



## REVIEW

# Effectiveness of health education in patients with fibromyalgia: a systematic review

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## ABSTRACT

**INTRODUCTION:** Fibromyalgia (FM) is a chronic illness characterized by the presence of generalised musculoskeletal pain among other symptoms, which reduce the quality of life of the patient. Clinical interventions such as patient education on central pain management could lead to promising results. The aim of this study is to evaluate the effectiveness of education techniques on the main symptoms such as pain, quality of life, anxiety, functionality or catastrophization in the treatment of FM.

**EVIDENCE ACQUISITION:** The bibliographic search was carried out on PubMed, Web of Science, Scopus, CINAHL, EMBASE, Medline, ProQuest, Cochrane Plus and PEDro databases. The quality assessment of the selected studies was carried out by means of the PEDro scale, obtaining external and internal validity scores to evaluate the generalizability and the appropriateness of design, conduction, and reporting.

**EVIDENCE SYNTHESIS:** The electronic search produced 2,050 articles up to February 2018. After applying the inclusion criteria, 12 articles were identified, without the presence of any RCT of high methodological quality (PEDro $\leq$ 8; Internal Validity Score [PVI]  $\leq$ 4). Despite the heterogeneity of the interventions, a significant reduction in the perception of the disease, the catastrophization, pain intensity and anxiety was observed.

**CONCLUSIONS:** Patient education is considered to be the first step in self-management for a patient with FM, but the scientific evidence that supports the effectiveness of education in the reduction of the main symptoms is limited. Future research designed on more solid and homogeneous interventions is required.

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**KEY WORDS:** Fibromyalgia; Patient education as topic; Pain management; Quality of life.

## Introduction

Fibromyalgia (FM) is a chronic disease that is characterized by the existence of a generalized musculoskeletal pain of unclear location, as well as by the difficulties that those who suffer from it have in precisely defining the beginning of this pain.<sup>1</sup> Hypersensitivity to pain is frequently expressed through the painful feeling due to pressure on numerous points on the locomotor system that are not seen

in healthy people. The pain is defined as continuous and many times tends to settle in muscular structures and tendinous areas, so it can be confused with an inflammatory joint disease during diagnosis. Some of the more frequent factors that worsen the pain are maintained positions, physical loads, emotional activation and weather changes<sup>2</sup>.

Due to the complexity of classifying FM, the American College of Rheumatology (ACR) established clinical classification criteria in 1990, which include generalized pain

lasting for at least three months and the observation of pain caused by pressure at specific anatomical sites referred to as soft spots.<sup>1</sup> FM can be classified as one of the most common problems of society in general and is considered to be the most frequent cause of diffuse chronic musculoskeletal pain.<sup>2</sup> According to the EPISER study (2010) by the Spanish Rheumatology Society, under RCT criteria, FM in Spain has a prevalence of 2.4% of the population over 20 years old, with women being affected more than men; 4.2% versus 0.2% respectively.<sup>3</sup>

In addition to pain, other symptoms and common clinical manifestations that affect the functionality of the patient and which, in most cases, are closely related to the illness are present in FM.<sup>4, 5</sup> In many cases, as a response to this painful experience a pathological anxiety and a continuance of the painful stimulus is produced even when it has already ceased.<sup>6</sup> Alterations in mood such as anxiety and also depression correlate with the perception of pain, although the percentage of the latter that coexists with FM is highly variable, revealing both an emotional discomfort in patients diagnosed with FM and lower expectations for the control of their own symptoms.

Alterations in sleep patterns, such as the lack of restful sleep or difficulties in sleeping with frequent awakenings, sometimes as a consequence of nocturnal pain, is another of the most common symptoms, correlating with the intensity of the FM syndrome.<sup>1</sup> Fatigue is another of the most common manifestations in patients with fibromyalgia and one of the symptoms, which together with pain, directs the life of the patient. This can occur in the form of an exhaustion crisis of intermittent and variable duration in terms of days or more frequently, ongoing, which does not improve at all and predominates over the pain, now becoming chronic fatigue syndrome.

All of these nonspecific symptoms, together with many others such as irritable bowel syndrome, morning stiffness or restless leg syndrome, create an important impact on the biological, psychological and social spheres of patients diagnosed with FM.<sup>1</sup> Thus, FM has an important impact on the quality of life of the people who suffer from it.<sup>7</sup> In many cases it causes severe disabilities as a result of the decline in functional capacity and thus requires retraining in coping and in the development of basic activities of daily life.<sup>8</sup>

Currently, several drugs are being used to treat each one of the main symptoms in FM.<sup>9</sup> However, recent scientific knowledge indicates that a broader multidisciplinary approach is needed, postulating non-pharmacological treatment as an important mainstay to tackle FM. The majority

of non-pharmacological interventions are consolidated as part of a treatment with cognitive-behavioral focus, physical exercise programs or a combination of both.<sup>10</sup> Since the main problem in the treatment of FM is heterogeneity, multicomponent treatments centered in part on patient education, suggest greater effectiveness than basic treatments.<sup>9</sup>

Patient education, which is defined as any set of educational activities planned by qualified professionals and aimed at improving a patient's health behaviors and/or health status, has as a specific objective to inform and restructure the perceptions regarding the disease.<sup>11</sup> To reduce the disparity between the perception of the pain that the patient and the health professional have and its treatment, it is crucial to change the maladaptive perception that patients have of the disease, reconceptualizing the pain, the disease itself and the presented symptoms.<sup>12</sup> Patients with diffuse chronic musculoskeletal pain who are poorly informed about this pain consider it more threatening and demonstrate less tolerance to it, greater catastrophic thoughts and weaker adaptation strategies.<sup>13</sup> This is why patient education, which consists mainly of strategies based on "pain neurophysiology education" among others, is indicated when the clinical picture is dominated by central sensitization, maladaptive cognitions of the pain and the disease, or coping strategies.<sup>12, 13</sup>

Therefore, patient education techniques emphasize that the patient does not have a life-threatening disease; helping to assure them that FM is a real disease<sup>14</sup> and recognizing the legitimacy of the ailment.<sup>15</sup> Likewise, patient education should be based on written material or in any other format that provides them with knowledge and information about the nature of the disorder, the planned treatment, strategies and the expected results.<sup>14, 15</sup>

It is suggested, in the guidelines of the German guide for the management of FM syndrome and based on evidence, that the following basic information be included in patient education: 1) reaffirmation that the symptoms are not caused by an organic disease (such as muscle or joint abnormality) but are based on a functional disorder of the brain (alteration of pain treatment and other external stimuli); 2) symptoms are persistent in the majority of adult patients and complete relief of symptoms is rarely achieved; 3) most patients learn to adapt to the symptoms over time, since the patient can learn to control the symptoms and improve their quality of life in regards to health through self-management strategies.<sup>15, 16</sup>

Patient education, incorporated into a broader multidisciplinary program, is considered to be not only useful but also necessary for patients with FM as it provides them

with the needed resources to help them optimally manage their life with a chronic disease.<sup>17</sup> As has been demonstrated in other rheumatological diseases, patient education is presented as a non-pharmacological aid that can increase the therapeutic adherence of patients to their treatment. Patient education also allows patients diagnosed with FM to be an active part of their treatment process, which has great personal benefits, favoring the adoption of behaviors and knowledge that will lead to bio psychosocial well-being and the highest quality of life possible.<sup>18</sup> A previous systematic review in Spanish concluded that patient education in itself has not proved to be effective for pain, quality or functionality in patients with FM, but it reported the effectiveness of combining patient education with exercise and active strategies for coping with pain, quality of life and functionality in the short, medium and long term in patients with FM.<sup>19</sup> Nevertheless, it should be noted that only five RCT were included in this study.

Patient education is postulated as new directions for professionals and researchers, since it seems to be a promising treatment pathway in FM.<sup>20</sup> This therapy approach is based on the premise that a better understanding of the nature of their illness may result in improved patient outcomes. Considering that an relevant aspect of the central sensitization mechanism as typically observed in patients with FM, pain education about neurophysiology and central sensitization in FM might restructure unfavorable cognitions and motivate the application of cognitive behavioral strategies to cope with their patients, diminishing patients' fear and attention toward pain. This is done by explaining patients that they have little chance of controlling peripheral nociceptive input, but may exert volitional control over top-down mechanisms. Therefore, the aim of this study is to evaluate the effectiveness of patient education as a therapeutic tool on aspects such as pain, quality of life, anxiety, functionality or catastrophizing in patients with FM.

## Evidence acquisition

### Bibliographic search strategies

A systematic review was conducted following the criteria in the PRISMA 2009 declaration on the methodology and conduction of reviews.<sup>21</sup> The bibliographic search was carried out in nine electronic databases: PubMed, Web of Science, Scopus, CINAHL, EMBASE, Medline, ProQuest, Cochrane Plus and PEDro. All publications in English and Spanish were included up to February 2018.

The following categories were used in the database

search strategy: “*pain education*,” “*patient programme*,” “*therapy education*,” “*fibromyalgia*,” “*musculoskeletal pain*” and “*chronic pain*.” Terms were established based on initial searches to find keywords (MeSH list) with PubMed. The search strategy for the databases was, with the exception of PEDro: (educat\* OR progra\* OR pain education OR patient education OR therapy based on education OR educational intervention) AND (fibromyalgia OR chronic pain OR widespread musculoskeletal pain) AND (decrease pain OR reduction pain OR increase quality of life) AND (randomized controlled trial OR clinical trials). The search strategy in PEDro was: educat\* pain\* and fibromyalgia.

### Selection criteria

To select potentially relevant studies and in order to avoid bias in the selection, the titles and abstracts were reviewed to determine if they met the following inclusion criteria:

- 1) articles published in scientific journals up to February 2018;
- 2) full text articles
- 3) classified as randomized clinical trials (RCTs);
- 4) focused on the education of patients with fibromyalgia;
- 5) or the combination of education with other therapeutic interventions;
- 6) assess variables related to pain, quality of life, functionality or catastrophizing.

Exclusion criteria were established as those articles duplicated in the different databases used, conference abstracts and those articles whose PEDro score was <4. Items were searched and extracted by one reviewer. The reviewer registered information relating to identification of outcome measurements, methods (characteristics of the intervention and the control group, technique, description of interventions) and obtained results).

### Evaluation of the methodological quality of the selected articles

The evaluation of the methodological quality of the selected studies was carried out using the PEDro (Physiotherapy Evidence Database)<sup>22</sup> scale translated and adapted to Spanish. The Spanish translation and adaptation of the PEDro scale has been previously published.<sup>23</sup> The methodological criteria were classified as follows: if it is met (1 point) and if it is not met (0 points), selecting only those studies that obtained a PEDro score  $\geq 4$ . In order to allow a more selective analysis of the methodological quality of

the systematic review,<sup>24</sup> the internal validity of each study was assessed by using an internal validity score (PVI). Seven representative items of internal validity were identified for the PEDro scale. Criteria 2, 3, 5, 6, 7, 8 and 9 were selected for the total PVI in this study with the assessment of the methodological quality being made according to their PVI in three categories:<sup>25</sup>

- studies with a PVI of 6-7 are considered to have a high methodological quality;
- studies with a PVI of 4-5 are considered to have medium methodological quality;
- studies with a PVI of 0-3 are considered to have limited methodological quality.

To reduce inter-examiner bias, the quality of the studies was evaluated by two independent reviewers. Inter-rater agreement between two reviewers was calculated using the coefficient  $\kappa$  (>0.7 means high level of agreement between the two reviewers; 0.5-0.7 means a moderate level of agreement, and <0.5, a low level).<sup>26</sup> Statistical analysis were performed SPSS version 20.0 (SPSS, Chicago, IL, USA).

### Criteria for the evaluation of the results

The qualitative method recommended by the Cochrane group with the use of evidence levels to synthesize the data was chosen:<sup>24</sup>

- solid evidence: multiple high quality RCTs;
- moderate evidence: multiple low quality RCTs and 1 high quality RCT;
- limited evidence: 1 low quality RCT;
- contradictory evidence: non-coherent findings in multiple RCTs;
- no evidence: no RCT.

## Evidence synthesis

### Study selection

A literature search was conducted including articles published in scientific journals up to February 2018. The procedure and search strategy in the different databases produced 2,050 articles in 8 databases: 234 from PubMed, 511 from Web of Science, 762 from Scopus, 211 from CINAHL, 50 from Medline, 93 from ProQuest, 71 from Cochrane Plus and 118 from PEDro. After filtering by randomised clinical trials, 772 articles were left. After eliminating those articles that were duplicates, 701 articles were selected to check if they met the previously determined inclusion and exclusion criteria. 3 articles from other al-

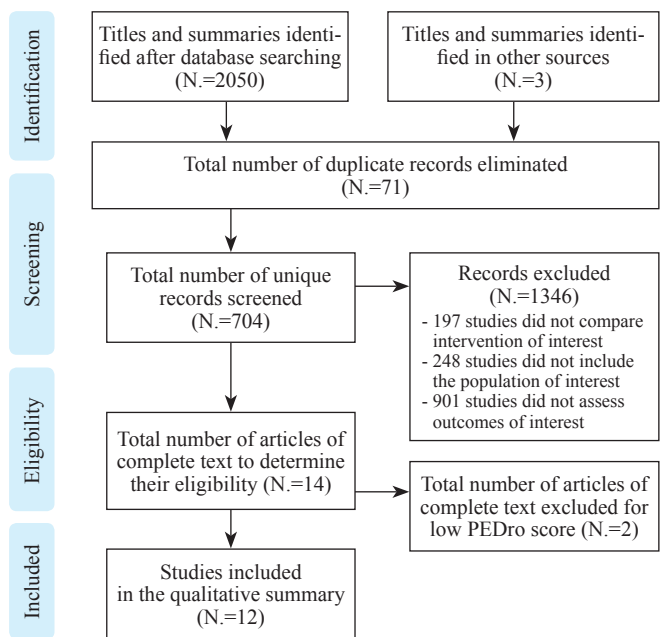


Figure 1.—Flow diagram according to PRISMA system.

ternative sources (searching the reference list of previous studies) were included, resulting in a total of 704 articles.

Finally, 14 full-text articles met the inclusion criteria. Those articles with a PEDro score less than 4 were eliminated, leaving a total of N.=12 articles. All articles included were published in English language. Figure 1 shows the flow chart for the process of selection and exclusion of studies.

### Characteristics of the selected studies

Table I<sup>27-38</sup> summarizes the characteristics of the selected studies. The studies found through the various search sources contained information that was too heterogeneous and not compatible with quantitative analysis. The extraction and analysis of the data obtained from the studies could not be grouped together, mainly because of the disparity of populations or therapeutic interventions; therefore, it was impossible to calculate the overall effect.

The largest sample of patients in the experimental group was N.=108<sup>28,38</sup> and the smallest was N.=15.<sup>27</sup> The articles presented a diversity of variables studied in relation to the involvement of FM: Revised Illness Perception Questionnaire (IPQ-R\_FM), Pain Catastrophizing Scale (PCS), Fibromyalgia Impact Questionnaire (FIQ), Spatial Summation of Pain (SSP), Pain Pressure Threshold (PPT), Pain Coping Inventory (IPC), Pain and Awareness Surveillance Questionnaire (PVAQ), Tampa Scale of Kinesiophobia

(TKS), EuroQoL-5D Questionnaire (EQ-5D), Adapted Customer Service Receipt Inventory (CSRI), Health Questionnaire (SF36), Adapted chronic pain self-efficacy scale (SE), Swedish version of the Multidimensional Pain Inventory (MPI-S), Arthritis Self-Efficacy Scales – AR and chronic pain (ASES-S), Arthritis Impact Measurement Scales (AIMS), Swedish Quality of Life Questionnaire (QOLS), Nottingham Health Profile (NHP), Visual Analog Scale (EVA), Psychological General Well-Being (PGWB) and Goldberg Scale of anxiety and depression (GADS).

### Evaluation of the methodological quality

Two of the articles, from among those selected, were excluded from the review despite meeting the inclusion criteria due to their low score on the PEDro scale (<4).<sup>39, 40</sup>

Table II<sup>27-40</sup> presents the methodological quality of the analysed studies. Of the twelve articles included in this review: Only one study scored 8/10. Three studies scored 7/10. Two studies scored 6/10. Five studies scored 5/10. A single study scored 4/10.

Three of these studies met criteria 2, 3, 5, 7, 8 and 9, and because of this present a PVI of moderate methodological quality.<sup>28, 29, 31</sup> However, the remaining nine articles present a PVI of limited nature.<sup>27, 30, 32-38</sup> Based on this and according to the Cochrane Group,<sup>24</sup> the results of this study have limited evidence since there is no RCT of high methodological quality. The agreement between the evaluators according to the coefficient  $\kappa$  it was high (0.81).

### Characteristics of the participants

Some disparity exists in the characteristics of the participants in the selected studies, which presents some difficulties in their analysis. On the one hand, gender presented some heterogeneity within the studies, with a predominance of female patients in most of the studies and male patients in only seven of them, which as previous studies have already reported, may be due to the fact that the disease has a greater effect on females than males.<sup>41</sup> This is important since the similarity between the gender of the participants in the intervention avoids certain important differences in terms of the effect of the study variables since previous studies show that there are gender differences in the clinical and psychosocial characteristics of women and men diagnosed with FM, as well as in the impact of the disease on their daily life. However, on the contrary, a certain bias regarding the variables studied is also established, as there is no equal division of men and women among the groups where the intervention is car-

ried out. On the other hand, a heterogeneous population as regards the socio-demographic age variable is observed in the analyzed articles, since they include subjects from 18 to 75 years of age, with an average age that lies between 33 and 51 years old.

In 6 of the selected studies it is specified that the diagnosis of patients with FM is carried out according to the criteria of the ACR<sup>28,29,30,32,333,34</sup>. However, no study specifies the time since the diagnosis of the disease. This should be considered, as early diagnosis resulting in early care is known to favor better management of symptoms, which is a positive prognostic factor in the evolution of a patient with FM disease.<sup>42</sup>

Another important aspect of our research, and one that presents great diversity in the analyzed studies is the education level of the patients. At the time of implementing educational therapy, adherence to it will depend to a large extent on the comprehension capacity of the patient to internalize the conceptualizations regarding the different topics dealt with in different sessions.

### Characteristics of education interventions

The analyzed studies present different characteristics regarding the direction of education and the development of the intervention sessions. In general, they vary in regards to the duration of the sessions or treatment and the implementation of the intervention technique, with the variation being either in the number of repetitions or the amount of time spent on the intervention. In addition, some authors made decisions in terms of the medication to which the participants were subjected during the intervention period and as to whether or not education was combined with other types of therapy.

Patients participating in six studies received education as the only intervention, either as neuroscience of pain, physiology of pain or simply centered on the patient.<sup>27, 29, 32, 34, 35</sup> Participants in one study received education combined with the practice of routine care for FM patients and with autogenic training.<sup>30</sup> The rest of the study participants received education during the intervention with other types of aerobic exercise therapies (strength, flexibility or relaxation therapies),<sup>31, 32, 37, 38</sup> combined with training in the pool<sup>33</sup> or combined with training in the pool and self-management.<sup>36</sup>

The 12 articles included in the study show a large variability in the duration of the sessions, with a minimum of 2 educational sessions<sup>29</sup> and a maximum of 12 sessions.<sup>36</sup> Four of the studies present an average of 4,<sup>34</sup> 5,<sup>30</sup> 6,<sup>33</sup> 7<sup>31</sup> and 10<sup>29</sup> sessions while the rest of the studies do not specify.<sup>27, 35, 38</sup>

TABLE I.—Description de selected articles.

Author (year)	Variables	Experimental Group	Control Group
Van Ittersum <i>et al.</i> (2014) <sup>28</sup>	Perception of the disease; catastrophe and state of health of patients with FM. IPQ-R_FM; PCS; Dutch version of FIQ.	Pain neuroscience education (PNE) (N.=53): 50 women and 3 men; patients in accordance with ACR criteria: ages between 18-65 years. Average 47 years old.	Education in relaxation techniques (RE) (N.=52): 48 women and 4 men; patients diagnosed with FM in accordance with ACR criteria: ages between 18-65 years. Average 47 years old.
Van Oosterwijck <i>et al.</i> (2013) <sup>29</sup>	Endogenous inhibition of pain in patients with FM. Pressure algometry; SSP; Neurophysiology of Pain Test; PTT; FIQ; ICP; PCS; PVAQ; TSK.	Education on physiology of pain (N.=15): 12 women and 3 men; patients in accordance with ACR criteria: ages between 18-65 years. Average of 45 years old.	Education in pace self-management techniques (N.=15): 14 women and 1 man; patients in accordance with ACR criteria: ages between 18-65 years. Average 46 years old.
Luciano <i>et al.</i> (2013) <sup>30</sup>	Functional status and well being of patients with FM. FIQ; EQ-5D; CSRI.	Psycho-education added to usual practise (N.=108): 105 women and 3 men; FM patients in accordance with ACR criteria: ages between 18-75 years. Average of 55 years old.	Usual practise (N.=108): 106 women and 2 men; FM patients in accordance with ACR criteria: ages between 18-75 years. Average of 55 years old.
Rooks <i>et al.</i> (2007) <sup>31</sup>	Symptoms and quality of life in patients with FM. FIQ; SF-36. Beck Depression Inventory; Arthritis Self-Efficacy Scale adapted for FM.	Self help Course Group (FSHC) (N.=50): 50 women with FM and 51 years old. Combination group of ST-FSHC (N.=55): 55 women with FM and 50 years old.	Aerobic exercise and flexibility group (AE) (N.=51): 51 women; patients with FM and 48 years old. Strength training, aerobic and flexibility exercise group (ST) (N.= 51): 51 women; patients with FM and 50 years old.
King <i>et al.</i> (2002) <sup>32</sup>	Pain, functional status and well being of FM patients with FM. SE; FIQ; 6MW; Tender Point Count;	Exercise group (N.=46) Average of 45 years old. Education group (N.=48) Average of 44 years old. Combination group (N.=37) Average of 47 years old. Women with FM in accordance with ACR criteria; 18 to 65 years old.	N.=39 women with FM in accordance with ACR criteria; 18 to 65 years old. Average 47 years old.
Mannerkorpi <i>et al.</i> (2000) <sup>33</sup>	Pain, functional status and quality of life of patients with FM. FIQ; SF-36; 6MW; Swedish version of MPI-S; ASES-S; AIMS; QOLS.	N.=28 patients; women with FM according to ACR. Average 45 years old.	N.= 30 patients; women with FM according to ACR. Average 47 years old.
Bosch <i>et al.</i> (2002) <sup>34</sup>	Quality of life, psychic discomfort. NHP; Mini International Neuropsychiatric Interview.	N.=33 female patients with FM according to ACR criteria; between 26 and 67 years old. Average 54 years old.	N.=32 female patients with FM according to ACR criteria; between 26 and 67 years old. Average 54 years old.

Technique	Intervention	Results
Cognitive approach to written education on the neuroscience of pain.	Experimental group: 1 educational brochure (15pp) with detailed written explanations and illustrations about the physiology of pain and the mechanism of central sensitization as an explanation based on evidence of their disease.	PNE improved the beliefs in a chronic FM chronology (P=0.03; ES=0.50), but it did not affect other domain perceptions of the disease.
Dual evaluation of education pre- (baseline) and postintervention; 6 months follow-up: FIQ, PCS y IPQ-R.	Control group: 1 written training brochure (15pages) on relaxation exercises and instructions on how to perform such exercises; 1 clarifying telephone call.	The total PCS score did not change with time or differ between PNE and RE. No statistically significant differences were observed between PNE and RE on the perceived symptoms and the impact on daily life.
Intensive education on the physiology of pain	Experimental group: 2 educational sessions on the neurophysiology of the nervous system and the pain system in particular; ability of the CNS to increase or decrease its sensitivity to help them cope with persistent pain (power point, pictures, etc.)	At follow-up, average pain scores for the experimental group were lower than those of the control group (P=0,041).
Preintervention evaluation (baseline: SSP- pressure algometry); intervention (Neurophysiology of Pain Test; PTT); postintervention and 3 month follow-up (SSP- pressure algometry; FIQ; ICP; PCS; PVAQ; TSK).	Control group: 2 individual educational sessions on self-management techniques in daily activities with respect to their symptoms. 30 min per session.	Neurophysiology of pain test increased in response to the experimental intervention (P<0.001); but not to the control intervention (P=0.150). Increase of scores in the scale of health and vitality perception in the experimental group (P<0.001).
Applied psycho-education treatment and autogenous training.	Experimental group: 6 groups of 18 patients maximum; 9 sessions of 2 hours for 2 months. 5 information education sessions (symptoms, causes, psychological pain factors, treatments, etc.). Four sessions of autogenic training linking emotional experience and relaxation.	At the 12 months follow-up: patients who received psycho-education showed improvement in overall functional status (Cohen d=0.36: 2.49 to 3,81), physical functioning (Cohen d=0.56: 0.08 to 1.00), days feeling good (Cohen d=0.40: 0.16 to 1.02), pain (Cohen d=0.35: 0.04 to 0.80), morning fatigue (Cohen d=0.24: 0.20 to 0.76), and depression (Cohen d=0.30: 0.26 to 0.93).
Preintervention evaluation (baseline) and postintervention (6-12 moth intervals)	Control group: standard medical attention.	
Education and self-management combined with exercise.	Experimental group: FSHC; self-management techniques, symptom management and wellbeing activities (meetings and lectures) 7 sessions 120 min every 2 weeks.	ST-FSHC reported improvement in social function scores compared to FSHC (median±21.8; CI of 95%, 2.5 at 41.2), mental health (median 13.5±21.9; P<0.001).
Preintervention evaluation (baseline) and postintervention (6 months).	ST-FSHC; participation in activities of both groups. Control group: AE; progressively increasing walks and flexibility exercises. ST; strength and resistance training (machine/repetitions combination) and flexibility. Sixty min per session 2 days per week.	Control over FM symptoms improved in STFSHC (average difference, 15.2; CI of 95%: 3.6 to 26.9), AE (average difference: 14.5; IC of 95%: 2.6 to 26.3), and ST (average difference, 13.2; IC of 95%, 1.0 to 25.3).
Education and self-management combined with exercise.	Group exercise: aerobic exercise (walking, aquasize etc.) gradually increasing. (3 times per week 15-40 min x 12 weeks)	The combined group increased its self-efficacy in coping with other symptoms from pre-test to post-test and the follow-up when compared to the control group (F [6.65]=3.48, P=0.003).
Preintervention evaluation (baseline); postintervention (completion) and follow-up (3 months)	Education group: self-management, coping, illness, energy, nutrition, etc. (1 weekly session 2 hours x 12 weeks) Combination group: 2 exercise sessions 1 education session. Control group: notebook, logbook, coping strategies.	FIQ and TP number demonstrated important main effects over time, with significant decreases from pre-test to post-test and follow-up.
Education combined with pool training	Experimental group: exercise in the pool once per week 35 min (resistance, flexibility, relaxation); education 6 sessions x 1 hour, brochure-informative book about symptoms, pain strategies etc.	The total FIQ score (P=0.017) the distance travelled in 6MW (P<0.0001), the physical functioning of FIQ (P=0.001) and the anxiety (P=0.019) improved in the training group.
Preintervention evaluation (baseline) and postintervention (at 6 months)	Control group: undertaking only education program.	The SF-36 general health (P=0.022) social functioning (P=0.049); pain severity in MPI-S (P=0.045) also improved in the experimental group with respect to the control group.
Health education.	Experimental group: 4 sessions of health education of 1 hr; 1-week intervals (1 month). Information about illness, relaxation etc.	In the intervention group, a statistically significant improvement was observed in pain dimension (P=0.003), in comparison with the control; but not in other dimensions.
Pre-intervention evaluation (baseline) and post-intervention.	Control group: normal care for FM.	

(To be continued)

TABLE I.—Description de selected articles (continues).

Author (year)	Variables	Experimental Group	Control Group
Fors <i>et al.</i> (2000) <sup>35</sup>	Pain, anxiety. EVA.	Education (N.=22) patients; women with FM between 21 and 68 years old. Average 46 years old. Guided imagery (N.=17) patients; women with FM between 21 and 68 years old. Average 46 years old.	N.=19 patients; women with FM between 21 and 68 years old. Average 46 years old.
Cedraschi <i>et al.</i> (2004) <sup>36</sup>	Quality of life, functional status, satisfaction, impact of FM. FIQ; French version of PGWB y SF-36;	N.=84 patients; 78 women with FM and 6 men according to ACR criteria and mainly between 41 and 50 years old. Average 49 years old.	N.=80 patients; 74 women with FM and 6 men according to ACR criteria and mainly between 41 and 50 years old. Average 49 years old.
Hammond <i>et al.</i> (2006) <sup>37</sup>	Impact of FM self-efficacy. FIQ; Arthritis Self-efficacy Scale.	N.=71 patients with FM according to ACR criteria; 63 women and 8 men older than 18 years old. Average of 49 years old.	N.=62 patients with FM according to ACR criteria; 57 women and 5 men over 18 years old. Average of 48 years old.
Alamo <i>et al.</i> (2002) <sup>27</sup>	Pain, anxiety, depression. EVA and Nottingham Health Profile Questionnaire; GHQ.	N.=48 patients with chronic musculoskeletal pain (CMD)/FM; 46 women and 3 men between 18 and 65 years old. Average of 39 years old.	N.=33 patients with CMD/FM; 32 women and 1 man between 18 to 65 years old. Average of 42 years old.
Demirbag <i>et al.</i> (2012) <sup>39</sup>	Depression, pain and Quality of Life. Beck questionnaire; EVE; FIQ.	N.=51 patients with FM according to ACR criteria; 47 women and 4 men between 19 and 59 years old. Average between 33 to 45 years old.	N.=51 patients with FM according to ACR criteria; 47 women and 4 men between 19 and 59 years old. Average between 33 to 45 years old.

\*The selected studies obtained a PEDro score  $\geq 4$  (see Table II).  
 FM: fibromyalgia; IPQ-R\_FM: Revised Illness Perception Questionnaire; PCS: Pain Catastrophizing Scale; FIQ: Fibromyalgia Impact Questionnaire; ACR: American College of Rheumatology; SSP: Spatial Summation of pain; PTT: pain pressure threshold; ICP: Pain Coping Inventory; PVAQ: Pain and Awareness Surveillance Questionnaire; TSK: Tampa Scale of Kinesiophobia; EQ-5D: EuroQoL-5D questionnaire; CSRI: Adapted Customer Service Receipt Inventory; SF-36: Health Questionnaire; SE: adapted chronic pain self-efficacy scale; 6MW: Six minute walk; MPI-S: Swedish version of the Multidimensional Pain Inventory; ASES-S: Arthritis Self-Efficacy Scales - (AR and chronic pain); AIMS: Arthritis Impact Measurement Scales; QOLS: Swedish Quality of Life Questionnaire; NHP: Nottingham Health Profile; EVA: Visual Analog Scale; PGWB: Psychological General Well-Being; GHQ: Goldberg Scale of anxiety and depression.

The duration of these sessions and the material that guides the educational sessions also present great plurality. Five studies favored education through information imparted by the professionals in change and discussion-debate groups about the patients' own experiences<sup>31, 32, 34, 36, 38</sup> while in two of the studies education was carried out in the form of brochures and informative books.<sup>28, 33</sup> In other studies, patients received talks and informative lectures,<sup>31</sup> as well as individual informative consultations with professionals when they required them.<sup>27</sup> Participants from two other studies received visual information by means of presentations and guided imagery.<sup>29, 35</sup> The educational material used in one of the studies was not specified.<sup>37</sup> Patients in one of the studies carried out self-administered

educational sessions with the process being previously explained by the therapist.<sup>33</sup>

In terms of the content employed as a basis for the educational interventions, the definition of FM disease, the symptoms, the course of the disease, the implications, the management of basic daily life activities, the benefits of exercise on the disease and the reconceptualization of misconceptions and myths were many of the topics covered in the analyzed studies.

#### Education centered on the patient and effects of the education

The analyzed studies present a large diversity in terms of variables that show the effectiveness of education once



Technique	Intervention	Results
Visual patient education. Preintervention evaluation and postintervention	Experimental group: education; educational visualization with teaching of natural systems of analgesia in the human body. Guided imagery; program of universal imagery aimed at this confrontation in a relaxed and positive way. (both 30 mins) Control group: interaction speaking about fibromyalgia pain problems.	EVA showed significant pain reduction in the education group (51.98 to 37.14 $t=4.30$ $P<0.001$ ) and in the guided imagery group (48.50 to 28.12 $t=4.70$ $P<0.001$ ). Anxiety in the education group reduced from pre-evaluation to post evaluation (47.98 to 29.39, $t=5.31$ $P<0.001$ )
Patient education combined with pool training and self-management. Preintervention evaluation (baseline) and postintervention (6-month follow-up)	Experimental group: 12 sessions-6 weeks of pool programs, relaxation, educational sessions and sessions on basic activities of daily life (planning, debate, etc.) Control group: waiting list for the intervention.	The treatment group showed significant improvement in PGWB anxiety ( $P=0.011$ ), vitality ( $P=0.013$ ) and total scores ( $P=0.032$ ). The treatment group showed significant improvements in the total FIQ score ( $P=0.025$ ) The treatment group registered improvement in eight of the nine measures of satisfaction in the areas of “psychosocial factors” and “information.”
Patient education with cognitive behavioral approach combined with exercise. Preintervention evaluation (baseline) (4 months); post- (8 months).	Experimental group: sessions of 2 hours-10 weeks; symptoms of FM, self-management, stress management and 15-45 minutes of exercise and postural training, Tai Chi etc. Control group: relaxation 1 hour- 10 weeks; relaxation-breathing method for FM symptoms.	FIQ showed a difference (4 months) between patient education group/3.38 (SD 9.35); relaxation group 0.3 (SD 8.85); $P/0.02$ . In the patient education group, 47% of the respondents reported improvement compared to 13% in the relaxation group.
Patient focused education. Preintervention evaluation (baseline) and postintervention (6-12 months)	Experimental group: Regular care + consultations of 30-45 min. of educational information on FM, mutual discussion. Control group: Regular primary care for patients with FM in Spain.	Experimental group showed improvement after 12 months with regards to the control in terms of anxiety (GHQ) (DMC 5.8 to 4.7 // FM 6.7 to 4.5), pain intensity (DMC 6.8 to 5.1//FM 7.1 to 6.8), pain as a problem (DMC 3.4 to 3.0//FM 4.5 to 3.1).
Patient education combined with exercise. Preintervention evaluation (baseline) and postintervention (1 month).	Experimental group: Information on FM, symptoms, control, diagnosis, treatments, etc. (20 min) Low aerobic exercises according to pain localization (15-20 min.) 1 month. Control group: Hand out forms and scales for participation in study.	Experimental group showed significant differences between the Beck, FIQ and EVA scores before (20.33 $\pm$ 7.4, 67.19 $\pm$ 13.9, 7.65 $\pm$ 1.44, respectively) and after the intervention (14.20 $\pm$ 4.5, 47.58 $\pm$ 11.82, 5.41 $\pm$ 1.15 respectively); $P<0.05$ .

the interventions have been made. Prior to the interventions, there is no similarity in either the location of pain in patients, or the subjectivity of its intensity, therefore it is difficult to establish comparisons about the benefits of education on this variable in the articles that analyses it.

Four of the studies that addressed the impact of education on pain in a concentrated manner and without combining it with another type of therapy, found statistically significant differences in this variable. Van Oosterwijk *et al.*<sup>29</sup> found a significant improvement in the efficacy of endogenous pain mechanisms in the long term with an intensive educational intervention on the neurophysiology of the nervous system and its ability to increase or decrease its sensitivity and thus help patients to fight persistent pain. Patients, whose interventions were carried out by Bosch *et al.*,<sup>34</sup> Fors *et al.*<sup>35</sup> and Alamo *et al.*,<sup>27</sup> using general health education targeted to the patient, visual education and relaxation, as well as informative consultations on basic aspects of the disease respectively, showed a significant im-

provement in the magnitude of the pain. However, the lack of masking and blinding in the participants, therapists and evaluators in these three studies makes the internal validity of these studies limited, and the results obtained may have been compromised and biased. As for the studies that analyzed the impact of education in combination with other therapies, they show a significant improvement in pain and pain catastrophizing. Due to a lack of uniformity by the variability of therapies used in most studies, it is difficult to clarify whether the benefits obtained in pain reduction or in its better acceptance and management is mainly due to education itself or its combination with aerobic exercise, flexibility, relaxation or hydrotherapy, the usual treatment in FM.<sup>33, 36, 38</sup>

Regarding the rest of the variables involved in the studies, Van Ittersum *et al.*<sup>28</sup> constituted improvements in the perception of the disease as well as the belief in a chronic chronology of it, which helped patients to be able to restructure unfavourable cognitions and therefore decrease

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TABLE II.—Methodological quality of the studies using the PEDro scale.

Author (year)	1*	(2)	(3)	4	(5)	(6)	(7)	(8)	(9)	10	11	Total	PVI
Van Ittersum <i>et al.</i> (2014) <sup>28</sup>	X	X	X	X			X		X	X	X	7/10	4/7 moderate
Van Oosterwijck <i>et al.</i> (2013) <sup>29</sup>	X	X		X	X		X	X	X	X	X	8/10	4/7 moderate
Luciano <i>et al.</i> (2013) <sup>30</sup>	X	X		X			X	X	X	X	X	7/10	3/7 limited
Rooks <i>et al.</i> (2007) <sup>31</sup>	X	X	X	X			X		X	X	X	7/10	4/7 moderate
King <i>et al.</i> (2002) <sup>32</sup>	X	X		X			X		X	X	X	6/10	3/7 limited
Mannerkorpi <i>et al.</i> (2000) <sup>33</sup>	X	X		X			X			X	X	5/10	2/7 limited
Bosch <i>et al.</i> (2002) <sup>34</sup>	X	X		X					X	X	X	4/10	1/7 limited
Fors <i>et al.</i> (2000) <sup>35</sup>		X		X				X		X	X	5/10	2/7 limited
Cedraschi <i>et al.</i> (2004) <sup>36</sup>	X	X	X	X						X	X	5/10	2/7 limited
Hammond <i>et al.</i> (2006) <sup>37</sup>	X	X	X	X					X	X	X	6/10	3/7 limited
Alamo <i>et al.</i> (2002) <sup>27</sup>	X	X		X				X	X	X		5/10	3/7 limited
Demirbag <i>et al.</i> (2012) <sup>38</sup>	X	X		X				X		X	X	5/10	2/7 limited
Casanueva-Fernández <i>et al.</i> (2012) <sup>39</sup>		X		X						X		3/10 †	1/7 limited
García <i>et al.</i> (2006) <sup>40</sup>	X	X		X						X		3/10 †	1/7 limited

1. The selection criteria were specified. 2. The subjects were randomly assigned to the groups. 3. The assignment was hidden. 4. The groups were similar at the beginning in relation to the most important prognostic indicators. 5. All subjects were blinded. 6. All the therapists who administered the therapy were blinded. 7. All evaluators who measured at least one key result were blinded. 8. Measurements of at least one of the key results were obtained from more than 85% of the subjects initially assigned to the groups. 9. Results were presented for all subjects who received treatment or were assigned to the control group, or when this could not be, the data for at least one key result was analysed by “intention to treat”. 10. The results of statistical comparisons between groups were reported for at least one key result. 11. The study provides specific measures and measures of variability for at least one key outcome.  
\*Non-summative criterion for the PEDro scale; †Items excluded from the study due to low PEDro score; N. criteria used to obtain the Internal Validity Score (PVI).

fear and attention towards pain. The intervention carried out by Luciano *et al.*,<sup>30</sup> revealed that after twelve months, the patients saw benefits in their overall functional state and improvements in depressive symptoms that had been exhibited preintervention. Improvements in the overall handling of the main symptoms of the disease were the most significant results of the studies by Rooks *et al.*<sup>31</sup> and King *et al.*,<sup>32</sup> as the combination of education with exercise made the improvements in self efficacy truly visible.

### Discussion

The effectiveness of patient-centered education in the treatment of people with FM has been investigated in this review. According to the Cochrane Group<sup>24</sup> there is limited evidence on the use of this therapy and the benefits of it in pain, functionality, catastrophization or the quality of life in general. The key impact of written education on patients with FM and without its combination with other therapies, was studied by Van Ittersum *et al.*<sup>28</sup> on pain neuroscience education and Van Oosterwijck *et al.*<sup>29</sup> on pain physiology education. They demonstrated that no significant changes were found on its impact on FM once the intervention was completed, although the results fluctuated over time in relation to variables such as perception or attitudes to the disease.<sup>28</sup> They established the usefulness of pain education as an important component in the treatment of those patients diagnosed with FM. While it is true that the number of articles selected was not high since the arti-

cles that deal exclusively and exhaustively with education are limited, the combination with other types of therapy highlights the important effect of education and the need for it to continue being included in the treatment of FM. The combination of exercise (strength training, aerobic and flexibility exercise) and education showed greater improvement compared with education or exercise applied as separate groups in FM symptoms.<sup>31</sup> Patients receiving the combination of exercise and education also improved their self-efficacy in control of perceived symptoms.<sup>32</sup> Similarly, in previous studies focused on combination of pool exercise and education, the exercise-education program showed significant, but small, improvement in health status,<sup>33</sup> quality of life and satisfaction in this population.<sup>36</sup> Thus, improvements in patients’ beliefs about their own abilities to cope with pain management and other associated symptoms is one of the most repetitious results in the studies analyzed, thus the usefulness of the educational component in therapies, whether multimodal or focused solely on patient education, is shown and produces psychological improvements in attitudes and coping with FM.

### Implications in research

A growing body of literature suggests that patient-centered educational interventions, either on their own and/or in combination with other types of therapies are beneficial and very useful in the rehabilitation process for people with FM.<sup>31</sup> Although there is evidence that programs that

focus their interventions on education are useful for patients with chronic musculoskeletal pain, current evidence regarding education in patients with FM is inconclusive. Hence, the obvious implication is that more interpretation models and additional data are required, as well as more research on the effectiveness of education to validate existing literature and give weight to the studies which have already been carried out.<sup>20</sup> Based on this, and even though there is no conclusive demonstration of direct effectiveness in pain or disability, the fact that there is, in the perceptions of the disease, the catastrophization or even that cognitive behavioral therapy is key in this type of patient, is an incentive to continue with this line of research.<sup>43</sup> However, it is true that it is necessary to specify an educational treatment protocol of uniform nature, both in terms of its frequency and duration, as well as the topics and their progress as this will grant greater validity and therapeutic seriousness to these educational procedures.

Since the diagnosis of FM is eminently clinical<sup>44</sup> and that its visibility is much greater in the field of rehabilitation, it is worth highlighting the implication of education in the social sphere in a patient with FM due to its close relationship with the quality of life and the well-being of the patient.<sup>2</sup> As in any chronic disease that is highly disabling and which fosters a risk of supervening incapacity, the development of social and work problems linked to the disease are possible, making these patients potentially at risk of social exclusion. Thus, their referral to the social work field, for as long as necessary is important to bear in mind.<sup>43</sup> It should also be noted that within the social sphere, the development of patient centered education is still in the process of development and implementation, which is why multidisciplinary work is necessary with the other fields involved, such as nursing, physiotherapy, psychology or occupational therapy, in order to jointly promote the development and mainstreaming of common knowledge.

The challenging nature and complexity of FM should inspire both scientists and professionals from the various fields involved in its treatment to investigate physiological and psychosocial elements and be able to approach the treatment in a creative, extensive and potentially multidisciplinary and comprehensive way to offer more optimal and better-quality care to the patients themselves.

### Strengths and limitations of the study

The main strength of this research is the fact that it focuses on the important clinical aspects of a complex disease with respect to a relatively novel intervention technique that has been minimally studied exclusively in the field of FM. On

the other hand, it has provided a broad and overall picture of the subject, promoting the dissemination of its understanding and its complexity in society.<sup>43</sup> Also noteworthy is the large number of databases that have been used for the review, which given the impossibility of performing a statistical analysis, resulted in an assessment being made regarding the quality of each article using the PEDro scale that objectively shows the reliability of the bibliographic review process. In addition, it should be noted that in order to reduce inter-examiner bias, the quality of the studies was evaluated by two independent reviewers.

However, this review has several limitations. First, the heterogeneity within some of the characteristics of the participants, as well as the direction of the education chosen in the interventions of the analyzed studies, and the combination of this with other therapies is a limitation that conditions the understanding of the possible effectiveness of preferential patient education in the studied field. Second, the selection of articles written in only English or Spanish, possibly ignoring articles written in other languages, is found to be another limitation. Finally, the fact that we did not include grey literature in this systematic review would be a potential limitation of this study. However, it should be highlighted that there is limited empiric evidence about the potential impact of selective searching and inclusion on the results of systematic reviews.

### Future perspectives

Due to the novelty of the subject and the surge in literature related to patient centered education in recent times, a subsequent review with more updated RCTs would be advisable. They should investigate education focused on patients with FM but without combining it with other therapies in which its effectiveness has already been consolidated. It is also of particular interest that future research creates groups where the education employed is more homogeneous and the age ranges are not so wide and not so high. It is worth noting the importance of the length of time since FM was diagnosed in order to be able to draw much clearer conclusions about the most effective moment or phase to carry out the education process, or to know if this education process should be continually fed back throughout the disease. Search results should also focus on immediate, short and long-term effects.

### Conclusions

There is limited evidence on the use of education centered on the patient with FM and the benefits of it in pain,

anxiety, functionality, catastrophization or quality of life in general. Based on the limited number of articles dealing exclusively with education, the usefulness of pain education in itself as an important component in patients diagnosed with FM has not been demonstrated. However, there is strong evidence to support the effectiveness of the combination of patient education with other types of therapy, highlighting the importance of education and the need to continue embracing the approaches to the treatment of FM and opening the way for future research on studies with higher methodological quality that can demonstrate its benefits with greater influence.

From the sociosanitary field, and in light of the generalities and difficulties that diseases present, which is the case here, it is necessary to know the peculiarities of the cases and their involvement in the different areas of activity, addressing the aspects of greatest suffering for the patients affected in each case to try to provide multidisciplinary care and an improvement in quality of life. The professional consensus for patient education follows from this as one of the primary needs since it is considered to be the first step in self-management for the patient with FM.

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