5 | .85 |
| Anti-inflammatory | 53.3 | 15.4 | 60.5 | .04 |
| Analgesics | 80 | 76.9 | 87.5 | .56 |

*Treatment effects on sleep quality*

Means, standard deviations, Student‟s *t* tests and ANCOVA data regarding sleep measures are shown on Table 3. There were no differences between men and women in these variables at pre-treatment (all $p > .23$).

The outcomes of the ANCOVA revealed a significant effect of Time on total sleep quality and almost all the subscales evaluated (i.e., subjective sleep quality, sleep latency, sleep efficiency, sleep disturbances, and daytime functioning) and an effect close to significance on sleep duration. However, we found no significant effects of Group or Time x Group on any of the sleep variables studied. In men, significant differences were observed between pre- and post-treatment in total sleep quality, subjective sleep quality, sleep duration, sleep efficiency, and sleep disturbances. In women, significant differences were observed between pre- and post-treatment in total-sleep quality, subjective sleep quality, sleep latency, sleep duration, and sleep efficiency; the female sample also exhibited significant differences between post-treatment and follow-up in use of sleeping medication. No differences were found between male and female groups of patients in sleep variables at any time, except in use of sleeping medication: men had higher scores than women at follow-up. According to the RCI, 91.7% of men and 93.33% of women showed positive changes in total sleep quality after CBT-I.

**Table 3.** Group and time effects on sleep variables.

| Variables | Group | Pre-treatment M (SD) | Post-treatment M (SD) | Follow-up M (SD) | Time F ($\eta^2$) | Group F ($\eta^2$) | Time x Group F ($\eta^2$) | T1 vs. T2 *t* (*d*) | T2 vs. T3 *t* (*d*) |
|---|---|---|---|---|---|---|---|---|---|
| Total-Sleep quality | Men | 16.54 (3.80) | 12.22 (3.86) | 11.78 (2.63) | 5.17* (.33) | .06 | .44 | 5.18**(1.5) | .54 |
| | Women | 15.40 (3.18) | 11.67 (3.75) | 10.33 (4.19) | | | | 4.96** (.90) | 1.16 |
| | Men vs. women *t (d)* | .86 | -.17 | .99 | | | | | |
| Subjective sleep quality | Men | 2.23 (.59) | 1.78 (.97) | 1.56 (.53) | 3.99* (.28) | 1.73 | .83 | 2.55* (.75) | .69 |
| | Women | 2.20 (.41) | 1.40 (.83) | 1.33 (.62) | | | | 4.58*** (1.41) | .29 |
| | Men vs. women *t (d)* | .16 | .80 | .90 | | | | | |
| Sleep latency | Men | 1.77 (1.23) | 1.22 (1.09) | 1.22 (.97) | 5.38** (.35) | .02 | .03 | 1.73 | .00 |
| | Women | 2.47 (.83) | 1.73 (.70) | 1.80 (1.01) | | | | 3.21**(.85) | -.37 |
| | Men vs. women *t (d)* | -1.72 | -1.80 | -1.37 | | | | | |
| Sleep duration | Men | 2.54 (.66) | 1.67 (.86) | 1.55 (.73) | 3.29 (.25) | .12 | .08 | 4.75**(1.33) | .55 |
| | Women | 2.40 (.83) | 1.53 (.83) | 1.33 (.90) | *p*=.06 | | | 4.03**(1.05) | .90 |
| | Men vs. women *t (d)* | .48 | .42 | .63 | | | | | |
| Sleep efficiency | Men | 2.38 (1.12) | 1 (1.22) | 1.33 (1.12) | 7.61** (.43) | .001 | .32 | 3.95**(1.20) | -1.41 |
| | Women | 2.07 (1.03) | 1.07 (1.01) | 1.07 (1.03) | | | | 4.42**(.93) | .00 |
| | Men vs. women *t (d)* | .78 | -.54 | .59 | | | | | |
| Sleep disturbances | Men | 2.23 (.72) | 1.78 (.83) | 1.55 (.73) | 3.75* (.27) | 3.42 | 2.40 | 3.92**(1.10) | 1.51 |
| | Women | 2.13 (.52) | 2.07 (.70) | 2.00 (.53) | | | | .32 | .43 |
| | Men vs. women *t (d)* | .41 | -1.40 | -1.72 | | | | | |
| Use of sleeping medication | Men | 2.62 (.96) | 2.67 (1) | 2.66 (1.00) | 2.24 | 2.33 | 2.83 | 1.00 | - |
| | Women | 2.13 (1.25) | 2.07 (1.28) | 1.40 (1.30) | | | | .25 | 2.47**(.64)* |
| | Men vs. women *t (d)* | 1.21 | .91 | 2.51* *(1.10)* | | | | | |
| Daytime functioning | Men | 2.23 (1.09) | 2.11 (.92) | 1.89 (.78) | 6.48** (.39) | .49 | .35 | .89 | .80 |
| | Women | 2.0 (.93) | 1.80 (1.01) | 1.40 (.91) | | | | .90 | 1.70 |
| | Men vs. women *t (d)* | .60 | .29 | 1.34 | | | | | |

Bootstrap (CI 95%, 1000) *p*-value: **p*<.05 ***p*<.01; ****p*<.001; T1=Pre-treatment; T2=Post-treatment; T3=Follow-up.

*Treatment effects on pain intensity, fatigue, functioning, emotional distress, pain anxiety and pain catastrophizing*

Means, standard deviations, t-Student and ANCOVA data for these outcome measures are shown on Table 4. A first analysis revealed no differences between female and male groups in these measures at pre-treatment (all $p > .40$).

The ANCOVA revealed significant effects of Time on pain intensity, mental fatigue, motivation and activity reduction, FM impact, anxiety, pain-related anxiety, and pain catastrophizing. We found no significant effects of Group or Time x Group on any of the variables evaluated, with the exception of anxiety, which showed a significant effect of Group: men showed a greater improvement. In men, significant differences were observed between pre- and post-treatment in pain-related anxiety and pain catastrophizing and effects close to significance were observed in FM impact. In women, significant differences were found between pre- and post-treatment in general fatigue and depression. Men and women only differed in anxiety: women had higher levels of anxiety than men at follow-up. According to the RCI, the following percentages of women showed positive changes: 26.7% in pain intensity, 53.3% in general fatigue, 46.7% in FM impact, 73.3% in depression, 20% in anxiety, 66.7% in pain-related anxiety, and 83.3% in pain catastrophizing. The following percentages of men showed positive changes: 45.5% in pain intensity, 33.3% in general fatigue, 63.6% in FM impact, 41.7% in depression, 66.7% in anxiety, 75% in pain-related anxiety, and 53.3% in pain catastrophizing.

**Table 4.** Group and time effects on pain, fatigue, functioning, emotional distress, pain anxiety and pain catastrophizing.

| Variables | Group | Pre-treatment M (SD) | Post-treatment M (SD) | Follow-up M (SD) | Time F ($\eta^2$) | Group F ($\eta^2$) | Time x Group F ($\eta^2$) | T1 vs. T2 *t* (*d*) | T2 vs. T3 *t* (*d*) |
|---|---|---|---|---|---|---|---|---|---|
| Pain intensity | Men | 7.40 (1.42) | 6.50 (1.96) | 6.55 (1.42) | 5.78** (.22) | .69 | .31 | 1.69 | 1.31 |
| (MPQ) | Women | 7.30 (1.93) | 7.33 (1.88) | 6.93 (1.48) | | | | .09 | 1.09 |
| | Men vs. women *t (d)* | .24 | -1.27 | -.61 | | | | | |
| General fatigue | Men | 4.19 (1.60) | 4.42 (.80) | 4.14 (.71) | 2.57 | .17 | .13 | -.35 | .18 |
| (MFI) | Women | 4.62 (.39) | 4.10 (.80) | 4.20 (.64) | | | | 2.36*(.67) | -53 |
| | Men vs. women *t (d)* | -1.37 | .56 | -.22 | | | | | |
| Physical fatigue | Men | 3.94 (1.15) | 3.97 (.85) | 4.19 (0.92) | 1.97 | .06 | 1.20 | .29 | -1.54 |
| (MFI) | Women | 4.23 (.57) | 3.98 (.70) | 3.83 (0.78) | | | | 1.39 | .77 |
| | Men vs. women *t (d)* | -.86 | -.29 | 1.03 | | | | | |
| Mental fatigue | Men | 3.36 (.97) | 3.43 (.92) | 3.69 (.81) | 5.68* (.36) | .03 | 1.39 | -.28 | -1.74 |
| (MFI) | Women | 3.45 (1.37) | 3.73 (1.24) | 3.50(1.07) | | | | -1.73 | 1.15 |
| | Men vs. women *t (d)* | -.19 | -.69 | .47 | | | | | |
| Motivation | Men | 3.50 (.83) | 3.07 (1.10) | 2.86 (.90) | 5.30* (.35) | .41 | .24 | 1.97 | .00 |
| reduction (MFI) | Women | 3.47 (.79) | 3.13 (.82) | 3.03 (.87) | | | | 1.21 | .56 |
| | Men vs. women *t (d)* | -.46 | -.47 | -.46 | | | | | |
| Activity reduction | Men | 3.52 (.89) | 3.555 (.72) | 3.17 (.91) | 10.17** | 1.04 | .52 | .50 | .27 |
| (MFI) | Women | 2.93 (1.01) | 2.77 (.92) | 2.77 (.80) | (.50) | | | .59 | .17 |
| | Men vs. women *t (d)* | 1.25 | 1.61 | 1.27 | | | | | |
| FM impact (FIQ) | Men | 62.40 (14.14) | 52.33 (17.60) | 50.15 (11.30) | 5.09* (.35) | .30 | .15 | 2.04 (*p=.07*) (.64) | .18 |
| | Women | 59.75 (12.17) | 56.16 (16.93) | 54.64 (15.84) | | | | .78 | .53 |
| | Men vs. women *t (d)* | -.45 | -.27 | -.74 | | | | | |
| Depression (HADS) | Men | 8.92 (4.48) | 9.83 (5.56) | 9.00 (5.34) | 2.29 | 3.99 | 2.58 | -.74 | .94 |
| | Women | 8.57 (2.90) | 7.33 (3.01) | 7.93 (2.05) | | | | 2.35*(.62) | -.97 |
| | Men vs. women *t (d)* | .28 | 1.49 | .70 | | | | | |
| Anxiety (HADS) | Men | 11.70 (5.09) | 9.90 (4.33) | 8.44 (2.07) | 17.75***(.64) | 4.87* (.19) | 3.19 | .98 | .73 |
| | Women | 9.60 (3.60) | 10.93 (2.94) | 10.93 (2.79) | | | | -1.35 | .00 |
| | Men vs. women *t (d)* | .46 | -.84 | -2.31* | | | | | |
| Pain anxiety | Men | 51.20 (15.33) | 41.30 (16.51) | 40.56 (19.31) | 4.72** (.32) | 4.10 | 4.21 | 2.66*(.46) | -1.39 |
| (PASS-20) | Women | 43.75 (21.37) | 38.07 (17.06) | 45.60 (20.46) | | | | 1.54 | -2.49 |
| | Men vs. women *t (d)* | -.30 | .22 | -.60 | | | | | |
| Pain catastrophizing | Men | 28.40 (13.61) | 24.10 (12.11) | 23.78 (11.93) | 5.04** (.33) | 1.11 | .54 | 2.45*(.00) | -1.26 |
| (PCS) | Women | 24.80 (14.86) | 21.40 (11.90) | 23.60 (13.83) | | | | 1.25 | -1.03 |
| | Men vs. women *t (d)* | -.05 | .09 | .03 | | | | | |

*$p$<.05 **$p$<.01; ***$p$<.001; T1=Pre-treatment; T2=Post-treatment; T3=Follow-up.

## Discussion

The aim of this study was to provide greater insight into gender differences in the clinical features of FM by evaluating the efficacy of CBT-I in men with FM and comparing the outcomes with current evidence on the efficacy of CBT-I in women with FM. We performed intergroup comparisons (i.e., between genders) and intragroup comparisons (i.e., between pre-treatment, post-treatment, and follow-up).

Results of data analysis revealed significant improvements after CBT-I in both genders in total sleep quality, subjective sleep quality, sleep efficiency, sleep disturbances, daytime functioning, pain intensity, mental fatigue, motivation and activity reduction, and FM impact. Only the male group exhibited significant and positive changes at post-treatment in sleep disturbances and pain-related anxiety and catastrophizing. The female group showed post-treatment improvements in sleep latency, general fatigue, and depression, which persisted at follow-up. The intergroup *t* test did not reveal any differences between male and female patients at pre-treatment, post-treatment, or follow-up in the sleep and clinical variables evaluated. A high percentage of patients exhibited clinical improvements in sleep quality – similarly in men (91.7%) and women (93.33%) – and other symptoms and pain-related cognitive variables.

Our study showed pain and others mainly symptoms reduction in the total group in line with others CBT-I developed in chronic pain patients (Martínez, Miró & Sánchez, 2014). As well, the studies conducted in female FM samples (Martínez et al., 2014; Miró et al., 2011; Sánchez et al., 2012) or FM samples mostly composed of women (Edinger et al., 2005) assessed patients‟ outcomes after CBT-I versus sleep hygiene education (SH) and reported improvements in subjective sleep quality, sleep latency, sleep duration, habitual sleep

efficiency and sleep disturbances (Edinger et al., 2005; Sánchez et al., 2012), attentional functioning (Martínez et al., 2014), and polysomnographic parameters, specifically an increase in deep sleep time and a decrease in light sleep time (Miró et al., 2011).

In the present study, the first analysis did not reveal any significant gender differences at pre-treatment in any demographic or clinical variables. Yet, some studies have reported that women with FM have a higher risk of claiming a disability pension than men with FM (Gjesdal, Bratberg & Maeland, 2011), and that men have lower health perception and more physical limitations than women (Hooten, Townsend, & Decker, 2007). Regarding endogenous aspects in pain modulation, studies reveal that women exhibit more efficient pain inhibition responses, however, inconsistent outcomes in these studies were observed (Fillimgim et al., 2009). In relation to psychological features, our results are in line with those of Yunus et al., who did not find any gender differences in pain, sleep quality, anxiety, depression, stress, or disability in patients with FM at any time of measure. Previous studies performed by our research group (Miró et al., 2012; Sánchez et al., 2013) did not reveal any differences in these variables of men and women with FM. The results obtained by previous studies addressing the complex relationship between gender and psychological manifestation of chronic pain showed discrepant data and remains understudied. This conditions is in part due to differential studies design, such as, the type of pain (e.g., experimentally induced pain or daily dysfunctional pain) or population evaluated (e.g., healthy volunteers, FM patients, or patients with other chronic pain disorders) or the method used to assess pain (e.g., self-reported measures or an algometer). More specific studies in FM patients are needed to reach clearer conclusions.

In responses to treatment, the present study showed significant gender differences. Although women and men obtained similar improvements after CBT-I in sleep and clinical

variables, we found a significant effect of group on anxiety (i.e., anxiety decreased in men but slightly increased in women). In addition, women exhibited improvements in sleep latency, general fatigue, and depression, but men did not. By the other hand, men exhibited improvements in sleep disturbances, pain catastrophizing, and pain-related anxiety, but women did not. These results differ from those reported by Hooten et al. who compared men and women with FM after multidisciplinary pain rehabilitation including CBT. That study reported gender differences at pre-treatment in interferences in health perception and role limitation related to physical problems; such differences persisted after treatment. Hooten et al. emphasize differential pain report between genders, and considered such contrast observed in FM patients were due to sociological influences (i.e., greater expectations about males being able to perform more physical tasks) rather than biological and psychological differences. In our study, a lack of pre-treatment gender differences is noted, and can be argued that sociological influences related to gender role are not enough in the Spanish population to lead to differences between males and females in the clinical manifestation of FM. In addition to treatment responses, Castro-Sánchez et al. also reported different results between males and females with FM: men exhibited greater improvements in depressive symptoms, while women showed a greater reduction in pain and FM impact. In another study, conducted with patients with chronic pain and not FM (Keogh, McCracken, & Eccleston, 2005), the authors explored the gender role in the efficacy of pain treatment. They assessed subjective pain and emotional distress in clinical settings after an interdisciplinary pain intervention based on acceptance and commitment therapy (ACT). Results revealed a significant effect of gender on distress and depression; men showed less depression and pain-related distress than women after treatment (Keogh, McCracken, & Eccleston, 2005). Dissimilar results are showed in the present study, women showed a reduction in depressive

symptoms after treatment, whereas men did not. It is worth to note that changes in depression in women were not followed by changes in pain-related index as pain anxiety and pain catastrophization, as contrary as observed in men. These outcomes are discrepant with those reported by Keogh, McCracken, and Eccleston may be explained by different basic theoretical approach of both treatments. Improvements in pain related variables especially in men could be associated at the effect of the support of the same gender group, given that men, besides of the symptoms of FM, are subjected to suffering from a "women disease". In the present study it is observed a CBT-I effectiveness with minor differences between sex. These changes from pre-treatment to post-treatment may be given by different mechanisms between men and women. However having made homogeneous groups in terms of sex, it did not allow us to perceive such diversity, as the contents of the subjects in the CBT-I might have been idiosyncratically worked intra-groups.

Our study has several limitations. First, the sample size may be considered small as being a preliminary study, although it should be noted that FM has a low prevalence in men. In addition, the sample was derived from a rheumatology service, a pain unit and a FM association, without taking into account the considerable number of patients who attend primary care services. Another limitation of this study is the fact that we did not assess other psychological aspects that are important to fully explain the adaptation of FM patients (i.e., coping strategies, chronic pain acceptance, vigilance of pain). More detailed analyses and evaluations would also be needed after a three-month follow-up to assess the maintenance of clinical gains after treatment and explore the impact of the improvements in quality of sleep on other symptoms in the long term.

As stated by other authors (Hooten, Townsend, & Decker, 2007; Keogh, McCracken, & Eccleston, 2005), there is still not enough data to develop a differential treatment for

women and men with FM. If it is necessary to include specifications in the treatment related to the gender of patients, the latter could include contents about daily life concerns that may help to complement the standard treatment. Our study revealed that women‟s improvements concerned clinical features such as depression and general fatigue that seem to be more general, whereas men‟s improvements were more related to sleep disturbances and pain-related variables such as pain anxiety and catastrophizing. These results should be highlighted so that clinicians can provide more specific psychological treatment to men or women with FM. Finally, although the present and other studies revealed some differences between men and women in the effect of treatments for FM, further research is needed to clarify how gender-tailored psychological therapy for FM patients should be developed.

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*Artículo 6*

# Efficacy of combined Cognitive-Behavioral Therapy for Insomnia and Pain in Fibromyalgia Patients: A randomized controlled trail

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(en revisión)

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# Efficacy of combined cognitive-behavioral therapy for insomnia and pain in patients with fibromyalgia: A randomized controlled trial


## Abstract

Fibromyalgia (FM) is characterized by widespread pain and other symptoms such as fatigue, cognitive dysfunction, and sleep disturbances, and patients show substantial impairments in functional status and mental and physical health. Sleep disturbances such as insomnia have been identified as a core symptom in the origin and maintenance of pain. **Objective:** 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 in women with FM. **Method:** One hundred and twenty-six patients with FM were randomly assigned to different treatment groups and completed a number of self-reports at pre-treatment, post-treatment, and three months of follow-up. **Results:** 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. **Conclusions:** 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 identify which patients are likely to benefit from each modality of CBT.

**Key words:** *fibromyalgia, cognitive-behavioral therapy, insomnia, randomized controlled trial*

## Introduction

Fibromyalgia (FM) is a rheumatic disease characterized by widespread pain in muscles and soft tissues for more than three months and tenderness in at least 11 of 18 specific points of the body (Wolfe et al., 1990). Patients with FM also report other symptoms with variable intensity. These symptoms include chronic fatigue, cognitive dysfunctions, sleep disturbances with unrefreshing sleep, and somatic symptoms such as irritable bowel syndrome, morning stiffness, or temporomandibular disorder (Fitzcharles & Yunus, 2012). FM has an estimated prevalence of 2.9% in the general European population (Branco et al., 2010). In Spain, it affects 2.4% of the population and is significantly more frequent in women (4.2%) than in men (0.2%) (Mas, Carmona, Valverde, & Ribas, 2008). Patients with FM experience substantial impairments in functional status and mental and physical health (Wolfe, Walitt, Katz, & Häuser, 2014) and are at high risk of developing anxiety, mood disorders, and substance misuse problems (Von Korff et al., 2005).

One of the clinical manifestations most often associated with FM is sleep disturbances. Recent studies have found that 88.75% of people diagnosed with FM report sleep difficulties (Wagner, DiBonaventura, Chandran, & Cappelleri, 2012) and 94.7% to 96% are defined as problem sleepers (Bigatti, Hernandez, Cronan, & Rand, 2008). Patients with FM report more insomnia and less restorative sleep than rheumatic patients and the general population (Belt, Kronholm, & Kauppi, 2009). Previous reviews (Díaz-Piedra, Di Stasi, Baldwin, Buela-Casal, & Catena, 2015; Moldofsky, 2009; Prados & 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 importance of sleep problems has been accepted in the latest clinical conceptualizations of

FM by the American College of Rheumatology (ACR; Wolfe et al., 2010). Indeed, unrefreshing sleep as well as widespread pain, cognitive symptoms, fatigue, and a number of somatic symptoms are currently considered as the most important diagnostic variables in the disease.

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, Catley & Karlson, 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 hyperalgesic state" in patients with FM. According to some studies, this is due to specific impairments such as loss of descending analgesic activity and central sensitization (Lee, Nassikas, & Clauw, 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).

The American Pain Society (APS) recommends a multidisciplinary approach to the treatment of chronic pain and particularly cognitive-behavioral therapy (CBT) over other psychotherapies (Häuser, Thieme, & Turk, 2010). In a previous review, the European League Against Rheumatism (EULAR) recommended that sleep, insomnia, and sleep disorders

should be reported in trials, and that the importance of sleep disturbances from the perspective of patients should be taken into account in the diagnosis and evolution of FM (Aletaha et al., 2008). Regarding FM treatment, the latest review conducted by EULAR recommends exclusively the use of drug therapies but surprisingly does not refer to the benefits of psychological treatment for this disease (Smolen et al., 2013). The Spanish interdisciplinary consensus document for FM treatment (Alegre de Miquel et al., 2010) highlights the importance of the psycho-education of patients as well as their psychological evaluation to identify subgroups of FM profiles and recommends CBT as the best approach for patients with high levels of catastrophizing and depression.

The observation that insomnia is the most common sleep disorder in patients with chronic pain (Belt, Kronholm, & Kauppi, 2009) has led to the development of psychological treatments based on cognitive-behavioral therapy focused on insomnia (CBT-I). Several studies have explored the efficacy of CBT-I in patients with chronic pain (Currie, Wilson, Pontefract, & deLaplante, 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, Wohlgemuth, Krystal, and Rice (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 sleep hygiene intervention in several parameters such as attentional functioning assessed by neuropsychological tests, 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 shown limitations in improving patients‟ ability to mitigate the severity of pain (Martínez, Miró, & Sánchez, 2014b). Therefore, in recent years a number of scholars have suggested combining CBT-I with procedures that contribute to a better management of pain. Several studies have analyzed the efficacy of combined CBT for insomnia and pain (CBT-IP) 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 by small samples and methodological differences (McCurry et al., 2014; Pigeon et al., 2012; Tang, Goodchild & Salkovskis, 2012; Vitiello et al., 2013). Pigeon et al. (2012) evaluated clinical changes in a small sample (n=4) of patients with chronic pain 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; however, the greatest improvements in pain intensity were observed after CBT-P, although 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 heterogeneous chronic pain sample. 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 by Vitiello et al. (2013) and the follow up shown by 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 CBT-P or the education intervention; CBT-IP and CBT-P were associated with significantly greater improvements in sleep efficiency than the education intervention but the three groups did not exhibit any differences in pain intensity (Vitiello et al., 2013). The study conducted by McCurry et al. (2014) assessed long-term changes in a subgroup of patients with severe pain and insomnia at baseline and revealed that, after 18 months, the benefits gained in pain and insomnia severity and sleep efficiency were more present in patients who had undergone CBT-IP than in those in the CBT-P and the education intervention groups.

The aim of this randomized controlled trial was to obtain additional evidence in order to identify the clinical improvements of CBT for management of insomnia and pain in patients with FM. For this purpose, the efficacy of CBT-IP was compared to CBT-P and usual medical care (UMC) regarding sleep quality and other troubling symptoms in women with FM. The specific hypotheses proposed were: (1) CBT-IP will lead to significantly greater statistical and clinical improvements in sleep quality than CBT-P and UMC; and (2) CBT-IP and CBT-P will produce significantly greater statistical and clinical improvements in pain-related variables (i.e., pain intensity, self-efficacy for coping with pain, pain catastrophizing, and pain acceptance), 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 three conditions: CBT for pain (CBT-P, *n* = 42), combined CBT for insomnia and pain (CBT-IP, *n* = 42), or usual medical care (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 (an FM association), both in Granada, Spain, and referred to the Psychology Clinic of the University of Granada, where the assessment and treatment sessions were conducted.

The inclusion criteria to participate in the study 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 more than 6 months (to avoid the first impact of the diagnosis); (3) being stable as regards the intake of analgesics, antidepressants, or other drugs (regarding to sleep and pain) at least one month before the study and not being treated with another psychological or physical 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 sleep 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).

One hundred and eighty-five eligible women with FM were screened using a short telephone interview administered by a psychologist. Of the pa
excluded at this stage due to not meeting the inclusion criteria, an
criteria ($n$ = 126) were given an appointment for an individual ps
semi-structured interview was conducted in two sessions. Session
course of FM and insomnia, patients‟ life history, lifestyle, work activity, family and social relations, and psychological state. After the interview, patients were given several self-report questionnaires and a sleep diary to complete at home. Session 2 was scheduled to obtain additional data about insomnia, collect questionnaires, and answer any questions. All patients completed the sleep diary for 2 weeks before treatment and during the intervention. A subgroup of patients was also assessed with polysomnography, actigraphy and a neuropsychological test at pre- and post-treatment. In order to allocate patients randomly to the treatments (42 patients to each condition), a computerized 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, 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 Figure 1 for the flowchart of this study).

59 excluded (did not meet inclusion criteria):
- 32 had severe dependence of hypnotic drugs or irregularities in circadian rhythm
- 14 had severe medical/psychological disorders
- 7 had sleep disorder not insomnia (i.e., apnea)
- 6 dropped due to changes in personal life

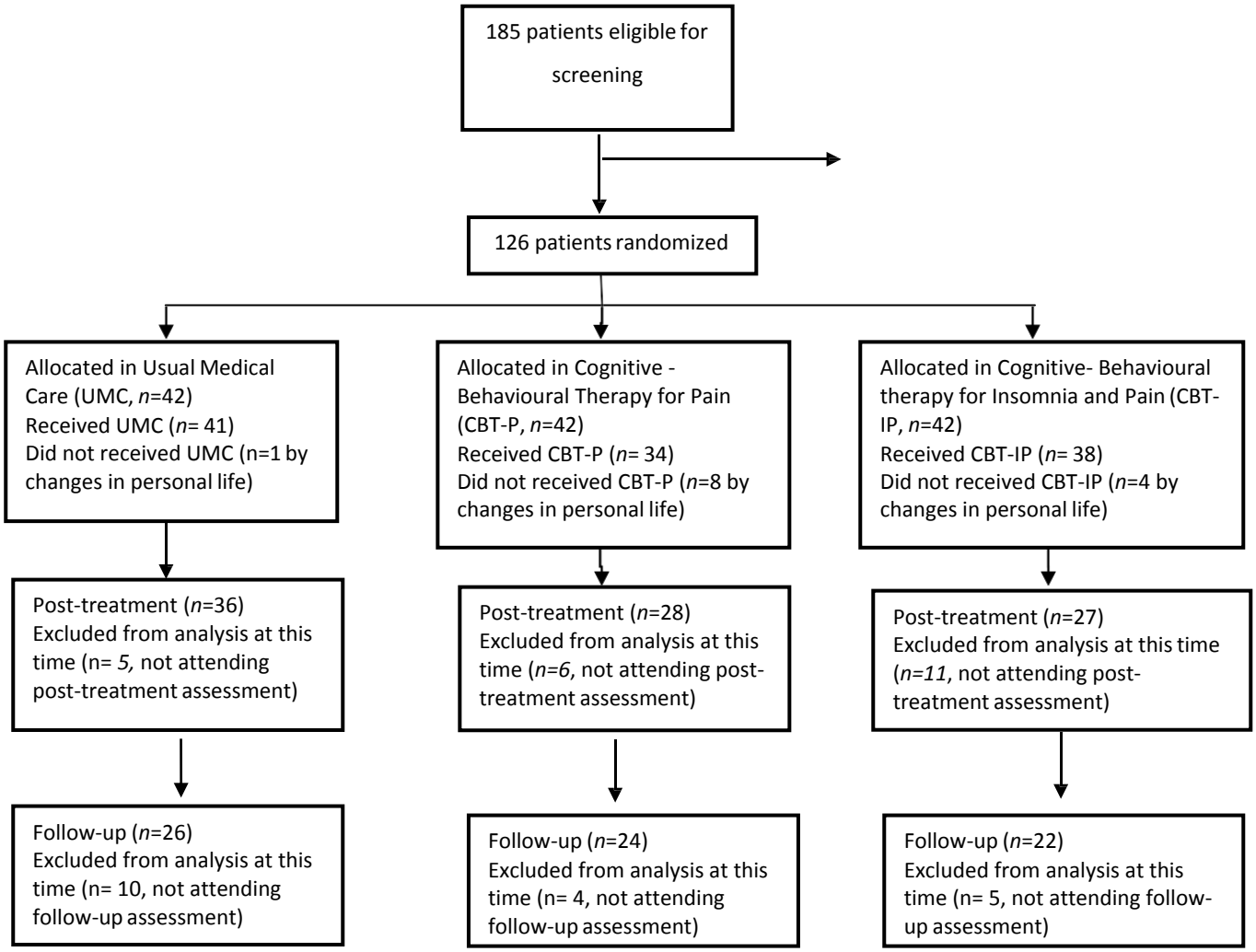


*Figure 1.* Flow diagram of participants through the phases of the trial

**Measures**

The assessments were performed at pre-treatment, post-treatment (one week after the completion of the intervention), and follow-up (three months later). A psychologist who was blinded to group assignment administered 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, Gallinaro, Lorenzi-Filho & Lage, 2006) and is frequently used in clinical trials on pain treatment (Cole, Dubois, & Kosinski, 2007). The Spanish adaptation of the PSQI has shown adequate psychometric characteristics (Royuela & Macías, 1997).

*McGill Pain Questionnaire-Short Form* (MPQ-SF; Melzack, 1987). This questionnaire assesses the sensory and affective dimensions of pain experience using 15 verbal pain descriptors, a current pain intensity index, and a visual analogue scale (VAS) to measure pain intensity in the last week (from 1 to 10). The present study used the VAS. 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, Garssen, Bonke, & De Haes, 1995; adaptation by Fillion, Gélinas, Simard, Savard, & Gagnon, 2003). This inventory explores five facets of fatigue using 20 items: *General fatigue, Physical fatigue, 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, Clark, & Bennet, 1991). This self-report inventory is composed of 10 items and evaluates the current health status of patients with FM by considering their functional impairment in daily life and work and other symptoms. Item 1 asesses 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/unable 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 & González, 2004).

*Chronic Pain Self-Efficacy Scale* (CPSS; Anderson, Dowds, Pelletz, Edwards, & Peeters-Asdourian, 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 for coping with symptoms, and self-efficacy 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, Bishop, & Pivik, 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, Vowles & Eccleston, 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. The sessions were conducted in a group format (5-7 participants) once a week for nine weeks and lasted about 90 minutes. During the study all participants were required to follow their usual medical care (on stable doses of medication) and not to participate in other interventions.

The protocol manual of CBT-P and CBT-IP consists 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 & Linton, 2012), and was aimed at modifying the reinforcement contingencies that maintain pain behaviors as well as dysfunctional attitudes and emotional reactions, considering the therapeutic guidelines for chronic pain collected in various publications (e.g., Thieme, Turk, & Flor, 2007; Turk, Vierck, Scarbrough, Crofford, & Rudin, 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).

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

**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). |
| | 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. Incorporation of pleasant activities for counteracts avoidance behaviors. | 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 related to pain (e.g., catastrophizing, vigilance, control of pain) | Cognitive therapy I: Identification of dysfunctional thoughts related to sleep (e.g., causes and consequences of sleep, sleep habits) and pain. |
| **8** | Cognitive therapy II: Strategies to replace dysfunctional thoughts for more adaptive ones. Cognitive restructuring. | |
| **9** | Integration of treatment components. Maintenance of gains. Anticipation of possible relapses. Planning future evaluations. | |

**Data analysis**

Statistical analyses were performed using IBM SPSS Statistics 19 software. Probabilities less than or equal to .05 were used as the level of significance. ANOVA, Krusskal-Wallis, and $\chi^2$ 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) x 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 $\eta^2$ and Cohen‟s *d*. Cohen‟s guidelines (1988) were considered: $d$=.2 is a small effect, .5 is a medium effect, and .8 is a large effect, and $\eta^2$=.01 is a small effect, .06 is a medium effect, and .14 is a large effect.

The clinical significance was estimated based on the Jacobson-Truax method (Reliable Change Index, RCI; Jacobson & Truax, 1991). Patients were classified into different categories according to this index (Salaberría, Páez, & Echeburúa, 1996): *Same* (with no positive or negative changes), *Deterioration* (negative change), *Improvement without*

*complete recuperation* (positive change but less than 1), *Somewhat positive change* (higher than 1 but less than 1.96), and *Very positive change* (higher than 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 $p \geq .10$), except in percentage of antidepressant and anxiolytic intake, which was higher in the CBT-IP group ($p \leq .05$). 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).

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

| Variables | Total sample (*n* =113) | CBT-P (*n* =34) | CBT-IP (*n* =38) | UMC (*n* =41) | CBT-P vs. CBT-IP vs. UMC | |
|---|---|---|---|---|---|---|
| | | | | | *F /H/ X²* | *p* |
| Age, *M* (*SD*) | 50.19 (8.24) | 49.35 (6.43) | 49.66 (8.44) | 51.37 (9.38) | .67 | .51 |
| Education (%) | | | | | 2.50 | .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 | .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 | .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), *M* (*SD*) | 6.62 (5.31) | 6.39 (5.60) | 5.94 (4.84) | 7.48 (5.51) | .78 | .46 |
| Duration of FM symptoms (years), *M* (*SD*) | 10.11 (9.08) | 10.10 (9.03) | 8.47 (6.99) | 11.57 (10.63) | 1.04 | .36 |
| Duration of sleep problem (years), *M* (*SD*) | 10.89 (8.89) | 10.40 (8.06) | 13.42 (9.99) | 8.10 (5.73) | 2.29 | .51 |
| Sleep latency (hours), *M* (*SD*) | 0:50 (0.36) | 0:46 (0.46) | 0:48 (0:29) | 0:38 (0:35) | .22 | .81 |
| Number of awakenings per night, *M* (*SD*) | 2.92 (1.63) | 2.86 (1.56) | 2.67 (1.30) | 3.47 (2.17) | 1.19 | .31 |
| Sleeping hours per night, *M* (*SD*) | 5:06 (1.41) | 4:45 (1.19) | 5:25 (1:40) | 5:20 (2:06) | .57 | .57 |
| Drug intake (%) | | | | | | |
| Antidepressants | 59.3 | 52.9 | 71.1 | 53.7 | 4.97 | .05 |
| Anxiolytics | 62.8 | 50 | 73.7 | 63.4 | 4.78 | .05 |
| Anti-inflammatory drugs | 76.1 | 82.4 | 78.4 | 68.3 | 4.51 | .10 |
| Analgesics | 77.9 | 79.4 | 84.2 | 70.7 | 4.31 | .17 |

### *Changes in sleep quality after treatments*

The ANCOVA for Sleep quality-Total revealed a significant and medium effect of Time, Group and Time x Group (see Table 3). 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 and Group. The CBT-IP group showed a significant improvement between pre- and post-treatment in this parameter but neither CBT-P nor the UMC did. Baseline differences between the CBT-IP and the UMC groups in this subscale were identified (the UMC group reported better Subjective sleep quality). In Sleep latency, a significant and medium effect of Time was found and significant improvements were observed at post-treatment in the CBT-IP group. Significant and large effects of Time and Group 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 large effects of Time, Group, and Time x 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 x 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 and a large effect of Group were observed, as well as a significant pre-treatment difference between the CBT-IP and UMC groups (the UMC group reported better Daytime functioning). These differences between CBT-IP and UMC and between CBT-P and UMC increased at follow-up.

**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 ($\eta^2$) | Group F ($\eta^2$) | Time x Group F ($\eta^2$) | T1 vs. T2 *t (d)* | T2 vs. T3 *t (d)* |
|---|---|---|---|---|---|---|---|---|---|
| Total-Sleep quality | CBT-P | 13.47 (4.45) | 13.68 (4.61) | 13.79 (4.22) | 8.38*** | 4.88** | 3.48** | -.18 | -.93 |
| | CBT-IP | 14.68 (3.70) | 13.19 (4.31) | 13.57 (3.64) | *(.12)* | *(.07)* | *(.10)* | 2.94***(.35)* | -1.39 |
| | UMC | 12.88 (5.01) | 13.08 (5.33) | 11.88 (4.68) | | | | -.78 | .85 |
| | CBT-P vs. CBT-IP t *(d)* | -1.25 | .81 | .19 | | | | | |
| | CBT-P vs. UMC t *(d)* | .54 | .47 | 1.51 | | | | | |
| | CBT-IP vs. UMC t *(d)* | 1.79 | .41 | 1.35 | | | | | |
| Subjective sleep quality | CBT-P | 2.00 (.78) | 1.86 (.85) | 1.79 (.78) | 10.09*** | 8.98** | .42 | 1.00 | .25 |
| | CBT-IP | 2.22 (.58) | 1.93 (.87) | 1.95 (.78) | *(.14)* | *(.12)* | | 2.13* *(.46)* | -.37 |
| | UMC | 1.73 (.74) | 1.86 (.76) | 1.65 (.69) | | | | -1.67 | 1.44 |
| | CBT-P vs. CBT-IP t *(d)* | -1.33 | -.30 | -.71 | | | | | |
| | CBT-P vs. UMC t *(d)* | 1.52 | -.02 | .66 | | | | | |
| | CBT-IP vs. UMC t *(d)* | 3.18** *(.74)* | .31 | 1.41 | | | | | |
| Sleep latency | CBT-P | 1.97 (1.03) | 1.71 (1.24) | 1.83 (1.01) | 5.77** | 3.81*(.50)* | .69 | 1.31 | -1.32 |
| | CBT-IP | 2.03 (.96) | 1.74 (.90) | 1.91 (.92) | *(.08)* | *p=.055* | | 2.81** *(.41)* | -.81 |
| | UMC | 1.94 (1.08) | 2.00 (1.15) | 1.77 (1.31) | | | | -.81 | .00 |
| | CBT-P vs. CBT-IP t *(d)* | -.24 | -.09 | -.27 | | | | | |
| | CBT-P vs. UMC t *(d)* | -.22 | -.95 | .19 | | | | | |
| | CBT-IP vs. UMC t *(d)* | .01 | -.97 | .42 | | | | | |
| Sleep duration | CBT-P | 1.97 (.87) | 2.18 (.90) | 1.87 (.90) | 11.86*** | 14.27*** | .82 | -1.80 | 1.22 |
| | CBT-IP | 1.81 (.99) | 1.93 (.83) | 2.00 (.89) | *(.16)* | *(.18)* | | -1.28 | .00 |
| | UMC | 1.90 (.99) | 1.86 (1.07) | 1.81 (.98) | | | | .37 | .44 |
| | CBT-P vs. CBT-IP t *(d)* | .72 | 1.08 | -.47 | | | | | |
| | CBT-P vs. UMC t *(d)* | .31 | 1.26 | .25 | | | | | |
| | CBT-IP vs. UMC t *(d)* | -.41 | .26 | .69 | | | | | |
| Sleep efficiency | CBT-P | 1.68 (1.22) | 1.61 (1.26) | 1.67 (1.09) | 15.29*** | 11.50*** | .95 | .14 | -.89 |
| | CBT-IP | 1.78 (1.17) | 1.64 (1.18) | 1.86 (1.19) | *(.20)* | *(.15)* | | 2.24* *(.46)* | -1.32 |
| | UMC | 1.80 (1.25) | 1.75 (1.18) | 1.81 (1.06) | | | | .25 | -.33 |
| | CBT-P vs. CBT-IP t *(d)* | -.35 | -.69 | -.56 | | | | | |
| | CBT-P vs. UMC t *(d)* | -.45 | -.47 | -.46 | | | | | |
| | CBT-IP vs. UMC t *(d)* | -.10 | -.40 | .15 | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sleep disturbances | CBT-P | 2.21 (.69) | 2.18 (.61) | 2.33 (.64) | 169.2*** | 132.01*** | 2.77** | .00 | -1.28 |
| | CBT-IP | 2.35 (1.75) | 2.07 (.73) | 2.00 (.69) | *(.72)* | *(.67)* | *(.80)* | 1.03 | .57 |
| | UMC | 1.95 (.70) | 1.94 (.79) | 1.77 (.76) | | | | .57 | .00 |
| | CBT-P vs. CBT-IP t *(d)* | -.45 | .58 | 1.70 | | | | | |
| | CBT-P vs. UMC t *(d)* | 1.57 | 1.29 | 2.82** *(.80)* | | | | | |
| | CBT-IP vs. UMC t *(d)* | 1.35 | .66 | 1.09 | | | | | |
| Use of sleeping medication | CBT-P | 1.74 (1.38) | 1.96 (1.34) | 1.79 (1.41) | 4.43 | 3.65* *(.10)* | 2.83* *(.08)* | -.49 | .96 |
| | CBT-IP | 2.30 (1.17) | 1.89 (1.31) | 1.91 (1.38) | | | | 2.16* *(.42)* | -.25 |
| | UMC | 1.76 (1.41) | 1.89 (1.39) | 1.58 (1.44) | | | | -.81 | 1.00 |
| | CBT-P vs. CBT-IP t *(d)* | -1.85 | .21 | -.28 | | | | | |
| | CBT-P vs. UMC t *(d)* | -.06 | .22 | .53 | | | | | |
| | CBT-IP vs. UMC t *(d)* | 1.83 | .00 | .81 | | | | | |
| Daytime functioning | CBT-P | 2.12 (.91) | 2.21 (.99) | 2.46 (.93) | 9.60*** | 14.76*** | 1.34 | .00 | -1.06 |
| | CBT-IP | 2.24 (.98) | 2.19 (.88) | 2.32 (.78) | *(.13)* | *(.19)* | | 1.29 | -.69 |
| | UMC | 1.71 (1.25) | 1.75 (1.20) | 1.62 (1.23) | | | | .00 | .00 |
| | CBT-P vs. CBT-IP t *(d)* | -.56 | .11 | .55 | | | | | |
| | CBT-P vs. UMC t *(d)* | 1.59 | 1.65 | 2.70**(.78) | | | | | |
| | CBT-IP vs. UMC t *(d)* | 2.09* *(.49)* | 1.59 | 2.31* *(.65)* | | | | | |

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

**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 ($\eta^2$) | Group F ($\eta^2$) | Time x Group F ($\eta^2$) | T1 vs. T2 *t (d)* | T2 vs. T3 *t (d)* |
|---|---|---|---|---|---|---|---|---|---|
| Pain intensity-VAS (MPQ-SF) | CBT-P | 7.58 (1.75) | 7.35 (2.08) | 7.21 (1.79) | 2.10 | 3.67* *(.15)* | 2.24 | .66 | 1.57 |
| | CBT-IP | 7.44 (1.33) | 7.29 (1.46) | 6.62 (1.47) | | | | .54 | 2.84* (.65) |
| | UMC | 7.16 (1.27) | 7.40 (1.29) | 7.20 (1.58) | | | | -.56 | .56 |
| | CBT-P vs. CBT-IP t *(d)* | .36 | .10 | 1.14 | | | | | |
| | CBT-P vs. UMC t *(d)* | 1.16 | -.11 | .21 | | | | | |
| | CBT-IP vs. UMC t *(d)* | .94 | -.28 | -1.28 | | | | | |
| General fatigue (MFI) | CBT-P | 4.40 (.72) | 4.31 (.68) | 4.35 (.72) | 22.88*** | 7.12*** | 8.41*** | .53 | -.34 |
| | CBT-IP | 4.31 (.76) | 4.31 (.66) | 4.05 (.67) | *(.51)* | *(.19)* | *(.18)* | .00 | 1.32 |
| | UMC | 4.01 (.96) | 3.18 (1.04) | 4.03 (.77) | | | | 4.27*** *(.67)* | -4.23*** *(-.78)* |
| | CBT-P vs. CBT-IP t *(d)* | .56 | .01 | 1.40 | | | | | |
| | CBT-P vs. UMC t *(d)* | 1.85 | 4.97*** *(1.31)* | 1.50 | | | | | |
| | CBT-IP vs. UMC t *(d)* | 1.42 | 4.80*** *(1.33)* | .12 | | | | | |
| FM impact (FIQ) | CBT-P | 65.53 (11.08) | 57.93 (14.16) | 53.33 (14.85) | 9.62** | 6.54* | .88 | 4.09*** *(.82)* | 1.29 |
| | CBT-IP | 61.98 (11.14) | 55.82 (14.52) | 56.53 (13.97) | *(.13)* | *(0.92)* | | 2.59* (.42) | -.47 |
| | UMC | 55.57 (18.14) | 55.45 (16.79) | 53.22 (16.59) | | | | .41 | 1.49 |
| | CBT-P vs. CBT-IP t (d) | 1.35 | .54 | -.76 | | | | | |
| | CBT-P vs. UMC t (d) | 2.79**(.69) | .62 | .24 | | | | | |
| | CBT-IP vs. UMC t (d) | 1.87 | .09 | .74 | | | | | |
| Self-efficacy (CPSS) | CBT-P | 72.85 (36.54) | 87.14 (30.21) | 78.36 (41.32) | 4.60** | 2.43 | 2.08 | -3.39** *(-.46)* | 1.87 |
| | CBT-IP | 76.38 (31.29) | 85.52 (38.22) | 90.41 (37.64) | *(.07)* | | | -.2.22* *(-.52)* | -.25 |
| | UMC | 76.56 (30.16) | 79.53 (25.66) | 81.79 (38.82) | | | | -1.33 | -.40 |
| | CBT-P vs. CBT-IP t *(d)* | -.43 | .17 | -1.04 | | | | | |
| | CBT-P vs. UMC t *(d)* | -.99 | 1.09 | -.31 | | | | | |
| | CBT-IP vs. UMC t *(d)* | -.60 | .74 | .78 | | | | | |
| Depression (SCL-90-R) | CBT-P | 2.15 (.88) | 2.15 (.78) | 2.11 (.90) | 4.38* | .49 | .43 | .05 | .71 |
| | CBT-IP | 2.20 (.79) | 2.03 (.96) | 2.02 (1.01) | *(.06)* | | | 1.21 | .31 |
| | UMC | 1.77 (.95) | 1.68 (.98) | 1.47 (.78) | | | | 1.36 | .02 |
| | CBT-P vs. CBT-IP t *(d)* | -.29 | .50 | .33 | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | CBT-P vs. UMC t *(d)* | 1.72 | 2.05* *(.36)* | 2.69** *(.76)* | | | | | |
| | CBT-IP vs. UMC t *(d)* | 2.13* *(.49)* | 1.40 | 2.10* *(.61)* | | | | | |
| Anxiety (SCL-90-R) | CBT-P | 1.63 (.81) | 1.71 (.94) | 1.60 (1.05) | 1.61 | 2.04 | 1.60 | -1.31 | 1.17 |
| | CBT-IP | 1.78 (.93) | 1.68 (1.05) | 1.62 (.98) | | | | .49 | .45 |
| | UMC | 1.50 (.93) | 1.37 (.91) | 1.18 (.69) | | | | 1.22 | .88 |
| | CBT-P vs. CBT-IP t *(d)* | -.72 | .81 | -.07 | | | | | |
| | CBT-P vs. UMC t *(d)* | .65 | 1.94 | 1.65 | | | | | |
| | CBT-IP vs. UMC t *(d)* | 1.34 | 1.24 | 1.79 | | | | | |
| Pain catastrophizing (PCS) | CBT-P | 24.91 (12.07) | 20.00 (10.59) | 22.84 (14.14) | 2.93 | 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 | .91 |
| | UMC | 23.55 (12.81) | 24.91 (12.41) | 24.20 (11.78) | | | | .75 | -.25 |
| | CBT-P vs. CBT-IP t *(d)* | -.40 | -1.38 | -.29 | | | | | |
| | CBT-P vs. UMC t *(d)* | .47 | -1.23 | .18 | | | | | |
| | CBT-IP vs. UMC t *(d)* | .89 | .26 | .49 | | | | | |
| Pain acceptance (CPAQ) | CBT-P | 51.74 (17.72) | 57.57 (13.62) | 53.46 (19.12) | 10.40*** *(.14)* | .84 | 1.43 | -4.20*** *(-.83)* | 2.38* *(.53)* |
| | CBT-IP | 52.16 (18.47) | 53.48 (21.41) | 53.68 (15.70) | | | | -1.33 | -.96 |
| | UMC | 54.05 (22.94) | 55.86 (21.48) | 57.54 (21.85) | | | | -.63 | -.69 |
| | CBT-P vs. CBT-IP t *(d)* | -.09 | .85 | -.04 | | | | | |
| | CBT-P vs. UMC t *(d)* | -.46 | .37 | -.70 | | | | | |
| | CBT-IP vs. UMC t *(d)* | -.39 | -.44 | -.69 | | | | | |

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

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 (see Table 5).

***Changes in clinical features (i.e., pain, fatigue, impact, 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 x Group on several clinical variables (see Table 4). The ANCOVA revealed a 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 x Group were identified in General fatigue. A significant reduction of 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 and Group 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 significant and small effect of Time was found in Depression. At pre-treatment, a significant difference between CBT-IP and UMC was revealed (depression was lower in the UMC group). At post-treatment, significant differences between CBT-P and UMC were observed; at follow-up, these differences remained and significant differences between CBT-IP and UMC were also observed. Regarding Anxiety, no significant effects of Group, Time or

Time x Group were observed. Pain catastrophizing did not exhibit any significant effects of Group, Time or Time x Group either but Pain acceptance showed a significant and medium effect of Time. Significant improvements in both variables after CBT-P were observed at post-treatment, but this trend was inverted at follow-up.

According to the RCI (see Table 5), Pain intensity improved in 50% of patients in both the CBT-P and the 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 5**. RCI calculated on sleep quality and clinical features in CBT-P, CBT-IP and UMC

| | CBT-P | | CBT-IP | | UMC | |
|---|---|---|---|---|---|---|
| **Total-Sleep quality** | Improvement (%) | 46.4 | Improvement (%) | 62.9 | Improvement (%) | 11.1 |
| **(PSQI)** | Same (%) | 14.3 | Same (%) | 14.8 | Same (%) | 66.6 |
| | Deterioration (%) | 39.3 | Deterioration (%) | 22.3 | Deterioration (%) | 22.3 |
| **Pain intensity-VAS** | Improvement (%) | 50 | Improvement (%) | 50 | Improvement (%) | 13 |
| **(MPQ-SF)** | Same (%) | 16.7 | Same (%) | 18 | Same (%) | 74 |
| | Deterioration (%) | 33.3 | Deterioration (%) | 32 | Deterioration (%) | 13 |
| **General fatigue** | Improvement (%) | 33.3 | Improvement (%) | 25 | Improvement (%) | 63.9 |
| **(MFI)** | Same (%) | 29.2 | Same (%) | 45.8 | Same (%) | 13.9 |
| | Deterioration (%) | 37.5 | Deterioration (%) | 29.2 | Deterioration (%) | 22.2 |
| **FM impact** | Improvement (%) | 78.6 | Improvement (%) | 61.5 | Improvement (%) | 25 |
| **(FIQ)** | Same (%) | 0 | Same (%) | 3.8 | Same (%) | 58.5 |
| | Deterioration (%) | 21.4 | Deterioration (%) | 34.7 | Deterioration (%) | 16.5 |
| **Self-efficacy** | Improvement (%) | 81.5 | Improvement (%) | 67 | Improvement (%) | 30.6 |
| **(CPSS)** | Same (%) | 0 | Same (%) | 33 | Same (%) | 11.1 |
| | Deterioration (%) | 18.5 | Deterioration (%) | 0 | Deterioration (%) | 58.3 |
| **Depression** | Improvement (%) | 64 | Improvement (%) | 52 | Improvement (%) | 30 |
| **(SCL-90-R)** | Same (%) | 0 | Same (%) | 4 | Same (%) | 56 |
| | Deterioration (%) | 36 | Deterioration (%) | 44 | Deterioration (%) | 14 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **Anxiety** | Improvement (%) | 57 | Improvement (%) | 77 | Improvement (%) | 72 |
| **(SCL-90-R)** | Same (%) | 4 | Same (%) | 0 | Same (%) | 3 |
| | Deterioration (%) | 39 | Deterioration (%) | 23 | Deterioration (%) | 25 |
| **Pain catastrophizing** | Improvement (%) | 78.6 | Improvement (%) | 55.6 | Improvement (%) | 28.6 |
| **(PCS)** | Same (%) | 4 | Same (%) | 7.4 | Same (%) | 54.3 |
| | Deterioration (%) | 17.4 | Deterioration (%) | 37 | Deterioration (%) | 17.1 |
| **Pain acceptance** | Improvement (%) | 78 | Improvement (%) | 59.3 | Improvement (%) | 28 |
| **(CPAQ)** | Same (%) | 4 | Same (%) | 7.4 | Same (%) | 53 |
| | Deterioration (%) | 18 | Deterioration (%) | 33.3 | Deterioration (%) | 19 |

CBT-P= Cognitive-behavioral therapy for pain; CBT-IP=Cognitive-behavioral therapy for insomnia and pain; UMC = Usual medical care

## Discussion

The aim of this trial was to evaluate the effects of CBT-IP compared to CBT-P and UMC in patients with FM, and the findings demonstrated differential responses among treatments. As expected according to the first hypothesis of this study, CBT-IP was associated with significant improvements in sleep-related variables between pre- and post-treatment (Subjective sleep efficacy, Sleep latency, Sleep efficiency, and Use of sleeping medication) that were not observed in the CBT-P or UMC groups. Likewise, regarding pain-related variables and other clinical parameters, results 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. Such positive changes were not shown by the UMC group, as predicted by the second hypothesis. However, several findings are in contrast with one another, as expected. Fatigue was not improved after CBT-IP or CBT-P, but positive changes were observed after UMC, although such improvements were transient and fatigue tended to return to pre-treatment levels at follow-up. Pain catastrophizing and Pain acceptance only showed positive changes after CBT-P, with a tendency towards a reduction of the improvements at follow-up. Finally, emotional distress (i.e. Anxiety and Depression) did not change significantly in any of the three treatment groups. Taking clinical improvements into

account, 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 focused on pain alone. Is lawful to mention that also is been observed a proportion of patients who showed deterioration after CBT-IP and CBT-P (see Table 5). Reading individuals values, it is observed that most cases of deterioration involve a slight decrease from baseline. Furthermore, an individualized analysis regarding deterioration proportions could be relevant in order to identify a clinical patient‟s profile who receives limited benefit from CBT interventions. There are hardly any researches addressing this issue.

The present study is the first to explore the efficacy of CBT-IP in comorbid FM and insomnia. Our results are congruent with those reported by Tang et al. (2012), Pigeon et al. (2012), and Vitiello et al. (2013). Although 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). Likewise, 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. However, no differences among the three treatment conditions in sleep variables were observed at 18 months of follow-up, although participants with higher levels of insomnia and pain at baseline showed greater improvements (although not

significant) in insomnia severity and sleep efficiency in the CBT-IP group than in the education intervention group (McCurry et al., 2014).

However, 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 taken with caution given the methodological differences between them, especially regarding sample type and sample size, 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 above-mentioned studies evaluated several dimensions of sleep disturbances with self-report questionnaires, sleep diaries, and actigraphy. By contrast, we evaluated sleep quality only via a self-report questionnaire focused on sleep quality rather than insomnia.

Regarding pain-related variables, neither Pigeon et al. (2012) nor Tang et al. (2012) nor Vitiello et al. (2013) showed significant improvements in pain intensity after CBT-IP or CBT-P nor the present study at post-treatment. Although the relationship between sleep and the origin and maintenance of chronic pain is well-established (Prados & Miró, 2012), the psychological process that CBT brings about in patients with FM may require more extensive periods of follow-up until the clinical benefits over pain intensity become evident. In our trial we observed a trend to decrease of pain severity with CBT-IP at 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 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, Buenaver, Runko & Smith, 2014), the authors argue 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. Considering this, the present study revealed a significant decrease of FM impact after CBT-P and CBT-IP. Although no previous studies have used FM impact questionnaires, Tang et al. (2012) found significant improvements after CBT-IP in pain interference than 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 previous studies with patients with FM (for a review, see Bernardy, Fueber, Koellner & Häuser, 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 Glombiewsky 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, although this study did not provide comparisons with any other CBT approach. According to the influential Fear-Avoidance Model of Chronic Pain (Leeuw et al., 2007; Vlaeyen & Linton, 2012), pain catastrophizing is a crucial cognitive variable involved in emotional distress and impairment associated to pain experience. A study revealed the catastrophizing of pain as a core mediating variable at the improvement of chronic pain patients functioning after CBT, active

physical treatment, as well as combined (Smeets, Vlaeyen & Kester, 2006). In our study, changes in pain catastrophizing brought about by CBT-IP or CBT-P were followed by improvements in impairment and self-efficacy, but no positive changes in depression or anxiety were observed after these forms of CBT. 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, Bryson, Read, Bush & Edwards (2014) observed that maladaptive thoughts such as pain catastrophizing predicted both insomnia severity and pain disability. 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.

The present trial has some limitations. Subjective (self-report questionnaires) and objective (polisomnography and actigraphy) sleep-related measures were applied at different stages of the clinical trial. However, it would be good to include measures of progress and continuity during the treatment (e.g., electronic diaries). In addition, pain intensity measurement should be complemented with objective measures such as a pressure algometer, which assesses pain threshold and tolerance. This study has an important sample compared with some previous research, however the number of withdrawal is relevant, and more in-depth research in this regard is needed. In this trial, data were analyzed considering only short-term changes, but as noted above it would be highly recommended to conduct the evaluation with a longer follow-up of at least 1 year or even more. Including comparisons with a CBT-I group would also provide relevant information.

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.

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 is a useful strategy to include in the multidisciplinary approach to patients with FM who have comorbid sleep disorders.

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# DISCUSIÓN

# Discusión

El presente trabajo de tesis doctoral incluye cuatro estudios dirigidos a abordar en profundidad aspectos psicológicos relacionados con la FM. El primer estudio (artículo 1) consistió en la evaluación psicométrica de la versión española de la Escala de Vigilancia y Conciencia del Dolor (Pain Vigilance and Awareness Questionnaire, PVAQ) en una muestra de mujeres con FM. Este trabajo permitió establecer los adecuados valores de consistencia interna, validez convergente y divergente, y validez predictiva de la versión española y con menor cantidad de ítems de este instrumento (PVAQ-9). En concordancia con estudios previos en población española con pacientes con dolor lumbar crónico (Esteve, Ramírez-Maestre, y López-Martínez, 2013) nuestro estudio confirmó la estructura bi-factorial compuesta por las subescalas "vigilancia activa" y "conciencia pasiva". Ambos estudios acentúan la importancia de contar con un instrumento de medida válido en pacientes con dolor crónico y específicamente en FM, teniendo en cuenta las relaciones existentes entre la hipervigilancia al dolor y los principales síntomas del síndrome (McCracken, 1997). Asimismo, esta escala sirve como instrumento fiable y útil en el ámbito clínico para medir los cambios consecuentes a los tratamientos psicológicos que buscan disminuir la hipervigilancia al dolor, como la TCC. El entrenamiento en el manejo del foco de la atención conlleva una disminución de la ansiedad relacionada con el dolor y del impacto del dolor en pacientes con dolor crónico (Elomaa, Williams, y Kalso, 2009).

El segundo estudio estuvo constituido por dos investigaciones empíricas (artículos 2 y 3) que tuvieron por objetivo: 1) evaluar y comparar los niveles de los principales síntomas de la FM (intensidad del dolor, depresión, ansiedad e impacto de la FM) y las principales variables asociadas (catastrofización del dolor, ansiedad y miedo al dolor, vigilancia del

dolor, aceptación y estrategias de afrontamiento) entre el grupo clínico y el grupo de mujeres sanas; 2) analizar las relaciones y la función moduladora de la alexitimia con las variables mencionadas; y 3) evaluar el rol mediador de la catastrofización del dolor, la aceptación del dolor y las diferentes estrategias de afrontamiento en las relaciones existentes entre el dolor y el impacto de la FM, y los síntomas de ansiedad y depresión. Estos estudios permitieron esclarecer las relaciones observadas entre las variables cognitivo-afectivas asociadas al dolor crónico y los síntomas de la FM. El primer trabajo destacó que la alexitimia, en sus dimensiones definidas como dificultad para identificar y expresar emociones modera la relación entre la ansiedad y la catastrofización, y la ansiedad y el miedo al dolor, respectivamente. Este hallazgo sugiere que la dificultad observada en las mujeres con FM para el manejo de los estados emocionales, también demostrada en estudios recientes (Di Tella et al., 2015), influye en el proceso de transformar la evaluación negativa de las sensaciones dolorosas a la manifestación de ansiedad como síntoma clínico. Asimismo, estudios de neuroimagen revelan que un desarrollo deficiente de estructuras neurales relacionadas con las emociones, como mecanismo subyacente en la alexitimia, conlleva una hipersensibilidad a las sensaciones corporales (Kano y Fukudo, 2013).

El segundo trabajo evidenció que las mujeres con FM además de mostrar niveles más elevados de intensidad del dolor y síntomas de ansiedad y depresión, en comparación con el grupo control, manifestaron mayores niveles de catastrofismo relacionado al dolor y menor aceptación del dolor. Profundizando en estas relaciones y diferencias, en este estudio se ha observado que la catastrofización del dolor es el mediador más importante en la relación existente entre la intensidad del dolor y los síntomas de ansiedad y depresión. Este hallazgo complementa la evidencia recabada en estudios empíricos y teóricos previos (Quartana et al., 2009), donde se observa que la tendencia a la catastrofización del dolor conlleva un aumento

de la experiencia dolor, del malestar psicológico asociado al dolor y la incapacidad. Asimismo, se observó que la aceptación del dolor, entendida como la disposición a vivir con la experiencia de dolor, sin tratar de cambiarlo o evitarlo, se relaciona con menores síntomas de depresión, ansiedad e impacto de la FM (McCracken y Eccleston, 2006).

El tercer estudio (artículo 4) consistió en una revisión teórica de las investigaciones sobre los tratamientos psicológicos desarrollados para la FM. Se ha reconocido la importancia del tratamiento psicológico en este síndrome de etiología desconocida y multidimensional, como complementario a los tratamientos médicos-farmacológicos (American Pain Society, 2005; Alegre de Miquel et al., 2010). Esta revisión permitió realizar un recorrido a través de las investigaciones acerca del tratamiento psicológico en la FM en los últimos 20 años. Se observó un creciente interés por el tema desde 2006 en adelante, y fueron analizados un total de 58 estudios. La mayoría de los trabajos estuvieron basados en la TCC, con leves modificaciones en los ejes de los programas terapéuticos. Esta revisión permitió identificar algunos déficits en la bibliografía publicada en esta área, a saber, sólo se ha hallado un estudio que abordó la TCC para el sueño, y por otro lado tampoco se ha encontrado grupos conformado solo por hombres. Además del amplio desarrollo en TCC, otros abordajes psicológicos estuvieron basados exclusivamente en la relajación o neuro-biofeedback, intervenciones conductuales, enfoque psico-educativos, hipnosis, entrenamiento en mindfulness y, por último intervenciones centradas en la expresión emocional y la exposición a eventos traumáticos. En cuanto a las variables que los estudios analizados pretenden mejorar, se encuentran variables cognitivo-afectivas relacionadas con la experiencia de dolor como catastrofización del dolor, aceptación del dolor, estrategias de afrontamiento, creencias de autoeficacia relacionadas el dolor y ansiedad-miedo al dolor; así también como variables sintomatológicas como dolor, fatiga, ansiedad, depresión, bienestar general e impacto de la

FM, evaluadas a través de auto-informes aplicados en estudios con diseños de tipo transversal y longitudinal (evaluaciones, pre, post y seguimiento). También se observaron otras técnicas de evaluación como el algómetro (o dolorímetro), polisomnografía y pruebas neuropsicológicas. Éstas fueron las principales medidas encontradas en la presente revisión. Si bien, este estudio no tuvo como objetivo analizar la eficacia de los tratamientos psicológicos, estudios meta-analíticos previos (Bernardy et al., 2010, 2013; Glombiewsky et al., 2010), demuestran claramente la eficacia de TCC con resultados robustos a corto plazo que persisten a largo plazo, en contraposición a lo que aseveran Bennett y Nelson (2006).

El cuarto estudio se compone de los artículos 5 y 6 que tuvieron como principal objetivo evaluar la eficacia de la TCC para el sueño y el dolor en los pacientes con FM. El primero de ellos, constituye un estudio preliminar sobre el análisis de los resultados y las diferencias de género obtenidos en un grupo de hombres y mujeres con FM tras haber participado en la TCC centrada en la mejora del sueño (TCC-I). Los datos actuales sobre prevalencia de FM identifican un mayor número de mujeres afectadas en comparación con los hombres (Mas et al., 2008), sin embargo, se han planteado diferentes hipótesis explicativas asociadas a dichas divergencias (Fillingim et al., 2009). De esta manera, son escasos los estudios de eficacia terapéutica en población masculina con diagnóstico de FM, siendo éste el primer estudio que analiza y compara la eficacia de la TCC-I en hombres y mujeres. Edinger et al. (2005) y el estudio de nuestro grupo de investigación son los únicos trabajos que evalúan la eficacia de la TCC-I en pacientes con FM. En comparación con el grupo control que recibió información sobre higiene del sueño, se destaca la superioridad de la TCC-I en la mejoría sobre la calidad subjetiva de sueño, latencia de sueño, duración total de sueño, eficiencia del sueño y perturbaciones durante el sueño (Edinger et al., 2005; Martínez et al., 2014). Resultados que se muestran semejantes a los datos observados en el artículo 5 de esta

tesis. Con respecto a las diferencias entre mujeres y hombres en respuesta a la TCC-I, no existen actualmente estudios con los que comparar nuestros resultados. En el artículo 5 se puede observar que las mujeres mejoraron en la latencia del sueño, fatiga general y depresión, mientras los hombres no lo hicieron, tras haber recibido el mismo protocolo de TCC-I; asimismo, los hombres mostraron alivio en las perturbaciones en el sueño, catastrofización del dolor y ansiedad relacionada con el dolor, pero las mujeres no lo evidenciaron. Los datos con respecto a la eficacia diferencial del tratamiento psicológico entre hombres y mujeres con dolor crónico no son congruentes, dado que se observan también diferentes abordajes psicoterapéuticos (Keogh, McCracken, y Eccleston, 2005). Esta investigación abre un campo interesante que necesita mayor estudio y análisis sobre la conveniencia de adecuar los tratamientos psicológicos según el género.

Por último, el artículo 6 describe un estudio controlado aleatorizado, que analiza y compara la eficacia terapéutica de tres tipos de abordaje: TCC orientada al dolor; TCC combinada para el sueño y el dolor, y el tratamiento médico estándar. Los componentes terapéuticos del protocolo de TCC-ID incluyen herramientas psico-educativas, cognitivo y conductuales orientados a mejorar el insomnio y el dolor, a través de 9 sesiones psicoterapéuticas. En los primeros encuentros se explicita que no existe ningún procedimiento curativo en la actualidad para la FM, por lo cual el objetivo de la intervención consiste en ayudar al paciente a desarrollar sus propios recursos personales para llevar una vida más plena y satisfactoria. La evaluación con medidas de auto-informe reveló mejoras significativas después de la TCC-D en impacto de la FM, así como otras variables cognitivo-afectivas del dolor. Asimismo, en coherencia con lo esperado, la TCC-ID mostró mejores resultados sobre las variables relacionadas con la calidad del sueño, y sobre la intensidad del dolor. Este estudio es el primero en evaluar la eficacia de la intervención combinada para el

sueño y el dolor en pacientes con FM, y dados los resultados favorables, resulta de interés seguir recabando evidencia empírica en este ámbito.

En resumen, el profundo y fructífero análisis que se ha realizado con el objetivo de dar luz sobre las variables psicológicas intervinientes en una enfermedad reumática, multidimensional y de etiología desconocida como es la FM, ha llevado a desarrollar procesos terapéuticos eficaces para la mejora en la calidad de vida de estos pacientes. Sin embargo, aún es necesaria mayor investigación en esta línea que conlleva beneficios a nivel individual y socio-económicos.

Con vistas a la investigación futura resultaría importante contar con registros que logren examinar diariamente las diversas dimensiones de la experiencia de dolor y permitan determinar las variaciones a lo largo del día de dicha experiencia de dolor que son contingentes a los cambios en la calidad del sueño, el estado de ánimo, la percepción del grado de estrés, la valoración del estado de salud, la hipervigilancia, la actitud tolerante y compasiva, etc. Para ello, resultaría interesante contar con los avances tecnológicos (como registros electrónicos en dispositivos móviles, por ejemplo), para registrar de manera inmediata estas oscilaciones de la experiencia del dolor y del deterioro asociado. Asimismo, sería relevante incluir medidas de tipo objetivo de las variables de sueño y dolor para analizar la relación entre el cambio de estos parámetros a nivel fisiológico y las restantes manifestaciones clínicas. Esto repercutiría de manera positiva en una valoración más completa y detallada del cambio tras las intervenciones psicológicas.

La investigación venidera también ha de tratar de establecer los componentes de la TCC para el sueño, de la TCC para el dolor, y de la modalidad combinada, que constituyen los principales agentes del cambio, e identificar con mayor precisión las mejorías clínicas que

posibilitan estas terapias. Asimismo, cabe prestar atención a la identificación de otras variables clínicas y/o individuales que pueden moderar los potenciales efectos beneficiosos de estas intervenciones, y que pueden ayudar a definir qué abordaje (TCC-D, TCC-I o protocolo combinado) sería más adecuado en cada caso.

Una alternativa al abordaje psicológico prescencial se podría encontrarlo en los nuevos desarrollos tecnológicos enmarcados en lo que actualemente se conoce como e-Salud o Salud 2.1. Estos recursos posibilitan la oferta de psicoterapia on-line de manera remota, a través de paginas web o programas interactivos psicoterapéuticos, dando acceso a personas con dificultades de traslado o funcionales, y de áreas alejadas a los centros de salud (Perle y Nierenberg, 2013). En pacientes con FM, esta podría ser una ventaja interesante, debido al impacto de la enfermedad sobre el funcionamiento diario. Una reciente revisión destaca la efectividad de la terapia psicológica por internet para los trastornos de ansiedad, depresión y dolor crónico (Hedman, Ljotsson y Lindefors, 2012) entre otros, y refiere que es igual de efectivo que la TCC estándar. Hasla fecha no existen estudios en pacientes con FM, por lo que constituye una línea con potencial desarrollo.

Recientemente, un creciente número de investigaciones destacan que el tratamiento con base en mindfulness representaría un abordaje útil y posiblemente eficaz en la FM (Henke y Chur-Hanse, 2014; Kozasa et al., 2012). En una importante muestra de pacientes con FM, se ha observado que una menor capacidad de conciencia plena se asocia a mayor impacto del síndrome (Jones, Mist, Casselberry, Ali, y Christopher, 2015). Además, en los últimos años se ha propuesto una interesante reformulación de los mecanismos del insomnio basada en los enfoques de mindfulness y aceptación (Ong et al., 2012). Y en esta línea, diversos estudios señalan que la terapia basada en mindfulness en pacientes con insomnio crónico logra

cambios importantes en parámetros de sueño, siendo estas mejorías similares a las de la eszopiclona (Gross et al., 2011), y superiores a las de la auto-observación (Ong et al., 2014) y la higiene del sueño (Black et al., 2015), aunque otros estudios no muestran evidencia favorable (Britton et al., 2010). Teniendo en cuenta estos datos, resultaría interesante determinar si el entrenamiento en mindfulness administrado junto a la TCC-I o la TCC-ID podría generar mayores beneficios clínicos en pacientes con FM.

Aunque la FM es un síndrome de manifestaciones heterogéneas y con mucha comorbilidad, podemos afirmar que las investigaciones sobre la eficacia del tratamiento psicológico del sueño son fructíferas. Por ello, cabe esperar que prosiga el desarrollo de investigaciones interdisciplinares y que los estudios ulteriores puedan dar respuesta a las cuestiones que quedan pendientes. Aunque todavía queda mucho por estudiar y dilucidar, los expertos destacan la importancia de ofrecer al paciente con FM la atención y los cuidados óptimos (Borchers, y Gershwin, 2015). Y en ese sentido, creemos estar transitando por una senda firme que puede ayudar al paciente a convivir con la enfermedad desarrollando su vida de manera valiosa.

# CONCLUSIONES

## Conclusiones

De acuerdo a los principales hallazgos de los estudios realizados y agrupados en la presente tesis doctoral, se pueden extraer las siguientes conclusiones:

- La Escala de Vigilancia y Conciencia al Dolor (PVAQ-9) se muestra fiable y válida para ser usada en nuestro contexto español en pacientes con diagnóstico de FM.
- Las mujeres con FM manifiestan mayores dificultades en la identificación y descripción de las emociones comparadas con las mujeres sanas.
- La alexitimia como característica de personalidad de las mujeres con FM, está asociada a una menor calidad de sueño, y mayor intensidad en los síntomas ansioso-depresivos, catastrofización y ansiedad y miedo al dolor.
- La dificultad para identificar emociones modera la relación entre la ansiedad y la catastrofización del dolor en mujeres con FM.
- La relación entre la ansiedad y el miedo al dolor se ve moderada por la dificultad para describir y expresar emociones observada en mujeres con FM.
- Los pacientes con FM manifiestan mayores niveles de catastrofización del dolor (PCS) y menores valores de aceptación del dolor (CPAQ).
- La catastrofización del dolor resulta una variable mediadora entre la intensidad del dolor y los síntomas de ansiedad y depresión.
- Con respecto al tratamiento psicológico de la FM, se ha observado un incremento en el interés y desarrollo de los abordajes cognitivo-conductuales para el tratamiento multidisciplinar de estos pacientes.
- La TCC centrada en el insomnio (TCC-I) genera resultados diferenciales en hombres y mujeres con FM. En los hombres se observa una notable mejoría en las perturbaciones en

el sueño, la catastrofización y la ansiedad ante el dolor; mientras que en las mujeres se constatan mejoras en latencia del sueño, fatiga y síntomas depresivos.

- El tratamiento médico estándar que actualmente brinda el servicio de salud pública en nuestro contexto, no resulta suficiente para abordar la complejidad de síntomas de la FM. Así, la FM continua siendo un síndrome que consume importantes recursos sanitarios de manera directa e indirecta.
- La TCC combinada para el sueño y el dolor (TCC-ID) repercute de manera positiva en términos clínicos y estadísticos, en la calidad de sueño de las pacientes con FM e insomnio, así como en variables cognitivo-afectivas relacionadas con el dolor.
- La TCC orientada al dolor (TCC-D) permite beneficios clínicos y estadísticos relevantes sobre el impacto de la FM y la autoeficacia en el manejo del dolor.
- Se observa una tendencia a largo plazo en la disminución de la intensidad del dolor en el grupo de pacientes que han recibido TCC-ID.
- Resulta necesaria mayor investigación con el objetivo de definir si existen perfiles de pacientes con FM y distintos trastornos comórbidos que puedan beneficiarse de los distintos abordajes.
- La relación entre el sueño y el dolor en la FM es compleja y recíproca, y resulta difícil revertir totalmente la afectación sobre la calidad de vida de estos pacientes, sin embargo el abordaje psicológico híbrido para el sueño y el dolor, mejora los principales síntomas (dolor e insomnio) y maximiza las probabilidades de que las personas con FM mejoren su calidad de vida.
- Actualmente los pacientes con FM reciben el diagnóstico más tempranamente y son derivados a un tratamiento médico estándar. Nuestra investigación muestra que la TCC-ID

y la TCC-D pueden resultar un complemento útil al abordaje habitual, y en algunos casos, la opción más eficaz y eficiente para mejorar los síntomas clínicos de la FM.

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# ANEXO

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# Spanish Version of the Pain Vigilance and Awareness Questionnaire: Psychometric Properties in a Sample of Women with Fibromyalgia

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**Abstract.** Excessive attention to pain is a common psychological characteristic among people who suffer from chronic pain. The Pain Vigilance and Awareness Questionnaire (PVAQ) is an internationally accepted tool to assess this feature, although there is no validated version of this measure for Spanish people with fibromyalgia. Since this pain syndrome mainly affects women, the aim of this study was to determine the psychometric properties of the PVAQ in Spanish women with fibromyalgia. A group of 242 women diagnosed with fibromyalgia aged between 20 and 66 years participated in the study. The goodness of fit of several structures of the PVAQ reported in previous studies was compared via confirmatory factor analysis. A two-factor solution (active vigilance and passive awareness) of the 9-item shortened version (PVAQ-9) was identified as the most appropriate (RMSEA = .08, NNFI = .96, CFI = .97, GFI = .87). It showed good reliability (internal consistency $\alpha$ = .82), convergent validity and divergent validity ($p$ < .01). The optimal cutoff point for identifying fibromyalgia women with worse daily functioning was a score of 24.5, with a sensitivity of .71 and a specificity of .75. The relevance of vigilance to pain for clinical research in fibromyalgia is discussed.

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**Keywords:** pain, fibromyalgia, vigilance, reliability, validity.

Fibromyalgia (FM) is characterized by widespread musculoskeletal pain for at least three months and pain on pressure in at least 11 of the 18 tender points (Wolfe et al., 1990). In addition to pain, FM patients experience other disturbing symptoms such as fatigue/tiredness, insomnia, muscle weakness, irritable bowel syndrome, nervousness, depression, and thinking/remembering problems (Wolfe et al., 2010). In Spain, FM has a prevalence of 2.3–4% (Branco et al., 2010) and the mean annual direct ambulatory cost per patient is higher in the FM group (908.67€) than in the reference medical group (555.58€) (Sicras-Mainar, Blanca-Tamayo, Navarro-Artieda, & Rejas-Gutiérrez, 2009).

Pain hypervigilance (i.e., excessive attention to pain and constant scanning of the body for annoying sensations) is a cognitive feature that intensifies pain perception and maladaptive responses to chronic musculoskeletal pain. Pain hypervigilance is an automatic and efficient process that emerges when painful sensations are appraised as dangerous, the fear system is activated, and the current goal is related to avoidance of/escape from pain (Crombez, Van Damme, & Eccleston 2005). Attentional processing of pain stimuli is a dynamic process that is modulated by competing demands, and pain may be given less priority when other competing and highly valued goals are present (Van Damme, Legrain, Vogt, & Crombez, 2010). In patients with chronic pain, the level of attention to pain has been associated with pain-related anxiety, depression, pain severity, physical and psychosocial disability, and number of physical visits due to pain (McCracken, 1997), pain severity, pain catastrophizing, and fear of movement/(re)injury (Goubert, Crombez, & Van Damme, 2004), and pain catastrophizing and pain anxiety (Martínez, Sánchez, Miró, Medina, & Lami, 2011). In the influential fear-avoidance model of chronic pain (Leeuw et al., 2007; Vlaeyen & Linton, 2000), pain hypervigilance is considered to explain the exacerbation of pain experience in musculoskeletal pain. According to this model, individuals who interpret pain catastrophically tend to experience fear of and anxiety about pain. This leads them to pay excessive attention to bodily signals and to show avoidance/escape behaviors toward activities that they believe increase the pain. These processes lead to deterioration of the muscular system and the ability to function and to the development of depressive symptoms. All this exacerbates the pain experience, contributing to a spiral that increases fear and avoidance. There is important empirical evidence supporting

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the validity of this model (for a review, see Leeuw et al., 2007; Pincus, Smeets, Simmonds, & Sullivan, 2010).

One of the main instruments used to assess pain hypervigilance is the Pain Vigilance and Awareness Questionnaire (PVAQ), a 16-item self-report measure developed by McCracken (1997). In 80 American patients with low back pain, the PVAQ showed adequate internal consistency, test-retest reliability, construct validity, and criterion validity (McCracken, 1997). An exploratory factor analysis (EFA) conducted with 256 Canadian university students revealed a hierarchical model with three lower-order factors (awareness of change, intrusion, and monitoring) and a single higher-order pain vigilance and awareness factor; the scale was found to have acceptable internal consistency and criterion validity (McWilliams & Asmundson, 2001). In 271 Dutch college students, an EFA showed a two-factor structure (attention to pain and attention to changes in pain), suitable internal consistency, test-retest reliability, and convergent and divergent validity (Roelofs, Peters, Muris, & Vlaeyen, 2002). In that study, a confirmatory factor analysis (CFA) conducted with 207 Dutch college students indicated good fit of the two and three-factor models; yet, the intrusion factor showed low internal consistency in the three-factor model. An EFA performed with 200 Dutch FM patients replicated the two-factor solution with 14 items (PVAQ-14), and a CFA conducted with 276 American patients with various chronic pain syndromes and 201 Dutch FM patients showed good fit of the two and three-factor solutions; however, the intrusion and monitoring subscales (i.e., three-factor model) were highly intercorrelated, suggesting that they represent the same construct (Roelofs, Peters, McCracken, & Vlaeyen, 2003). In that study, the PVAQ-14 showed adequate internal consistency and convergent validity in Dutch patients. In 227 American patients with chronic pain, an EFA revealed a two-factor structure (active vigilance and passive awareness) with 13 items (PVAQ-13), and this scale showed adequate internal consistency (McCracken, 2007). In 242 Chinese patients with chronic pain, a CFA and a comparison between different factor solutions (i.e., two- and three-factor, hierarchical and non-hierarchical) identified the two-factor structure proposed by McCracken (2007) as having the best data-model fit, and this scale showed acceptable internal consistency and construct and predictive validity (Wong, McCracken, & Fielding, 2011). Finally, in 468 Spanish patients with chronic low back pain, a comparison of various structures (i.e., single-, two-, and three-factor structures) via CFA identified the two-factor structure proposed by Roelofs et al. (2003) as the most suitable (Esteve, Ramírez-Maestre, & López-Martínez, 2013). In that study five items were excluded in order to optimize model fit, resulting in a 9-item version (PVAQ-9) with active vigilance and passive awareness factors, and this scale showed adequate internal consistency and convergent validity.

Previous research has shown that the PVAQ is a valid and reliable measure and that the two-factor model is the most replicated structure. However, no psychometric studies of the PVAQ have been conducted with Spanish patients with FM. The only study with a Spanish population was conducted with subjects with low back pain, a pain condition that greatly differs from FM. Since FM is more prevalent in women than in men (Branco et al., 2010) and women suffer from greater clinical pain and pain-related distress than men (Paller, Campbell, Edwards, & Dobs, 2009), it may be important to develop a Spanish version of the PVAQ for use in FM women. Therefore, this study included FM women and was aimed at analyzing the following: (a) The goodness of fit of several two-factor structures of the PVAQ identified in previous studies. The proposed hypothesis was that the PVAQ-9 would show the best fit; (b) The reliability (i.e., internal consistency) and construct validity (i.e., convergent, divergent, and predictive validity) of the most appropriate PVAQ structure. The proposed hypothesis was that the PVAQ would show high correlations with pain-related cognitive-affective variables (i.e., pain catastrophizing and pain anxiety) and moderate correlations with pain intensity, impairment, and emotional distress (i.e., anxiety and depression).

## Method

### *Participants and Procedure*

The sample was composed of 242 FM women recruited through consecutive sampling from the Pain Unit and Rheumatology Service of Hospital Universitario Virgen de las Nieves in Granada, Spain, and several associations of FM patients in Andalusia, Spain. Inclusion criteria were: (a) being a woman aged between 18 and 67 years, (b) having adequate reading comprehension, and (c) having been diagnosed with FM according to the criteria of the American College of Rheumatology (ACR, Wolfe et al., 1990). Exclusion criteria were: (a) presence of other chronic pain conditions, (b) presence of serious medical illness, (c) presence of a major depressive disorder with severe symptoms or suicide ideation or other major Axis I disorders of the DSM-IV-TR (APA, 2000), and (d) a history of alcohol or drug abuse. Patients were administered a semi-structured interview collecting socio-demographic and clinical data (i.e., onset and course of FM symptoms, life history, lifestyle, work, personal relationships, the family and the patient's attitudes about illness, and psychological status). In this interview, the possible presence of psychological problems was assessed through a shortened

and adapted screening test derived from the structured clinical interview for DSM-IV Axis I disorders (SCID-I) (First, Spitzer, Gibbon, & Williams, 1999). After that, they were given several questionnaires to complete at home and deliver within a week.

A total of 325 FM women from the hospital and the FM associations were invited to participate in a study about the relationships between perceived health status and pain-related behaviours and attitudes. As 46 subjects did not meet the criteria to participate in the study, 21 subjects refused to participate in the study, and 16 subjects did not return the questionnaires, the final sample was composed of 242 subjects.

The mean age of participants was 48.29 years (*SD* = 8.23). Most of them were married (81%) and had secondary studies (38.4%), elementary studies (33.8%) or university studies (27.9%). As regards labor status, 41.3% were active workers, 24.6% were off work on disability, 20.4% were unemployed, and 13.8% were retired/students. Mean time since FM diagnosis was 5.43 years (*SD* = 4.41). Most participants (88.54%) were receiving drug treatment. All patients signed informed consent to participate in the research. The study was approved by the Ethics Committee of the Universidad de Granada.

### *Instruments*

The McGill Pain Questionnaire-Short Form (MPQ-SF, Melzack, 1987) assesses the pain experience via 15 verbal descriptors of pain, an index of current pain intensity, and a visual analog scale to assess pain intensity during the last week (from 1 = no pain to 10 = extreme pain). Several studies (e.g., Lázaro et al., 2001) have reported the reliability and validity of the Spanish version of the MPQ.

The Fibromyalgia Impact Questionnaire (FIQ, Burckhardt, Clark, & Bennett, 1991) consists of 10 items assessing health status in FM patients. Item 1 explores daily functioning ability (scored from 0 to 3), items 2 and 3 evaluate the days per week that the subject feels well/unable to work, and items 4 through 10 assess physical and emotional symptoms (scored from 0 to 10). The Spanish version has shown adequate reliability, validity and sensitivity to change (Rivera & González, 2004).

The Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983) assesses symptoms of anxiety and depression in non-psychiatric hospital settings with 14 items (scored from 0 to 3). It includes two subscales: Anxiety and Depression. The Spanish version has shown appropriate internal consistency in chronic pain patients (Vallejo, Rivera, Esteve-Vives, Rodríguez-Muñoz, & ICAF Group, 2012).

The Pain Vigilance and Awareness Questionnaire (PVAQ, McCracken, 1997) evaluates awareness, consciousness, vigilance, and observation of pain through 16 items measured on a Likert scale from 0 (never) to 5 (always). The PVAQ has shown acceptable reliability and validity (see the Introduction section).

The Pain Anxiety Symptoms Scale (PASS-20, McCracken & Dhingra, 2002) explores fear, escape/avoidance, physiological anxiety, and cognitive anxiety. It includes 20 items scored from 0 (never) to 5 (always) on a Likert scale. The PASS-20 has shown good internal consistency, reliability, and predictive and construct validity (McCracken & Dhingra, 2002).

The Pain Catastrophizing Scale (PCS, Sullivan, Bishop, & Pivik, 1995) consists of 13 items assessing rumination, magnification, and helplessness scored from 0 (not at all) to 4 (all the time) on a Likert scale. The Spanish version has shown adequate internal consistency, test-retest reliability, and sensitivity to change (García-Campayo et al., 2008).

The PVAQ was translated into Spanish, and then translated back into English in order to ensure semantic equivalence. Only small semantic differences between both translations were identified in several items and these differences were reconciled by a professional English translator.

### *Data Analysis*

Considering the subject-item ratio of 10:1 recommended for factor analysis (Thorndike, 1982), and since the PVAQ includes 16 items, a minimum sample size of 160 subjects was required, so the sample recruited (242 FM women) was adequate. Data were computed with SPSS 20.0 and LISREL 8.80. Significance levels lower than .05 were considered. In order to identify the most suitable factor model of the PVAQ, a CFA with the Robust ML method was applied. The following indexes were computed: Satorra-Bentler $\chi^2$ statistic, Root Mean Square Error of Approximation (RMSEA), Non-Normed Fit Index (NNFI), Comparative Fit Index (CFI), Goodness of Fit Index (GFI) and Expected Cross Validation Index (ECVI). Values < .08 in the RMSEA (Thompson, 2004), and > .90 in the NNFI, CFI and GFI (Stevens, 2002) indicated acceptable model fit.

Reliability (internal consistency) of the PVAQ was examined with Cronbach's alpha, considered as suitable minimum values between .70 and .80 (Nunnally & Bernstein, 1995). The standard error of measurement was also estimated. The convergent and divergent validity of the PVAQ was determined by the magnitude of the relationship with other variables using the Pearson correlation coefficient. Correlations were considered low (from .10 to .29), medium (from .30 to .49), or high (.50 or higher) (Cohen, 1988). An ROC curve was obtained to examine the predictive validity of the PVAQ in identifying FM patients with clinical/high levels of pain,

FM impact, anxiety, and depression. For the instrument to be predictive, the area under the curve must be higher than .50. The cutoff score with the best sensitivity and specificity was identified.

## Results

### *Descriptive Statistics*

As expected, pain intensity in the last week ($M$ = 7.48, $SD$ = 1.56) was relatively high in FM patients. FM impact ($M$ = 61.05, $SD$ = 14.70) was severe (score ≥ 59) (Bennett, Bushmakin, Cappelleri, Zlateva, & Sadosky, 2009). Anxiety ($M$ = 11.03, $SD$ = 4.48) indicated clinical range (score ≥ 11), and depression ($M$ = 9.93, $SD$ = 4.69) was indicative of a doubtful clinical problem (score between 8 and 10) (Zigmond & Snaith, 1983). Pain vigilance ($M$ = 45.32, $SD$ = 12.64), pain catastrophizing ($M$ = 25.79, $SD$ = 12.48), and pain anxiety ($M$ = 48.64, $SD$ = 20.31) were similar to those reported in previous studies (e.g., Roelofs et al., 2003). Table 1 shows the descriptive statistics for each item of the PVAQ.

### *Confirmatory Factor Analysis*

As a previous step to the CFA, multivariate normality was examined and atypical observations in the PVAQ were identified. Missing values (0.36%) were imputed with the expected maximization method. Seven cases were excluded due to outliers, so the final sample was composed of 235 subjects. The multivariate normality test showed non-normal values for both asymmetry ($z$ = 17.97, $p$ < .001) and kurtosis ($z$ = 10.52, $p$ < .001), so a CFA with the Robust ML method was computed.

Table 2 shows the CFAs corresponding to the two-factor models proposed in previous research. Results showed good fit of the three models based on NNFI and CFI indexes, while GFI and RMSEA indexes were not adequate. The PVAQ-9 was identified as the best structure, with slightly better indexes than the others. The standardized factor loadings of the PVAQ-9 items were significant ($p$ < .05) (see Figure 1). The remaining analyses were conducted using the structure of the PVAQ-9.

### *Reliability and Validity*

The reliability (internal consistency) of the PVAQ-9 was adequate in the total scale (α = .82) and subscales (active vigilance, α = .76, and passive awareness, α = .82). In the PVAQ-9, the standard error of measurement was 3.64. The PVAQ-9 showed significant and low correlations with anxiety ($r$ = .22, $p$ < .01) and depression ($r$ = .20, $p$ < .01), indicating divergent validity, and significant and high correlations with pain anxiety ($r$ = .55, $p$ < .01) and pain catastrophizing ($r$ = .53, $p$ < .01), indicating convergent validity. The PVAQ-9 showed significant and moderate correlations with pain intensity in the last week ($r$ = .30, $p$ < .01) and FM impact ($r$ = 0.36, $p$ < .01).

An ROC curve was used to study the predictive validity of the PVAQ-9 and several groups were established to examine this psychometric characteristic. Two groups were created based on current pain intensity (MPQ-SF): patients who estimated pain as low (absent, mild, or uncomfortable) ($n$ = 103) and patients who estimated pain as high (intense, terrible, or unbearable) ($n$ = 123). Based on the cutoff points of < 39 (mild impact) and ≥ 59 (severe impact) in the FIQ (Bennett et al., 2009),

**Table 1.** *Mean (M), Standard Deviations (SD), Item-Total Correlation ($r_{tot}$) and Internal Consistency (α) if the Item is Deleted of the PVAQ*

| Items | *M* | *DT* | $r_{tot}$ | α |
|---|---|---|---|---|
| 1. I am very sensitive to pain | 2.87 | 1.48 | .48 | .79 |
| 2. I am aware of sudden or temporary changes in pain | 3.89 | 1.29 | .54 | .79 |
| 3. I am quick to notice changes in pain intensity | 3.91 | 1.25 | .55 | .79 |
| 4. I am quick to notice effects of medication on pain | 2.34 | 1.50 | .27 | .81 |
| 5. I am quick to notice changes in localization or extent of pain | 3.67 | 1.24 | .50 | .79 |
| 6. I focus on sensations of pain | 2.12 | 1.49 | .56 | .79 |
| 7. I notice pain even if I am busy with another activity | 3.82 | 1.41 | .38 | .80 |
| 8. I find it easy to ignore pain | 2.55 | 1.73 | −.01 | .83 |
| 9. I know inmediately when pain starts or increases | 3.68 | 1.50 | .59 | .79 |
| 10. When I do somethig that increases pain, the first thing I do is check to see how much pain was increased | 1.70 | 1.65 | .47 | .80 |
| 11. I know inmediately when pain decreases | 3.29 | 1.59 | .43 | .80 |
| 12. I seem to be more conscious of pain than others | 2.14 | 1.75 | .45 | .80 |
| 13. I pay close attention to pain | 1.85 | 1.46 | .58 | .79 |
| 14. I keep track of my pain level | 2.20 | 1.54 | .53 | .79 |
| 15. I become preoccupied with pain | 2.76 | 1.60 | .47 | .79 |
| 16. I do not dwell on pain | 2.45 | 1.51 | −.02 | .83 |

**Table 2.** *Goodness of Fit Indexes of the Structural Models Proposed for the PVAQ*

| Model | *Satorra-Bentler* $\chi^2$ | *df* | RMSEA | ECVI | NNFI | CFI | GFI |
|---|---|---|---|---|---|---|---|
| Two-factors model, PVAQ-14 (Roelofs et al., 2003) | 216.21 | 76 | .08 | 1.17 | .94 | .95 | .80 |
| Two-factors model, PVAQ-13 (Wong et al., 2011) | 160.01 | 64 | .08 | 0.91 | .95 | .96 | .83 |
| Two-factors model, PVAQ-9 (Esteve et al., 2013) | 69.83 | 26 | .08 | 0.46 | .96 | .97 | .87 |

101 women with severe FM impact and 12 women with mild FM impact were identified. Considering a cutoff score of ≥ 11 in the HADS as an indicator of a clinical problem (Zigmond & Snaith, 1983), 129 patients with a clinical problem of anxiety and 106 without this problem, and 98 patients with a clinical problem of depression and 137 without such problem were identified. Table 3 shows the best cutoff points of the PVAQ-9 to classify these groups. The score that reflected acceptable sensitivity and sensitivity was 24.5; it correctly classified 71% of cases of severe FM impact (and 75% of cases of mild FM impact).

## Discussion

In this study we examined the reliability and validity of the Spanish version of the PVAQ. This is the first instrumental study of this questionnaire in Spanish women with FM. The findings support the psychometric suitability of the 9-item short form (PVAQ-9; Esteve et al., 2013) in this clinical population. The PVAQ-9 showed appropriate internal consistency, convergent validity, divergent validity, and predictive validity, which means that it is a good instrument to measure attention to and awareness of painful sensations. It is relevant to have a validated Spanish version of this self-report for use in our community context, especially considering the relationship between pain hypervigilance and pain experience, emotional distress, and disability in chronic pain patients (Goubert et al., 2004; McCracken, 1997).

CFAs were conducted to examine the goodness of fit of several two-factor structures of the PVAQ identified in previous studies with chronic pain patients

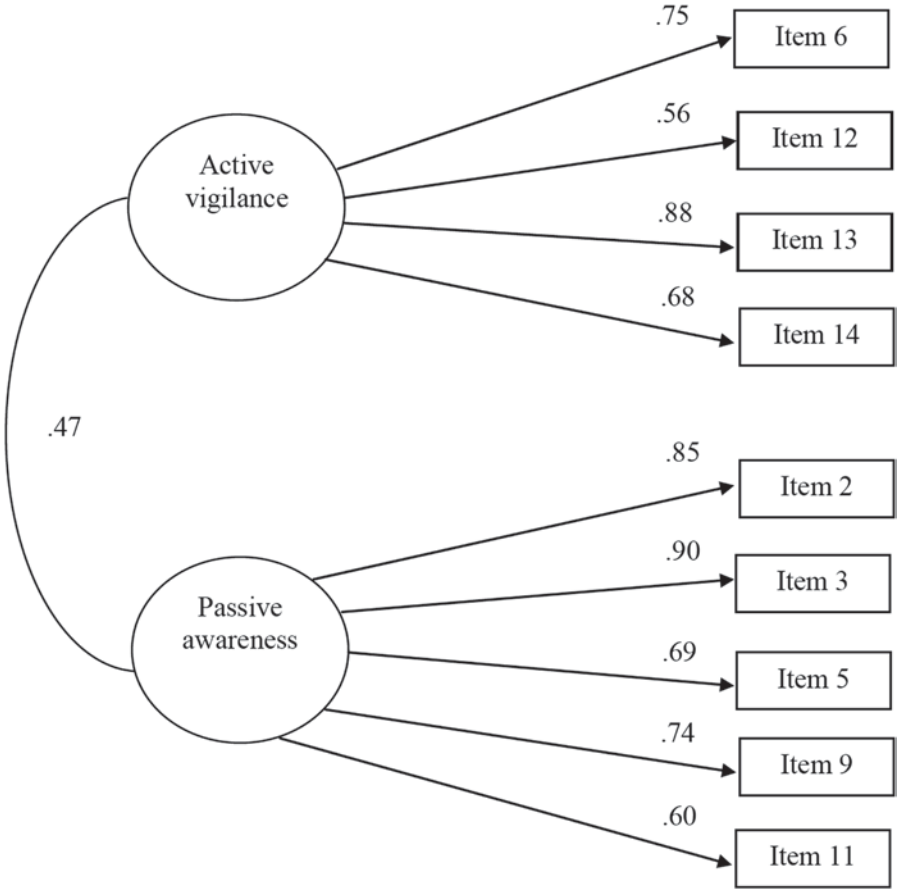


**Figure 1.** Standardized solution for the two-factor model of the PVAQ-9 (Esteve et al., 2013).

**Table 3.** *Area Under the Curve, Better Cutoff, Sensitivity and Specificity of the PVAQ-9 (Esteve et al., 2013)*

| | | | 95% CI | | | | |
|---|---|---|---|---|---|---|---|
| | Area | *p* | Lower limit | Upper limit | Better cutoff | Sensitivity | Specificity |
| High pain intensity (positive) | .60 | .007 | .53 | .67 | 25.5 | .63 | .54 |
| High impact of fibromyalgia (positive) | .70 | .021 | .54 | .86 | 24.5 | .71 | .75 |
| Clinical anxiety (positive) | .63 | .001 | .56 | .70 | 25.5 | .63 | .55 |
| Clinical depression (positive) | .59 | .012 | .52 | .66 | 26.5 | .60 | .55 |

(Esteve et al., 2013; Roelofs et al., 2003; Wong et al., 2011). Results revealed that all models (PVAQ-14, PVAQ-13 and PVAQ-9) represented the data well according to several fit indexes (NNFI and CFI), with the PVAQ-9 model (Esteve et al., 2013) showing the best fit. The PVAQ-9 had good internal consistency in both the total scale and the active vigilance and passive awareness subscales.

The PVAQ-9 showed satisfactory convergent validity, as indicated by the high correlations between this measure and other cognitive-affective constructs of pain such as pain anxiety and pain catastrophizing. These findings are in line with previous studies (Esteve et al., 2013; Goubert et al., 2004; Martínez et al., 2011; Roelofs et al., 2003). The PVAQ-9 was associated with other clinical measures considered, although we found moderate correlations with pain intensity and FM impact and low correlations with anxiety and depression, suggesting adequate divergent validity. These results are consistent with those reported in previous studies (McCracken, 1997, 2007; Wong et al., 2011). Regarding predictive validity, the PVAQ-9 was found to be useful in identifying cases with severe FM impact. A cutoff score of 24.5 reflected higher sensitivity (71%) and specificity (75%). There are no studies with which to compare these results.

The present study has some limitations. Participants were Spanish FM women, so it may not be possible to generalize its results to FM men, other cultural/ethnic groups, or other chronic pain syndromes. Using a pressure algometer to assess the pain tolerance threshold and the Stroop task to examine selective attention to pain-related stimuli would have enriched the data collected. It would also have been relevant to include measures of self-efficacy beliefs and coping strategies, given their important contribution to the pain experience (Ramírez-Maestre, Esteve, & López, 2012; Sánchez, Martínez, Miró, & Medina, 2011). No other psychometric properties such as test-retest reliability and sensitivity to change were explored.

This study shows that the PVAQ-9 has satisfactory psychometric properties in Spanish FM women. This instrument is suitable for use in clinical settings, given its simplicity and reduced application time. The PVAQ-9 makes it possible to determine the attention level that FM patients direct to their painful sensations, which may be indicative of higher affective suffering and impaired functioning. This self-report may also be useful as an index of improvement, reflecting the degree to which individuals with chronic pain can live without cognitively focusing on pain and prioritizing it over other valuable life goals.

Several studies have provided evidence that psychological treatments aimed at promoting changes in vigilance and awareness of pain are beneficial for patients with chronic pain. Cognitive-behavioral treatment (i.e., education about pain, graduated exercises, applied relaxation training, training in pacing and goal setting, problem solving, and cognitive restructuring) can increase pain self-efficacy and reduce pain severity, catastrophizing, fear of re-injury, depression, stress, and attentional bias towards sensory pain words in chronic pain conditions (Dehghani, Sharpe, & Nicholas, 2004). Attention management strategies (via attention diversion, imagery, and mindfulness exercises) are useful for reducing pain-related anxiety, hypervigilance, and interference of pain in chronic pain patients (Elomaa, Williams, & Kalso, 2009). Attentional bias modification (a modified version of the dot-probe task to implicitly train subjects to attend away from pain-related stimuli) has been found to reduce anxiety sensitivity, fear of pain, and pain severity in patients with FM (Carleton, Richter, & Asmundson, 2011). Mindfulness-based treatment (aimed at helping patients to become aware of their present-moment experience without judging it, accepting it as it is through meditative body scan, meditation focused on breathing, and mindful yoga) facilitates a more flexible use of attention. Mindfulness training enhances attention modulation of 7–14Hz alpha rhythms that play an important role in filtering inputs to the primary sensory neocortex, and such training in chronic pain may work by "debiasing" the sensory attentional system and freeing up resources to attend to other demands (Kerr, Sacchet, Lazar, Moore, & Jones, 2013). In this regard, a recent study has shown that a multimodal mindfulness-oriented intervention including

complementary aspects of mindfulness training, cognitive-behavioral therapy, and techniques used in positive psychology was able to reduce selective attention to pain-related stimuli, increase perceived control over pain, and attenuate reactivity to distressing thoughts and emotions in patients with chronic pain (Garland & Howard, 2013). Considering these therapeutic approaches, a good self-report instrument such as the PVAQ-9 can be helpful to estimate clinical improvements regarding excessive attention to pain in FM patients.

In conclusion, the Spanish version of the PVAQ seems to be an adequate instrument to identify FM patients who show an increased tendency to observe, monitor, and focus on pain, which contributes to a maladaptive response to disease.

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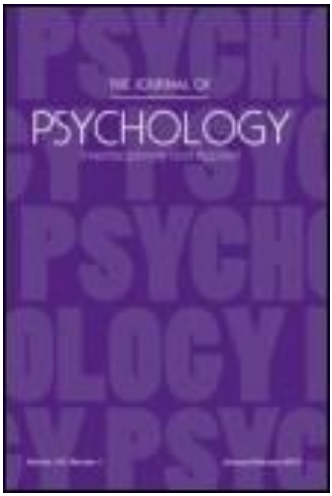




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# Relationships Between Physical Symptoms, Emotional Distress, and Pain Appraisal in Fibromyalgia: The Moderator Effect of Alexithymia

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# Relationships Between Physical Symptoms, Emotional Distress, and Pain Appraisal in Fibromyalgia: The Moderator Effect of Alexithymia

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ABSTRACT. Alexithymia is a personality construct that is frequently identified in fibromyalgia (FM). Previous studies have explored the relationship between alexithymia and emotional distress in this disease. Yet, the additional link with factors of pain appraisal is unknown. This study examined the moderating effect of alexithymia in the relationship between emotional distress and pain appraisal in 97 FM women. A control group of 100 healthy women also participated in the study. All participants completed several self-reports about pain experience, sleep quality, impairment, emotional distress, pain appraisal, and alexithymia. FM women showed significantly more difficulty in identifying and describing feelings, but less externally oriented thinking than healthy women. In the clinical group, difficulty in identifying feelings and difficulty in describing feelings significantly correlated with lower sleep quality, higher anxiety and depression, and increased pain catastrophizing and fear of pain. Difficulty in describing feelings significantly correlated with higher pain experience and vigilance to pain. Externally oriented thinking was not correlated with any of the clinical variables. Difficulty in identifying feelings moderated the relationship between anxiety and pain catastrophizing, and difficulty in describing feelings moderated the relationship between anxiety and fear of pain. Implications of the findings for the optimization of care of FM patients are discussed.

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Keywords: alexithymia, emotional distress, fear of pain, fibromyalgia, pain catastrophizing



FIBROMYALGIA (FM) IS A SYNDROME characterized by widespread musculoskeletal pain for at least three months and pain on digital palpation in at least 11 of the 18 sensitive points according to the American College of Rheumatology (ACR; Wolfe et al., 1990). In Europe, this syndrome affects 2.9–4.7% of the general population, with a higher prevalence in females than males (Branco et al., 2010). In the United States, annual mean healthcare costs are three times higher for FM patients ($ 9,573) than for control group patients without any healthcare encounters for FM ($ 3,291) (Berger, Dukes, Martin, Edelsberg, & Oster, 2007).

The clinical understanding of FM has evolved over the last twenty years to consider symptoms beyond pain as an integral part of this condition (Fitzcharles & Yunus, 2012). In fact, FM patients report a wide range of symptoms including, among others, morning stiffness, fatigue, non-restorative sleep, forgetfulness, poor concentration, difficulty falling asleep, muscle spasms, anxiety, and depression (Bennett, Jones, Turk, Russell, & Matallana, 2007). Several reports have shown a high prevalence of mood and anxiety disorders and emotional distress in this pain condition. FM patients have shown higher levels of mental distress including depression and anxiety than healthy controls (Gormsen, Rosenberg, Bach, & Jensen, 2010). In FM patients, the prevalence of mood disorders is 29–34.8% and that of anxiety disorders is 22.3–32.2% (Epstein et al., 1999; Thieme, Turk, & Flor, 2004; Uguz et al., 2010).

Previous research in several chronic pain conditions including FM has documented the negative influence of affective distress in the pain experience. In FM patients, anxiety and depression scores have been associated with a poorer subjective rating of general health (Jensen et al., 2010), higher pain intensity, poor sleep quality, and worse functioning (Miro´, Mart´ınez, Sa´nchez, Prados, & Medina, 2011). FM patients with comorbid anxiety disorders show the highest number of physical symptoms, the highest level of pain intensity and interference, and frequent solicitous behaviors of significant others and avoidance behaviors (Thieme et al., 2004). FM patients with depressive symptoms show more sleep disturbances, sexual dysfunctions, and loss of physical function, and poorer quality of life than FM patients without depressive symptoms (Lange & Petermann, 2010).

Several factors of pain appraisal contribute to the pain experience. The most outstanding ones are pain catastrophizing, fear of pain, and vigilance to pain. In FM patients, pain catastrophizing has been associated with pain intensity and impairment (Mart´ınez, Sa´nchez, Miro´, Medina, & Lami, 2011), fear of pain has been associated with increased pain and tender point sensitivity as well as decreased tolerance for physical performance and speed of cognitive performance (de Gier, Peters, & Vlaeyen, 2003), and vigilance to pain has been related to pain intensity and negative affectivity (Crombez, Eccleston, van den Broeck, Goubert, & van

Houdenhove, 2004). These factors are considered in the fear-avoidance model of chronic pain (Leeuw et al., 2007; Vlaeyen & Linton, 2000, 2012), the most influential model of chronic pain from a biopsychosocial perspective. According to this model, catastrophic appraisal of pain is a potential precursor of pain-related fear, which triggers a hypervigilance to possible somatic signals of threat and avoidance and escape behaviors. These reactions lead to detrimental changes in the musculoskeletal system, disability, and depression. All this ultimately intensifies the pain experience, contributing to a vicious circle of fear and avoidance. The fear–avoidance model has inspired a number of experimental, prospective and clinical studies on the changes in the aforementioned variables and relationships between them; it is a process model with a natural flow from diagnostic information to treatment that is easy to adopt as a framework from multidisciplinary clinical practice and has been considered as credible by patients (Crombez, Eccleston, van Damme, Vlaeyen, & Karoly, 2012). There is wide scientific evidence supporting the validity of the fear-avoidance model in several chronic pain conditions (for a review see Leeuw et al., 2007; Pincus, Smeets, Simmonds, & Sullivan, 2010). This conceptual framework is open to additional refinements and extensions that may strengthen its clinical value. In the context of the refinement of this model, for example, scholars have explored the links between pain catastrophizing, pain-related fear and vigilance to pain and personality traits such as neuroticism (Goubert, Crombez, & Van Damme, 2004; Mart´ınez et al., 2011).

Psychological research has proven that greater pain is associated with emotional distress and limited emotional awareness, expression, and processing (for a review see Lumley et al., 2011). Alexithymia is a personality construct that denotes a deficit in cognitive processing of emotional experience and emotional regulation (Taylor, Bagby, & Parker, 1997) and is frequently associated with chronic diseases (Baiardini, Abba, Ballaur´ı, Vuillermoz, & Braido, 2011). Alexithymia is characterized by difficulties in identifying and communicating feelings, problems distinguishing between emotions and physical sensations, restricted imaginal capacity, and a concrete, externally oriented way of thinking (Sifneos, 1996). These psychological characteristics contribute to heightened physiological arousal, certain types of unhealthy behavior, and a biased perception and reporting of somatic sensations and symptoms (for a review see Lumley, Neely, & Burger, 2007; Lumley, Stettner, & Wehmer, 1996). Alexithymia may influence illness behavior via cognitive mechanisms as follows (Lumley et al., 1996): alexithymic individuals are likely to have high body awareness that makes them notice benign somatic sensations and focus on them, magnifying them and generating a feedback loop; as a result, they may experience these sensations as physical illness because they attribute these sensations to biological causes rather than psychological ones.

Deficit in the ability to regulate one's affective states is frequent in FM. Patients with FM have shown higher levels of alexithymia than healthy controls (Brosschot & Aarsse, 2001; Sayar, Gulec, & Topbas, 2004; Tuzer et al., 2011; van Middendorp et al., 2008) and chronic low back pain patients (Tuzer et al.,

2011). When pain severity or depression was controlled, FM patients showed higher levels of alexithymia than rheumatoid arthritis patients (Sayar et al., 2004). However, Malt, Olafsson, Lund, and Ursin (2002) reported no differences in alexithymia between FM and control groups. Moreover, it has been reported that 39.2–44% of FM patients are alexithymic (Evren, Evren, & Guler, 2006; Steinweg, Dallas, & Rea, 2011). This rate is significantly higher than that of general medicine patients (8%) and rheumatoid arthritis patients (21%) (Steinweg et al., 2011). Several studies have identified alexithymia as an important factor involved in the pain experience of FM patients. In these patients, alexithymia has been related to general distress, anxiety, and depression (Malt et al., 2002), pain intensity (Sayar et al., 2004), and current general psychiatric symptoms, as well as severity of depression and anxiety (Evren et al., 2006). In FM patients, difficulty in identifying feelings has been significantly correlated with mental distress, pain, and fatigue; however, difficulty in describing feelings has only shown significant associations with mental distress, and this component of alexithymia has been found to moderate the relationship between pain and affect intensity (van Middendorp et al., 2008). In these patients, difficulty in identifying feelings was related to higher affective ongoing pain and lower cold pressor pain tolerance, but this alexithymic factor ceased to predict affective ongoing pain when psychological distress or illness behavior was controlled (Huber, Suman, Biasi, & Carli, 2009). However, in FM patients, alexithymia (or some of its facets) was not related to impairment (Sayar et al., 2004), pain severity (Evren et al., 2006), sensory ongoing pain, or experimental pain thresholds (Huber et al., 2009).

Most studies on FM have focused on the relationship between alexithymia and emotional distress. Yet, no studies have further explored the links with pain appraisal factors (pain catastrophizing, fear of pain, and vigilance to pain) outlined in the fear-avoidance model of chronic pain. To the best of our knowledge, only three studies have explored this topic but only included nonfibromialgic pain conditions or nonclinical samples. In a sample of 80 patients with chronic myofascial pain, Lumley, Smith, and Longo (2002) found that alexithymia was related with greater catastrophizing and was a significant predictor of affective pain severity (but not of physical impairment) while controlling for catastrophizing. In a group of 67 healthy subjects, Katz, Martin, Page´, and Calleri (2009) used a magnitude estimation procedure and found that sex, fear of pain, and alexithymia (difficulty in identifying feelings and difficulty in describing feelings) were significant predictors of average heat pain intensity. In a group of 128 patients with chronic pain, Makino et al. (2012) found that alexithymia was associated with pain interference (influence of pain on patient functioning) and catastrophizing, however, alexithymia was not a significant predictor of these clinical variables when demographic variables and negative affectivity were controlled.

The present study is the first to explore the relationship between alexithymia, emotional distress, and pain appraisal components of the fear–avoidance model of chronic pain in FM patients. Determining how deficits in affective regulation are

related to pain appraisal may contribute to a better understanding of psychological factors that exacerbate FM. Considering this assumption and the previous findings, the objectives of this cross-sectional study with FM women and healthy women were the following:

1. Determine the differences between both groups regarding alexithymia, physical symptoms (pain experience and sleep quality), impairment, emotional distress (anxiety and depression), and variables of pain appraisal (pain catastrophizing, fear of pain, and vigilance to pain).
2. Analyze the relationship between alexithymia and these clinical variables in FM women.
3. Assess whether alexithymia makes a unique contribution to physical symptoms and impairment of these patients beyond the effect of emotional distress and pain appraisal.
4. Explore the moderator role of alexithymia in the relationship between emotional distress and pain appraisal in this clinical group.

## Method

### Subjects and Procedure

Ninety-seven women with FM with a mean age of 47.64 years ($SD = 8.03$) participated in the study. Patients were recruited from the Rheumatology Service and Pain and Palliative Care Unit of Virgen de las Nieves University Hospital and AGRAFIM, a FM association, both in Granada, Spain. According to several reports women experience greater clinical pain, pain-related distress, and sensitivity to experimentally induced pain than men (Paller, Campbell, Edwards, & Dobs, 2009), and FM is more frequent in women than in men (Branco et al., 2010). For these reasons, socio–demographic variables were controlled and only women were selected for this study. Inclusion criteria to participate in the study were: (a) being a woman aged between 18 and 65 years, (b) having been diagnosed with FM according to the criteria of the ACR (Wolfe et al., 1990), and (c) having adequate reading comprehension. Exclusion criteria were as follows: (a) having a history of alcoholism or drug addiction, (b) having concomitant major medical conditions, and (c) having a major depressive disorder with severe symptoms, schizophrenia, borderline personality disorder, or other major Axis I/Axis II diagnoses of the DSM-IV-TR (APA, 2000).

Female patients diagnosed with FM from the hospital and the FM association were contacted by telephone and invited to cooperate in the study. Considering the abovementioned criteria, 97 participants were selected as the clinical group. The psychological assessment included a semi-structured interview and several self-report questionnaires. The interview lasted approximately one hour and focused on onset and course of symptoms, life history, lifestyle, work, personal relations,

family and participant's attitudes about her illness, and psychological status. After the interview, participants were given a set of questionnaires to be completed at home and returned within a week.

Most FM patients were married (78.1%), had elementary or secondary education (65.3%), and were not employed at the time (60.5%). Mean duration of the diagnosed disease was 5.98 years ($SD$ = 5.52). Among participants, 95.9% were receiving current pharmacological treatment (e.g., analgesics, anti-inflammatory drugs, anxiolytics, and antidepressants), and 96.6% of them were also following other treatments (e.g., physical exercise, psychological therapy, acupuncture).

One hundred healthy women with a mean age of 48.39 years ($SD$ = 7.53 years) participated in the study. This group was recruited from non-clinical community settings (e.g., by friends and family of college students and associations of housewives or trade workers), and was matched to FM women in the main socio–demographic variables. Inclusion criteria for the healthy group were: (a) being a woman aged between 18 and 65 years, (b) being free of pain conditions and other important medical or psychological diseases, and (c) having adequate reading comprehension. Exclusion criteria were the same as those of the clinical group. Most healthy participants were married (88.8%), had elementary or secondary education (76.2%), and were employed at the time (64.4%). This group completed the same set of questionnaires as the clinical group.

All subjects received detailed information about the study and gave their written informed consent. The study received ethical approval from the Ethics Committee of the University of Granada.

## Measurements

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

This instrument assesses pain experience using 15 verbal (sensory and affective) pain descriptors rated on a scale from 0 (no) to 3 (severe), a current pain intensity index, and a visual analogue scale to assess pain intensity in the last week. Previous studies have reported the reliability (internal consistency = .74) (Masedo & Esteve, 2000) and validity of the Spanish version of the MPQ (La´zaro et al., 2001). In the present study, the sensory–affective scale of pain was used.

*Pittsburgh Sleep Quality Index (PSQI; Buysse, Reynolds, Monk, Berman, & Kupher, 1989)*

This index includes 19 items that assess several dimensions of sleep quality: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. In the

present study the total score (from 0 "absence of perturbation" to 21 "severe perturbation") was used. The Spanish adaptation of the PSQI has acceptable internal consistency (between .67 and .81), sensitivity and specificity (Royuela & Mac´ıas, 1997).

*Impairment and Functioning Inventory (IFI; Ram´ırez-Maestre & Valdivia, 2003)*

This instrument is composed of 19 items that evaluate the level of functioning and impairment of patients with chronic pain in several areas of life (household activity, independent functioning, social activities, and leisure activities). The IFI has adequate reliability (.76 in the functioning scale and .72 in the impairment scale) and a four-factor structure (Ram´ırez-Maestre & Valdivia, 2003). In the present study the level of impairment as the number of activities affected was considered.

*Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983)*

This scale explores anxiety and depression symptoms in non-psychiatric hospital contexts using 14 items that are rated on a scale ranging from 0 to 3. The HADS includes two subscales: Anxiety and Depression. The Spanish version of this instrument has good internal consistency (.85 in the Anxiety scale and .84 in the Depression scale) and external validity and favorable sensitivity and specificity (Herrero et al., 2003).

*Pain Catastrophizing Scale (PCS; Sullivan, Bishop, & Pivik, 1995)*

This scale assesses the rumination, magnification, and helplessness associated with pain. This instrument includes 13 items measured on a Likert scale ranging from 0 (not at all) to 4 (all the time). The Spanish version of the PCS has shown good internal consistency (.79), test-retest reliability and sensitivity to change (Garc´ıa-Campayo et al., 2008).

*Pain Anxiety Symptoms Scale-20 (PASS-20; McCracken & Dhingra, 2002)*

This instrument assesses the fear, cognitive anxiety, escape and avoidance behavior, and physiological anxiety associated with pain. This scale includes 20 items that are evaluated using a Likert scale ranging from 0 (never) to 5 (always). The PASS-20 has shown good convergent validity and reliability (internal consistency ranging from .91 to .92) (Roelofs et al., 2004).

*Pain Vigilance and Awareness Questionnaire (PVAQ; McCracken, 1997)*

This instrument consists of 16 items that evaluate the awareness, consciousness, vigilance and observation of pain using a Likert scale ranging from 0 (never)

to 5 (always). The PVAQ has shown adequate convergent validity and internal consistency (.87) (Roelofs, Peters, McCracken, & Vlaeyen, 2003).

*Toronto Alexithymia Scale (TAS-20; Bagby, Parker, & Taylor, 1994)*

The TAS-20 is the most widely and frequently used measure of alexithymia (Bagby, Taylor, Quilty, & Parker, 2007). This scale includes 20 items that assess different aspects of alexithymia: difficulty in identifying feelings, difficulty in describing feelings, and externally oriented thinking. The Spanish adaptation has adequate internal consistency (.82), temporal reliability, and validity and a three-factor structure that is similar to that of the original version (Moral & Retamales, 2000). In this adaptation, the items are rated on a Likert scale ranging from −3 (totally disagree) to +3 (totally agree).



**Data Analyses**

Statistical analyses were performed with IBM SPSS Statistics 19 software (SPSS Inc.), a program that graphically displays moderating effects (ModGraph-I; Jose, 2008), and an effect size calculator (Statistics Calculators, version 3.0 beta; Soper, 2006). All analyses were two-tailed and probabilities less than or equal to .05 were taken as the level of significance.

The reliability (internal consistency) of the measures was examined and Cronbach's alpha values greater than .70 were considered acceptable (Nunnally & Bernstein, 1994). The clinical and healthy groups were compared for demographic and psychological variables using Student' *t* and $\chi^2$ tests. Cohen's d was computed to assess effect sizes. The relationship between physical symptoms (pain experience and sleep quality), impairment, emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing, fear of pain and vigilance to pain), and alexithymia in the FM group was analyzed using Pearson's correlation coefficient. Several hierarchical regression analyses were conducted to test alexithymia as a predictor of physical symptoms or emotional distress. The guidelines provided by Frazier, Tix, and Barron (2004) for testing moderation effects were followed. The moderating role of alexithymia was analyzed using the criteria proposed by Baron and Kenny (1986): in predicting emotional distress (dependent variable, DV), the model considers the impact of physical symptoms and pain appraisal factors (predictors), the impact of alexithymia (moderator), and the interaction of both (predictor x moderator); the moderating role is supported if the interaction is significant. Following the recommendations of Aiken and West (1991) to reduce multicollinearity, the predictor and moderator variables were centered (this was accomplished by subtracting the sample mean from all individual scores). Later, the interaction term was obtained by multiplying the centered scales. As a post-hoc analysis of the moderator effect, several simple slopes were computed for low, medium, and high levels of alexithymia.

## Results

### Differences Between FM and Healthy Groups in Demographic and Clinical Variables

The Cronbach's alpha of the measures administered in both the clinical and control groups was adequate (higher than .70) with only two exceptions (see Table 1): it was slightly low in the Depression scale for the control group, and markedly low in the Externally oriented thinking scale for both groups, but similar to the indices reported in previous studies of the TAS-20 (Bagby et al., 1994).

No significant differences were found between FM and healthy groups in age ($t_{187} = -0.66$, $p = .508$) or education level ($x^2_3 = 2.90$, $p = .406$). However, as expected, significant differences were found in employment status ($x^2_4 = 29.92$,

**TABLE 1. Internal Consistency of the Scales and Comparison Between Fibromyalgia Women and Healthy Women in Clinical Variables**

| | Fibromyalgia women | | Healthy women | | | |
|---|---|---|---|---|---|---|
| Variable | $\alpha$ | *M* (*SD*) | $\alpha$ | *M* (*SD*) | *t* | *d* |
| Pain experience-SF-MPQ | .87 | 23.66(10.31) | .86 | 4.45(6.60) | 14.74** | 2.21 |
| Sleep quality-PSQI | .77 | 14.43(4.46) | .77 | 6.33(3.58) | 13.78** | 2.00 |
| Impairment-IFI | .76 | 4.15(3.30) | .78 | 1.58(1.96) | 6.07** | 0.94 |
| Anxiety-HADS | .82 | 11.14(4.62) | .80 | 5.93(3.84) | 8.59** | 1.22 |
| Depression-HADS | .86 | 9.36(4.82) | .69 | 3.03(2.70) | 11.30** | 1.62 |
| Pain catastrophizing-PCS | .94 | 24.10(12.05) | .94 | 15.88(11.00) | 4.97** | 0.71 |
| Fear of pain-PASS-20 | .91 | 49.72(19.09) | .94 | 29.88(20.69) | 6.93** | 0.99 |
| Vigilance to pain-PVAQ | .82 | 47.31(12.11) | .89 | 36.70(15.14) | 5.40** | 0.77 |
| Difficulty in identifying feelings-TAS-20 | .87 | 3.88(11.01) | .85 | −6.68(10.46) | 6.84** | 0.98 |
| Difficulty in describing feelings-TAS-20 | .74 | 0.32(5.77) | .72 | −1.28(5.93) | 1.90* | 0.27 |
| Externally oriented thinking-TAS-20 | .61 | 4.53(5.78) | .63 | 6.29(6.75) | −1.94* | 0.28 |

*Note*. *d* of .20, .50, and .80 represents small, medium, and large effect size, respectively.
*$p \leq .05$. **$p \leq .01$.

$p < .001$). In the FM group, compared to the control group, a higher proportion of participants had an inactive employment status (mainly due to sick leave).

Table 1 shows the comparisons between FM women and healthy women in self-reports. Pain experience and impairment were significantly higher and sleep quality was significantly lower in the clinical group than in the control group. This is consistent with the expected scores of patients with persistent pain.

Anxiety and depression were significantly higher in FM patients than in healthy participants. Given the cut-off scores in the HADS (Zigmond & Snaith, 1983), the scores of the FM group identified anxiety as a clinical problem (score of 11 or higher) and depression as a problem that was not necessarily clinical. At an individual level, 55.7% and 37.1% of FM patients had scores above the cut-off indicative of clinical problem on the anxiety and depression scales, respectively. Pain experience, pain catastrophizing, fear of pain, difficulty in identifying feelings and difficulty in describing feelings were significantly higher and sleep quality was significantly lower in patients with clinical level of anxiety than in patients with nonclinical level of anxiety (between $t_{94} = 2.82$, $p < .01$, and $t_{94} = 4.60$, $p < .001$), however the groups did not differ in impairment ($t_{82} = 1.87$, $p = .06$), vigilance to pain ($t_{95} = 0.37$, $p = .70$) and externally oriented thinking ($t_{93} = -0.38$, $p = .69$). Pain experience, impairment, pain catastrophizing and fear of pain were significantly higher and sleep quality was significantly lower in patients with clinical level of depression than in patients with nonclinical level of depression (between $t_{87} = 2.24$, $p < .05$, and $t_{93} = 3.63$, $p < .001$), however the groups did no differ in vigilance to pain ($t_{95} = 0.89$, $p = .37$) and subescales of alexithymia (between $t_{93} = -0.49$, $p = .62$, and $t_{94} = 1.71$, $p = .09$).

Pain catastrophizing, fear of pain, and vigilance to pain were significantly higher in FM women than in healthy women. Difficulty in identifying feelings and difficulty in describing feelings were significantly higher in FM participants than in control subjects. However, externally oriented thinking was significantly lower in the clinical group than in the healthy group.

**Association Between Clinical Measures in the FM Group**

Table 2 shows the Pearson correlations between the clinical measures. The main results were the following: (a) greater pain experience was related to higher anxiety, depression, pain catastrophizing, fear of pain, vigilance to pain, and difficulty in describing feelings; (b) poorer sleep quality was related to higher anxiety, depression, pain catastrophizing, fear of pain, difficulty in identifying feelings, and difficulty in describing feelings; (c) greater impairment was related to higher depression and pain catastrophizing; (d) greater anxiety was related to higher pain catastrophizing, fear of pain, difficulty in identifying feelings, and difficulty in describing feelings; and (e) greater depression was related to higher pain catastrophizing, fear of pain, vigilance to pain, difficulty in identifying

**TABLE 2. Intercorrelation Between Clinical Variables in Fibromyalgia Women**

| Variable | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. Pain experience-SF-MPQ | | | | | | | | | | |
| 2. Sleep quality-PSQI | .37** | | | | | | | | | |
| 3. Impairment-IFI | .29** | .12 | | | | | | | | |
| 4. Anxiety-HADS | .46** | .40** | .20 | | | | | | | |
| 5. Depression-HADS | .35** | .48** | .40** | .66** | | | | | | |
| 6. Pain catastrophizing-PCS | .54** | .38** | .22* | .49** | .44** | | | | | |
| 7. Fear of pain-PASS-20 | .56** | .43** | .16 | .54** | .47** | .76** | | | | |
| 8. Vigilance to pain-PVAQ | .33** | .17 | .11 | .15 | .22* | .58** | .48** | | | |
| 9. Difficulty in identifying feelings-TAS-20 | .18 | .26* | .01 | .42** | .32** | .37** | .42** | .18 | | |
| 10. Difficulty in describing feelings-TAS-20 | .23* | .21* | .00 | .33** | .27** | .36** | .24* | .27** | .43** | |
| 11. Externally oriented thinking-TAS-20 | .03 | −.04 | .06 | −.04 | −.14 | .08 | .06 | .16 | .22* | .21* |

*Note.* $^{*}p \leq .05$. $^{**}p \leq .01$.

feelings, and difficulty in describing feelings. Externally oriented thinking did not correlate with any variable.

In the following regression analysis, only measures significantly correlated with the dependent variable, DV (pain experience, sleep quality, and anxiety), were included as predictors. Impairment was not considered as a DV in the prediction analysis because it did not correlate significantly with the alexithymia measures. Depression was not considered as a DV in the moderation analysis because it was not identified as a clinical problem according to the cut-off scores in the HADS, and differences were not found in alexithymia between patients with clinical level of depression and patients with nonclinical level of depression. Vigilance to pain was not included as an independent variable in the moderation analysis because it did not correlate significantly with anxiety. Externally oriented thinking was not analyzed as a potential moderator because it did not correlate significantly with anxiety.

**Alexithymia as a Predictor of Physical Symptoms (Pain Experience and Sleep Quality) in the FM Group**

Table 3 shows the hierarchical model of prediction of pain experience from emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing, fear of pain, and vigilance to pain), and alexithymia (difficulty in describing feelings). In Step 1, only anxiety made a significant contribution. The predictive effect was maintained when pain appraisal factors were included in Step 2, but none of these factors proved to be significant predictors. In Step 3, which also included difficulty in describing feelings, anxiety remained significant, but this alexithymia measure was not identified as a significant predictor.

Table 4 shows the hierarchical model of prediction of sleep quality from emotional distress (anxiety and depression), pain appraisal factors (pain catastrophizing and fear of pain), and alexithymia (difficulty in identifying feeling and difficulty in describing feelings). In Step 1, only depression made a significant contribution. This predictive effect was maintained when pain appraisal factors were considered in Step 2, but none of these factors made a significant contribution. In Step 3, which also included difficulty in identifying feelings and difficulty in describing feelings, depresion remained significant but none of these alexithymia measures had a significant predictor effect.

**TABLE 3. Hierarchical Models Predicting Pain Experience in Fibromyalgia Women**

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Anxiety-HADS | 0.93 | .41 | 3.21** | .21 | .21 | 11.32** |
| Depression-HADS | 0.13 | .06 | 0.49 | | | |
| Step 2 | | | | | | |
| Anxiety-HADS | 0.59 | .26 | 1.98* | .37 | .16 | 9.65** |
| Depression-HADS | −0.18 | −.08 | −0.69 | | | |
| Pain catastrophizing-PCS | 0.16 | .18 | 1.26 | | | |
| Fear of pain-PASS-20 | 0.15 | .27 | 1.85 | | | |
| Vigilance to pain-PVAQ | 0.09 | .10 | 0.92 | | | |
| Step 3 | | | | | | |
| Anxiety-HADS | 0.60 | .27 | 1.98* | .37 | .00 | 7.96** |
| Depression- HADS | −0.18 | −.08 | −0.70 | | | |
| Pain catastrophizing-PCS | 0.16 | .18 | 1.27 | | | |
| Fear of pain-PASS-20 | 0.15 | .26 | 1.83 | | | |
| Vigilance to pain-PVAQ | 0.09 | .10 | 0.94 | | | |
| Difficulty in describing feelings-TAS-20 | −0.04 | −.02 | −0.24 | | | |

*Note.* $^{*}p \leq .05$. $^{**}p \leq .01$.

**TABLE 4. Hierarchical Models Predicting Sleep Quality in Fibromyalgia Women**

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Anxiety-HADS | 0.12 | .13 | 1.05 | .23 | .23 | 13.44** |
| Depression-HADS | 0.35 | .38 | 3.11** | | | |
| Step 2 | | | | | | |
| Anxiety-HADS | 0.01 | .01 | 0.11 | .28 | .05 | 8.57** |
| Depression-HADS | 0.30 | .32 | 2.67** | | | |
| Pain catastrophizing-PCS | 0.00 | .01 | 0.11 | | | |
| Fear of pain-PASS-20 | 0.06 | .26 | 1.73 | | | |
| Step 3 | | | | | | |
| Anxiety-HADS | −0.00 | −.00 | −0.02 | .28 | .00 | 5.66** |
| Depression-HADS | 0.30 | .32 | 2.62** | | | |
| Pain catastrophizing-PCS | 0.00 | .00 | 0.01 | | | |
| Fear of pain-PASS-20 | 0.05 | .25 | 1.67 | | | |
| Difficulty in identifying feelings-TAS-20 | 0.01 | .04 | 0.41 | | | |
| Difficulty in describing feelings-TAS-20 | 0.02 | .02 | 0.24 | | | |

*Note.* $^{**}p \leq .01$.



**Alexithymia as a Moderator Between Anxiety and Pain Appraisal (Pain Catastrophizing and Fear of Pain) in the FM Group**

Moderation analyses were performed separately for each potential moderator (difficulty in identifying feelings and difficulty in describing feelings).

Two moderation analyses tested whether the pain catastrophizing x difficulty in identifying feelings interaction and the pain catastrophizing x difficulty in describing feelings interaction were significant predictors of anxiety after controlling the influence of physical symptoms, pain catastrophizing, and difficulty in identifying feelings (or difficulty in describing feelings) (see Table 5). In Step 1, pain experience and sleep quality were identified as significant predictors. In Step 2, the effects of sleep quality disappeared when pain catastrophizing was included, and pain experience and pain catastrophizing were significant predictors. In Step 3a, the contribution of pain experience and pain catastrophizing remained significant when difficulty in identifying feelings was included, and this measure of alexithymia was also a significant predictor. In Step 3b, pain experience and difficulty in identifying feelings remained significant, and a significant effect was observed in the pain catastrophizing x difficulty in identifying feelings interaction; this revealed that the relationship between anxiety and pain catastrophizing is moderated by this facet of alexithymia. In Step 4a, pain experience and pain

**TABLE 5. Alexithymia as a Moderator Between Anxiety and Pain Catastrophizing in Fibromyalgia Women**

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Pain experience-SF-MPQ | 0.17 | .37 | 3.72** | .26 | .26 | 14.96** |
| Sleep quality-PSQI | 0.25 | .23 | 2.33* | | | |
| Step 2 | | | | | | |
| Pain experience-SF-MPQ | 0.10 | .23 | 2.12* | .32 | .06 | 13.46** |
| Sleep quality-PSQI | 0.19 | .18 | 1.82 | | | |
| Pain catastrophizing-PCS | 0.12 | .30 | 2.82** | | | |
| Step 3a | | | | | | |
| Pain experience-SF-MPQ | 0.11 | .24 | 2.32* | .39 | .06 | 13.39** |
| Sleep quality-PSQI | 0.14 | .13 | 1.39 | | | |
| Pain catastrophizing-PCS | 0.08 | .21 | 2.03* | | | |
| Difficulty in identifying feelings-TAS-20 | 0.11 | .28 | 3.03** | | | |
| Step 3b | | | | | | |
| Pain experience-SF-MPQ | 0.13 | .28 | 2.84** | .45 | .06 | 13.66** |
| Sleep quality-PSQI | 0.06 | .05 | 0.60 | | | |
| Pain catastrophizing-PCS | 0.06 | .16 | 1.57 | | | |
| Difficulty in identifying feelings-TAS-20 | 0.12 | .29 | 3.30** | | | |
| Pain catastrophizing X difficulty in identifying feelings | −0.00 | −.26 | −3.05** | | | |
| Step 4a | | | | | | |
| Pain experience-SF-MPQ | 0.10 | .22 | 2.11* | .35 | .02 | 11.03** |
| Sleep quality-PSQI | 0.17 | .16 | 1.64 | | | |
| Pain catastrophizing-PCS | 0.10 | .25 | 2.31* | | | |
| Difficulty in describing feelings-TAS-20 | 0.13 | .16 | 1.69 | | | |
| Step 4b | | | | | | |
| Pain experience-SF-MPQ | 0.11 | .25 | 2.32* | .36 | .01 | 9.48** |
| Sleep quality-PSQI | 0.13 | .12 | 1.20 | | | |
| Pain catastrophizing-PCS | 0.10 | .26 | 2.38* | | | |
| Difficulty in describing feelings-TAS-20 | 0.15 | .18 | 1.96* | | | |
| Pain catastrophizing X difficulty in describing feelings | −0.00 | −.14 | −1.57 | | | |

*Note.* $^{*}p \leq .05$. $^{**}p \leq .01$.

catastrophizing were significant predictors, and in Step 4b, the contribution of both variables was retained and difficulty in describing feelings was an additional significant predictor.

Figure 1 shows the pain catastrophizing x difficulty in identifying feelings interaction. Low, medium, and high levels (for both terms) were computed using the mean as the medium value and considering 1 *SD* below the mean as the low level and 1 *SD* above the mean as the high level (Aiken & West, 1991). Simple slope in the line showing low difficulty identifying feelings ($t_{93} = 3.08$, $p < .01$) was significant. Patients with different levels of difficulty in identifying feelings did not differ in anxiety under conditions of high pain catastrophizing. By contrast, differences were observed under conditions of medium-low pain catastrophizing: subjects reporting high difficulty in identifying feelings scored significantly higher in anxiety than subjects reporting low difficulty in identifying feelings.

Two moderation analyses tested whether the fear of pain x difficulty in identifying feelings interaction and the fear of pain x difficulty in describing feelings interaction were significant predictors of anxiety after controlling the effect of physical symptoms, fear of pain and difficulty in identifying feelings (or difficulty in describing feelings) (see Table 6). In Step 1, pain experience and sleep quality

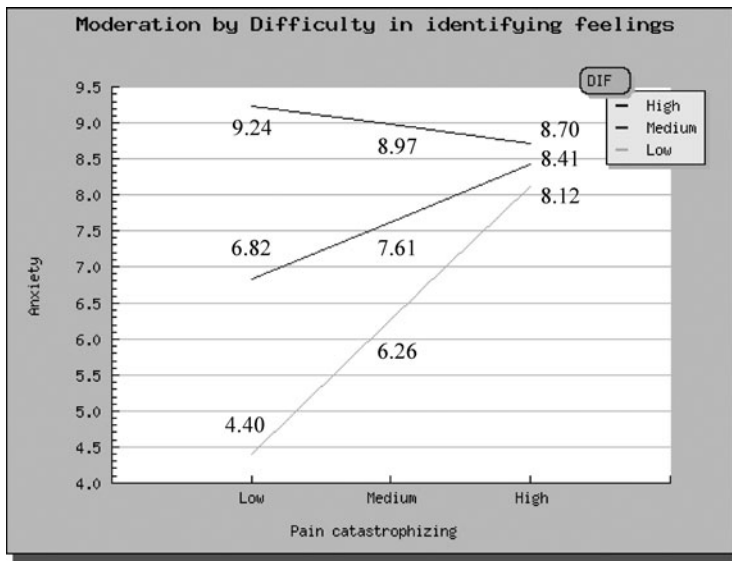


**FIGURE 1. Moderating role of alexithymia (difficulty in identifying feelings, DIF) in the relationship between anxiety and pain catastrophizing.**

**TABLE 6. Alexithymia as a Moderator Between Anxiety and Fear of Pain in Fibromyalgia Women**

| Predictor variables | *B* | ß | *t* | $R^2$ | $R^2$ *Change* | *F* |
|---|---|---|---|---|---|---|
| Step 1 | | | | | | |
| Pain experience-SF-MPQ | 0.16 | .37 | 3.63** | .24 | .24 | 13.43** |
| Sleep quality-PSQI | 0.23 | .22 | 2.15* | | | |
| Step 2 | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .14 | 1.31 | .37 | .12 | 16.14** |
| Sleep quality-PSQI | 0.14 | .13 | 1.35 | | | |
| Fear of pain-PASS-20 | 0.11 | .44 | 4.06** | | | |
| Step 3a | | | | | | |
| Pain experience-SF-MPQ | 0.07 | .16 | 1.60 | .43 | .05 | 15.27** |
| Sleep quality-PSQI | 0.09 | .08 | 0.95 | | | |
| Fear of pain-PASS-20 | 0.08 | .33 | 2.98** | | | |
| Difficulty in identifying feelings-TAS-20 | 0.11 | .27 | 2.88** | | | |
| Step 3b | | | | | | |
| Pain experience-SF-MPQ | 0.07 | .15 | 1.52 | .45 | .02 | 13.24** |
| Sleep quality-PSQI | 0.08 | .08 | 0.87 | | | |
| Fear of pain-PASS-20 | 0.08 | .32 | 2.95** | | | |
| Difficulty in identifying feelings-TAS-20 | 0.10 | .26 | 2.85** | | | |
| Fear of pain X difficulty in identifying feelings | −0.00 | −.15 | −1.83 | | | |
| Step 4a | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .13 | 1.27 | .39 | .01 | 12.93** |
| Sleep quality-PSQI | 0.12 | .11 | 1.21 | | | |
| Fear of pain-PASS-20 | 0.10 | .41 | 3.73** | | | |
| Difficulty in describing feelings-TAS-20 | 0.11 | .14 | 1.56 | | | |
| Step 4b | | | | | | |
| Pain experience-SF-MPQ | 0.06 | .14 | 1.37 | .42 | .03 | 11.69** |
| Sleep quality-PSQI | 0.09 | .08 | 0.91 | | | |
| Fear of pain-PASS-20 | 0.10 | .41 | 3.81** | | | |
| Difficulty in describing feelings-TAS-20 | 0.14 | .17 | 1.91* | | | |
| Fear of pain X difficulty in describing feelings | −0.00 | −.18 | −2.12* | | | |

*Note.* $^{*}p \leq .05$. $^{**}p \leq .01$.

were identified as significant predictors. In Step 2, the effects of these predictors disappeared when fear of pain was included and fear of pain was identified as a significant predictor. In Step 3a, the contribution of fear of pain remained significant when difficulty in identifying feelings was included, and this measure of

alexithymia was also a significant predictor. In Step 3b, fear of pain and difficulty in identifying feelings were retained as significant predictors. In Step 4a, only fear of pain was identified as a significant predictor. In Step 4b, fear of pain and difficulty in describing feelings were significant predictors and a significant effect was observed in the fear of pain x difficulty in describing feelings interaction; this indicated that the relationship between anxiety and fear of pain is moderated by this facet of alexithymia.

Figure 2 shows the fear of pain x difficulty in describing feelings interaction. Simple slope in the line showing medium ($t_{93} = 3.28$, $p < .01$) and low difficulty in describing feelings ($t_{93} = 3.98$, $p < .001$) were significant. Under conditions of medium-low fear of pain, subjects reporting high difficulty in describing feelings scored significantly higher in anxiety than subjects reporting low difficulty in describing feelings.

## Discussion

In the current psychological approach to medical illness, personality characteristics are considered as moderators or mediators that influence illness from

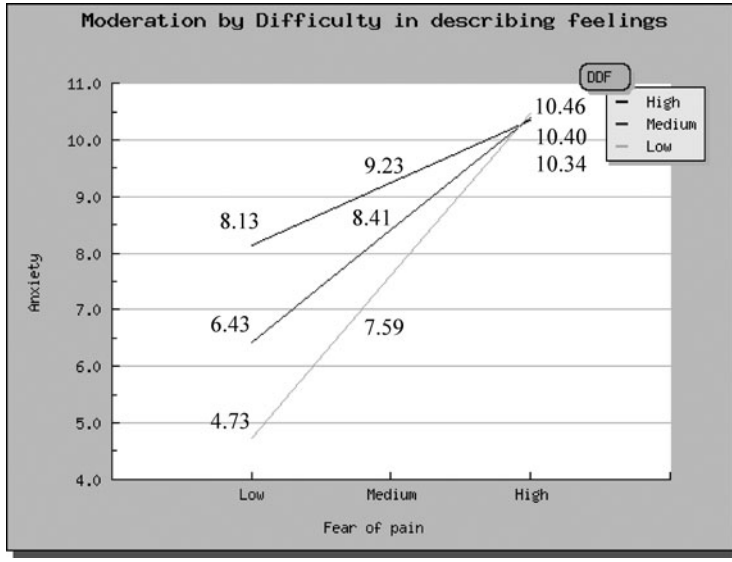


**FIGURE 2. Moderating role of alexithymia (difficulty in describing feelings, DDF) in the relationship between anxiety and fear of pain.**

risk and vulnerability factors to maintenance of symptoms and recovery (Porcelli & McGrath, 2007). The present study falls within this perspective, analyzing the moderating role of alexithymia in the relationship between emotional distress and pain appraisal variables in FM.

First, FM women and healthy women were compared regarding various components of alexithymia. Women in the clinical group showed more limitations in connecting with their affective states and recognizing the type of emotion they experience, and they also had greater difficulty in expressing their affective states and communicating them to others than those in the control group. These results are consistent with previous studies indicating that FM patients are more alexithymic than healthy controls (Brosschot & Aarsse, 2001; Sayar et al., 2004; Tuzer et al., 2011; van Middendorp et al., 2008). The present study identified a large effect size in difficulty in identifying feelings and small effect sizes in the other alexithymia scales, in line with previous evidence (van Middendorp et al., 2008). In the present study, healthy women showed higher levels of externally oriented thinking than FM women. This is consistent with the consideration that this cognitive component may be less representative of alexithymia than emotional components.

Second, the relationship between alexithymia and clinical measures in FM women was explored. Difficulty in identifying feelings and difficulty in describing feelings were significantly correlated with lower sleep quality, higher anxiety and depression symptoms, and increased tendency to make a catastrophic appraisal of pain and experience fear associated with pain. Yet, none of these components of alexithymia were significantly associated with impairment in daily functioning. Difficulty in describing feelings—but not difficulty in identifying feelings—was significantly correlated with higher pain experience (sensory–affective aspects) and increased vigilance to and observance of pain. By contrast, externally oriented thinking was not correlated with any of the clinical variables. These findings are similar to those reported in previous studies that have shown strong links between alexithymia and emotional distress (Evren et al., 2006; Malt et al., 2002; van Middendorp et al., 2008) and catastrophizing (Lumley et al., 2002; Makino et al., 2012), but no relationship between alexithymia and disability (Sayar et al., 2004) or pain severity (Evren et al., 2006). These results partially differ from those of the study by Huber et al. (2009), which showed that alexithymia was associated with affective pain and pain tolerance but not with sensory pain. One might expect the affective dimension of pain (the closest one to emotions) to be more strongly associated with alexithymia; however, the current study shows that the three dimensions of pain (i.e., sensory, affective, and evaluative) are related to this personality characteristic. It should be noted that this study used the combined sensory-affective scale of pain, which included mainly sensory items. Previous studies have suggested that alexithymia may result from disrupted brain structures involved in emotional processing. Healthy subjects identified as alexithymic have

shown higher activation of the pregenual anterior cingulate cortex, right insula, and midbrain (Kano, Hamaguchi, Itoh, Yanai, & Fukudo, 2007). Considering previous neuroimaging studies, Kano and Fukudo (2013) have proposed that deficient development of emotional neural structures may lead to hypersensitivity to bodily sensations and unhealthy behaviors, and this may be a mechanism underlying the link between alexithymia and psychosomatic disorders. Further research is needed to determine the facet of pain most influenced by alexithymia and the neuropsychological substrate of this process.

Third, the contribution of alexithymia to physical symptoms was analyzed. Alexithymia was not a significant predictor of pain experience or sleep quality when the effect of emotional distress and pain appraisal factors was considered. The best predictor of pain experience was anxiety and the best predictor of sleep quality was depression. This result can be explained considering alexithymia as a personality characteristic and catastrophizing, fear, and vigilance to pain as pain appraisal characteristics of vulnerability, both types of characteristics may be acting as precursors to emotional distress, whether expressed as manifestations of depression or anxiety; in turn, this emotional distress may ultimately intensify pain and disrupted sleep. The findings differ partially from those of Lumley et al. (2002), who found that alexithymia and catastrophizing were significant predictors of pain; however, when depression was considered along with alexithymia, only depression significantly predicted pain. The findings also differ from those of Katz et al. (2009), who identified sex, fear of pain, and alexithymia as significant predictors of pain. Such findings are not directly comparable to the present study. Lumley et al. did not examine anxiety, fear of pain, and vigilance to pain as predictors and included patients with chronic myofascial pain; Katz et al. did not examine vigilance to pain as predictor and included healthy subjects, and neither of these studies analyzed the variables that contribute to sleep quality.

The differential role of negative emotions in the manifestations of FM shown in the present study is consistent with the accumulating evidence. Several reports have shown that anxiety and depression were independently associated with severity of pain and fatigue in FM (Kurtze, Gundersen, & Svebak, 1998), that anxiety—but not depression—was a significant predictor of physical functioning (Epstein et al., 1999), that, in comorbidity patients, fatigue was associated with depression whereas pain was associated with anxiety (Kurtze & Svebak, 2001), and that dysfunctional patients mainly reported anxiety disorders and interpersonally distressed patients mainly reported mood disorders (Thieme et al., 2004). It has been hypothesized that stress and depression contribute to deregulating neuroendocrine, immune, and central pain mechanisms in FM (see van Houdenhove & Luyten, 2006, for a review), yet, the specific mechanisms through which each negative emotional state exerts its influence are unknown.

Last, the moderating role of alexithymia in the relationship between anxiety and pain appraisal factors (pain catastrophizing and fear of pain) was explored. Difficulty in identifying feelings moderated the link between anxiety and pain catastrophizing. This finding reveals that the tendency to evaluate pain as threatening can have greater impact on secondary emotions (such as anxiety) when the patient shows a deficit in recognizing emotions and in differentiating between emotions and bodily sensations. It was also observed that difficulty in describing feelings moderated the relationship between anxiety and fear of pain. This suggests that the effect of tendency to experience pain-related fear upon secondary emotions (such as anxiety) is stronger when the patient finds it difficult to express and communicate the emotions experienced. In a previous study, van Middendorp et al. (2008) found that difficulty in describing feelings moderated the relationship between pain and affect intensity. The current study extends these findings, suggesting that inadequate affective regulation may have a considerable influence on the transition process from negative pain appraisal to the development of maladaptive secondary emotions. In other words, individuals who have the ability to properly handle negative thoughts about pain and fear of pain are likely to show lower levels of anxiety.

In summary, our findings suggest that FM patients have difficulties identifying their affective states, differentiating them from other emotions or physical complaints, and expressing and communicating their feelings. These facets of alexithymia in interaction with negative pain appraisal (pain catastrophizing and fear of pain) may contribute to the development of emotional distress (anxiety), which in turn is associated with more severe symptoms (increased pain experience and poorer sleep quality). Therefore, interventions that guide patients to acquire an adequate knowledge of their emotional experiences may improve their clinical condition.

The present research has some weaknesses. Physical symptoms were only evaluated using self-report questionnaires. Assessing pain with a pressure algometer and sleep with polysomnography would have provided objective measures that might have shown a different relationship with alexithymia. A self-report was used to assess alexithymia; adding a clinical interview and measures estimated by significant others may have allowed a better assessment of this construct. It was not possible to report the validity of the measures applied in the clinical and control groups. In addition, including a control group of nonfibromyalgic chronic pain patients would have contributed clarifying the specific alexithymic characteristics of FM patients. The effect of other personality traits such as neuroticism, which may share some variance with alexithymia, was not controlled. Only Spanish women with FM were considered, so results may not be applicable to other demographic or cultural groups. Last, the cross-sectional design of the study does not allow establishing causal relationships.

This study has practical implications. As alexithymia can play an important role in the manifestations of FM, the whole therapeutic approach should consider

patients' style of affective processing and regulation. Techniques aimed at reducing emotional avoidance and promoting emotional expression may be helpful. For example, helping patients with FM identify their emotional experiences (e.g., fear of pain) as being distinct from other emotions or bodily sensations and express these emotional experiences, may contribute to reducing dysphoric affective states such as anxiety. Several controlled trials have shown that interventions focused on written emotional disclosure (Broderick, Junghaenel, & Schwartz, 2005; Gillis, Lumley, Mosley-Williams, Leisen, & Roehrs, 2006) and affective self-awareness (Hsu et al., 2010) were associated with clinical improvements in FM. Recently, Geenen, van Ooijen-van der Linden, Lumley, Bijlsma, and van Middendorp (2012) have suggested that adjustment in FM depends on the specific combinations of emotion processing style and emotion regulation strategies. They found that, in patients high in affect intensity, emotion expression—but not cognitive reappraisal—was associated with less impairment; yet, they did not find cognitive reappraisal to be more adaptive than emotion expression in alexithymic patients. Therefore, we consider it would be advisable to apply a treatment that combines both strategies according to the clinical profile of the FM patient. The intervention should aim to reduce emotional distress or alexithymia depending on the type of emotion. Experiencing and communicating secondary emotions (e.g., anxiety, depression) may increase pain and interventions focused on reducing these emotions are recommended, by contrast, awareness and expression of primary adaptive emotions (e.g., fear, sadness) may reduce pain and therapies such as emotional disclosure may be beneficial (Lumley et al., 2011). The recent study by Woolfolk, Allen, and Apter (2012) has shown that affective–cognitive–behavioral therapy including, among others, facilitation of emotional awareness and cognitive restructuring resulted in substantial improvements in pain and functioning in FM patients.

In conclusion, alexithymia is a personality trait that is notably involved in the clinical manifestations of FM. Difficulty in identifying emotions and difficulty in describing emotions in interaction with dysfunctional pain appraisal (pain catastrophizing and fear of pain) may contribute to a clinical problem of anxiety. Assessing the level of alexithymia in FM patients is important not only to identify inadequate emotional regulation that may affect the disease, but also to choose the most appropriate psychological intervention strategies.

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# *Systematic Review of Psychological Treatment in Fibromyalgia*

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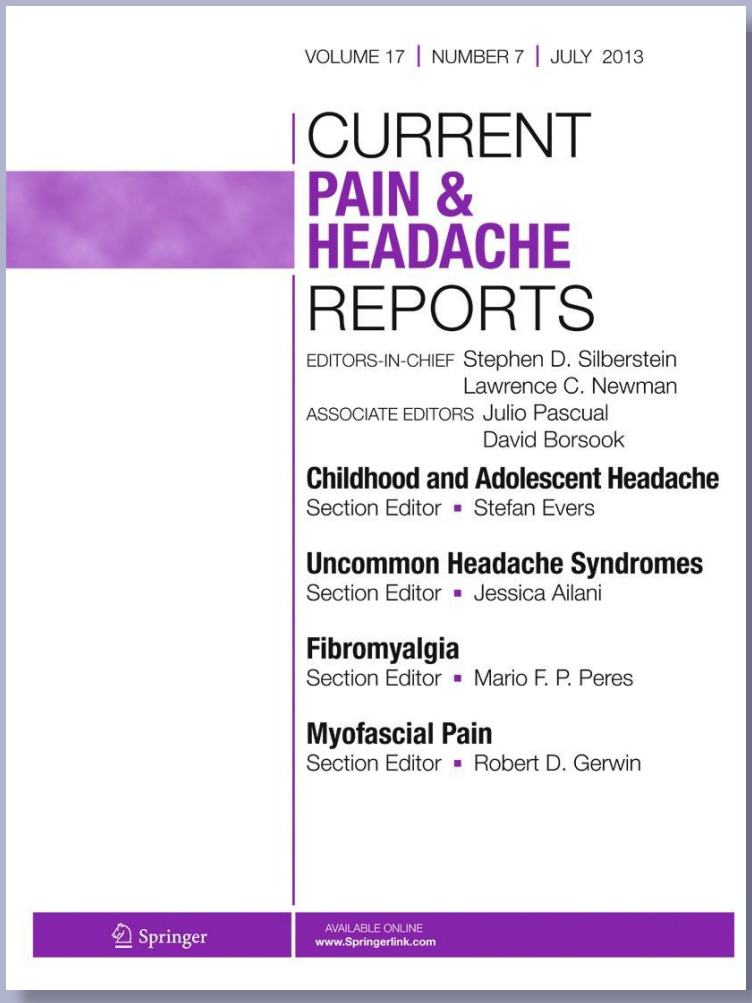

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FIBROMYALGIA (M PERES, SECTION EDITOR)

# Systematic Review of Psychological Treatment in Fibromyalgia

María José Lami & María Pilar Martínez & Ana Isabel Sánchez

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Abstract Fibromyalgia (FM) is a debilitating rheumatic disorder characterized mainly by the presence of continual and widespread musculoskeletal pain, in addition to other disturbing symptoms. There is inconsistent evidence about the effectiveness of the treatments developed so far, making FM a chronic disease that is difficult to treat. The aim of this literature review was to analyze the empirical studies about psychological treatment of FM that have been published over the last twenty years. We conducted a literature search of studies published between 1990 and 2012 using Medline and PsycINFO in the Ovid and ProQuest platforms and hand searching. In total, 58 original studies were identified. The present review presents a comprehensive analysis of the main characteristics of these studies and a description of the interventions developed in order to improve FM symptoms. The most used intervention modality was group treatment with a cognitive-behavioral approach. We also found intensive and remote treatments as well as multimodal therapy, hypnosis, cognitive-behavioral therapy for insomnia, behavioral therapies, mind–body–based techniques, and biofeedback components. Finally, we discuss the clinical relevance of addressing the symptoms of patients with FM and its scientific validation.

This article is part of Topical Collection on *Fibromyalgia*

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## Introduction

According to the American College of Rheumatology (ACR), fibromyalgia (FM) is a debilitating disorder characterized by the presence of continual and widespread musculoskeletal pain for 3 months or longer and tenderness in specific points of the body [1]. In addition to pain, patients with FM report fatigue, sleep disturbance [2], anxiety and depression, cognitive deficits in attention, concentration and memory, and other symptoms such as irritable bowel syndrome, morning stiffness, headaches, or cramps [3, 4], with significant negative consequences for patients' quality of life and daily functioning [5, 6]. In the latest diagnostic criteria review, Wolfe et al. [7] emphasized the clinical approach and proposed pain, sleep disturbance, cognitive dysfunction, and physical symptoms as the most important diagnostic variables. In Europe, FM affects 2.9–4.7 % of the general population [8], mostly middle-aged women, generating considerable economic, social, and personal costs. It is estimated that people with FM spend almost twice as much on health services in 4 years than people of the same age and gender [9].

Due to the complex pathophysiological mechanisms involved in the genesis and maintenance of FM, and considering a psychobiological model in order to fully understand the pain experience, current treatments involve multidisciplinary approaches. Evidence-based treatment guidelines developed by the American Pain Society (APS) [10], the European League Against Rheumatism (EULAR) [11], and the Association of Scientific Medical Societies in Germany (AWMF) [12] mostly recommend multimodal approaches that include pharmacological treatment, physical exercise, and psychological

intervention, specifically cognitive-behavioral treatment (CBT). The EULAR essentially recommends pharmacological treatment and highlights the common use of mixed serotonin and norepinephrine reuptake inhibitors (SNRIs) such as milnacipran and duloxetine, and anticonvulsants such as pregabalin [10, 13]. These drugs decrease pain intensity, reduce sleep disturbance and fatigue and thereby improve patients' quality of life. However, controlled pharmacological trials show that treatments are effective only in the short term (approximately 6 months after the beginning of use) [14] or are usually abandoned by patients because of their side effects [15].

Multicomponent treatments including at least two nonpharmacological interventions are recommended by the APS [10] and the AWMF [12]. In this area, previous meta-analytic reviews highlighted the positive results of treatments including physiotherapy and physical exercise [16], complementary and alternative medicine [17], psychoeducational programs [18, 19], and psychotherapy for groups, families, couples, and individuals [20••] as well as combined and comprehensive treatments [21]. It should be noted that the recommendations of the AWMF are based not only on empirical evidence, but also on other issues such as consistency of study results, clinical relevance and effect size, cost–benefit relationship, ethical obligations, patient preferences, and practicability [12].

There is currently a controversy about the effectiveness and positive results of psychological treatments in FM as well as their long-term maintenance. Recent systematic reviews have reached different conclusions. Glombiewsky et al. [20••] analyzed 23 studies and found that psychotherapy significantly reduced pain intensity and depressive symptoms and that interventions based on relaxation/biofeedback were especially effective for sleep disturbance. Other meta-analytic studies have recognized the effectiveness of CBT at improving coping strategies, self-efficacy, and pain behavior [22, 23•, 24•], observing that such positive effects persist after the end of treatment [25]. At the same time, Bernardy et al. [24•] conducted a review of CBT in FM and did not identify any significant effects after treatment regarding pain intensity, fatigue, and subjective sleep disturbance. Sim and Adam [26] and Bennett and Nelson [23•] compared different kinds of nonpharmacological treatments for FM patients and concluded that there was not enough evidence to highlight any intervention over the others. Nevertheless, most of these reviews have limitations due to heterogeneity of the studies and potential methodological biases [20••].

Having observed the inconsistent evidence obtained so far, it is useful to analyze the characteristics of treatments applied in FM in order to identify the psychological proposals that may be of greater clinical utility.

The aim of the present study was to systematically and qualitatively review psychological treatments developed for FM over the last 20 years. In this regard, we described and integrated the contributions provided, and reviewed the potential inconsistencies in the different approaches and interventions. Finally, we propose future directions to obtain the maximum benefit in the management of FM.

## Method

This systematic review was performed according to the recommendations of PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) [27]. Studies were identified through an exhaustive bibliographic search in Medline and PsycINFO in the Ovid and ProQuest platforms. The terms used were *treatment* OR *therapy* OR *intervention* AND *fibromyalgia*. The literature search applied from 1990—the year of publication of FM diagnostic criteria [1]—to August 2012.

The following inclusion criteria were set to select the studies: (1) empirical articles (experimental, quasi-experimental, or single-case design studies) published in scientific journals; (2) written in English or Spanish; (3) including psychological treatment (at least 60 % of total intervention time); and (4) adult samples (18 years or over) with FM diagnosis according to the ACR criteria.

The search identified 568 articles. After eliminating duplicates, 526 papers were selected for more detailed analysis. All titles and abstracts were reviewed against the inclusion criteria, which led to excluding 466 articles (Fig. 1). Subsequently, 60 articles were fully analyzed. Four of them were excluded due to noncompliance with some of the criteria: two of them were secondary analyses of treatment results and did not assess psychological variables, one was not a scientific publication, and one was a study protocol. After a manual analysis of reviews and empirical articles, we included two additional papers that were not in the previous list. Finally, a total of 58 original articles were included in the present review.

Qualitative data were collected using a table to collect information about substantive characteristics (i.e., participants, context, treatment variables), methodological characteristics (i.e., design and instruments), and external characteristics (i.e., publication bias, year of publication). Studies were analyzed and described following the recommendations of Sánchez-Meca and Botella [28] for conducting systematic reviews of psychological interventions. We also used the quantitative procedure developed by Yates, Morley, Eccleston, and Williams [29] for assessing psychological treatments for pain.

## Results and Discussion

Table 1 shows the 58 articles analyzed in the present review. The studies are listed in alphabetical order under the name of the first author, including a brief abstract with relevant information about each article.

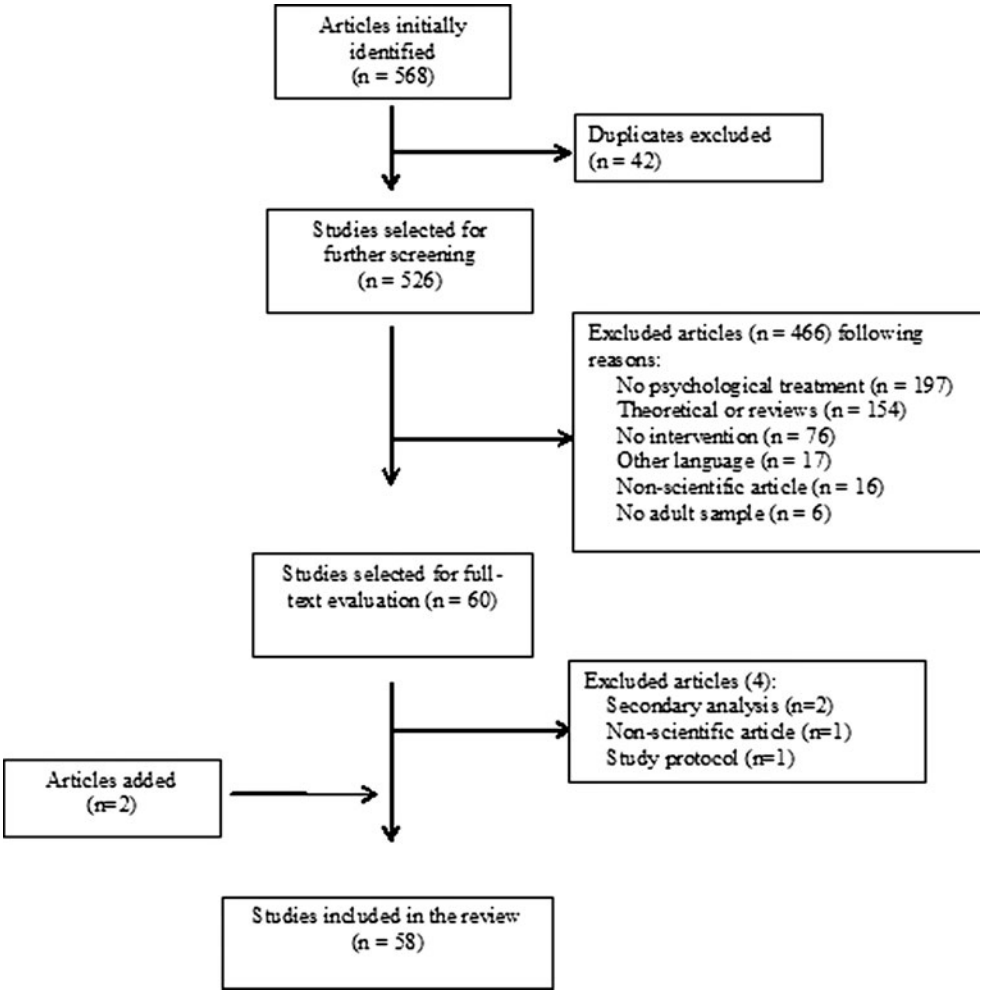


Fig. 1 Flowchart of the study selection process

## Study Quality Analysis

The analysis of the studies included in this review was conducted using the scale mentioned above [28]. Given that the review included experimental, quasi-experimental, and single-case design studies, high score variability was expected. In some cases it was not possible to complete all the data because of the methodological design of the main study (e.g., single-case design) or lack of information.

The scale had two parts, the first of which assessed the quality of the treatment performed in the study and was scored from 0 to 9. The issues considered in the assessment were a clear rationale of the treatment applied, an appropriate description of its contents, information about duration and number of sessions, treatment manual development and adherence to it, adequate professional training, and participants' commitment to the activities prescribed. None of the reviewed studies obtained a score below 5, which indicates a good quality of treatment.

The second part of the scale assessed the quality of the design and methodology used and was scored from 0 to 26. Although we observed a higher variability in scores, the aim of this review was not to perform a quantitative analysis. This part evaluated the criteria used to select the sample, evidence of validity of such criteria, a detailed description of dropouts and the total sample, equivalence between control and experimental groups, randomization of subjects, methodology for the assessment of subjects, equivalence in the expectation of treatment, justification of the outcome variables assessed, validity and reliability of the instruments used, follow-up measurement, adequacy and quality of the control groups, and statistical strategies used.

## Analysis of Substantive Characteristics

A total of 5,876 participants received intervention in control or experimental groups. In the studies reviewed, 41.38 % of studies included mixed groups composed of men and women, although women were more prevalent, and 58.62 % of studies included only women. We did not find any group treatments including only men. The mean age of participants was 38.3 years (SD = 5.13). Most studies included participants from 18 to 65 years old, except for one, in which the age limit was 45 years [30]. The average time from the onset

Table 1 Abstract of the treatment studies included in the review

| Study | Sex Age | Type of treatment | Sessions/ frequency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT +MD |
|---|---|---|---|---|---|---|---|---|
| Alda et al. [60] | Mixed 46.35 | CBT: cognitive restructuring of automatic thoughts and dysfunctional beliefs about pain (ruminations and catastrophizing). Training in coping and assertiveness. | 10/weekly/15 | Group | None | 1.TAU[a] 2.PHT[b] | Catastrophizing (PCS), depression (HAM-D), anxiety (HARS), pain (VAS), impact (FIQ) and acceptance (CPAQ) | 7+22 |
| Ang et al. [34] | Women 49 | CBT: cognitive restructuring, pleasant activity scheduling, time-contingent activity pacing, relaxation-stress. | 6/weekly/3.5 | Telephone/ virtual | TAU | TAU | Nociceptive flexion reflex, impact (FIQ), depression (PHQ-8). | 5+17 |
| Astin et al. [90] | Women 47.7 | Mindfulness/mind-body: mindfulness training, attention to the present moment without judging personal experiences. | 8/weekly/20 | Group | Qigong | Education/ support | Pain (SF-36), impact (FIQ), depression (BDI) | 7+20 |
| Buckhardt et al. [22] | Women 43.5 | Psycho-education: education about FM, stress management, exercise program and support group for patients and family. | 6/weekly/NA | Group | PE[c] | TAU | Impact (FIQ), depression (BDI), quality of life (QoLS) | NA |
| Buckelew et al. [82] | Mixed NA | Biofeedback: relaxation training and biofeedback + physical exercise. | 6/weekly/NA | Individual | PE | 1.Relaxation 2.PE | NA[d] | 6+17 |
| Carbonel-Baeza et al. [51] | Women 51.4 | ACT: education about FM, vital values clarification, acceptance of private events, awareness of avoidance, assertiveness and problem solving. | 12/intensive/ 45 | Group | PE | TAU | Impact (FIQ), depression and anxiety (HADS), coping (VPMI), self-esteem (RSES) | 6+18 |
| Caro et al. [83] | Mixed 66.7 | Biofeedback: Neuro-biofeedback training (Neurocybernetics® software package). | 40/NA/≈ 17,33 | Individual | None | TAU | Attention (TOVA®), pain, fatigue and emotional distress (VAS) | 7+14 |
| Castel et al. [80] | Mixed 44.2 | Hypnosis: self-hypnosis with analgesic suggestion + CBT (information, cognitive restructuring, behavioral activation and problem solving). | 12/weekly/18 | Group | None | 1.TAU 2.CBT | Pain (MPQ), impact (FIQ) | 6+13 |
| Cedraschi et al. [44] | Mixed 48.9 | Multimodal: Physical exercise, relaxation, daily activity scheduling (occupational therapy), education and support group. | 12/intensive/ 18 | Group | PE + OT[e] | Waiting list | Psychological well-being PGWB), general health (SF-36), pain (RPS), impact (FIQ) | 6+21 |
| Comeche-Moreno et al. [61] | Mixed 46 | CBT: education about FM and active coping (cognitive restructuring), pleasant activities, relaxation, sleep hygiene, sexual relations, assertiveness, improved attention and memory problems. | 10/weekly/20 | Group | None | No | Depression (BDI and HADS), self-efficacy (SES), catastrophizing (PCS), pain (VAS) | 6+15 |
| de Voogd et al. [71] | Mixed NA | Behavioral: psychomotor techniques for relaxation, assertiveness and learning to recognize symptoms. | NA | Group | Couple therapy | Waiting list | Symptoms (SCL-90-R) | |
| Edinger et al. [72] | Mixed 48.6 | CBT for insomnia: information about sleep, circadian rhythms and sleep disturbances. Stimulus control techniques and sleep restriction. | 6/weekly/≈3 | Individual | None | 1. Sleep hygiene 2.TAU | Sleep (polysomnography, actigraphy and sleep logs), pain (MPQ and BPI), mood (PoMS), general health (SF-36) | 7+20 |
| Gillis et al. [36] | Mixed 50.3 | Other: disclosure and expression of traumatic events through writing. | 4/intensive/≈1 | Individual | None | Placebo | | 5+18 |

Table 1 (continued)

| Study | Sex Age | Type of treatment | Sessions/ frequency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT +MD |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Negative mood (PANAS-X), impact (FIQ), pain (AIMS2), fatigue, sleep quality (VAS) | |
| Goldenberg et al. [62] | Mixed NA | CBT: stress-reduction oriented. | 10/weekly/20 | Group | None | TAU | Pain and sleep (VAS), impact (FIQ), symptoms (SCL-90-R). | |
| González-Ramírez et al. [35] | Women 45.7 | CBT: Information, goal setting, relaxation/ hypnosis, cognitive restructuring, assertiveness and self-esteem. | 12/weekly/NA | Telephone/ virtual | None | No | Stress (PSS), impact (FIQ), memory (PMRQ-S), negative thoughts (ATQ), catastrophizing (PCS) | 6+12 |
| Grossman et al. [88] | Women 54.4 | Mindfulness/mind-body: for stress reduction. Includes relaxation, stretching and social support. | 8/weekly/20 | Group | None | Education/ support | Quality of life (QoLS), anxiety and depression (HADS), pain (PRSS and IPR). | 7+21 |
| Gunther et al. [93] | Mixed 45.2 | Relaxation: Jacobson's progressive muscle relaxation. | 4/intensive/ NA | Individual | None | Hydrogalvanic therapy | Pain (MPQ) | 4+16 |
| Haanen et al. [78] | Mixed 44.6 | Hypnosis: oriented to pain management, muscle relaxation and improving sleep problems. | 8/Weekly/8 | Individual | None | PE | Pain (dolorimeter), fatigue and sleep (VAS), symptoms (HSCL-90) | 4+15 |
| Jensen et al. | Women 45.6 | CBT: based on ACT, exposure to activities and emotions or thoughts that have been avoided. | 12/weekly/18 | Group | None | Waiting list | Pain (VAS), depression (BDI), anxiety (STAI), global change (PGIC), neuroimaging | 7+19 |
| Kayiran et al. [30] | Women 31.78 | Biofeedback: neurofeedback program. Conditioning for modifying the amplitude/ frequency of neurophysiological dynamics. | 20/Intensive/ 10 | Individual | None | PHT | Pain (VAS), FIQ, depression (BDI), anxiety (BAI) general health (SF-36), diagnosis (SCID-I) | 7+19 |
| Keel et al. [45] | Mixed 49 | Multimodal: information, relaxation, cognitive restructuring, self-management strategies and training in self-efficacy. | 15/weekly/30 | Group | PE | Relaxation (autogenic) | Pain and sleep (VAS), medication intake | 7+15 |
| Kravitz et al. [84] | Mixed 46.9 | Biofeedback: Neurofeedback flexy neurotheraphy system®. | 22/Intensive/ NA | Individual | None | Placebo | Pain (dolorimeter), fatigue, memory and depression, symptoms (SCL-90-R), impact (FIQ) | 7+19 |
| Kroese et al. [43] | Mixed 44.2 | Multimodal: information, rational emotive therapy, problem solving, relaxation, coping, life goals, activity-rest balance. | 36/intensive/ 54 | Group | PE + socio + art therapy. | No | Quality of life (EuroQoL-5D), impact (FIQ) | 7+14 |
| Lera et al. [47] | Women 50.2 | Multimodal: education, sleep hygiene, pleasant activities, cognitive restructuring, coping, assertiveness and psychosocial support | 15/weekly/ 22,5 | Group | PE + TF | PE + PHT | Symptoms (SCL-90-R), general health (SF-36), impact (FIQ) | 6+19 |
| Luciano et al. [21] | Mixed 55.17 | Psycho-education: symptoms and course of FM, psychological factor/pain and autogenic relaxation. | 9/intensive/18 | Group | TAU | TAU | Health (checklist), anxiety (STAI), impact (FIQ) | 7+20 |
| Luedtke et al. [37] | Mixed NA | Multimodal: education, relaxation, social skills and time schedule. | 1/intensive/5,5 | Group | PE + OT | No | Health status (HSQ), impact (FIQ) | 4+13 |
| Lumley et al. [53] | Women 56 | Other: emotional disclosure and expression through writing about traumatic events. | 10/weekly/10 | Individual | None | No | Pain (MPQ), FIQ, life satisfaction (SWLS), Impact of the event (IES-R) | 5+12 |

Table 1 (continued)

| Study | Sex Age | Type of treatment | Sessions/ frequency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT +MD |
|---|---|---|---|---|---|---|---|---|
| Lundervold et al. [72] | Women 44 | Behavioral: behavioral activation for pain (BAT-P) education, relaxation-activity cycles (feedback) and valued activities. | 14/weekly/NA | Individual | None | No | Pain (VAS), depression (GDS-15), pain anxiety (PASS) | 6+NA |
| Martínez-Valero et al. [79] | Women 44.3 | Hypnosis: hypnosis for pain, self-esteem or insomnia +CBT (information, cognitive restructuring, behavioral activation and problem solving). | 10/weekly/10 | Individual | TAU | 1.TAU 2.CBT (without hypnosis) | Pain (PBPI), impact (FIQ), sleep and fatigue (VAS) | 7+13 |
| Mason et al. [48] | Women 46.2 | Multimodal: exercise/physical therapy + CBT (sleep education, depression and maladaptive pain behaviors, cognitive restructuring and relaxation). | 24/intensive/ 144 | Group | PE + TF | TAU | Pain (dolorimeter and VAS), coping (CSQ), impact (FIQ), depression (BDI) | 7+12 |
| Miró et al. [73] | Women 46.45 | CBT for insomnia: sleep hygiene, sleep restriction and stimulus control, relaxation, cognitive restructuring and assertiveness. | 6/weekly/9 | Group | TAU | TAU + sleep hygiene | Pain (MPQ), sleep (PSQI), anxiety and depression (HADS), impact (FIQ) | 7+17 |
| Mueller et al. [85] | Mixed 50.7 | Biofeedback: electroencephalographic activity modulation by stimulation. | 52/intensive/ 52 | Individual | PE | No | Pain (VAS), impact (FIQ), symptoms (SCL-90-R) | 7+12 |
| Nelson et al. [36] | Mixed 44 | Psycho-education: info about pain, coping strategies, catastrophizing, relaxation and personal goals with patients and families. | 1/NA/2 | Group | None | No | Catastrophizing | 5+5 |
| Nicassio et al. [54] | NA | Behavioral: training in coping strategies. | 10/weekly/15 | Group | None | Education/ support | Pain, depression, disability and pain behaviors (NA) | NA |
| Nielson et al. [49] | Mixed 44.9 | Multimodal: CBT (cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education) + physical and occupational therapy. | 16/Intensive/ 96 | Group | PE + OT | No | Pain (MPQ and tender points), impact (FIQ) | NA |
| Nielson et al. [63] | Mixed NA | CBT: cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education. | Not available | | None | No | NA | 6+15 |
| Oh et al. [38] | Mixed 48.3 | Multimodal: education + CBT (relaxation, social skills, stress management, daily planning) + physical and occupational therapy. | 1/intensive/5,5 | Group | PE+OT | No | Impact (FIQ), general health (SF-36) | 7+13 |
| Pfeiffer et al. [39] | Mixed 44.7 | Multimodal: education + CBT (relaxation, social skills, stress management, daily planning). | 1/intensive/5,5 | Group | PE + OT | No | Impact (FIQ), depression (CES-D) | 7+12 |
| Redondo et al. [74] | Women NA | CBT: info about FM/pain and emotional factors, relaxation, coping, daily activities, assertiveness, sleep/rest, problem solving. | 8/weekly/20 | Group | TAU | PE | Pain (tender points), impact (FIQ), general health (SF-36), anxiety (BAI), depression (BDI), self-efficacy (CPSS), coping (CPCI) | 7+12 |
| Rodero et al. [75] | Mixed 50.5 | CBT: info about stress/pain, cognitive restructuring, emotional exposure by writing and assertiveness. | 11/weekly/ ≈16,5 | Group | None | No | Pain (VAS), FIQ, anxiety (HADS), catastrophizing (PCS) | 9+13 |
| Sánchez et al. [76••] | Women 46.79 | CBT for insomnia: info about sleep/FM, sleep restriction therapy, stimulus control, | 6/weekly/9 | Group | None | Sleep hygiene | Polysomnography | 7+17 |

Table 1 (continued)

| Study | Sex Age | Type of treatment | Sessions/ frequency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT +MD |
|---|---|---|---|---|---|---|---|---|
| | | relaxation and cognitive therapy for dysfunctional beliefs of insomnia/sleep. | | | | | | |
| Sales et al. [66] | Women 44.88 | CBT: diaphragmatic breathing and relaxation, cognitive restructuring and stress management. | 10/weekly/NA | Group | None | TAU | Pain (VAS), FIQ, general health (SF-36), anxiety (STAI), depression (BDI) | 5+18 |
| Singh et al. [89] | Women NA | Mindfulness: education on mind-body connection, relaxation/mindfulness + Qigong. | 8/weekly/20 | Group | None | No | Depression (BDI), FIQ, coping (CSQ), general health (SF-36) | |
| Smyth et al. [37] | Women 45.75 | Other: emotional expression through writing, cognitive reappraisal and relaxation. | 8/intensive/8 | Individual | None | Placebo | Quality of life, sleep, pain and mood (PANAS) | 5+9 |
| Suman et al. [47] | Women 44.8 | Multimodal: education, cognitive restructuring, adaptation to pain and self-efficacy. | 15/intensive/ 25 | Individual | PE | No | Pain (VAS), depression (CES-D), coping (BPCI). | 6+11 |
| Thieme et al. [67] | Women 49.13 | CBT: cognitive restructuring of catastrophic beliefs, problem solving, coping and relaxation. Operant conditioning: reinforcement of behaviors incompatible with pain. | 15/weekly/30 | Group | None | Education/ support | Pain (MPI), impat (FIQ), health service utilization | 7+22 |
| Thieme et al. [73] | Women 46.6 | Behavioral: reinforcement of behaviors incompatible with pain. | 25/intensive/ 75 | Group | None | PE | Pain (MPI), pain behaviors | 6+15 |
| Toussanint et al. [40] | Mixed 48 | Mind-body: based on amygdala retraining program combined with CBT and graded exercise therapy. | 1/intensive/2,5 | Group | TAU | TAU | General health (SF-36), fatigue (MFI), sleep (ESS), impact (FIQ) | 6+16 |
| Turk et al. [51] | Mixed NA | Multimodal: psychotherapy, occupational and physical therapy. | NA | | NA | NA | Pain, distress, depression, anxiety, disability, fatigue | NA |
| van Koulil et al. [57] | Women 47 | CBT: Education and planning. Changing cognitive-behavioral patterns (avoidant or persistent patterns). Psycho-education and assertiveness training for couples. | 16/intensive/ 32 | Individual | PE | No | Pain, anxiety, depression, impact (FIQ), coping (CSQ), fatigue | 8+NA |
| | Women 40 | | 16/intensive/ 32 | Individual | PE | No | | |
| van Koulil et al. [58] | Mixed 41.7 | CBT: Changing cognitive-behavioral patterns according to patient profile. | 16/intensive/ 32 | Group | PE | Waiting list | Impact (FIQ) | 9+22 |
| van Santen et al. [86] | Women NA | Biofeedback | NA | Group | None | PE | Pain (VAS and dolorimeter), symptoms (SCL-90-R), fatigue (VAS) | NA |
| Vázquez-Rivera et al. [68] | Women 51.9 | CBT: education, sleep hygiene, cognitive-affective factors, adaptive coping strategies. | 5/weekly/10 | Group | None | TAU | Depression (BDI), anxiety (STAI), coping (CPCI), impact (FIQ) | 7+20 |
| Vlaeyen et al. [69] | Mixed 44 | CBT: education, self-efficacy and self-control, relaxation/biofeedback. | 12/intensive/ 20 | Group | PE | TAU | Pain (MPQ), Catastrophizing, coping (CSQ) | 8+16 |
| White et al. [69] | NA | CBT: cognitive restructuring, reduction of pain behaviors, assertiveness, relaxation and education. | NA | Group | PE+OT | NA | Pain/control behaviors | NA |
| Wigers et al. [55] | Mixed NA | Relaxation/biofeedback: stress management oriented. | 14/weekly/NA | Group | None | TAU | Pain, fatigue, sleep and depression (dolorimeter and VAS), | NA |
| Williams et al. [84] | Mixed 47.7 | CBT: psychological education, relaxation, increasing of activity, assertiveness, | 10/weekly/NA | Individual | TAU | TAU | Pain (VAS), general health (SF-36), self-efficacy (CPSE), | 7+20 |

Table 1 (continued)

| Study | Sex Age | Type of treatment | Sessions/ frequency/ total hours | Modality | Cointervention | Control Group | Target variables | Quality QT +MD |
|---|---|---|---|---|---|---|---|---|
| | | cognitive CBT: based on affective approach. Cognitive restructuring, activity regulation, relaxation and interpersonal communication training. | | | | | depression (BDI), anxiety (BAI) | |

*Notes:* [a] TAU = Treatment-as-usual; [b] PHT = Pharmacological treatment; [c] PE = Physical exercise; [d] NA = Not available; [e] OT = occupational therapy

*Abbreviation of instruments used:* AIMS-2 = Arthritis Impact Measurement Scale-2; ATQ = Automatic Thoughts Questionnaire; BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; BPCI = Brief Pain Coping Inventory; BPI = Brief Pain Inventory; CES-D = Center for Epidemiologic Studies Depression Scale; CPAQ = Chronic Pain Acceptance Questionnaire; CPCI = Chronic Pain Coping Inventory; CPSE = Chronic Pain Self-efficacy Scale; CSQ = Coping Strategies Questionnaire; EuroQol-5D = European Quality of Life Scale-5D; ESS = Epworth Sleepiness Scale; FIQ = Fibromyalgia Impact Questionnaire; GDS-15 = Geriatric Depression Scale 15; HAM-D = Hamilton Rating Scale for Depression; HARS = Hamilton Anxiety Rating Scale; HSCL-90 = Hopkins Symptom Check-list; HSQ = Health Status Questionnaire; IES-R = Impact of Event Scale-Revised; IPR = Inventory of Pain Regulation; ISQ = Insomnia Symptom Questionnaire; MFI = Multi-Dimensional Fatigue Inventory; MPQ = McGill Pain Questionnaire; PANAS-X = Positive and Negative Affect Schedule; PASS = Pain Anxiety Symptom Scale; PBPI = Pain and Belief Perception Inventory; PCS = Pain Catastrophizing Scale; PGWB = Psychological General Well-Being Index; PHQ-8 = Patient Health Questionnaire 8-item depression scale; PoMS = Profile of Mood States; PMRQ-S = Prospective and Retrospective Memory Questionnaire; PRSS = Pain Related Self-Statements Scale; PSS = Perceived Stress Scale; QoLS = Quality of Life Scale; RPS = Regional Pain Score; RSES = Rosenberg Self-Esteem Scale; SES = Self-Efficacy Scale; SF-36 = Short-Form Health Survey; SCID-I = Structured Clinical Interview for DSM-IV Axis I Disorders; SCL-90-R = Symptom Checklist-90-Revised: SWLS = Satisfaction With Life Scale: VAS = Visual Analogue Scale: VPMI = Vanderbilt Pain Management Inventory

of the first symptoms or a diagnosis by a rheumatologist to the time of evaluation was 8.24 years (SD = 5.21) (see Table 1). In total, 37.93 % of studies did not mention the time from diagnosis.

Table 1 includes a brief description of each intervention. Most interventions involved group treatment (n = 38, 65.52 %), compared to 27.58 % (n=16) of interventions, which involved individual treatment. We also identified an intervention conducted by telephone following a treatment protocol manual [31] and three studies in which the therapist sent all the information and treatment contents by e-mail [32] or regular mail [33, 34] and treatment was applied by participant themselves, with general guidelines but flexibility regarding intensity and duration. We found evidence of the efficacy of CBT in groups [35], although there were difficulties regarding costs and transfer of patients to the place of treatment because of the distance or the disability generated by FM. Distance intervention was useful to overcome such difficulties, but poor adherence was observed when treatments lacked a protocol or a system to ensure adherence to the treatment manual by the therapist [33, 34], or in the absence of a tutor/psychologist [32]. In this regard, the study by Ang et al. [31] combined distance treatment with a protocol manual and a psychologist who monitored treatment by telephone. In some cases, this could be a suitable alternative.

Other studies attempted to overcome the difficulties related to treatment attendance by scheduling an intensive group program for one [36] or two days [37–41]. Nelson and Tucker [36] developed an intervention conducted by trained nurses in the primary care framework and included a two-hour educational session aimed at modifying catastrophizing. This study included FM patients and their families and analyzed the impact of knowledge about the syndrome on pain and related psychological variables. Studies by Luedtke et al. [38], Oh et al. [39], and Pfeiffer et al. [40] referred to the same one-and-a-half-day interdisciplinary program that included components such as pain education and FM, an interactive self-management session based on CBT, discussion on the benefits of physical activity and the display of graded exercise training, and occupational therapy. The last of these short treatments by Toussaint et al. [41] also included a mind-body technique known as 'amygdala retraining', applied in a 2.5-hour program. This technique was aimed at deconditioning certain emotional responses, such as fear, that are mediated through the amygdala in order to decrease FM symptoms. Patients were encouraged to continue applying what they had learned, and results showed that improvements in both the impact of disease and quality of life were maintained at 6- and 12-month follow-up [39]. Improvements after amygdala retraining were significant in pain, physical health, and distress [41], compared with standard short treatment.

However, an important limitation of this type of intervention is that there is no assurance that the results are not due to uncontrolled external variables. This is because, among other issues such as lack of a control group, there is no guarantee of patients' adherence to the techniques learned after the end of treatment. Therefore, treatment modalities that are continuous in time seem to be more common.

In this review, 55.17 % of studies included interventions performed in weekly sessions that varied from 4 to 52 sessions. In total, 63 % of studies included interventions with 4 to 12 sessions. Table 1 shows the number and frequency of sessions ("intensive" refers to more than once a week). Mean total intervention time was 24.61 hours (SD = 27.26). As expected, multimodal programs required more hours of treatment, as they included two or more specialties in different areas of health.

We found 11 multimodal interventions [37–48] that included mainly physical exercise, information about the illness, relaxation, CBT (except for one intervention, which involved rational emotive therapy instead [43], occupational therapy [37–40, 46] and art therapy [43].

*Types of Intervention*

Out of the 59 groups/cases of treatment conditions analyzed, 11 involved a multimodal approach [37–48], eight were based on relaxation or neuro/biofeedback [30, 49–55], four had a behavioral orientation, such as operant conditioning with reinforcement of healthy behaviors and behavioral activation [56–59], three provided psychoeducation [18, 19, 36], three worked with hypnosis [60–62], and four were based on mindfulness or mind–body intervention [41, 63–65]. Most treatments implemented were cognitive-behavioral-based [31, 32, 66–75, 76··, 77–85], with some modifications in their components. The remaining studies [33, 34, 86] referred to the same intervention based on written emotional disclosure and exposure of traumatic success especially oriented to FM patients with symptoms of post-traumatic stress disorder.

An important issue in previous reviews of CBT in FM and chronic pain in general is which components are effective and for whom [87]. Some components such as psychoeducation are common to almost all treatment programs. The aim of psychoeducation is to provide information to the patient about the psychological process that may be maintaining or exacerbating pain problems. In some studies the contents of this information were not clearly explained. In most cases, the first hours of treatment were devoted to providing information about the characteristics of the syndrome (e.g., main symptoms, chronic and acute pain, progress and evolution, common comorbidities, benefits of a healthy diet and exercise, pharmacologic and non-pharmacologic treatments available) [18, 19]. In the intervention carried out by Luciano et al. [18], the educational sessions were performed by a rheumatologist; in the study by Nelson and Tucker [36], the information was provided by nurses and was based on catastrophizing. Nevertheless, none of these studies evaluated whether information in itself led to improvements in participants, although it is an essential component in the start of any treatment.

Educational components such as an introduction to CBT are particularly interesting. It is useful to explain the psychological factors that affect pain experience based on a biopsychosocial model. It is worth highlighting that the aim of CBT is not to eliminate pain but rather to train patients in the skills necessary to manage the symptoms in order to learn to live with it. Thus, Williams et al. [84] refer to the "gate control" theory of pain, according to which pain perception is modulated by certain emotional, cognitive, and social aspects [88], and Van Koulil et al. [79, 80] apply the "fear-avoidance" model of pain, which postulates that mechanisms such as anxiety, fear of pain, and catastrophizing generate avoidance behavior and hypervigilance to pain that increase the complications and disabilities associated to it [89]. In both studies, Van Koulil et al. adapted the treatments according to patient profile, which could be characterized by avoidance of pain (passive patients) or persistence in pain and non-acceptance of the limits imposed by chronic pain and fatigue (active patients). The intervention was applied to FM patients with high scores in negative mood and anxiety, considered high-risk patients. The authors found a considerable proportion of high-risk patients with clinically significant improvements in pain intensity, fatigue, daily functioning, anxiety, and negative mood, compared to the control groups on the waiting list [80]. These results agree with the systematic review conducted by Lohnberg [90], which demonstrated the success of CBT aimed at reducing fear and avoidance of pain in patients with chronic pain. In general, CBT-based treatments seek to modify dysfunctional thoughts and behaviors through cognitive techniques (i.e., restructuring) or behavioral activation techniques [57] that include planning daily activities that are consistent with personal values and operant conditioning addressed to increase healthy behaviors that are incompatible with pain [59, 78]. In this behavioral approach, de Voogd et al. [56] included training sessions for couples with the aim of modifying the contingencies of behaviors associated with pain.

Most interventions examined in this review involved social skills training, relaxation through various techniques (e.g., guided imagery, controlled and deep breathing, progressive relaxation), assertiveness training, problem-solving strategies, and coping skills training in order to increase self-efficacy expectations. The inclusion of these components is justified by the existence of evidence about the mediator or modulator role of these psychological factors in exacerbation

of discomfort and disability. Three studies applied CBT focused on insomnia (CBT-I) [69, 72, 76••], based upon recent evidence of the relationship between poor sleep quality and pain increase and negative moods [91]. Evidence of clinical experimental studies suggested that disorders characterized by a disruption of deep sleep (slow waves) generate hypersensitivity to noxious stimuli and increase musculoskeletal pain symptoms [92]. The interventions included information about normal and pathological sleep processes, circadian rhythms, and their relation with pain, and proposed specific techniques to overcome insomnia such as sleep hygiene, sleep restriction, and stimulus control, and cognitive therapy in order to change misconceptions about sleep [72, 76••]. These studies showed significant improvements in subjective variables of sleep quality compared to control groups that only received sleep hygiene information [69, 72], significant improvements in objective measures of sleep using actigraphy [69] and polysomnography [76••], and in neuropsychological measures [72]. A recent review in chronic pain patients concluded that CBT-I obtained significant improvements in sleep and consequently in mood, subjective well-being, and confidence in pain management. Surprisingly, these improvements in sleep were not followed by reductions in pain severity, perhaps because modifications in polysomnographic parameters are not sufficient to recover normal sleep patterns [93].

Efforts were also made to improve sleep quality using other techniques such as hypnosis. Three studies were based on hypnosis [60–62], a technique that requires patients' active participation in order to achieve greater self-control [94]. Cognitive hypnotherapy has been used in a variety of chronic pain diseases (e.g., cancer, low back pain, arthritis, temporomandibular disorder) with beneficial results. However, due to the methodological limitations of the studies, it is only recommended as a complementary intervention for FM patients [95]. In the studies conducted by Castel et al. [60] and Martínez-Valero et al. [62], hypnosis was combined with CBT and led to significant improvements in the affective dimension of pain and overall functioning, although results were not significantly better than those of CBT without hypnosis. A recent publication analyzed the 6-month follow-up data of the intervention performed by Castel et al. and showed significantly better results in psychological distress after CBT plus hypnosis than standard pharmacological treatment, although with no statistically significant differences compared to CBT alone [96].

The present review also identified other approaches aimed at achieving objective changes in biomarkers, as illustrated by seven studies characterized by biofeedback or neurobiofeedback (EGG-BF) [30, 49–55]. In these cases, the intervention involved using specific software aimed at correcting of EEG rhythm abnormalities in patients with FM through reinforcement of desired frequencies or nonreinforcement (inhibition) of the unwanted amplitude. This technique was applied to patients noninvasively and interactively as feedback in order to change their EEG patterns [53, 55]. These studies varied in the number of sessions received by participants (20 to 52 sessions), time spent on each session (15 to 30 minutes) and total treatment time, with an average of 26.41 hours (SD = 22.38).

Alternative approaches that have recently received wide acceptance are mindfulness or mind–body interventions. Four studies included mindfulness-based interventions, one of them assessed a mindfulness-based stress reduction program (MBSR) [64], one study provided CBT based on mind-body connection [65], one study was exclusively based on mindfulness training [63], and another study provided specific amygdala retraining based on mind–body notions [41]. These treatment programs include meditation exercises, yoga, and *qigong* (or *chi kung*, a Chinese technique that integrates physical postures, breathing, and focused intentions and accomplishment), in addition to training in the ability to be fully aware of the present moment, without judging or reacting either to internal experiences (feelings, thoughts, and emotions) or external stimuli [63]. Intensity, frequency, and total treatment time were comparable to CBT. Results of these studies showed improvements in pain, depression, anxiety, and quality of life in FM patients. Positive outcomes were also revealed in a recent review of mindfulness treatments for FM [97]. However, both Veehof et al., in a review of 22 studies of acceptance-based interventions in chronic pain [97] and Kozasa [98], concluded that such interventions cannot be considered more favorable than CBT and mentioned the lack of methodological quality of the studies.

*Analysis of Methodological Characteristics* Regarding the qualitative analysis of the methodological characteristics of the studies included in this review, 46.4 % of studies used an experimental design with random assignment of subjects to experimental or control groups and 44.6 % of the studies applied a quasi-experimental design, according to the classification proposed by Montero and León [99]. Two of the studies were defined as single-case design studies [79, 86]. Almost all studies (98 %) included pre-post evaluation, 13 % included only one assessment at the end of treatment but did not evaluate follow-up, 28 % included 6-month follow-up, and 18 % included follow-up after one year, with a mean follow-up of 9.22 months (SD = 16.74).

We found that 70.7 % of the studies comprised a control group, and only four studies included a passive waiting list control group [37, 56, 71, 80], although many of them did not describe the protocol used in the control groups in detail. Most control groups received pharmacological treatment as usual (32.75 %), although we also observed other types of control, including educational components or support

groups (6.89 %), physical exercise (10.34 %), placebo treatment (5.17 %), relaxation activities (3.44 %), sleep hygiene (5.17 %), or hydrogalvanic therapy (1.72 %).

Concerning the source of the sample, all the studies adequately described the procedures and inclusion criteria. However, a significant proportion of interventions were conducted in specific contexts such as specialized pain units in clinics or hospitals (41.1 %), the primary care setting (3.6 %), patient associations (3.6 %), or the general public (3.6 %), with a strict medical control in order to ensure compliance with the inclusion criteria and FM diagnosis according to the ACR criteria. Level of care is relevant because of the high economic cost that FM represents for the health system [9]. Nevertheless, a recent meta-analysis compared treatments by level of care and found no significant differences in the results evaluated [100], concluding that the treatment of FM in specialized care has no advantage over treatment in primary care.

### Analysis of External Characteristics

External characteristics include those that are not directly related to the scientific process of research but may affect the results. We found growing interest in this topic from 2006, when six articles were published (see Fig. 2). The most productive year was 2008, with seven publications.

In the analysis of publications by countries, the United States stands out with 22 publications, Spain with 13 and Germany with 8. Yet, it should be noted that the language in which the scientific articles were written may have led to a certain bias. In this review, most publications were in English and only two were in Spanish.

### Study Limitations

Besides the language issues, another limitation of the study is the exclusion of the term "fibrositis", which was previously used to refer to the syndrome currently known as FM. The term "fibrositis" was popularized in the 1970s but gradually fell into disuse and is now fully replaced by the term "fibromyalgia". Regarding the aims of this review, with the intention of including as many published types of treatments developed for FM, the search may not have considered databases such as the Cochrane Library, which may have limited the number of items included for review.

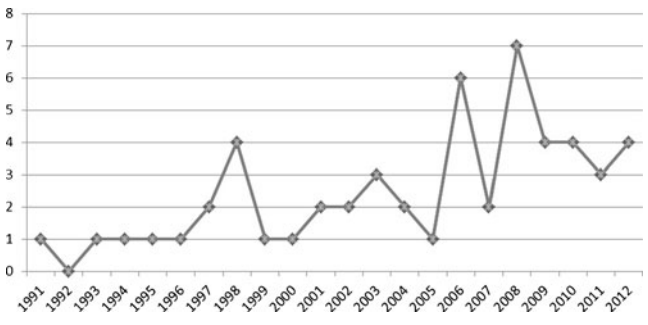


Fig. 2 Frequency per year of published articles included in the review

## Conclusions

Psychological treatment of FM has developed to improve various aspects of symptoms referred by patients. Most interventions described in this review focused on direct symptoms of the disease, particularly pain and fatigue, although some specifically focused on sleep disturbances. We found treatments based on CBT, CBT-I, and multimodal treatments. Studies also included other treatments aimed at improving symptoms associated with distress, such as depression, anxiety, general psychopathology symptoms, or impact of disease. When such treatments were delivered, better results were obtained when combined with treatments such as relaxation, mind-body techniques, and CBT and/or CBT-I. In addition, variables such as pain catastrophizing, self-efficacy, pain anxiety, and pain coping styles were poorly evaluated in most studies.

It is important to emphasize that the instruments used in the assessment were heterogeneous. Many studies used the Visual Analogue Scale (VAS) for pain, fatigue, and sleep, although the data obtained with such instruments were sometimes incomplete. A useful tool to measure the impact of patients with FM included in many studies was the Fibromyalgia Impact Questionnaire [101], but it had the disadvantage of not being recommended for making comparisons with healthy individuals or individuals with other diseases.

### Clinical and Scientific Implications

This work highlights the different modalities that have been developed over the last twenty years to address FM, a complex and chronic syndrome. Psychology is a discipline where multiple paradigms coexist, which contributes to the existence of various treatments for FM. Among them, cognitive-behavioral approaches have been well developed.

Although CBT has proven to be partially effective [24], the evidence argues that CBT components should be complemented by pharmacotherapy and physical exercise, as recommended by clinical practice guidelines [10, 12]. Moreover, treatment goals should be set by professionals in clinical practice, taking into account the specific circumstances of the patient and the variety of symptoms associated with fibromyalgia (i.e., level functioning, sleep problems, mood disorder, coping strategies, tendency to pain catastrophizing). It is important to note that changes and

improvements are possible with these treatments, although they are not immediate and require perseverance and effort.

In a context of public health systems, it is crucial to evaluate the cost-benefit of treatment. Therefore, there is a need for more controlled studies of treatment effectiveness that meet the standard methodological requirements [102], with three objectives: (1) evaluate and compare the effectiveness of all types of treatment; (2) define specific treatment components that reflect the best results; and (3) identify patient characteristics that predict therapeutic success. As highlighted by Vlaeyen et al. [103], more research is needed to identify moderating and mediating variables that lead to a suitable match between the psychological characteristics of patients and treatment.

Finally, knowledge of psychological intervention strategies that improve the quality of life of FM patients is an area of growing interest and useful practical application that future research should continue to examine.

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Compliance with Ethics Guidelines

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Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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· Of importance

· · Of major importance


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