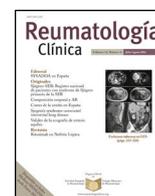




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## Special Article

## Recommendations by the Spanish Society of Rheumatology on the management of patients with fibromyalgia. Part II<sup>☆</sup>



Javier Rivera Redondo,<sup>a,\*</sup> Petra Díaz del Campo Fontecha,<sup>b</sup> Cayetano Alegre de Miquel,<sup>c</sup> Miriam Almirall Bernabé,<sup>d</sup> Benigno Casanueva Fernández,<sup>e</sup> Cristina Castillo Ojeda,<sup>f</sup> Antonio Collado Cruz,<sup>g</sup> Pilar Montesó-Curto,<sup>h</sup> Ángela Palao Tarrero,<sup>i</sup> Eva Trillo Calvo,<sup>j</sup> Miguel Ángel Vallejo Pareja,<sup>k</sup> Noé Brito García,<sup>b</sup> Carol Merino Argumánez,<sup>l</sup> M. Nieves Plana Farras<sup>m</sup>

<sup>a</sup> Servicio de Reumatología, Hospital General Universitario Gregorio Marañón, Madrid, Spain

<sup>b</sup> Unidad de Investigación, Sociedad Española de Reumatología, Madrid, Spain

<sup>c</sup> Hospital Universitario Dexeus-Quiron, Barcelona, Spain

<sup>d</sup> Servicio de Reumatología, Hospital Universitario Vall d'Hebron, Barcelona, Spain

<sup>e</sup> Servicio de Reumatología, Centro Interdisciplinar de Psicología y Salud, CIPSA, Santander, Spain

<sup>f</sup> Paciente. ALK, Madrid, Spain

<sup>g</sup> Servicio de Reumatología, Hospital Clínic, Barcelona, Spain

<sup>h</sup> Departamento y Facultad de Enfermería, Universitat Rovira i Virgili, Campus Terres de l'Ebre, Tortosa, Tarragona, Spain

<sup>i</sup> Servicio de Psiquiatría, Hospital Universitario La Paz, Madrid, Spain

<sup>j</sup> Medicina de Familia, Centro de Salud Campo de Belchite, Belchite, Zaragoza, Spain

<sup>k</sup> Departamento de Psicología Clínica, Facultad de Psicología, Universidad Nacional de Educación a Distancia (UNED), Madrid, Spain

<sup>l</sup> Hospital Universitario Puerta de Hierro, Majadahonda, Madrid, Spain

<sup>m</sup> Hospital Príncipe de Asturias, CIBER de Epidemiología y Salud Pública, Meco, Madrid, Spain

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### ABSTRACT

**Objective:** To prevent the deterioration of patients with fibromyalgia due to potentially avoidable harmful actions in clinical practice.

**Methods:** A multidisciplinary panel of experts identified key areas, analysed the scientific evidence and formulated recommendations based on this evidence and qualitative techniques of “formal assessment” or “reasoned judgement”.

**Results:** Thirty-nine recommendations were made on diagnosis, ineffective and unsafe treatments, patient education and practitioner training. This part II shows the 12 recommendations, referring to the latter two areas.

**Conclusions:** Good knowledge of fibromyalgia on the part of patients improves their coping and acceptance of the disease and reduces the severity of some clinical manifestations. Healthcare professionals treating patients with fibromyalgia should be well trained in this disease to improve treatment outcomes and patient relationships.

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## Recomendaciones SER sobre el manejo de los pacientes con fibromialgia. Parte II: educación del paciente y formación de los profesionales

### RESUMEN

**Objetivo:** Evitar el deterioro de los pacientes con fibromialgia por actuaciones perjudiciales en la práctica clínica potencialmente evitables.

**Métodos:** Un panel multidisciplinar de expertos identificó las áreas clave, analizó la evidencia científica y formuló las recomendaciones a partir de esta evidencia y de técnicas cualitativas de «evaluación formal» o «juicio razonado».

#### Palabras clave:

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\* Corresponding author.

E-mail address: javierrivera@ser.es (J. Rivera Redondo).

**Resultados:** Se han elaborado 39 recomendaciones sobre diagnóstico, tratamientos no eficaces ni seguros, educación del paciente y formación del profesional. En esta parte II se reflejan las 12 recomendaciones, referidas a las dos últimas áreas.

**Conclusiones:** Un buen conocimiento de la fibromialgia por el paciente mejora el afrontamiento y la aceptación de la enfermedad reduciendo la gravedad de algunas manifestaciones clínicas. Los profesionales sanitarios que tratan a los pacientes con fibromialgia deben tener una buena formación sobre esta enfermedad para mejorar los resultados del tratamiento y la relación con el paciente.

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## Methodology

### Design

A qualitative summary of scientific evidence and consensual techniques were used. These reflect experts' agreement, based on clinical experience and scientific evidence.

### Procedural phases

The following steps were followed during the development of this document:

1 *Creation of the workgroup.* A multidisciplinary workgroup was created, comprising 5 rheumatologists who were members of the Spanish Society of Rheumatology (SER for its initials in Spanish), one family doctor, one psychologist, one psychiatrist, one nurse and one patient with FM. The rheumatologists were chosen through a tender open to all SER members. The Commission of Clinical Practice Guidelines (CPG) and SER recommendations assessed the curriculum vitae of all candidates in keeping with the objective criterion of their FM knowledge, mainly through participation in publications in high yield journals over the last 5 years.

Each participant was endorsed by their society for participation in this document. Coordination of the clinical and methodological aspects were made, respectively, by one of the rheumatologists as main researcher (MR) and a specialist in methodology who was a technician from the SER Research Unit (RU).

2 *Identification of key areas.* All workgroup members participated to structure the document and establish the key contents and aspects. They first identified the clinical issues of research which could have the most impact in offering information on FM management. After this, they focused on which of them required a response through PICO question formulation (Patient, Intervention; Comparison, Outcome). They also used the SPICE format (Setting, Perspective, Intervention, Comparison, Evaluation) to identify qualitative evidence that was able to offer information from the "patient's outlook". The methodology to follow during the recommendation creation process was also defined.

3 *Bibliographic search.* A bibliographic search was made in the databases: Pubmed (MEDLINE), EMBASE (Elsevier), Cochrane Library (Wiley Online), Cinhal (EBSCOhost) and PsycInfo. The searches were closed in July 2019. After this an updating of the search was performed in April 2020. The process was completed with a manual search for references and posters and summaries of conferences which the reviewers and experts considered to be of interest.

4 *Analysis and summary of scientific evidence.* Several rheumatologists, from the SER evidence review group, and methodologists from the RU were in charge of systematically reviewing the available scientific evidence. The overall level of scientific evidence was assessed, using the levels of evidence from the *Scottish Intercollegiate Guidelines Network* (SIGN) for the PICO questions (see [Appendix 3](#)) and the focus *Confidence in the Evidence from Reviews*

*of Qualitative research* (GRADE-CERQual), in the case of qualitative evidence deriving from the SPICE questions (See [Appendix 3](#)).

5 *Formulation of recommendations.* Once the critical reading was finalised, the MR and the components of the group of experts proceeded to formulate specific recommendations based on the scientific evidence. In the case of quantitative evidence this formulation was based on "formal assessment" or "reasoned judgement", summarising the evidence previously for each of the clinical questions. They also considered the quality, quantity and consistency of the scientific evidence, the general nature of the outcomes, their applicability and their clinical impact. The graduation of the recommendations was made with the SIGN system (see [Appendix 3](#)). For qualitative research evidence, again the GRADE-CERQual focus was used (see [Appendix 3](#)). Recommendations were divided into four main areas: diagnosis and prognosis of FM; ineffective and insecure therapeutic interventions; education and information of the FM patient, and training of professionals in FM.

6 *External review.* Once the previous phase was terminated, a final draft of the document was created, which was sent to the professionals selected for their knowledge on FM to make an independent external review aimed at increasing the external validity of the document and ensuring the precision of the recommendations.

7 *Public exposure.* Later this draft was submitted to a process of public exposure to members of the SER and to different interest groups (pharmaceutical industry, other scientific societies and patient associations) for validation and for their scientific discussion regarding methodology or recommendations.

8 *Scientific societies.* The scientific societies involved in the development of this guide, represented by members of the creative group, were the Spanish Society of Rheumatology (SER), the Spanish Society of Primary Care Physicians (SEMERGEN) the Spanish Society of Clinical Psychology and Health (SEPCyS), the General Board of the Official Spanish Nurses Colleges (CGE) and the Spanish Society of Fibromyalgia and Chronic fatigue (SEFIFAC) (all acronyms are the initials of the Spanish titles).

### Structure

This document contains the recommendations subdivided into the before-mentioned different areas.

### Additional information

The document of complete recommendations and the information for patients is available on the SER website.

## Results

The total recommendations formulated on FM is 39 and covers four main areas: diagnosis and prognosis of FM; ineffective and insecure therapeutic interventions; education and information of the FM patient, and training of professionals in FM. In

**Table 1**  
SER recommendations on fibromyalgia patient management (part II).

|   | LR     |
|---|--------|
| <b>Education and information for the patient with FM</b>  |        |
| <i>Recommendation 28:</i> It is recommended that patients with fibromyalgia receive information about their disease or receive educational interventions as part of the treatment to improve some of the clinical symptoms. These include pain; quality of life; disease impact; anxiety; familiarity of the disease and its treatment; self-management, and acceptance of the disease. | A      |
| <i>Recommendation 29:</i> It is recommended that the educational interventions complementary to conventional treatments contain several sessions on the neurophysiology of pain; coping; relaxation and self-management of the disease, and that they do not simply rely on informative leaflets.   | B      |
| <i>Recommendation 30:</i> It is recommended that educational interventions are weekly and that they last for a period of between 4 and 12 weeks so as to offer more effective results.  | B      |
| <i>Recommendation 31:</i> It is recommended that the activities carried out by patient associations and in the mutual self-help groups include information and debates on fibromyalgia management options and that they are not limited to meetings where the patients talk about the frustrating experiences they encounter with their disease.  | Strong |
| <i>Recommendation 32:</i> It is recommended that the educational interventions form part of the overall treatment patients with fibromyalgia should receive.  | ✓      |
| <i>Recommendation 33:</i> It is recommended that information on the disease is facilitated both for patients and family members.  | ✓      |
| <b>FM training for professionals</b>  |        |
| <i>Recommendation 34:</i> It is recommended that the clinicians who care for FM patients take specific courses as part of their training on communication; patient-centred medicine and shared decision-making to improve their relationship with patients.   | B      |
| <i>Recommendation 35:</i> It is recommended that continuous training of clinicians also includes information on the pathogenesis of FM; clinical symptoms; diagnosis; treatment and prognosis of the disease, to improve their skills and management strategies for accurate patient management.  | A      |
| <i>Recommendation 36:</i> In general, it is recommended that the training of clinicians includes modules on the existing myths, stigmas and controversies surrounding FM, to increase patient empowerment in coping with the disease, and also prevent their vulnerability and dissatisfaction with care received.  | B      |
| <i>Recommendation 37:</i> To improve the therapeutic process of patients with fibromyalgia information must be included within the specific training of the clinicians on the different treatment options and also on the therapies which are ineffective against their disease.  | Strong |
| <i>Recommendation 38:</i> It is recommended that the teaching programmes aimed at medical students should include specific training on the diagnostic and therapeutic aspects of FM, aimed at improving the willingness to treat patients with this disease.  | B      |
| <i>Recommendation 39:</i> It is recommended that self-help groups for patients are managed by healthcare professionals (for example psychologists, nurses or physiotherapists) specifically trained in FM and in how to help patients to establish objectives and proposals to cope with their health status.   | Strong |

FM: Fibromyalgia; LR: Level of recommendation (see Appendix 3).

this document the last 12 recommendations are reflected, referring to the areas of patient education and information and the training of professionals in FM (Table 1). The complete recommendations and patient information documents are available on the SER website.

### Education and information for the patient with FM

What is the efficacy of the educational intervention and information programmes aimed at people with fibromyalgia and/or their family members?

*Recommendation 28:* it is recommended that patients with fibromyalgia receive information on their disease or carry out educational interventions, as part of the treatment to improve some of the clinical signs such as pain, quality of life, impact of the disease, anxiety, knowledge of the disease and its treatment, self-management and acceptance of the disease (grade A recommendation).

*Recommendation 29:* it is recommended that the educational interventions added onto the conventional treatment contain several sessions on neurophysiology of pain, coping, relaxation and self-management of the disease, and which are not simply reduced to informative brochures (Recommendation grade B).

*Recommendation 30:* it is recommended that the educational interventions are carried out weekly, and that they last between 4 and 12 weeks for their most effective results (Recommendation grade B).

*Recommendation 31:* it is recommended that the activities carried out by patient associations and in mutual help groups include information and debates on fibromyalgia management options, and are not limited to meetings where the patients state what frustrating experiences they have had with their disease (Recommendation strongly in favour).

*Recommendation 32:* it is recommended that the educational interventions form part of the overall treatment patients with fibromyalgia should receive (Recommendation grade ✓).

*Recommendation 33:* it is recommended that information on the disease be given to both patients and family members who live with them (Recommendation grade ✓).

FM does not fit into the conventional disease model. It is a biopsychosocial model in which all aspects surrounding the patient have to be properly understood and which contribute to the disease severity.<sup>1</sup> Patients have to be familiar with the disease and for this they must be well informed, since in some of the therapeutic approaches it is essential to directly involve the patient.<sup>2</sup> Furthermore, the patient's lack of knowledge about everything concerning their disease appears to relate to a poorer evolution of FM, due to incorrect management by the patient of available resources.<sup>3</sup>

As a result of all of this, it is necessary to be aware of the importance education and information programmes have in controlling clinical signs of patients with FM.

The scientific evidence found regarding efficacy or effectiveness of several training or information programmes aimed at patients with FM come from studies with two types of design: quantitative and qualitative. Twelve RCT<sup>4–15</sup> have been identified, 7 of which were included in a SR.<sup>16</sup> Another 7 qualitative studies have been identified as well.<sup>17–23</sup> Most of the studies are of high or medium quality. Lastly, studies have been identified which do not meet with the inclusion criteria but may provide additional information in other aspects of diagnosis.<sup>24–31</sup>

The results obtained in these studies cover five different areas: clinical signs, disease impact, coping, healthcare attendance and role of patient associations. It has also been possible to assess the different educational interventions. Complete information on the results obtained from review of the evidence are available in the SER website.

The creative group considers that the quantitative and qualitative studies both show great consistency on the importance the education and information programmes have for patients with FM to manage their disease under the best possible circumstances. There are different education and information programmes but no clear superiority of any of them, with the exception of the simple informative brochures which are ineffective.

The results of the studies identified could be directly applied to our healthcare system, since the characteristics and prevalence of FM in our population was similar to that of other countries where most studies had been conducted.

However, the problem of FM in other countries is also similar and the patients with the disease are coping with the same challenges as ours.

The absence of specific education on their disease is perceived by the patient as a negative factor which makes the situation worse and damages their expectations and their quality of life.

The group considers that the patients with FM may clearly benefit from the education and information programmes on their disease. A patient who is aware of the limitations imposed by FM and the resources that may be used, both by the patient and by the physician concerned, to manage the disease, is a patient with a better short and long-term prognosis.

Lastly, there are indications that a good knowledge of the disease may suggest a considerable saving of health resources by the patient.

#### Training of FM professionals

For people with fibromyalgia, what is the efficacy of the training programmes aimed at healthcare professionals involved in their care?

**Recommendation 34:** It is recommended that the clinicians who care for patients with FM take specific courses as part of their training on communication, patient-focused care or shared decision-making to improve the relationship with the patient (Recommendation grade B).

**Recommendation 35:** It is recommended that continuous training of physicians also includes information on the FM pathogenesis, medical symptoms, diagnosis, treatment and prognosis of the disease, to therefore improve their skills and strategies in appropriate management of these patients (Recommendation grade A).

**Recommendation 36:** In general, it is recommended that the training of physicians includes modules on the existing myths, stigmas and controversies on FM, aimed at increasing the empowerment of patients against their disease, prevention of their vulnerability and dissatisfaction on the care received (Recommendation grade B).

**Recommendation 37:** to improve the therapeutic process of patient with fibromyalgia which should be included in the specific training on clinical information regarding the different existing treatment options and also on the therapies which are ineffective compared with the disease (Recommendation strongly in favour).

**Recommendation 38:** it is recommended that the teaching programmes aimed at medical students include specific training on the diagnostic and therapeutic aspects of FM, aimed at improving future willingness to treat patients with this disease (Recommendation grade B).

**Recommendation 39:** it is recommended that the self-help groups, aimed at patients be directed by healthcare professions (for example psychologist, nursing staff or physiotherapists) specifically trained in FM and in how to help patients to establish objectives and proposals to deal with their health status (Recommendation strongly in favour).

Diagnosis of FM continues currently being questioned by many physicians, both family doctors and rheumatology specialists, who have not received appropriate training on this disease.<sup>32</sup>

For FM patients, the experience of this lack of comprehension towards their disease leads to a high level of dissatisfaction with healthcare staff and also leads to an increase in visits to other centres and healthcare professionals (*doctor shopping*) searching for satisfactory healthcare and effective medical treatment.<sup>33</sup>

From the point of view of the disease itself, this level of dissatisfaction in patients has led to an impairment in the quality of life and functional physical capacity.<sup>34</sup>

Several surveys reveal the limitations of some specialists in establishing the diagnosis of FM, with the PC physicians having the greatest difficulties and the rheumatologists being those in the best position to establish differential diagnosis with other diseases.<sup>35</sup>

It is therefore important to be able to assess the impact the specific FM training programmes have on health professionals to identify their role in the improvement of quality of life and prognosis of the disease in these patients, and the possible positive impact in the use of healthcare resources.

Scientific evidence found on the efficacy or effectiveness of the training programmes aimed at healthcare professionals involved in FM patient care originate from two types of study design. Four quantitative studies have been therefore identified (experimental or quasi-experimental)<sup>36–39</sup> and 4 qualitative studies (interviews and focus groups with patients).<sup>18,22,37,40</sup> The studies present with high and moderate quality. Studies were also identified which did not meet with the inclusion criteria but which were able to provide additional information in other aspects of the diagnosis.<sup>41–46</sup>

The results obtained in the studies cover five different areas: clinical care, medical symptoms, treatment of the disease, impact on quality of life and care trajectory. The complete information on the results obtained from the review of the evidence is available on the SER website.

The creative group considers that the results of all the selected studies are consistent with providing evidence that despite barriers that may arise, the FM training programmes aimed at the clinicians are effective in improving the quality of the doctor-patient relationship, both from the patient's viewpoint and from the doctor or healthcare professional involved.

The group of experts therefore consider that a training programme model in FM, where all healthcare professionals participate in the process of managing people with FM, could lead to a more fluid communication in healthcare relationships. Also, it would mean that patients would possess more comprehensible information on their disease and greater levels of satisfaction with decisions and conflicting opinions regarding decisions would be obtained. All of the above would create better management of the disease, in addition to effectiveness and adherence to different treatments.

#### Conclusions

It is more beneficial for the patient to have a good knowledge of their disease and the resources which they may use to deal with it. One of the solid recommendations that may be made after this review is precisely that patients with FM receive appropriate information regarding their disease or undertake educational interventions as part of the treatment to improve some of the clinical symptoms such as pain, quality of life, impact of the disease, knowledge of their disease and its treatment, self-management and acceptance of the disease.

Due to the many aspects that need improving with regard to patient education programmes the disease must be explained to

the patient with FM and specific education programmes must be available for patients and families.

Lastly, it would not have been possible to create the recommendations we made in this study if the healthcare personnel who care for FM patients were not in turn familiarised with the disease. The systematic review made here has clearly outlined the lack of knowledge by the clinicians regarding the disease, the therapeutic modalities, communication, patient-focused medicine and shared decision making which are essential for improving treatment results and patient relations.

#### Future research agenda

Following systematic review of the existing scientific evidence for the management of patients with FM made for the creation of these recommendations, the panel of experts consider that many aspects remain to be included in the future research agenda. These would include the following:

- More randomised, controlled clinical trials with standard treatment are needed to assess the efficacy of multicomponent therapies that include education in the neuroscience of pain, therapeutic physical exercise, and cognitive-behaviour therapy in the treatment of patients with FM.
- More randomised, controlled clinical trials with standard treatment are needed to assess the efficacy of therapies based on acceptance (ACT) and Mindfulness therapies (MBSR mainly), searching for common therapeutic factors or patient profiles with FM who would benefit from one intervention or another.
- Studies are needed that assess the efficacy of education programmes for patients with FM relating to the employment environment, particularly regarding lost working days, causes and duration of temporary disability at work (TDW) or number of total permanent disabilities at work (PDW)

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#### Evidence reviewer group

Cayetano Alegre de Miquel. Hospital Universitario Dexeus-Quiron. Barcelona.

Noé Brito García. Unidad de Investigación. Sociedad Española de Reumatología. Madrid.

Petra Díaz del Campo Fontecha. Unidad de Investigación. Sociedad Española de Reumatología. Madrid.

Carol Merino Argumánez. Hospital Universitario Puerta de Hierro. Majadahonda, Madrid.

M. Nieves Plana Farras. Hospital Príncipe de Asturias. CIBER de Epidemiología y Salud Pública. Madrid.

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#### Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.reumae.2021.01.005>.

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