



# Fibromyalgia has a larger impact on physical health than on psychological health, yet both are markedly affected: The al-Ándalus project



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## ABSTRACT

**Objectives:** To characterize a representative sample of fibromyalgia women based on a set of relevant factors known to be related to this disease. To distinguish specific factors of the disease from other symptoms that might also exist in non-fibromyalgia women. To test whether fibromyalgia affects more severely physical or psychological outcomes.

**Methods:** A total of 459 fibromyalgia women vs. 214 non-fibromyalgia (control) women from Southern Spain (Andalusia) took part in this cross-sectional study. Several instruments were used to assess tenderness, impact of fibromyalgia, fatigue, health-related quality of life, mental health, and cognitive performance.

**Results:** Overall, fibromyalgia women showed a worse status in pain, fatigue, health-related quality of life, depression, and anxiety than controls ( $P < 0.01$ ). In general, the observed associations presented very large effect sizes (Cohen's  $d$  from  $\sim 1$  to  $\sim 5.5$ ). No differences between fibromyalgia and controls were observed in cognitive and memory performance, except for delayed recall, but the observed effect size was low ( $\sim 0.25$ ). The effect size observed for the global physical component ( $\sim 3.3$ ) was larger than that for the global psychological component ( $\sim 1.3$ ), all  $P < 0.001$ .

**Conclusions:** Our results reinforce the understanding of fibromyalgia as a polysymptomatic distress condition with pain as its main symptom. Our findings support that fibromyalgia seems to have a greater impact on physical than on psychological outcomes, though both are largely affected.

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## Introduction

Fibromyalgia is a chronic musculoskeletal pain condition of unknown etiology. General prevalence of fibromyalgia varies from 0.5% to 5% depending on the different countries [1–3]. Similarly to

the differences observed in the fibromyalgia prevalence among countries [1–3], the specific characteristics and symptoms reported by patients with fibromyalgia might differ depending on the region. In fact, previous studies have shown geographical variations in reported symptoms among patients with chronic widespread musculoskeletal pain [4,5]. Fibromyalgia patients are a heterogeneous group, and the rating, number, and impact of different symptoms are expected to vary between different populations.

Fibromyalgia has become a worryingly health condition in our modern society, and its treatment implies time-consuming and high economic burdens [1]. Beyond a chronic widespread pain condition, fibromyalgia has recently been defined as a complex dimensional disorder with pain as its main symptom [2], and the inclusion of equally presumable important non-pain symptoms,

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such as fatigue, stiffness, cognitive problems, depression, anxiety, and a long list of other complaints [2,6,7]. This new approach highlights the need to know which of this large variety of symptoms are more characteristic of this disease, which might help in its accurate management.

According to Queiroz [3], epidemiological studies are important to better understand the extent of the problem in specific settings. No previous large population-based studies examining a vast variety of symptoms have been carried out previously in Spanish fibromyalgia patients and an age-matched control group. Furthermore, it is unknown if fibromyalgia affects more severely those components related to physical (e.g., functionality), or psychological domains (e.g., depression). A deep study of the fibromyalgia's key symptoms may provide a more fitted and appropriate guidance for treatment decisions and strategies. Therefore, the present study aimed (1) to characterize a representative sample of fibromyalgia patients from Southern Spain (Andalusia) in a set of relevant factors known to be related to this disease. This will provide useful reference values for clinicians and researchers so that they can better interpret their evaluations according to our population-based sample. (2) Many symptoms have been suggested to be related to fibromyalgia, but it is unknown which of them are more specific of the disease. In the present study, we will include a region and age-matched non-fibromyalgia sample in order to distinguish specific factors of the disease from other symptoms that might also exist in non-fibromyalgia women. For this purpose, we will use standardized statistic (effect size) to be able to compare different factors and dimensions. (3) A “global physical component” and a “global psychological component” will be created to clarify which of them is more affected in fibromyalgia patients compared with controls.

## Methods

### Participants

In order to obtain a fibromyalgia sample representative of the Andalusian population, the sample size needed was calculated ( $n = 300$ ). Then, a sex and province proportional recruitment was planned (Supplementary Table 1). Fibromyalgia patients were recruited from different fibromyalgia associations via e-mail, letter, or telephone. We also asked those fibromyalgia patients interested in participate to recruit a pairwise non-fibromyalgia individual (control) with similar age and socio-demographic characteristics in order to carry out appropriate comparisons between groups. We additionally contacted control participants via e-mail and internet advertisements. The study assessments were carried out between November 2011 and January 2013. All interested participants ( $n = 960$ ) gave their written informed consent after receiving detailed information about the aims and study procedures. The inclusion criteria for fibromyalgia patients were as follows: (i) to be previously diagnosed by a rheumatologist, (ii) to meet the 1990 American College of Rheumatology (ACR) fibromyalgia classification criteria [8], and (iii) not to have acute or terminal illness, and severe dementia [Mini-Mental State Examination (MMSE) < 10] [9]. The inclusion criteria for control participants were as follows: (1) not to meet the 1990 ACR fibromyalgia criteria [8] and (2) not to have acute or terminal illness, and severe dementia [Mini-Mental State Examination (MMSE) < 10] [9]. Men were not included in the present study (86 men excluded). A total of 38 patients were not previously diagnosed. Moreover, 92 fibromyalgia patients did not meet the 1990 ACR criteria whereas 6 control participants met it. Additionally, 1 fibromyalgia patient had severe dementia. To achieve age-matched groups, women <37 years and >65 years were not included in the present study (64 participants excluded).

The final study sample comprised 459 fibromyalgia vs. 214 control women. The study was reviewed and approved by the Ethics Committee of the “Hospital Virgen de las Nieves” (Granada, Spain).

### Procedure

Measurements were performed on 2 different occasions separated by 1 day and performed by the same trained researchers group in order to reduce inter-examiner error. The first day the MMSE was applied, and self-reported socio-demographic data and Beck Depression Inventory (BDI-II) were filled by participants. Furthermore, assessment of tender points according to the 1990 ACR criteria was performed, and weight and height were measured. Subsequently, participants received several questionnaires to be filled at home. At the second appointment, participants returned the filled questionnaires to the research team and were interviewed on the Paced Auditory Serial Addition Task (PASAT) and the Rey Auditory Verbal Learning Test (RAVLT).

### Outcome measures

#### Anthropometric measures

Weight (kg) and height (cm) were measured using a portable eight-polar tactile-electrode impedanciometer (InBody R20, Biospace, Seoul, Korea) and a stadiometer (Seca 22, Hamburg, Germany), respectively. Body mass index (BMI) was calculated as weight (kg) divided by height (m) squared.

#### Tenderness

We assessed 18 tender points according to the 1990 ACR criteria for classification of fibromyalgia [8] using a standard pressure algometer (FPK 20; Wagner Instruments, Greenwich, CT, USA). Two alternative measurements at each tender site were performed, and the mean score was recorded. A pressure threshold  $\leq 4 \text{ kg/cm}^2$  was considered a positive tender point. The total count of positive tender points (tender points count) was recorded for each participant. An algometer score was calculated as the sum of the minimum pain–pressure values obtained for each tender point.

#### Fibromyalgia impact

The Revised Fibromyalgia Impact Questionnaire (FIQR) is a self-administered questionnaire, comprising 21 individual questions with a rating scale of 0–10. These questions compose 3 different domains: function, overall impact, and symptoms score (ranging: 0–30, 0–20, and 0–50, respectively) [10]. The FIQR total score ranges from 0 to 100, with a higher score indicating greater effect of the condition on the person's life. We used the Symptom Impact Questionnaire with control participants. The SIQR [11] is a slightly modified version of the FIQR used with non-fibromyalgia patients. Number of questions, domains, and scoring is the same as the FIQR.

#### Fatigue

The Spanish version of the Multidimensional Fatigue Inventory (MFI-S) was used to measure fatigue severity. Five subscales compose this questionnaire: general fatigue, physical fatigue, mental fatigue, reduced activity, and reduced motivation [12,13]. Each subscale includes 4 items with 5-point Likert scales. Scores on each subscale range from 4 to 20, with higher scores indicating greater fatigue.

#### Health-related quality of life

The Short-Form Health Survey 36 (SF-36) is a generic instrument for assessing health-related quality of life [14]. It contains 36 items

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