Six-and 12-month follow-up of an interdisciplinary fibromyalgia treatment programme: results of a randomised trial

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ABSTRACT

Objective. *To assess the efficacy of a 6-week interdisciplinary treatment that combines coordinated psychological, medical, educational, and physiotherapeutic components (PSYMEPHY) over time compared to standard pharmacologic care.*

Methods. *Randomised controlled trial with follow-up at 6 months for the PSYMEPHY and control groups and 12 months for the PSYMEPHY group. Participants were 153 outpatients with FM recruited from a hospital pain management unit. Patients randomly allocated to the control group (CG) received standard pharmacologic therapy. The experimental group (EG) received an interdisciplinary treatment (12 sessions). The main outcome was changes in quality of life, and secondary outcomes were pain, physical function, anxiety, depression, use of pain coping strategies, and satisfaction with treatment as measured by the Fibromyalgia Impact Questionnaire, the Hospital Anxiety and Depression Scale, the Coping with Chronic Pain Questionnaire, and a question regarding satisfaction with the treatment.*

Results. *Six months after the intervention, significant improvements in quality of life (p=0.04), physical function (p=0.01), and pain (p=0.03) were seen in the PSYMEPHY group (n=54) compared with controls (n=56). Patients receiving the intervention reported greater satisfaction with treatment. Twelve months after the intervention, patients in the PSYMEPHY group (n=58) maintained statistically significant improvements in quality of life, physical functioning, pain, and symptoms of anxiety and depression, and were less likely to use maladaptive passive coping strategies compared to baseline.*

Conclusion. *An interdisciplinary treatment for FM was associated with improvements in quality of life, pain, physical function, anxiety and depression, and pain coping strategies up to 12 months after the intervention.*

Introduction

Fibromyalgia (FM) is a chronic disorder of largely unknown etiology characterised by widespread pain and exaggerated tenderness on palpation in at least 11 of 18 tender point sites (1). It is associated with fatigue (2), poor sleep, other functional somatic syndromes, and mental and physical disorders (1, 3, 4). FM affects mainly women, with new diagnoses peaking between the ages of 40 and 49 years (5). FM 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, as well as their relationships with others (6). This disorder also imposes large economic burdens on society (7, 8). In Spain, the prevalence of FM is 2.4% (9). This is in keeping with estimates of 2.9% in five European countries (10) and 2% in the United States (11). In certain populations, however, the prevalence is higher, such as 12% among patients referred to rheumatology specialists in Spain (12, 13).

The complex and poorly understood etiology of FM (14, 15), along with its wide range of signs and symptoms and multiple comorbidities, make identifying effective therapies particularly difficult. As a result, there is no consensus on the best therapeutic approach, and treating FM is a challenge for clinicians (16). Clinical research suggests that pharmacological treatment alone is not the best approach (17, 18), since up to 50% of patients do not improve significantly with standard pharmacologic treatment alone (19). An integrated biopsychosocial approach that includes both non-pharmacological and pharmacological therapies improves outcomes in FM patients (20-29). The typical

components of multidisciplinary programmes for FM include educational, cognitive and behavioural strategies, physical training (30), and medication (19, 30, 31), though not all of these strategies may be employed (33, 34). The objective of these approaches is to decrease the level of pain and improve general functioning.

Several studies of integrated therapies have been conducted, with promising results (33-36). One systematic review concluded that multicomponent therapy is effective for decreasing pain and the overall impact of FM (37). It must be noted, however, that some of these studies did not included control groups, which complicates interpretation of the results (35, 36). To date, pharmacological treatment remains the primary option offered to Spanish FM patients. Taking into account the prevalence and the substantial cost of care – approximately €10,000 per patient year (38) – it is important to develop and implement multidisciplinary FM treatments that are methodologically rigorous and that overcome the limitations of previous studies (33-36). A recent meta-analysis (39) concluded that there is strong evidence that multimodal therapy reduces some key symptoms of FM measured during the treatment programme, but these beneficial effects decline with time. Another systematic review concluded that the benefits of multidisciplinary therapy are limited and disappear over time (28).

We developed an interdisciplinary treatment for FM based on the biopsychosocial model (40) that combines coordinated PSYchological, Medical, Educational, and PHYsiotherapeutic components (PSYMEPHY). To assess its efficacy, we instituted a prospective, randomised, controlled clinical trial aimed to assess changes over time in biopsychosocial health and quality of life among FM patients recruited from a hospital pain management unit who received the intervention compared with those who received usual care.

Material and methods

Participants

The study population was drawn prospectively 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 our hospital, between 5%and 10% of patients newly diagnosed with FM are referred to the pain management unit. Between 2007 and 2009, 194 patients were referred to the 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 point sites (1). Other eligibility criteria included age >18 years and having had continuous chronic pain for at least 6 months. Patients were excluded if they declined to participate in the study, were suffering from a severe psychiatric (psychosis or suicide risk) or organic disorder, or were involved in employment-related legal proceedings related to their FM. All participants in the trial were required to sign an informed consent form.

Based on the literature (41), we estimated *a priori* that a sample size of 58 in each group would have 80% power to detect a difference in means in the total score of the Fibromyalgia Impact Questionnaire (FIQ) of 5,000 (the difference between a Group 1 mean, μ_1, of 10,000 and a Group 2 mean, μ_2, of 5,000) assuming that the common standard deviation is 9,500 using a two-group *t*-test with a 0,050 two-sided significance level. Beta=61%.

Study design and interventions

FM patients attending the pain management unit were contacted by telephone. An investigator explained the purpose, objectives, and methodology of the study, and invited them to participate. 180 agreed to participate voluntarily in the research. Once the sample was determined, a list of random numbers was developed by the statistician, so that patients could be randomly assigned to the experimental (EG) or control group (CG). Randomisation was made by means of an electronic numbers generator (SPSS).

Patients in the CG received what is currently the standard pharmacologic care for FM in Spain. This included pharmacological treatment with a tricyclic antidepressant (amitriptyline, maximum dose of 75mg/24h), an analgesic (paracetamol, maximum dose of 4gr/24h), and an opioid central analgesic (tramadol, maximum dose of 400mg/24h).

Patients in the EG received the same pharmacologic treatment. They also participated in 6 weeks of PSYMEPHY delivered by a team that included a physician, a clinical psychologist, and a physiotherapist experienced in chronic pain management. Each team member had extensive experience in treating chronic pain in patients with and without FM. Patients in the PSYMEPHY group were divided into groups of 12 individuals. The same treatment team managed all of the groups. Each patient attended twice-weekly group sessions of 105 minutes for 6 weeks (a total of 12 sessions). During each 6-week series, one of the sessions consisted of 1 hour with a psychologist plus 45 minutes of educational activities with a physician and psychologist. Another session included 1 hour with a psychologist plus 45 minutes with a physiotherapist. The treatment programme followed a protocol written by three members of our team under the supervision of the pain management unit and the rheumatology and psychiatry services of Hospital Galdakao-Usansolo, based on the cognitive-behavioural treatment developed by Philips (42). Patient attendance was recorded at each session.

The psychological component of PSYMEPHY was focused around cognitive-behavioural therapy (CBT) interventions developed in line with the recommendations of Bennett and Nelson (43). The CBT component, administered by a PhD-qualified psychologist, targeted three domains: cognitive, physiological, and behavioural. At the cognitive level, the intervention was

designed to help patients identify and challenge overly negative pain-related thoughts and to replace them with more adaptive coping thoughts. At the physiological level, patients were trained to perform diaphragmatic breathing and progressive muscle relaxation. At the behavioural level, patients were trained in communication skills to enhance appropriate assertiveness and strengthen interactions with healthcare providers and others. They were also trained in appropriate behavioural pacing of activities in order to avoid excessively high or low levels of activity. The group sessions had the following structure: 1) a brief summary of the topics covered in the previous session and discussion of activities carried out at home; 2) introduction of the topic for the current session; 3) practical exercises and other activities on the topic of the day, as well as practicing breathing and relaxation exercises; and 4) an explanation of the tasks to be carried out at home during the following week.

The educational component of the intervention addressed topics related to the characteristics of FM such as the nature of the condition, its usual course, treatment possibilities, appropriate organisation of daily activities (including the gradual increase of intensity and planning of breaks), and the physician-patient relationship. Also explored were the mechanisms and the psychology of pain (gate control concept, learning processes, and psychosocial influences) in order to give patients a basis for understanding and applying self-control techniques. In addition, patients were given the opportunity to discuss the impact of FM on their lives and to ask questions of their peers and staff.

For the physiotherapeutic component, patients performed warming and stretching exercises. The physical therapy session focused on the benefits of exercise and provided the rationale for a regular exercise programme. Exercise and stretching routines were demonstrated and practiced during the session. Training focused on activity modification principles, such as working at a moderate pace, frequent position changes, and resting before fatigue sets in.

After the 6-month follow-up assessment, patients in the CG were offered the PSYMEPHY treatment.

The study was approved by the Research and Ethics Committee of the Hospital Galdakao-Usansolo.

Instruments and data collection

Sociodemographic data were collected by a physician of the pain management unit. The self-administered questionnaires were collected by a researcher who was not involved in providing treatment.

Sociodemographic data collected 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.

The primary outcome measure was the Fibromyalgia Impact Questionnaire (FIQ), to assess the impact of FM on health-related quality of life (HRQoL) (44-46). 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 (47). This questionnaire is considered to have a good reliability and validity, justifying its use in clinical practice and research (48). A version of the FIQ has been translated into and validated in Spanish (46).

Secondary outcomes included the Hospital Anxiety and Depression Scale (HADS), a 14-item instrument used to screen for anxiety and depression in non-psychiatric settings (49). It is divided into two subscales, one evaluating symptoms of anxiety, the other evaluating symptoms of depression. A subscale score of 0 to 7 indicates absence of anxiety or depression, a score of 8 to 10 indicates possible anxiety or depression, and a score of 11 or above indicates the presence of anxiety or depression. The validity and reliability of the HADS has been confirmed (50), and the instrument has been adapted and validated in a Spanish population (51). To gauge patients coping skills, we used the Coping with Chronic Pain Questionnaire (CAD-R) (52), a self-administered instrument for assessing coping strategies among patients with chronic pain. It includes 24 items grouped into 2 scales: active and passive coping. Responses for each item are scored on a 5-pointLikert scale. The higher the value, the more likely a patient uses that coping strategy. The psychometric characteristics of this questionnaire have been evaluated by the authors showing appropriate values (52, 53) and satisfactory reliability of the scales. We created an ad-hoc satisfaction scale to assess patients' opinions of the treatment they received. It consists of one question, "Are you satisfied with the treatment?" to be answered on a 5-point Likert scale.

PSYMEPHY patients completed all of these instruments at baseline and 6 weeks upon completion of the intervention, 6 months, and 12months after the interdisciplinary treatment; control patients completed them at baseline and again at 6 months.

Statistical analysis

Frequencies and percentages were calculated for categorical data and mean and standard deviations for continuous variables. To compare baseline data in the EG and CG groups, we used the Student's *t*-test and the Chi-square or Fisher's exact test.

Change in the outcomes (physical functioning, pain score, and total score of the FIQ questionnaire; anxiety and depression measured by the HADS; and scores on the active and passive coping scales of the CAD-R) at 6 months after treatment was defined as the difference in value between baseline and 6 months after treatment. For the mean comparison between baseline and 6 months, the Wilcoxon non-parametric test for independent samples was used. To estimate the magnitude of important changes in the analysed measures, Cohen's effect size (ES) with confidence intervals at 95% was calculated (54). A positive ES favours the EG. The Chi Square test was used to evaluate the difference in satisfaction with the treatment in both groups.

We also performed an evolutive analy-

sis of the outcomes in the EG. At each measurement point we calculated means and standard deviations. Linear mixed models were then developed to evaluate the effect of the treatment over the follow-up period. In addition, we graphed the evolution plots.

Effects were deemed statistically significant if the *p*-value was <0.05. All statistical analyses were performed using SAS System version 9.2 (SAS Institute, Inc., Carey, NC). Graphs were depicted by R release 2.12.

Results

A total of 180 patients were randomised, while 110 completed the study at 6 months (Fig. 1). Sociodemographic and clinical variables of the participants are described in Table I. Of the 110 patients who completed all of the instruments at baseline and 6 months, 90.91% were women, the mean age was 50 years (SD=9.26), 53.64% were employed, and 20% were non-paid workers, such as homemakers. Mean time since the onset of pain was 14.13 years (SD=10.01), with a range of 1 to 40 years. No statistically significant differences were observed in any of these variables between the PSYMEPHY and control groups at baseline. In addition, no significant differences were observed among baseline variables between patients who did not complete the FIQ at 6 months (n=43) and those who did (n=110).

Table II shows differences in biopsychosocial variables between baseline and six months in the PSYMEPHY and control groups. Among control patients, we found statistically significant differences indicating ongoing impairment in the FIQ subscores for physical functioning (p=0.04), and pain (p=0.01). In the PSYMEPHY group, we found statistically significant differences indicating ongoing improvement in the total FIQ score (p=0.006), and the use of active coping strategies (p=0.04). There were no statistically significant differences for HADS scores in the PSYMEPHY or control groups 6 months after treatment.

Between baseline and 6 months, patients in the PSYMEPHY group improved significantly more than those in the CG as measured by changes in the total FIQ score (p=0.04), as well as the physical functioning (p=0.01) and pain (p=0.03) FIQ subscores. In these variables, the effect sizes for the change in the PSYMEPHY group were notably higher than 0.20 (Table II). Change in the HADS scores between baseline and 6 months were not significantly different between the PSYMEPHY and control groups (Table II). Patients receiving the multimodal intervention were more satisfied with their treatment than control patients, who received only standard pharmacologic therapy (Table III).

Twelve months after the intervention, patients in the PSYMEPHY group maintained statistically significant changes in the total FIQ score, physical function, and pain (Fig. 2a), but not with the use of active coping strategies. There were statistically significant improvements in anxiety and depression compared to baseline (Fig. 2b). There was also a statistically significant decrease in the use of passive coping strategies (Fig. 2c) (Table IV).

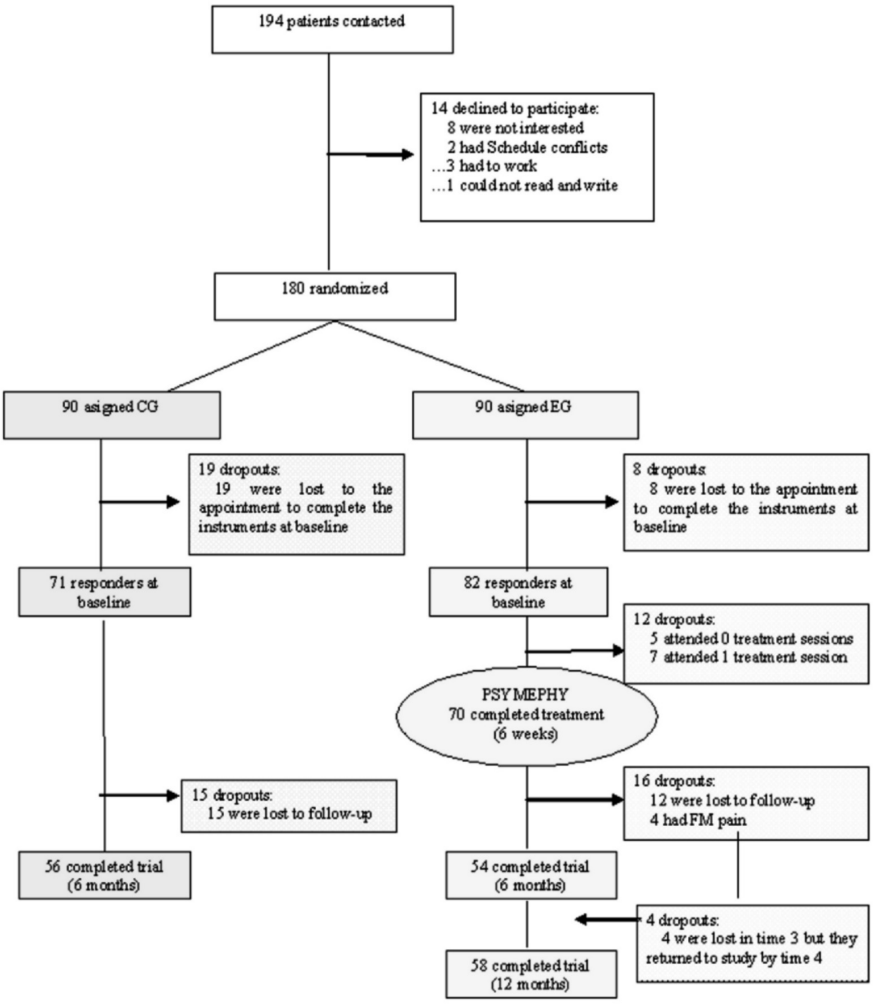

Fig. 1. Flow chart of the sample of patients with fibromyalgia.
Note. CG: Control Group; EG: Experimental Goup; PSYMEPHY: Interdisciplinary treatment.

Discussion

In a prospective, randomised, controlled clinical trial conducted in a group setting in a hospital environment, an intervention for FM that combined coordinated psychological, medical, educational, and physiotherapeutic therapy significantly improved HRQoL, physical function, and pain, and increased the use of active coping pain strategies, 6 months after the completion of treatment. Patients also reported begin quite satisfied with the treatment. In comparison, control patients who received only standard pharmacologic therapy showed a continuous deterioration in

Table I. Baseline data on patients with fibromyalgia who completed the instruments 6 months after the intervention.

	Total patients (n=110)	Control group (n=56)	Experimental group (n=54)	
	n (%)	n (%)	n (%)	*p*-value
Sex				0.95
Female	100 (90.91)	51 (91.07)	49 (90.74)	
Male	10 (9.09)	5 (8.93)	5 (9.26)	
Age (years) $\bar{x}$ (SD)	50.15 (9.26)[a]	51.57 (9.65)[b]	48.68 (8.68)[c]	0.07
Marital status				0.28
Single	5 (4.55)	3 (5.36)	2 (3.70)	
Married	94 (85.45)	45 (80.36)	49 (90.74)	
Separated or divorced	8 (7.27)	5 (8.93)	3 (5.56)	
Widow/Widower	3 (2.73)	3 (5.36	0 (0.00)	
Level of education				0.10
Primary education	62 (56.36)	37 (66.07)	25 (46.30)	
Secondary education	37 (33.64)	14 (25.00)	23 (42.59)	
First university degree or above	11 (10.00)	5 (8.93)	6 (11.11)	
Employment status				0.22
Active	59 (53.64)	25 (44.64)	34 (62.96)	
Non-paid work	22 (20.00)	13 (23.21)	9 (16.67)	
Disabled	16 (14.55)	11 (19.64)	5 (9.26)	
Retired	13 (11.82)	7 (12.50)	6 (11.11)	
Physical illnesses				
Hypothyroidism	13 (11.82)	4 (7.14)	9 (16.67)	0.12
Hypertension	11 (10.00)	8 (14.29)	3 (5.56)	0.13
COPD	13 (11.82)	6 (10.71)	7 (12.96)	0.71
Diabetes mellitus	3 (2.73)	1 (1.79)	2 (3.70)	0.54
Rheumatoid arthritis	3 (2.73)	2 (3.57)	1 (1.85)	0.58
Other	46 (41.82)	20 (35.71)	26 (48.15)	0.19
Years since the onset of pain $\bar{x}$ (SD)	14.13 (10.01)	13.5 (10.09)	14.78 (9.97)	0.41
Presence of 18 tender points	46 (45.54)	21 (40.38)	25 (51.02)	0.28

Note. $\bar{x}$: mean; SD: standard deviation. [a]Overall age range, 29-70 years; [b]CG age range, 29-69 years; [c]EG age range, 31-70 years. COPD: Chronic Obstructive Pulmonary Disease. The Chi-square or Fisher's exact test were used for comparing qualitative variables, while the Student's *t*-test for independent samples was used for quantitative variables. *p*-value: Comparisons performed for CG *vs*. EG. Level of significance $p<0.05$.

physical function and pain during the follow-up period. Twelve months after the completion of treatment, most improvements observed in the PSYMEPHY group were maintained, with the exception of the use of active coping skills. Interestingly, at 12 months patients in the PSYMEPHY group reported statistically significant improvements in anxiety and depression and a decrease in the use of passive coping skills.

Our results are in line with previous studies (33, 37, 39, 55, 56) showing that multimodal therapy is effective for decreasing FM-related pain and the impact of FM on quality of life at the conclusion of the treatment. They contradict other studies (28, 39) that found no evidence long-term efficacy of multidisciplinary therapy on FM symptoms.

Six months after completing the interdisciplinary PSYMEPHY treatment, patients receiving the intervention reported a reduced impact of FM on HRQoL. This corresponds with findings of other studies of multimodal treatments in which HRQoL was also assessed using the FIQ (31, 57-60). Furthermore, the effect size of the impact of FM on HRQoL in our intervention group compared to controls was 0.45, slightly larger than the value of 0.32 reported by Mannerkorpi *et al*. (60).

Pain scores were also lower at 6 months among FM patients who received the PSYMEPHY intervention than among controls. Other studies have found improvements in perceived pain after a psychoeducational intervention. For example, Keel *et al*. (61) studied 27 patients, some of whom received a 15-week intervention that included once-weekly outpatient sessions that included cognitive-behavioural therapy, physical exercise, and information. They reported a reduction in pain at 3 months after the completion of the intervention compared to control patients who received only relaxation training. Lemstra and Olzynsky (26) also observed a reduction in pain among patients receiving cognitive-behavioural therapy and physical exercise for 6 weeks on an outpatient basis, compared to control patients.

Even though overall HRQoL improved in our study, we did not observe any improvement in anxiety or depression at 6 months. This is in agreement with findings of Rivera *et al*. (46), who reported no significant improvements in symptoms of anxiety and depression after an 8-week intervention consisting of either cognitive-behavioural therapy or a programme based on physical exercise, since the efficacy of cognitive-behavioural therapy on pain and HRQoL in patients with FM is not as satisfactory as multimodal therapy (62). Other investigators have reported similar results (25, 58). Some researchers, however, have observed significant improvements in anxiety (although they did not persist to the end of the follow-up period) (63) and depression (26). Overall, it seems that having symptoms of anxiety and/or depression does not prevent FM patients from improving in other respects, such as a decrease in pain or an increase in HRQoL, as observed in our study and others (25, 36, 64, 65).

Active coping strategies have been suggested to be the most appropriate for FM patients (66). PSYMEPHY patients used active coping strategies at 6 months more than did control patients. This is similar to the findings of Torre *et al*. (67), in which the use of passive coping was associated with a greater degree of maladjustment among patients on usual treatment after 6 months. Patients in our study, for example, expressed the use of active cop-

Table II. Treatment outcomes. Difference between baseline and six months.

	Control group $\bar{x}$ (SD)	*p*-value	Experimental group $\bar{x}$ (SD)	*p*-value	*p*-value of change	Effect size [95% CI]
Total FIQ score						
Baseline	76.23 (14.88)	0.87	76.28 (13.57)	**0.006**		
6 months after the PSYMEPHY	76.81 (14.18)		70.33 (16.48)			
Change	0.58 (13.57)		-5.95 (15.58)		**0.04**	0.45 [0.07, 0.83]
Physical functioning (FIQ)						
Baseline	5.40 (1.76)	**0.04**	5.47 (1.87)	0.15		
6 months after the PSYMEPHY	5.92 (1.84)		5.19 (1.83)			
Change	0.52 (1.83)		-0.27 (1.38)		**0.01**	0.50 [0.11, 0.87]
Pain (FIQ)						
Baseline	7.53 (2.19)	**0.01**	7.51 (1.97)	0.45		
6 months after the PSYMEPHY	8.22 (1.62)		7.24 (2.17)			
Change	0.71 (2.06)		-0.25 (2.31)		**0.03**	0.45 [0.05, 0.83]
Anxiety (HAD)						
Baseline	13.39 (3.45)	0.08	13.83 (3.39)	0.40		
6 months after the PSYMEPH	12.75 (4.55)		13.41 (4.31)			
Change	-0.64 (2.93)		-0.42 (3.62)		0.72	-0.07 [-0.44, 0.31]
Depression (HAD)						
Baseline	10.57 (4.06)	0.31	10.63 (4.51)	0.11		
6 months after the PSYMEPH	10.2 (4.22)		9.77 (4.09)			
Change	-0.32 (2.39)		-0.85 (3.86)	0.19		0.17 [-0.21, 0.54]
Active coping (CAD-R)						
Baseline	32.09 (10.58	0.98	31.32 (9.15)	**0.04**		
6 months after the PSYMEPHY	31.98 (10.41)		33.76 (8.79)			
Change	0.01 (8.18)		2.17 (7.40)		0.16	-0.28 [-0.66, 0.11]†
Passive coping (CAD-R)						
Baseline	11.70 (7.81)	0.26	9.08 (6.56)	0.41		
6 months after the PSYMEPHY	10.89 (7.86)		10.10 (6.83)			
Change	-0.78 (5.15)		0.77 (5.06)		0.11	-0.32 [-0.69, 0.07]†

Note. $\bar{x}$: mean; SD: standard deviation; FIQ: Fibromyalgia Impact Questionnaire, a higher score representing a greater impact: 50–69= average to high impact; ≥70: severe impact; CAD-R: Spanish Pain Coping Questionnaire; HADs: The Hospital Anxiety and Depression Scale. We used the Student *t*-test (t) or non-parametric test of Wilcoxon (Z) for quantitative variables for 2 independent samples; CG (n=56) and EG (n=54). Change: difference between baseline and 6 months after the treatment between EG and CG. §: comparisons of change; ES: effect size (0.20=small effect; 0.50=medium effect); positive ES favours the EG; negative ES favours the CG; †: negative ES favours the EG; [95% CI]: confidence interval at 95%; *p*-values in bold indicate a significance level of $p<0.005$.

ing strategies by using statements such as "I have learned to ask less of myself and to have more self-esteem as well as to cope with day-to-day activities more safely and with more patience."

FM patients often feel frustrated and dissatisfied with the treatment they receive (68). In our study, patients reported that they were satisfied with the PSYMEPHY treatment. Our results are consistent with those reported by Cedraschi *et al.* (33) – patients who participated in a programme combining exercise in a heated swimming pool and education showed greater satisfaction with their treatment than control patients. This is an important outcome, since satisfied patients are more likely to cooperate with their doctors and participate in their own treatment (69, 70).

Follow-up 12 months after the intervention had ended showed that patients receiving the PSYMEPHY intervention maintained statistically significant improvements in HRQoL, physical functioning, and pain, and reductions in the use of passive coping skills. Of note, although no improvements in anxiety and depression were observed at 6 months, there was a significant reduction in these at 12 months. Improvements in anxiety and depression at 12 months, but not at 6 months, could be attributed to the fact that the PSYMEPHY intervention diminishes the impact of FM on HRQoL, which may gradually translate into less anxiety and depression. A recent meta-analysis (39) concluded that there is strong evidence of the efficacy of multidisciplinary therapy to reduce some key symptoms of FM, but these positive effects are not maintained at 6 or 12 months. Therefore, an important finding in our study is that patients maintain over time improvements in biopsychosocial symptoms achieved with the PSYMEPHY treatment.

Strengths of our study include the employment of a randomised trial design, inclusion of a CG, a reasonable sample size, and measurements at baseline, 6 months, and 12 months. Our assessment at 6 months produced highly satisfactory results, both in terms of statistical significance and magnitude of change. The 12-month follow-up demonstrated maintenance of some of the improvements seen at 6 months. We believe that it was ethically important to have offered the PSYMEPHY intervention to control patients after the 6 month follow-up, given the benefits observed among patients receiving the multimodal therapy. We plan to analyse the effects of the interdisciplinary treatment in the control patients who were later offered the PSYMEPHY intervention.

Limitations of the study must also be noted. All participants were selected from patients referred to a hospital pain management unit, which could limit the generalisation of our findings. It is possible that our patient sample may have been experiencing a greater impact of FM on HRQoL than patients treated in primary care. It would be important to investigate whether the interdisciplinary treatment is as successful in a wider context, such as in primary care centres. Another limitation is that

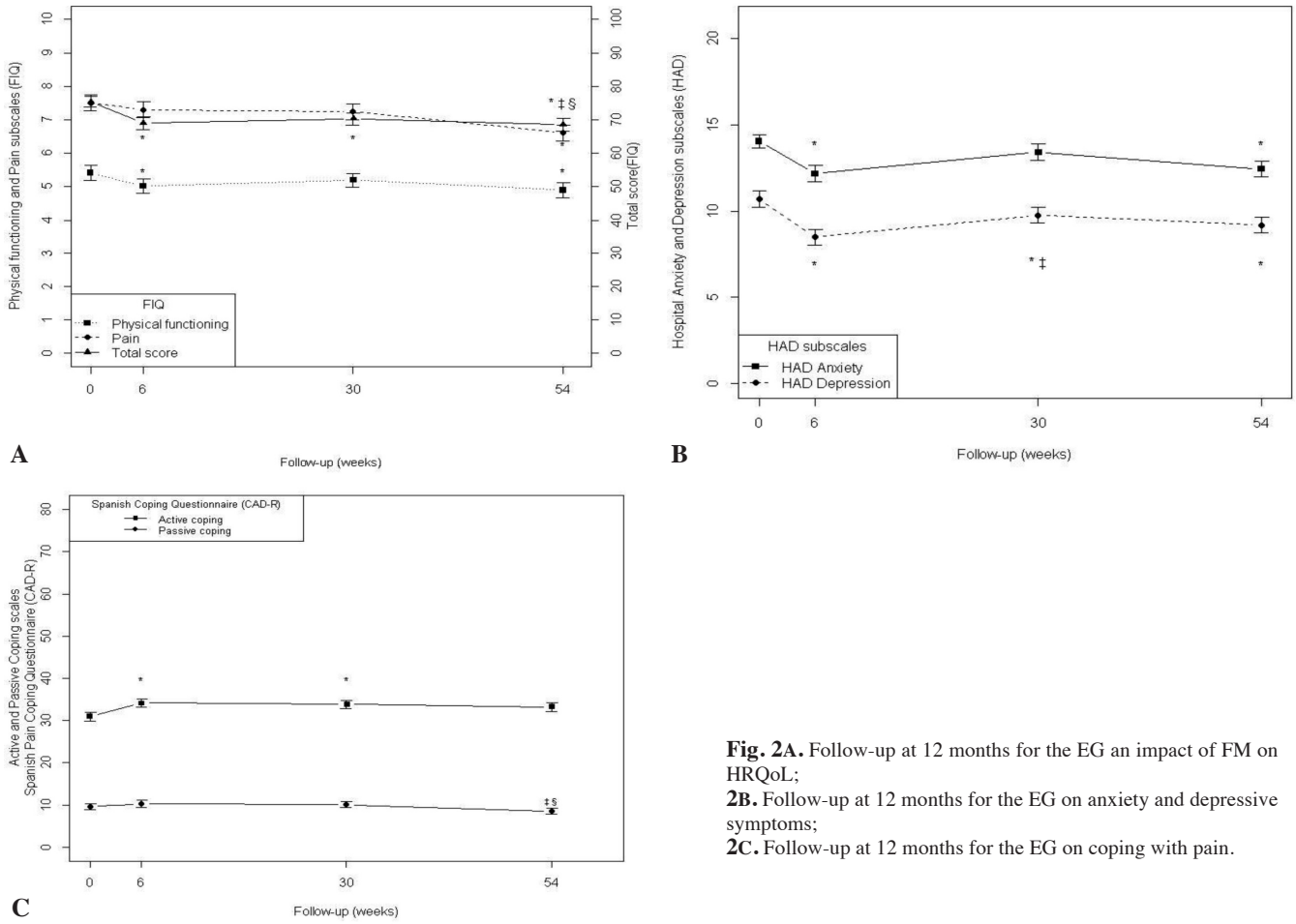

Fig. 2A. Follow-up at 12 months for the EG an impact of FM on HRQoL;
2B. Follow-up at 12 months for the EG on anxiety and depressive symptoms;
2C. Follow-up at 12 months for the EG on coping with pain.

comparisons were not made between the PSYMEPHY and control groups at the 12-month follow-up. Control patients were not asked to complete the questionnaires at 12 months because, after seeing the intermediate results at 6 months, we thought that it was ethically important to offer them the PSYMEPHY intervention. It would be useful to compare the effectiveness of this treatment over 12 months or longer between EG and CG. Another limitation is that, characteristic of the FM patient population, females were over-represented in our sample and the extent to which our findings would generalise to men with FM is unclear. There is no internationally accepted definition of multidisciplinary therapy for FM. In designing the PSYMEPHY intervention, we relied on existing systematic reviews which agree that multimodal therapy for FM should include at least 1 psychological or educational therapy and at least 1 exercise intervention (39). Future studies of follow-up assessments should examine the PSYMEPHY treatment in varying contexts to determine the direct and indirect costs of the intervention, as well as the savings that might accrue from it, which are of crucial importance for policymakers.

In summary, our results suggest it could be especially valuable to offer this interdisciplinary treatment in hospital pain management units. Pain units are the last step of the health system for patients with FM, whose treatment in our country is only pharmacologic, while in other countries like Germany -whose updated guideline recommends

Table III. Satisfaction with the treatment at 6 months.

	6 months after the treatment				
	Total patients (n=110)	Control group (n=56)	Experimental group (n=54)		
Satisfaction with the treatment	n (%)	n (%)	n (%)	Statistic test	*p*-value
				$\chi^2_{(4)}$=30.62	**<0.0001**
Not satisfied	6 (5.83)	6 (12.00	0 (0.00)		
Only somewhat satisfied	31 (30.10)	24 (48.00)	7 (13.21)		
Moderately satisfied	14 (13.59)	7 (14.00)	7 (13.21)		
Very satisfied	44 (42.72)	13 (26.00)	31 (58.49)		
Completely satisfied	8 (7.77)	0 (0.00)	8 (15.09)		

Note. The Chi-square(χ^2) test was used for comparing qualitative variables for independent samples. *p*-values in bold indicate a significance level of $p<0.05$.

Table IV. Follow-up at 12 months in the Experimental group.

	Evaluation times for the Experimental group			
	Baseline (n=82)	6 weeks (n=70)	6 months (n=54)	12 months (n=58)
	$\bar{x}$ (DT)	$\bar{x}$ (DT)	$\bar{x}$ (DT)	$\bar{x}$ (DT)
Total FIQ score	75.38 (13.93)	69.00 (17.46)*	70.33 (16.48)*	68.53 (17.82)*
Physical functioning (FIQ)	5.42 (1.99)	5.02 (2.03)*	5.19 (1.83)	4.90 (2.10)*
Pain (FIQ)	7.50 (2.11)	7.31 (2.13)	7.24 (2.17)	6.61 (2.13)*‡§
Anxiety (HAD)	14.04 (3.30)	12.16 (4.33)*	13.41 (4.31)	12.43 (4.14)*
Depression (HAD)	10.71 (4.21)	8.51 (4.09)*	9.77 (4.09)*‡	9.21 (3.97)*
Active coping (CAD-R)	30.86 (9.55)	34.09 (8.24)*	33.77 (8.79)*	33.16 (9.54)
Passive coping (CAD-R)	9.59 (6.87)	10.29 (7.32)	10.10 (6.83)	8.49 (6.42)‡§

Note. $\bar{x}$: mean; SD: standard deviation; FIQ: Fibromyalgia Impact Questionnaire; total FIQ score (0–100); 50-69: average to high impact; ≥70: severe impact; HADs: The Hospital Anxiety and Depression Scale; CAD-R: Spanish Pain Coping Questionnaire; Lineal Mixed Models and the F-Fisher test were used. *p*-values in bold indicate a significance level of $p<0.05$. *: $p<0.05$ compared to baseline; ‡: $p<0.05$ compared to the 6 weeks time; §: $p<0.05$ compared to the 6 months time. n=54 for EG baseline and 6 months, n=56 for CG baseline and 6 months.

cognitive-behavioural therapy only in combination with aerobic exercise (71) and prefers multicomponent treatment (73) – inpatient multicomponent therapy is reimbursed by health insurance companies (61). Fibromyalgia is a frustrating condition for patients to have and for physicians to treat. Our finding that the PSYMEPHY treatment is effective and provides long-lasting improvements offers an incentive to develop and study similar treatment programmes.

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