

Prevalence and impact of fibromyalgia on function and quality of life in individuals from the general population: results from a nationwide study in Spain

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Abstract

Objective

To estimate the prevalence of fibromyalgia (FM) and to compare some descriptive epidemiological and quality of life data between persons with and without FM criteria in a representative sample of the general Spanish population.

Methods

Cross sectional study of 2,192 Spaniards aged 20 or above, selected by cluster sampling. Subjects were invited to a structured interview carried out by trained rheumatologists to ascertain various musculoskeletal disorders. The visit included screening and examination, validated instruments for measuring function (HAQ) and quality of life (SF-12) and questions about socio-demographic characteristics and musculoskeletal, mental, and other general symptoms. FM was suspected in subjects with widespread pain for more than three months. FM was defined by the American College of Rheumatology classification criteria. All estimates are adjusted to sampling scheme.

Results

The prevalence of FM in Spain is 2.4% [95% CI: 1.5-3.2]. FM is significantly more frequent in women (4.2%) than in men (0.2%), with an OR for women of 22.5 [95%CI: 7.2- 69.9], mainly in the 40-49 years age interval. It is more frequent in rural (4.1%) than in urban settings (1.7%), with an OR for rural settings of 2.5 [95%CI: 1.03-5.9]. FM is associated with a low educational level, to a low social class, and to self-reported depression. The scores in the HAQ and in the SF-12 were significantly lower in FM subjects, despite adjustment by covariates.

Conclusion

FM has a high prevalence in the general population. FM is associated to female gender, comorbidities, age between 40 and 59 years, and a rural setting. Persons fulfilling FM criteria show impaired functioning and quality of life.

Key words

Fibromyalgia, prevalence, epidemiology, cross-sectional studies, quality of life.

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Introduction

Fibromyalgia (FM) is a controversial entity of unknown origin with many predisposing factors. It is characterized by benign, chronic, and diffuse musculoskeletal tenderness, usually accompanied by non-restorative sleep, generalized fatigue, and morning stiffness. In 1990, the American College of Rheumatology (ACR) established the classification criteria for FM, which include widespread pain present for at least three months and the observation of pain brought on by pressure in specific anatomical sites (1).

FM has a different prevalence depending on the population studied and the criteria used, oscillating from 0.7% to 20% (2, 3). Most FM patients are middle-aged women (73-88%). However it has also been described in children (4), as well as in the elderly (5). In a rheumatology unit, about 10-20% of the patients suffer FM, a proportion that descends to 2.1-5.7% in non-specialized clinics (2, 6). Very few studies have estimated the prevalence of FM and chronic widespread pain in the general population even though the classification criteria are fairly easy to apply in an epidemiological context (2, 7, 8).

FM patients studied in specialized and non-specialized clinics usually report inability to perform daily tasks (9). Disability, health status and comorbidities have seldom been assessed in cases from the general population (10).

The objective of this study is to estimate the prevalence and distribution of FM in the general population and to measure its impact on function, quality of life and use of health resources.

Patients and methods

The Spanish Society of Rheumatology promoted the EPISER study, a nationwide study focused on the prevalence of musculoskeletal diseases, including FM. The study also measured the social and health related impact of these diseases. Methods and characteristics of the study sample have been detailed elsewhere (11, 12). Briefly, a significant sample of 2,998 Spaniards over the age of 20 were selected by cluster sampling from an eligible population of 972,255 by multistage probability sampling. First,

provinces were selected at random within eight strata with a similar population. Then, cities or villages were randomly selected, observing the rural/urban ratio of 25:75 present in Spain. Finally, subjects were selected at random from the city censuses, in gender and age strata proportional to those of the total Spanish population. The sample size was chosen to achieve a 95% confidence interval in the estimate of the prevalence of 0.5-1% taking into account an expected 30% dropout rate and 20% to account for the effect of design. All selected subjects were invited to participate. The sample studied comprised 2,192 people, similar to those selected who could not be interviewed, as shown previously (11, 12). The reasons for exclusion were: 203 census errors (not living at the address registered, dead, younger than 20), 213 unwilling to participate, and 390 who could not be reached after following a comprehensive contact protocol. A comparison with the general population of Spain, depicted by National Statistics, revealed the adequate representativity of the sample in EPISER (11, 12).

Survey interviews were carried out at local primary care facilities after permission was obtained from the local authorities. Subjects were asked about sociodemographic aspects including level of education, main occupation (matched to a social class level according to the protocol by the Spanish Society of Epidemiology), and a list of chronic diseases (subjects were asked whether any physician had given them a diagnosis, including depression, or hypertension, or hypercholesterolemia, or whether they were taking any chronic medication for any reason and the disease recorded), height and weight. The list of chronic diseases elicited by the subjects was reduced to groups of diseases that were in accordance with the specialty that usually treats that type of patient (for instance, migraine and stroke were included under neurologic diseases). The subjects completed the Spanish validated versions of the Short Form 12 item questionnaire (SF-12) and the Health Assessment Questionnaire (HAQ). The SF-12 measures health related quality of life

Competing interests: none declared.

in two scales, physical and emotional, both in continuous scores ranging from 0 to 100 (worst to excellent). The HAQ assesses functional capacity, showing the ability to perform daily activities in 8 domains, yielding a discrete result ranging from 0 to 3 (perfect ability to completely impaired).

FM was defined by the American College of Rheumatology (ACR) classification criteria (1): 1) widespread pain on the day of the interview, defined as a) pain in at least one point in both the right and the left half of the body, above and below the waist, and axial pain, b) which must be greater than one in a visual analogue scale (0-10), c) which had been present for more than three months, and d) which was unrelated to cancer or traumatism; and 2) finding of 11 out of 18 possible tender points on examination as established by the ACR.

Other rheumatic conditions were also target diseases in the EPISER study, such as hand or knee osteoarthritis, rheumatoid arthritis, low back-pain, and osteoporosis. Cases were screened and confirmed following meticulous protocols and standardized definitions, which were detailed previously, and their prevalence estimated (11, 12).

Prevalence estimates and confidence intervals were obtained by using the *svy* commands of Stata (Stata 9.2, Stata corporation, Texas, 2006), by which analysis are adjusted to the sampling scheme. Comparisons between groups were tested with two-tailed chi-square tests and Fisher's exact tests, adjusted by design. The effect of specific conditions on quality of life and function was assessed by n-factor ANCOVA, controlling for age, sex, presence of comorbidity, and social class, and adjusting by cluster sampling. Logistic regression (*svylogit*) was used to obtain independent measures of association with prevalent FM.

The study protocol was reviewed and approved by the Research Ethics Committee of the Hospital Universitario de La Princesa, Madrid and by the evaluators of the Research Fund of the Social Security. The data set used for the random sampling and location of participants, which was discarded once

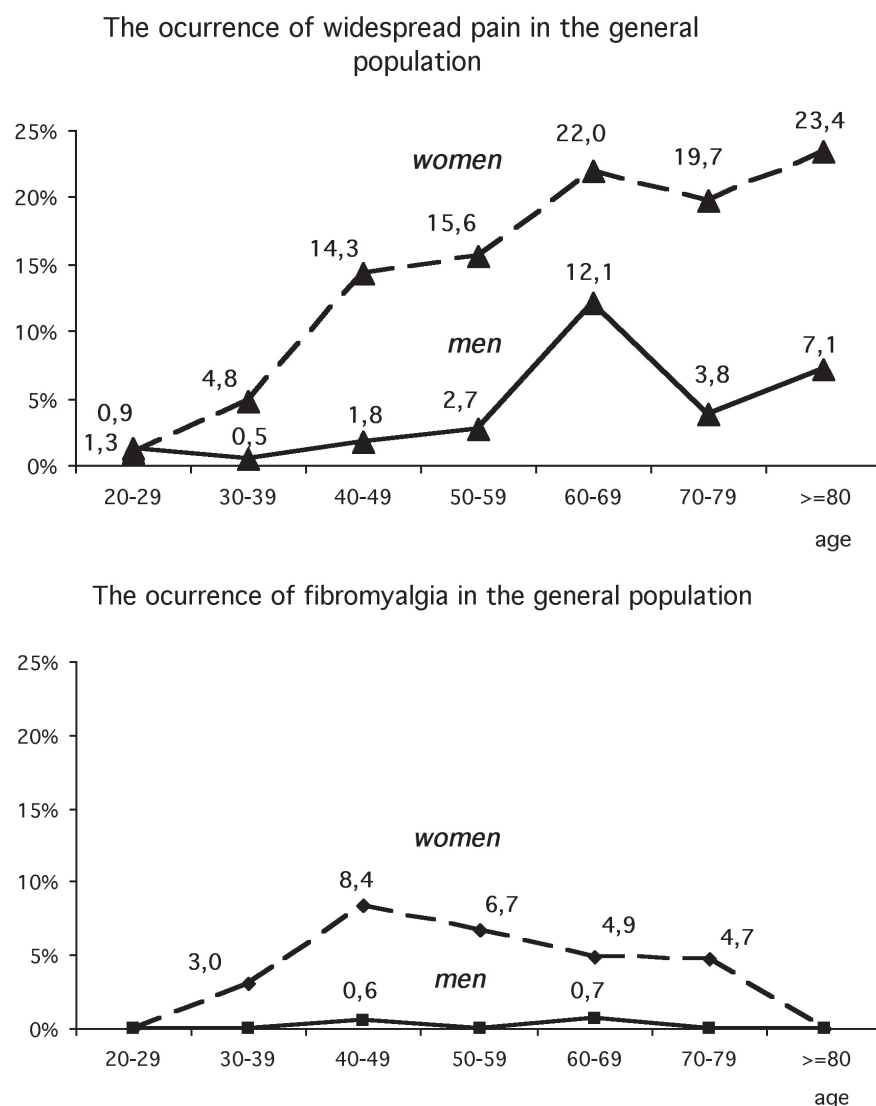


Fig. 1. EPISER study: occurrence of widespread pain and fibromyalgia, by age and gender, in the adult Spanish population, 1998-99.

the subjects were contacted, had been registered at the Official Agency for Data Protection, according to Spanish regulations.

Results

Of the 2,192 persons, 176 reported widespread pain on the day of the visit (adjusted prevalence estimate of 8.0% [95% CI: 5.9-10.1]), and 52 (2 men and 50 women) of them fulfilled the FM criteria. The prevalence of FM in the adult Spanish population is estimated at 2.37% (95% CI: 1.53-3.21). Spain has a current population of 32 million over 20 years old, which correspond to two and a half million Spaniards suffering widespread pain, and of whom 750,000 fulfil the FM criteria.

With respect to its demographic distribution, FM appears more frequently in women (4.2% [95% CI: 2.9-5.6]) than in men (0.2% [95% CI: <0.5]), giving a women-to-men ratio of 21:1 ($p<0.001$). No cases of FM were found in extreme age intervals, and most cases were ascertained in the interval between 40 and 49 years; an age distribution that is different from that of widespread pain (Fig. 1). The prevalence of FM was twice as high in rural settings than in large cities ($p<0.01$). The years of schooling were inversely related to the frequency of FM ($p<0.01$). Among persons with no studies or only elementary level, the prevalence of FM was, 4.8% and 3%, respectively, while among persons with studies at university level, the

Table I. EPISER study. Determinants of FM prevalence and their magnitude, expressed in odds ratios, in the adult Spanish population, 1998-99.

Variable	Odds ratio (95%CI) Unadjusted	p-value After adjustment
Female sex	22.4 (5.4-94.4)*	44.3 (5.8-337.0)*
Age between 40-60	3.1 (1.8-5.4)*	1.8 (0.9-3.8)
Rural residence	2.5 (1.4-4.3) [†]	2.5 (1.2-5.4) [†]
Low study level (elementary or less)	3.4 (1.7-6.7)*	1.3 (0.5-3.4)
Depression	4.5 (1.9-12.0) [†]	1.0 (0.5-3.4)
Non-rheumatic comorbidity	1.0 (0.5-1.8)	4.3 (1.6-11.8) [†]
Low social class	2.4 (1.2-4.8) [†]	0.9 (0.4-2.1)
Obesity	2.0 (1.1-3.7) [†]	0.9 (0.4-2.1)
Short height under first quartile for gender**	2.6 (1.5-4.6) [†]	3.0(1.4-6.3) [†]

Only variables that reached a $p < 0.10$ in the bivariate plus non-rheumatic comorbidity, which was forced into the model, are presented. The adjusted model included all variables in the first column.

* $p < 0.001$

[†] $p < 0.005$

**167 cm men, 155 cm women. See reference 26 (Carmona *et al.*) for further details on this finding.

prevalence of FM decreased to 0.6%. Social class was also inversely related to the prevalence of FM ($p < 0.01$). Regarding working status, persons with FM criteria present a lower prevalence of active work (32.7%) than the general population (52.3%); a significant proportion among FM cases were housewives (32.7%) compared to the percentage in the general population (16.6%); the proportion of unemployed among FM cases (5.8%) was higher than that of the general population (2.9%); and the proportion of people with temporary work disability among FM cases (3.8%) was also higher than that of the total population (0.5%). All these differences were statistically significant ($p < 0.001$). Table I shows the odds ratios and 95% confidence intervals for all associations.

People with FM show a lower functional capacity for daily activities and

health-related quality of life than other subjects from the general population, even after adjustment by factors that affect the score in the questionnaires utilized, such as female sex, age, presence of comorbidity, and social class (Table II). On comparing FM with other rheumatic diseases, it produces a similar degree of disability to knee, hand, and lumbar spine osteoarthritis ($p = 0.284$) and slightly less than rheumatic arthritis ($p < 0.01$). In this way, a lower quality of emotional life than people with osteoarthritis ($p < 0.001$) and with rheumatoid arthritis ($p < 0.01$) is rendered objective, with no existing differences on the physical side of the quality of life (Table II). Moreover, 11.5% of the subjects with FM criteria showed a HAQ score over 1.5, which could be considered a moderate-to-high impairment in daily activities, versus 2.7 in non-FM ($p < 0.01$). Also, 78.8% of the FM cases

thought that their general health was regular to poor, as assessed by the first item of the SF-12 questionnaire, compared to 26.1% of individuals without FM ($p < 0.01$).

Table III shows the prevalence of different comorbidities in FM and non-FM subjects. Interestingly, the difference in prevalence of any chronic disease is very large and statistically significant. Forty subjects with FM criteria (76.9%) had visited at least one physician for musculoskeletal symptoms in the last year (vs. 32.1% of non-FM individuals; $p < 0.01$), with a median of number of different physicians visited of two, 13% of whom had been visits to the emergency room. The results were similar for generalized pain, since 79.1% had visited at least one physician for musculoskeletal symptoms in the last year and only 29.4% of the rest of individuals from the general population.

Individuals with FM criteria present a greater risk of consumption of NSAIDs than the rest of the population (RR: 5.04 (IC95%: 2.88-8.80; $p < 0.001$) and a RR: 5.99 (IC95%: 3.42-10.47; $p < 0.001$) in the consumption of analgesic medication in comparison with the general public. The results in generalized pain were similar. No association was found in FM cases between gender, age group, rural or urban setting, years of schooling, social class, HAQ or SF-12 score, and having visited any physician for musculoskeletal pain in the last year. Up to 42 (81%) of the FM cases had taken pain-killers for at least one month in the last year (the proportion of non-FM taking pain killers was 29.4%; $p < 0.01$). Up to 11.5% of the

Table II. Effect of FM in the score of the HAQ and SF-12 questionnaires, and depression. Results are expressed as estimated coefficient (HAQ, and SF-12) or as odds ratio (depression) and 95% confidence interval. All estimations are given adjusted to cluster sampling and to gender, age, social class and presence of any chronic comorbidity.

Rheumatic disease	HAQ	SF-12 _{physical}	SF-12 _{mental}	Depression
Fibromyalgia	0.31 (0.21, 0.41)*	-4.40 (-7.53, -1.27)	-11.29 (-15.22, -7.35)*	3.1 (1.1, 9.0)
Rheumatoid arthritis	0.74 (0.26, 1.22)*	-7.27 (-15.63, 1.08)	-2.27 (-8.96, 4.41)	NA
Low back pain	0.14 (0.06, 0.23)*	-5.91 (-7.72, -4.09)*	-3.05 (-4.26, -1.83)*	1.3 (0.5, 3.4)
Knee osteoarthritis	0.21 (0.11, 0.30)*	-7.77 (-10.39, -5.15)*	-0.40 (-2.89, 2.08)	0.7 (0.2, 2.5)
Hand osteoarthritis	0.11 (0.001, 0.22)	0.61 (-1.64, 2.89)	-1.86 (-4.64, 0.92)	0.5 (0.2, 1.4)
Osteoporosis	0.12 (0.07, 0.17)*	-0.91 (-2.63, 0.80)	-2.01 (-3.56, -0.45)	1.3 (0.4, 4.4)

* $p < 0.01$

NA: no cases of depression among rheumatoid arthritis cases identified.

Table III. Prevalence of chronic diseases in subjects from the general population, depending on whether or not they meet the ACR criteria for fibromyalgia.

Disease or group of diseases*	Prevalence [95% confidence interval] in subjects from the general population		
	Without FM criteria	With FM criteria	<i>p</i> -value
Any chronic disease	58.0 [53.3, 62.7]	92.3 [71.9, 98.3]	<0.01
Neurologic diseases	18.0 [14.0, 22.9]	16.0 [6.9, 32.8]	0.777
Psychiatric disease	16.8 [11.6, 23.8]	32.0 [17.9, 50.3]	0.028
Depression	2.8 [1.8, 4.3]	11.5 [3.9, 29.4]	0.011
Anxiety	0.3 [0.1, 1.0]	3.8 [2.3, 6.4]	<0.01
Hypertension	16.5 [14.8, 18.5]	36.5 [25.0, 49.8]	<0.01
Hypercholesterolemia	13.4 [10.0, 17.6]	21.2 [9.9, 39.6]	0.130
Vascular disease	12.2 [7.6, 18.9]	8.0 [1.2, 38.8]	0.387
Endocrine disorder	10.1 [6.0, 16.3]	4.0 [0.6, 21.9]	0.314
Diabetes	5.4 [4.8, 6.0]	9.6 [4.7, 18.7]	0.092
Gastrointestinal diseases	10.0 [7.3, 13.5]	5.8 [1.3, 22.1]	0.369
Allergies	8.2 [5.7, 11.6]	9.6 [1.9, 37.1]	0.829
Eye disease	7.5 [4.2, 12.8]	4.0 [0.3, 33.9]	0.610
Glaucoma	0.6 [0.3, 1.5]	1.9 [0.3, 11.8]	0.335
Skin diseases	7.5 [4.0, 13.5]	-	
Heart diseases	6.2 [5.5, 7.0]	3.8 [0.9, 15.0]	0.455
Pulmonary diseases	6.0 [4.8, 7.4]	9.6 [3.8, 22.1]	0.276
Ear nose and throat	4.7 [2.2, 9.8]	4.0 [0.4, 30.2]	0.884
Kidney disease	3.7 [2.0, 6.9]	8.0 [1.9, 28.2]	0.226
Cancer	3.5 [1.6, 7.5]	12.0 [1.9, 48.9]	0.068

*Disease definition was by self-report (See **Methods**). Diseases are combined into groups depending on the specialty that usually treats them.

cases identified with FM were receiving work disability compensations, versus 3.5% in the non-FM population ($p < 0.01$).

Discussion

The EPISER study was an initiative of the Spanish Society of Rheumatology to establish the prevalence of different rheumatic diseases, including FM, and to study their impact on function, quality of life, work status, and use of health resources. The study sample was representative of the general Spanish population as demonstrated elsewhere (11, 12) and so generalization of the results, at least to the general Spanish population, is reasonable.

The prevalence of FM in the general population had been previously reported from 0.7 to 4.9% (2, 7, 13-18). Our study shows a prevalence of FM at an intermediate point among those previously described, which is, in fact, very close to the one estimated in Italy (18). The prevalence of FM was greater in persons between 40 and 50 years old similar to one study (13), but lower than that found in other studies that point out

a greater prevalence between 55 and 64 years of age (16), 50-59 (14) or 60 and 79 (2). The female to male ratio found by our study was immense, even after multiple statistical adjustment, but still lower than the ratio found in a Brazilian study (13), although clearly superior to the 3:1 or 6-8:1 of more classical studies (16, 2).

The prevalence of generalized pain was 8%, which was not very different from previous studies (2, 8, 19), despite the scarce standardization of the definition of generalized pain. And it is interesting that the prevalence of generalized pain increases with age as in other studies (8, 19), while that of FM presents a maximum peak around the age of 45. It is not clear why some people with widespread pain also have a compatible FM exam and others do not. The data in the general public is of great interest in that it differs greatly with that of FM subjects who seek medical assistance. The prevalence of FM in rheumatology practices ranges from 10 to 20% of all the visits, and in 5 to 6% of adult patients at general medical practices (6, 20). Physicians who deal

with FM patients have a biased idea of what FM is in the general population, and one of the most interesting findings of the study is precisely, having found persons who fulfill completely the criteria for FM who live their lives without seeking medical help.

A very important relationship with associated comorbidities in patients affected by FM have been objectified, highlighting a significantly higher presence of non rheumatologic comorbidities, having been previously rendered objective both in patients with chronic pain (21), and with FM (22), although not previously reflected in the general public. Our data agrees with that of other studies that have shown an increase of depression in patients with FM (21) both in the community (2) and in medical attention (23, 24), as well as in patients with generalized pain (3). However, the prevalence of depression in FM is not too high when it is compared to other chronic illnesses that cause pain, such as rheumatoid arthritis (25). Moreover, in one study the authors found no increase of depression in persons with FM in the community (24). As a matter of fact, our study shows that depression is not independently associated to the prevalence of FM. On the contrary, the association between depression and the prevalence of FM clearly wears off when other factors are included in the model, namely low social class and other comorbidity. Another possible explanation is that our study is focused on the general population; while the large prevalence of psychiatric illnesses in FM has been found in patients attending medical consultation (24).

It is important to highlight the increase of prevalence of FM, although not with generalized pain, in the group of people studied in the rural setting, independent of the social class and the study level. This increase coincides with other studies where a greater prevalence of FM exists in rural than in urban zones (7, 26), maintaining this difference considering the zone inhabited both by poor people as well as an affluent part inhabited by middle class people (26). This is discordant with other works, where the prevalence of FM is higher in the urban population than in the rural (27),

although the proportion is inverted according to some conditioners of community behavior (27). In other studies, the prevalence is greater both in the poorest areas of the city and rural population, in comparison with middle class neighborhoods (7). A very low prevalence (1.3%) has also been described in rural populations (10). We must be cautious, however, as most cases occurred in urban settings on islands, and we cannot rule out an islander effect.

In the bivariate analysis, we saw an increase in the prevalence of FM in persons with a lower level of education and lower social class. However, these associations were not maintained in the multi-variate analyses. There is data which has been described in other studies (2, 14, 16), although a greater prevalence of generalized pain in those people with a lower level of education was found.

In the present study, a greater consumption of resources has been established on the part of people affected by FM in comparison with the non-affected population. Even though the economic costs were not studied as in other studies (22, 28-30), the costs derived from FM that increase the expense of these patients have been enumerated. An increase in consumption, both of NSAIDs and of general analgesics, has been noticed in comparison with non-FM subjects, as it has been described in previous studies (28). Also, there is an increase in the number of medical visits, probably related to the larger number of comorbidities in FM compared to non-FM subjects, as has been described in other works (28, 29). However, not all studies agree with this augment (2). Of note, no differences were found between FM and generalized pain neither in terms of analgesic consumption nor in medical visits (general medicine, specialized, emergencies), as others described previously (30). Another data of indirect economic repercussion is the low rate of active work among FM subjects, with many people on sick leave, and the large amount of women dedicated to home-tasks.

The concept of quality of life refers to self-perception of pain, economic status,

social relations, free time, work, self-satisfaction, functional capacity, and sense of safety. All these elements are inter-related and could be altered by various factors (31, 32). We have used the SF-12 that presents values comparable to SF-36 (33), divided into a physical component and a mental one, in a validated Spanish version (34). Coinciding with other studies (22, 35, 36) a clear decrease of both components exists in FM subjects. At the same time, we have objectified a lower quality of life and worsened functional capacity in people with FM in comparison to those with generalized pain, reflecting differences between both. A possible explanation could be the finding of a relationship of the means of psychological distress with the tender point count (37) or this count with self-reported pain that is related to a worse quality of life (38). FM patients present an increased pain perception, a lower symptom control and a worse quality of life than the patients affected by rheumatoid arthritis (RA), systemic lupus erithematosus, ankylosing spondilitis, osteoarthritis and others (39-44). And concomitant FM worsens quality of life, as it has been demonstrated in lupus patients with secondary FM (43, 45). We have described a decrease of the quality of physical and mental life in comparison with the general public. Compared to other rheumatic problems, people with FM do not fare significantly worse than those with osteoarthritis or rheumatoid arthritis, not at least in the physical aspects of quality of life. This observation is still controversial as other authors have found a great vitality in rheumatoid arthritis patients compared to FM sufferers (46), and a very low stamina in FM (36, 47, 48), while others did not find differences in physical functioning (36), nor did they find that rheumatoid arthritis patients had lower scores than FM (49).

In conclusion, our study found a prevalence of FM in the general population of Spain that completely matches that of other very different settings, and which is a large number of people affected, not all of whom will seek medical attention. The lives of people with FM is affected accordingly.

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Appendix

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