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Assessment of predictors of the impact of fibromyalgia on health-related quality of life 12 months after the end of an interdisciplinary treatment

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ABSTRACT

Objective: Fibromyalgia is a chronic pain disorder with a range of comorbid symptoms, including anxiety. We aimed to prospectively identify predictors of the long-term impact of fibromyalgia on health-related quality of life after the end of an interdisciplinary intervention.

Methods: 138 patients with fibromyalgia, selected from a hospital pain management unit, participated in a 6-week interdisciplinary treatment that combined coordinated psychological, medical, educational, and physiotherapeutic interventions. Participants completed the Fibromyalgia Impact Questionnaire and the Hospital Anxiety and Depression Scale at baseline and 6 weeks, 6 months, and 12 months after the intervention. Multivariable generalized linear mixed models were developed, using the Fibromyalgia Impact Questionnaire score as a continuous variable.

Results: Variables that were significant predictors of the long-term impact of fibromyalgia on health-related quality of life in patients who completed a 6-week interdisciplinary treatment were marital status, the number of concurrent conditions, years since the onset of pain, and symptoms of anxiety. In the longitudinal analysis, patients with symptoms of anxiety had lower rates of improvement than those without symptoms of anxiety.

Discussion: Our results suggest that patients with lower level of anxiety have less impact on their HRQoL. The results also provide evidence that starting interventions as soon as possible is an important factor for improving health-related quality of life.

1. Introduction

Fibromyalgia (FM) is a chronic disorder characterized by widespread pain and exaggerated tenderness on palpation in at least 11 of 18 tender points (Wolfe et al., 1990). Patients with FM frequently describe sensations of fatigue, disturbed sleep, morning stiffness, symptoms associated with irritable bowel syndrome, or symptoms of anxiety or depression (Aguglia et al., 2011). It is a persistent and debilitating disorder that can have a devastating effect on patients' lives, affecting their ability to work and engage in everyday activities and relationships. It primarily affects women, with new diagnoses peaking between the ages of 40 and 49 years (Valverde et al., 2001). In Spain, the prevalence of FM is 2.4% (Carmona et al., 2001). This is in keeping with estimates of 2.9% in five European countries (Branco et al., 2010) and 2% in the United States (Chakrabarty and Zoorob, 2007).

Characteristics of FM, such as its complex and unknown etiology, its wide range of symptoms and signs, and multiple comorbidities make identifying effective therapies particularly difficult. Indeed, no treatment to date has proven effective in fully alleviating its symptoms. Despite the chronic and complex nature of FM, several pharmacological (Goldenberg et al., 2004; Häuser et al., 2009b) and nonpharmacological interventions have demonstrated clinical benefit (Burckhardt, 2006; Häuser et al., 2009a; van Koulil et al., 2007). However, there is no consensus on the best therapeutic approach, and treatment of FM is a challenge for clinicians (Berger et al., 2007). An integrated biopsychosocial approach that includes both nonpharmacological and pharmacological therapies has also been shown to improve outcomes (Burckhardt et al., 2005; Carville et al., 2008; García-Campayo et al., 2010; Häuser et al., 2009a; Lemstra and Olszynsky, 2005; Luedtke

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et al., 2005; Pfeiffer et al., 2003; Samwel et al., 2010; Sauer et al., 2011; Sim and Adams, 2002; Turk et al., 2008; van Koulil et al., 2007). Multidisciplinary programs for FM typically include education, cognitive and behavioral strategies, physical training, and medication (Burckhardt, 2006; Goldenberg et al., 2004). Although several studies of integrated therapies have been conducted, with promising results (Cedraschi et al., 2004; Kroese et al., 2009; Mannerkorpi et al., 2002; Worrel et al., 2001), some did not include a cognitive-behavioral component (Cedraschi et al., 2004; Kroese et al., 2009; Mannerkorpi et al., 2002) or a control group (Kroese et al., 2009; Mannerkorpi et al., 2002; Worrel et al., 2001). So far, there is no consensus on the effectiveness of this approach. One systematic review concluded that multidisciplinary therapy is effective for decreasing the impact of FM (Burckhardt, 2006). A recent meta-analysis (Häuser et al., 2009a) concluded that there is strong evidence that multidisciplinary therapy alleviates some key symptoms of FM but these beneficial effects decline with time, while another systematic review concluded that the benefits of multidisciplinary therapy are limited and disappear over time (van Koulil et al., 2007).

We developed an interdisciplinary treatment for FM based on the biopsychosocial model (Martín et al., 2013) that combines coordinated psychological, medical, educational, and physiotherapeutic components. We tested it in a randomized clinical trial among FM patients recruited from a hospital pain management unit (Martín et al., 2013). The trial demonstrated the efficacy of this interdisciplinary treatment and showed positive changes over time in biopsychosocial health and quality of life.

Given the paucity of available research to guide the management of FM, identifying factors that improve the response to treatment in this population would have significant clinical implications. Therefore, we aimed to prospectively identify predictors of the long-term impact of FM on health-related quality of life (HRQoL) after the end of interdisciplinary treatment for FM. A secondary goal was to examine longitudinally the impact of FM on HRQoL after an interdisciplinary intervention.

2. Materials and methods

2.1. Study participants

The study population was prospectively drawn from patients referred to the pain management unit of the Hospital Galdakao-Usansolo, a 400-bed teaching hospital in the Basque Country (northern Spain) with a catchment population of 300,000. The hospital is part of the network of public hospitals of the Basque Health Service, which provides unlimited free care to nearly 100% of the population. In this hospital, between 5% and 10% of patients newly diagnosed with FM are referred to the pain management unit, primarily from the departments of internal medicine and trauma.

To be eligible for the study, a patient must have been diagnosed with FM according to criteria of the American College of Rheumatology. These include widespread pain for at least 3 months in combination with pain on palpation in at least 11 of 18 specified tender points (Wolfe et al., 1990). Other eligibility criteria included age > 18 years and having had continuous chronic pain for at least 6 months. Patients were excluded if they had a severe psychiatric or organic disease, could not complete the questionnaires because of language barriers, or were involved in employment-related legal proceedings related to their FM. Patients who agreed to participate were required to provide written informed consent.

The sample originated from the randomized controlled trial conducted by Martín et al. (2013). Between 2007 and 2009, 138 patients with FM referred to the pain management unit participated in a 6-week interdisciplinary treatment that combined coordinated psychological (PSY), medical (M), educational (E), and physiotherapeutic (PHY) interventions (PSYMEPHY). In brief, patients received what is currently the standard pharmacologic care for FM in Spain. They also received 6 weeks of interdisciplinary therapy delivered by a team that included a physician, a clinical psychologist, and a physiotherapist experienced in chronic pain management. Each patient attended twice-weekly group sessions for 6 weeks. These sessions covered educational activities focused on better understanding FM; cognitive-behavioral therapy to target the cognitive, physiological, and behavioral domains of FM; and a physiotherapeutic component that included appropriate warm-up, exercise, and stretching routines for patients with FM.

Table 1
Baseline data on patients with fibromyalgia who completed the Fibromyalgia Impact Questionnaire..

	Total Patients (n =138)
	n (%)
Age (years)[*]	50.09 (9.27)
Sex	
Female	128 (92.75)
Male	10 (7.25)
Marital status	
Single	7 (5.07)
Married	117 (84.78)
Divorced/ Widowed	14 (10.15)
Level of Education	
Primary education	74 (53.62)
Secondary education	52 (37.68)
College or above	12 (8.70)
Employment status	
Employed	75 (54.35)
Non-paid work	27 (19.57)
Disabled	21 (15.22)
Retired	15 (10.87)
Number of concurrent physical illnesses	
None	48 (34.78)
One	57 (41.30)
Two or more	33 (23.91)
Years since the onset of pain[*]	14.01 (9.97)
Tender points	
< 18	72 (56.25)
18	56 (43.75)
Total FIQ score[*]	75.72 (14.28)
Anxiety-HAD[*]	13.78 (3.36)
≥11	115 (83.33)
8–10	18 (13.04)
0–7	5 (3.62)
Depression-HAD[*]	10.65 (4.13)
≥11	64 (46.38)
8–10	47 (34.06)
0–7	27 (19.57)

Note. $\bar{x}$

[*] Results showed as mean (standard deviation). FIQ: Fibromyalgia Impact Questionnaire. HAD: Hospital Anxiety and Depression Scale. 18 tender points is the maximum number of tender points according to the ACR diagnostic criteria of FM. Level of significance $p < 0.05$.

2.2. Instruments and data collection

At baseline, a physician associated with the pain management unit recorded sociodemographic data that included age, sex, marital status, level of education, and employment status. Patients' medical histories were also recorded, including any diagnosed physical illnesses, number of years since the onset of pain, and number of tender points. A researcher who was not involved in providing treatment asked participants to complete two self-administered questionnaires that assessed the impact of FM on HRQoL, and symptoms of anxiety/depression.

Patients completed the *Fibromyalgia Impact Questionnaire (FIQ)* (Burckhardt, 1991; Monterde et al., 2004; Rivera and González, 2004). This validated instrument uses visual analogue scales to measure how much FM affects functional capacity, such as the amount of pain and presence of anxiety or depression. The FIQ score can range from 0 to 100; the higher the score, the greater the impact of FM on HRQoL