Evaluation of the Interdisciplinary PSYMEPHY Treatment on Patients with Fibromyalgia: A Randomized Control Trial

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Abstract

Objective. Fibromyalgia (FM) is a chronic disorder that can have a devastating effect on patients’ lives. This study assessed the efficacy of a 6-week interdisciplinary treatment that combines coordinated PSYchological, Medical, Educational, and PHYsiotherapeutic interventions (PSYMEPHY) compared with standard pharmacologic care.

Design. The study was a randomized controlled trial (54 participants in the PSYMEPHY group and 56 in the control group [CG]) with follow-up at 6 months. PSYMEPHY patients were also assessed at 12 months. The main outcomes were changes in total Fibromyalgia Impact Questionnaire (FIQ) score, pain, fatigue, morning tiredness, anxiety, and use of pain coping strategies as measured by the FIQ, the visual analog scale, and the Coping with Chronic Pain Questionnaire. After the 6-month assessment, patients in the CG were offered the PSYMEPHY treatment, and completed all of the instruments immediately after treatment, and at 6- and 12-month follow-up visits (N = 93).

Setting. Subjects received therapy at two different outpatient clinical locations.

Patients. Fibromyalgia patients.

Results. Six months after the intervention, significant improvements in total FIQ score (P = 0.04), and pain (P = 0.03) were seen in the PSYMEPHY group compared with controls. Twelve months after the intervention, all patients in the PSYMEPHY group maintained statistically significant improvements in total FIQ score, and pain, and showed an improvement in fatigue, rested, anxiety, and current pain compared with baseline. Data from the control patients who underwent the PSYMEPHY intervention corroborated the initial results.

Conclusions. This study highlights the beneficial effects of an interdisciplinary treatment for FM patients in a hospital pain management unit. A 6-week interdisciplinary intervention showed significant improvement in key domains of fibromyalgia, as quality of life, pain, fatigue, rested, and anxiety at 12 months.

Key Words. Fibromyalgia; Interdisciplinary Treatment; Randomized Trial

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Introduction

Fibromyalgia (FM) is a chronic disorder characterized by widespread pain and exaggerated tenderness on palpation in at least 11 of 18 tender point sites [1]. 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. FM is associated with fatigue, poor sleep, other functional somatic syndromes, and mental and physical disorders [2–4]. It mainly affects women, with new diagnoses peaking between the ages of 40 and 49 years [5]. In Spain, the prevalence of FM is 2.4% [6]. This is in keeping with estimates of 2.9% in five European countries [7] and 2% in the United States [8].

The characteristics of FM, such as its complex and unknown etiology, wide range of symptoms and signs, and multiple comorbidities make identifying effective therapies particularly difficult. Despite the chronicity and complexity of FM, there are pharmacological and nonpharmacological interventions available that have clinical benefits [9]. Nevertheless, there is no consensus on the best therapeutic approach, and treatment of FM is a challenge for clinicians [10]. Instead, an integrated biopsychosocial approach that includes both nonpharmacological and pharmacological therapies improves outcomes [11–21]. Multidisciplinary programs for FM typically include educational, cognitive, and behavioral strategies, physical training, and medication [9,22,23]. The most effective interdisciplinary approach, however, is unknown. Although several studies of integrated therapies have been conducted, with promising results [24–27], some did not include a cognitive-behavioral component [24,26] or a control group [25,27]. One systematic review concluded that multicomponent therapy is effective for decreasing FM impact [9]. While one recent meta-analysis [14] has concluded that there is strong evidence of the efficacy of multicomponent therapy to reduce some key symptoms of FM at post-treatment, but these beneficial effects decline with time, another systematic review concluded that the benefits of multidisciplinary therapy are limited and disappear over time [21].

Taking into account the prevalence and the substantial cost of care—approximately €10,000 per patient year [28]—it is important to develop and implement multidisciplinary FM treatments that are methodologically rigorous and that overcome the limitations of previous studies [24–27].

We developed an interdisciplinary treatment for FM based on the biopsychosocial model [29] that combines coordinated PSYchological, Medical, Educational, and PHYsiotherapeutic components (PSYMEPHY). To assess its efficacy, we instituted a prospective, randomized, controlled clinical trial designed to assess changes over time in biopsychosocial health and quality of life among FM patients recruited from a hospital pain management unit.

Methods

Subjects

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, it is estimated that between 5% and 10% of patients newly diagnosed with FM are referred to the pain management unit. Between 2007 and 2009, 194 FM patients were referred to this unit, primarily from the departments of internal medicine and trauma.

To be eligible for the study, a patient must have been classified 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 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 to be included in the study.

Based on the literature [30], 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 5.0 (the difference between a Group1 mean, μ1, of 10.0 and a Group2 mean, μ2, of 5.0) assuming that the common standard deviation is 9.5 using a two-group t-test with a 0.05 two-sided significance level and Beta = 61%.

For ethical issues, once the investigation was completed (at the conclusion of the 6-month follow-up assessment), the control patients were invited to receive the interdisciplinary PSYMEPHY treatment. Of the 56 control patients who were offered the treatment, 38 agreed to participate (Figure 1).

Study Design and Interventions

A total of 194 patients with FM were contacted by telephone. An investigator explained the purpose, objectives, and methodology of the study, and invited them to participate. Of these, 180 agreed to take part in the trial (92.8% response rate). Once the sample was determined, patients were randomly assigned to the control group (CG, N = 90) or the experimental group (EG, N = 90). Randomization was made by means of an electronic number generator. 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
75 mg/24 hour), an analgesic (paracetamol, maximum dose of 4 g/24 hour), and an opioid central analgesic (tramadol, maximum dose of 400 mg/24 hour).

Patients in the EG1 received the same standard medical care. They also received 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 treating chronic pain in patients with and without FM. The treatment program 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-Ussansolo, based on the cognitive-behavioral treatment developed by Philips [31]. Patients in the EG1 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 the psychologist plus 45 minutes of educational activities with a physician and a psychologist;
The study was approved by the Research and Ethics Committee of the Hospital Galdakao-Usansolo (NCT 01266733).

**Instruments and Data Collection**

At baseline, a physician associated with the pain management unit recorded socio-demographic 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. Self-administered questionnaires were collected by a researcher who was not involved in providing treatment.

Patients completed the FIQ [33–35] as a disease-specific health-related quality of life (HRQoL). This validated instrument uses visual analog 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 impairment [36]. This questionnaire is considered to have a good reliability and validity, justifying its use in clinical practice and research [37]. A version of the FIQ has been translated into and validated in Spanish [35].

The visual analog scale (VAS) was used to assess pain intensity. The VAS is based on 10 degrees of pain intensity, ranging from the absence of pain (score 0) to the strongest pain one can imagine (score 10). The intensity of pain can be mild (≤3), moderate [4–6], or severe (≥7). This categorization is commonly used in the field of pain control and specifically in fibromyalgia [40]. The VAS is easy to use and quick to complete, and has proven reliable and valid as a measurement of pain intensity [41]. It has also been shown to be sensitive to changes in pain associated with treatment [42].

To gauge patients’ coping skills, we used the Coping with Chronic Pain Questionnaire (CAD-R) [43], a self-administered instrument for assessing coping strategies among patients with chronic pain. It includes 24 items grouped into two scales: active and passive coping. Responses for each item are scored on a 5-point Likert scale. The higher the value, the more likely a patient uses that coping strategy. The CAD-R has been shown to have good psychometric properties [43,44] and satisfactory reliability.

EG1 patients completed all of these instruments at baseline and then 6 weeks, 6 months, and 12 months after the interdisciplinary treatment. CG patients completed them at baseline and again 6 months later. After this last measurement, the EG2 received the interdisciplinary treatment and also completed all of the instruments at 6 weeks, 6 months, and 12 months.

**Statistical Analysis**

Baseline socio-demographic and clinical characteristics of the EG1 and CG groups were computed using mean and
standard deviations for continuous variables and frequencies and percentages for qualitative data. To assess the relationship between baseline data and treatment group, the nonparametric Wilcoxon test was used for continuous variables and the Chi-square test (or Fisher’s exact test when needed) for categorical data.

The outcomes of interest were changes in pain, fatigue, morning tiredness, anxiety, and total FIQ score; changes in perceived pain as determined by the VAS; and the use of active and passive coping strategies, as measured by the CAD-R questionnaire. Values of these scores at baseline and 6 months after the intervention were recorded and calculated using mean and standard deviations. Change on each scale was defined as the difference between the baseline data and 6 months measurements. A positive value represents an improvement. To evaluate statistical between-group mean change score differences, the Wilcoxon nonparametric test for independent samples was used. In the experimental group, we also calculated mean and standard deviations for all the above-mentioned scales at 12 months after the intervention. A longitudinal analysis for each scale was conducted to evaluate the effect of the PSYMEPHY treatment over time in different studied instruments. The outcome was assessed as the recorded values in all measurements from baseline to 12 months after the intervention. Follow-up time was taken as a random effect. This was performed using general linear mixed-effects models.

Effects were deemed statistically significant if \( P < 0.05 \). All statistical analysis were developed using SAS System version 9.2 (SAS Institute, Inc., Carey, NC).

Results

Patient Flow

The flow of patients through the study is shown in Figure 1. A total of 153 patients completed all of the instruments at baseline, and 110 completed the 6-week intervention. Patients in the CG were offered the interdisciplinary PSYMEPHY treatment after the 6-month follow-up evaluation; 38 CG patients completed the interdisciplinary treatment at 6 weeks, and 36 and 35 patients completed it at 6 and 12 months, respectively.

Baseline Characteristics of Fibromyalgia Patients

Characteristics of the patients who completed all the instruments at baseline are shown in Table 1. The CG and EG were similar in all variables, with no statistically significant differences. Overall, 93.5% of participants were women, and the mean age was 50 years \( (SD = 9.07) \). The mean time since the onset of pain was 13.4 years \( (SD = 9.9) \), and ranged from 1 to 40 years. No significant differences were observed among baseline variables between patients who did not complete the questionnaires at 6 months \( (N = 43) \) and those who did \( (N = 110) \), or among patients who completed the instruments 12 months after the intervention \( (EG_1 = 58, EG_2 = 36) \) and those who did not complete them \( (EG_1 = 24, EG_2 = 20) \).

Differences in Biopsychosocial Variables after the Intervention

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 \( (P = 0.04) \) and the pain FIQ subscale \( (P = 0.03) \) (Table 2). No significant differences were observed between the PSYMEPHY and control group in other variables, including fatigue, morning tiredness, anxiety, pain, and coping, between baseline and 6 months (Table 2).

Long-Term Changes in the PSYMEPHY Group

Twelve months after the intervention, patients in the PSYMEPHY group maintained statistically significant changes in the total FIQ score, pain, fatigue, morning tiredness, and anxiety (Table 3) but not with the use of active coping strategies.

Discussion

Among the patients with FM referred to a hospital pain management unit, undergoing the interdisciplinary PSYMEPHY was associated with improvements in pain, fatigue, morning tiredness, and anxiety. Given the positive results of the intervention, it would have been unethical to withhold it from the participants in the control group [45]. Thus, once the trial was completed, we provided the same interdisciplinary program to control group participants.

Similar results were observed in this group.

Our results are in line with previous studies [9,14,24,46] which concluded that a completed course of multicomponent therapy is effective for decreasing the impairment as well as improving pain, fatigue, morning tiredness, and anxiety. This agrees with the findings of other studies of multimodal treatments, which also used the FIQ [22,47–50].

Pain scores were lower at 6 months among FM patients who received the PSYMEPHY intervention than among controls. Other studies have demonstrated improvements in perceived pain after a psycho-educational intervention. For example, Keel et al. [51] studied 27 patients, some of whom received a 15-week intervention consisting of once-weekly outpatient sessions that included CBT, physical exercise, and education. They reported a reduction in pain at 3 months after the completion of the intervention compared with control patients who received only relaxation training. Lemstra and Ozlinsky [15] also observed a reduction in pain among patients receiving CBT and physical exercise for 6 weeks on an outpatient basis compared with control patients.

Even though total FIQ score improved in our study, we did not observe any improvement in anxiety at 6 months. This is in agreement with findings of Rivera and González [35].
who reported no significant improvements in symptoms of anxiety after an 8-week intervention consisting of either CBT or a program based on physical exercise. Other investigators have reported similar results [17,48]. In contrast, Nielson et al. [52] observed a significant improvement in anxiety, although they did not persist to the end of the follow-up period. Overall, it seems that having symptoms of anxiety does not prevent FM patients from improving in other respects, such as a decrease in pain or total FIQ score, as observed in our study and in others [17,27,53].

Patients receiving the PSYMEPHY intervention maintained statistically significant improvements in total FIQ score and pain, and reductions in fatigue and morning tiredness 12 months after the intervention had ended. Of note, although no improvements in anxiety were observed at 6 months, there was a significant reduction in it at 12 months. Improvements in anxiety at 12 months, but not at 6 months, could be attributed to the fact that the PSYMEPHY intervention diminishes the impairment, which may gradually translate into less anxiety. A recent meta-analysis [14] concluded that there is strong evidence for the effectiveness of multidisciplinary treatment in FM, supporting the findings of our study and others.

### Table 1

Data on patients with fibromyalgia who completed the Fibromyalgia Impact Questionnaire at the baseline

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Control Patients</th>
<th>Experimental Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N = 153)</td>
<td>(N = 71)</td>
<td>(N = 82)</td>
</tr>
<tr>
<td><strong>Age (years) X (SD)</strong></td>
<td>50.12 (9.07)†</td>
<td>51.33 (9.17)‡</td>
<td>49.07 (8.92)§</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>143 (93.46)</td>
<td>66 (92.96)</td>
<td>77 (93.90)</td>
</tr>
<tr>
<td>Male</td>
<td>10 (6.54)</td>
<td>5 (7.04)</td>
<td>5 (6.10)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>7 (4.58)</td>
<td>3 (4.23)</td>
<td>4 (4.88)</td>
</tr>
<tr>
<td>Married</td>
<td>128 (83.66)</td>
<td>56 (78.87)</td>
<td>72 (87.80)</td>
</tr>
<tr>
<td>Separated or divorced</td>
<td>12 (7.84)</td>
<td>7 (9.86)</td>
<td>5 (6.10)</td>
</tr>
<tr>
<td>Widow/Widower</td>
<td>6 (3.92)</td>
<td>5 (7.04)</td>
<td>1 (1.22)</td>
</tr>
<tr>
<td><strong>Level of education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary education</td>
<td>81 (52.94)</td>
<td>44 (61.97)</td>
<td>37 (45.12)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>58 (37.91)</td>
<td>20 (27.17)</td>
<td>38 (46.34)</td>
</tr>
<tr>
<td>College or above</td>
<td>14 (9.15)</td>
<td>7 (9.86)</td>
<td>7 (8.54)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>86 (56.21)</td>
<td>36 (50.70)</td>
<td>50 (60.98)</td>
</tr>
<tr>
<td>Nonpaid work</td>
<td>28 (18.30)</td>
<td>14 (19.72)</td>
<td>14 (17.07)</td>
</tr>
<tr>
<td>Disabled</td>
<td>24 (15.69)</td>
<td>14 (19.72)</td>
<td>10 (12.20)</td>
</tr>
<tr>
<td>Retired</td>
<td>15 (9.80)</td>
<td>7 (9.86)</td>
<td>8 (9.76)</td>
</tr>
<tr>
<td><strong>Physical illnesses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>18 (11.76)</td>
<td>6 (8.45)</td>
<td>12 (14.63)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>17 (11.11)</td>
<td>10 (14.08)</td>
<td>7 (8.54)</td>
</tr>
<tr>
<td>COPD</td>
<td>15 (9.80)</td>
<td>6 (8.45)</td>
<td>9 (10.98)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>6 (3.92)</td>
<td>2 (2.82)</td>
<td>4 (4.88)</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>4 (2.61)</td>
<td>2 (2.82)</td>
<td>2 (2.44)</td>
</tr>
<tr>
<td>Other</td>
<td>67 (43.79)</td>
<td>27 (38.03)</td>
<td>40 (48.78)</td>
</tr>
<tr>
<td><strong>Number of physical illnesses</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>53 (34.64)</td>
<td>25 (35.21)</td>
<td>28 (34.15)</td>
</tr>
<tr>
<td>One</td>
<td>63 (41.18)</td>
<td>26 (36.62)</td>
<td>37 (45.12)</td>
</tr>
<tr>
<td>Two or more (2–4)</td>
<td>37 (24.18)</td>
<td>20 (28.17)</td>
<td>17 (20.73)</td>
</tr>
<tr>
<td><strong>Years since onset of pain X (SD)</strong></td>
<td>13.44 (9.88)</td>
<td>12.36 (9.75)</td>
<td>14.37 (9.96)</td>
</tr>
<tr>
<td>Precipitating event in FM</td>
<td>69 (46.94)</td>
<td>31 (45.59)</td>
<td>38 (48.10)</td>
</tr>
<tr>
<td>Presence of tender points</td>
<td>18</td>
<td>58 (41.43)</td>
<td>23 (35.94)</td>
</tr>
</tbody>
</table>

N (%) = sample size (percentage); X = mean; SD = standard deviation.
† Overall range of age of patients = 29–70.
‡ Range of age of patients in the control group = 29–69.
§ Range of age of patients of the experimental group = 31–70.
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. Level of significance: P < 0.05. No significant differences were found in baseline scores between the groups.

COPD = chronic obstructive pulmonary disease.
Table 2  Differences in biopsychosocial variables between baseline and 6 months after the intervention

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CG (x DT)</td>
<td>EG (x DT)</td>
</tr>
<tr>
<td>N</td>
<td>71</td>
<td>82</td>
</tr>
<tr>
<td>Total FIQ score</td>
<td>76.23 (14.88)</td>
<td>76.28 (13.57)</td>
</tr>
<tr>
<td>Pain in the last week (FIQ)</td>
<td>7.53 (2.19)</td>
<td>7.51 (1.97)</td>
</tr>
<tr>
<td>Fatigue (FIQ)</td>
<td>8.75 (1.37)</td>
<td>8.54 (1.64)</td>
</tr>
<tr>
<td>Morning tiredness (FIQ)</td>
<td>8.17 (2.38)</td>
<td>8.24 (1.91)</td>
</tr>
<tr>
<td>Anxiety (FIQ)</td>
<td>13.39 (3.45)</td>
<td>13.83 (3.39)</td>
</tr>
<tr>
<td>Current pain (VAS)</td>
<td>7.06 (2.04)</td>
<td>6.76 (1.98)</td>
</tr>
<tr>
<td>Active coping (CAD-R)</td>
<td>32.09 (10.58)</td>
<td>31.32 (9.15)</td>
</tr>
<tr>
<td>Passive coping (CAD-R)</td>
<td>11.70 (7.81)</td>
<td>9.08 (6.56)</td>
</tr>
</tbody>
</table>

We used the Student t-test(t) or nonparametric test of Wilcoxon (Z) for quantitative variables for two independent samples; CG (N = 56) and EG (N = 54). Change: difference between baseline and 6 months after the treatment between EG and CG. P value obtained from the Wilcoxon nonparametric test for independent samples to assess the mean change differences between both study groups. P values in bold indicated a significance level of P < 0.05.
† Between-group change.

CAD-R = Spanish Pain Coping Questionnaire; FIQ = Fibromyalgia Impact Questionnaire, a higher total score representing a greater impact: 50–69 = average to high impact; ≥70 = severe impact; SD = standard deviation; VAS = visual analogue scale; x = mean.

Table 3  Follow-up of the impact of fibromyalgia on total FIQ score, pain, and pain coping strategies in patients who completed the interdisciplinary treatment

<table>
<thead>
<tr>
<th>Variable</th>
<th>Evolutive Descriptive Statistics</th>
<th>Linear Mixed-Effects Model of Evolutive Measured Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (N = 138)</td>
<td>6 weeks (N = 108)</td>
</tr>
<tr>
<td>Total FIQ score</td>
<td>75.96 (13.99)</td>
<td>76.23 (14.88)</td>
</tr>
<tr>
<td>Pain in the last week (FIQ)</td>
<td>7.53 (2.19)</td>
<td>7.51 (1.97)</td>
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<tr>
<td>Passive coping (CAD-R)</td>
<td>11.70 (7.81)</td>
<td>9.08 (6.56)</td>
</tr>
</tbody>
</table>

** P < 0.001; Beta(se) and P values of evolutive measured scores determined by linear mixed-effects models. Time effect beta values refer to increments or decrease in the outcomes for 1-week increment in the study. Interpretation of time effect is evaluated in units per week.
CAD-R = Spanish Pain Coping Questionnaire; FIQ = Fibromyalgia Impact Questionnaire, a higher total score representing a greater impact; N = experimental group; + experimental group; SD = standard deviation; se = standard error; 50–69 = average to high impact; ≥70 = severe impact; VAS = visual analogue scale; x = mean.
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 can maintain over time improvements in biopsychosocial symptoms achieved with the PSYMEPHY treatment.

Strengths of our study include a carefully considered methodology and design, a reasonable sample size, inclusion of a second EG (the control participants who later underwent the PSYMEPHY protocol), and both mid-term and longer term measurements. Our assessment at 6 months produced highly satisfactory results on disease-specific HRQoL. We also conducted a 12-month follow-up, which demonstrated that improvements were maintained. In addition to being ethically responsible, offering the PSYMEPHY intervention to patients in the CG after the 6-month follow-up provided data that corroborated our initial findings.

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 generalization of our findings. Our patient sample may have been experiencing a greater impairment than patients treated in primary care. It would be important to investigate whether the interdisciplinary treatment is successful in a wider context, such as in primary care centers. Another limitation is that 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 an experimental group and a control group. A limitation is that our control condition being managed in a passive way; for future research, we propose a comparison group, which receive 2 hours of Education about FM. Finally, 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 potential savings that might accrue from it, data that are of crucial importance for policy makers.

Conclusions

In summary, FM is a frustrating condition for patients to have and for physicians to treat. Our results indicate that the interdisciplinary PSYMEPHY approach to FM is effective and should be used more widely. More research should be focused on creating and evaluating the most effective interventions. Our finding that the PSYMEPHY treatment is effective and provides long-lasting improvements offers an incentive to develop and study similar treatment programs. These results suggest that it could be especially valuable to offer an interdisciplinary intervention such as PSYMEPHY in hospital pain management units.

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