Determinants of sleep quality in middle-aged women with fibromyalgia syndrome

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SUMMARY The objectives of this study were: (i) to compare the sleep quality at home of patients with fibromyalgia with that of healthy controls; and (ii) to examine the factors associated with sleep quality in patients with fibromyalgia. In addition to anthropometric measures, 75 women with fibromyalgia and 48 healthy controls completed standardized questionnaires that assessed sleep quality, functional impairment (Fibromyalgia Impact Questionnaire), depression, anxiety and physical activity level. Comparisons between groups, correlation coefficients and a series of hierarchical multiple regressions were performed. The global Pittsburgh Sleep Quality Index scores were worse in patients with fibromyalgia than in the controls. This result was partly explained by the Fibromyalgia Impact Questionnaire score. For the patients with fibromyalgia, the results of the first model that tested the importance of demographic factors were not statistically significant. In the disease-related model, the duration of symptoms and symptom severity contributed to poor sleep quality. A measurement of physical activity participation and the sum of the skinfold thickness were added to the demographic factors. In the psychological model, the level of anxiety contributed to poor sleep quality. When all variables were entered simultaneously, the level of physical activity, duration of symptoms and symptom severity remained significant determinants of sleep quality. In conclusion, our results showed that the symptoms associated with fibromyalgia contributed to poor overall sleep quality in patients compared with healthy subjects. The findings also suggest that the duration of symptoms, symptom severity and especially a sedentary lifestyle contributed to decreased sleep quality in patients with fibromyalgia.

KEYWORDS fibromyalgia, multiple regressions, physical activity, questionnaires, sleep quality

INTRODUCTION Fibromyalgia syndrome (FS) is a systemic chronic musculo-skeletal pain characterized by multiple tender points that is found primarily in woman and is associated with a wide variety of symptoms. Whereas the initial diagnostic criteria require tenderness on palpation (tender points) of at least 11 out of 18 defined anatomical sites with the presence of widespread pain, the other seminal features of the disorder, such as cognitive dysfunction, unrefreshing sleep, fatigue and mood disorders, clearly play an important role in the diagnosis using the new set of proposed criteria (Wolfe et al., 2010).

Although pain is the primary chronic symptom and disturbed sleep is not included in the standard FS criteria, disturbed sleep is consistently ranked by patients as a highly bothersome symptom of FS (Bennett et al., 2007). This symptom has a negative effect on the lives of patients with FS, and several studies have suggested that 74–99% of patients with FS complain of non-restorative sleep and poor sleep quality (Bigatti et al., 2008). Patients report difficulty falling
asleep, a significant number of night-time awakenings, awak-
ening feeling tired and unrefreshing sleep (Harding, 1998).

Poor sleep quality has been related to pain, fatigue, 
depression and low levels of physical (Bigatti et al., 2008) 
and social functioning among patients with FS in numerous 
studies. However, little is known about the contribution of 
other factors (e.g. active lifestyle, anthropometry, anxiety) on 
patients with FS sleep quality. These latest factors have been 
associated with sleep quality in other chronic medical condi-
tions. Thus, the relationships between standardized measures 
of poor sleep quality and other factors have not been well 
documented in patients with FS, particularly in studies 
conducted at home.

The purposes of the present study were as follows: (i) to 
compare the sleep quality at home in a group of patients with 
FS and a group of healthy women matched for age, weight, 
body mass index (BMI), and educational and physical activity 
level; and (ii) to examine the factors associated with sleep 
quality in patients with FS. We were guided by a biopsycho-
social model of sleep that included variables identified in 
epidemiological sleep studies that may be relevant in FS.

**MATERIALS AND METHODS**

**Study population**

An invitation to participate in the study was sent to all 
members between the ages of 18 and 60 years (n = 250) of a 
local FS association in Seville (Spain). Because 95% of 
individuals with FS are women (Mas et al., 2008), for clarity 
and feasibility we studied women only. Seventy-five potentially 
eligible subjects responded and sought more information.

After receiving an explanation of the study protocol, these 75 
patients provided written consent for a study that was 
approved by the Committee on Biomedical Ethics of the 
University Pablo de Olavide. To determine the sleep quality 
differences between patients with FS and healthy controls, a 
group of 48 healthy female volunteers, matched according to 
age, weight, BMI, education and physical activity levels, was 
recruited. All healthy subjects gave written consent. The 
exclusion criteria for both groups included age under 18 years 
or over 60 years; the presence of other factors that could affect 
sleep, such as diagnosed sleep disorders or having a young 
child at home; night-shift work; and caffeine, cigarette or 
sleep, such as diagnosed sleep disorders or having a young 

The respondents were asked to provide 
the following three levels: (i) 0.5–1.5 h week⁻¹; (ii) 2–4 h week⁻¹; 
and (iii) >4 h week⁻¹. The respondents were asked to provide 
answers in hours. The PAHWI is composed of seven items, 
standardized self-report instrument had been available for 
international comparisons of patients with FS. The LTPAI is 
composed of four items with three activity levels: light, 
moderate and vigorous (a short description of each category 
was presented). Subjects were asked to recall the average 
number of hours per week during the previous 4 weeks that 
they had spent engaged in a particular type of physical activity 
and at what activity level. The scale was simplified into the 
following three levels: (i) 0.5–1.5 h week⁻¹; (ii) 2–4 h week⁻¹; 
and (iii) >4 h week⁻¹. The respondents were asked to provide 
questions correctly; therefore, 66 patients and 48 
healthy women were included in the analyses.

**Measures**

Sleep quality and disturbances over a 1-month interval were 
assessed using the Spanish version of the PSQI (Macias 
Fernandez and Royuela Rico, 1996), an instrument previously 
administered to patients with FS (Osorio et al., 2006) with 
established reliability and validity. The level of depression was 
assessed with the validated Spanish version of the BDI-II 
(Beck et al., 2006), and the level of current anxiety with the 
Spanish version of the STAI (Spielberger et al., 2002).

Total physical activity was assessed with the total physical 
activity score (the sum of the LTPAI and PAHWI scores) of the 
Spanish versions of the LTPAI and PAHWI (Munguia-
Izquierdo et al., 2011). The LTPAI and PAHWI were used to 
measure the intensity and duration of work, domestic garden-
ing, and leisure/sport activities over the previous 7 days. The 
LTPAI and PAHWI are new instruments to assess health-
related physical activity and physical inactivity in FS surveys.

They have been validated against accelerometry and have 
acceptable measurement properties (Munguia-Izquierdo et al., 
2011). Before the LTPAI and PAHWI were designed, no 
standardized self-report instrument had been available for 
international comparisons of patients with FS. The LTPAI is 
composed of four items with three activity levels: light, 
moderate and vigorous (a short description of each category 
was presented). Subjects were asked to recall the average 
number of hours per week during the previous 4 weeks that 
they had spent engaged in a particular type of physical activity 
and at what activity level. The scale was simplified into the 
following three levels: (i) 0.5–1.5 h week⁻¹; (ii) 2–4 h week⁻¹; 
and (iii) >4 h week⁻¹. The respondents were asked to provide 
answers in hours. The PAHWI is composed of seven items, 
with three categories for work performed at home (light, 
moderate and heavy activity) and four categories for employ-
ment (sedentary, light, moderate and heavy activity). A short 
description of each category was presented, and the respon-
dents were asked to report the amount of time spent 
performing each of the activity categories. The hours for each 
category were added together to obtain the total score for the 
LTPAI and PAHWI. From the LTPAI and PAHWI, four 
outcome measures were computed: light total [ < 3 metabolism
equivalents (METs); moderate total (3 ≤ METs ≤ 6); vigorous total (> 6 METs); and active total (> 3 METs) time over the previous 7 days.

Functional impairment and health status was assessed with the validated Spanish version of the FIQ (Rivera and Gonzalez, 2004). This instrument was designed to evaluate the severity of FS on daily activities. Previous research has shown an adequate reliability and validity for this measure. The self-administered questionnaire consisted of 10 criteria, including physical function, work status, anxiety, pain, fatigue, sleep, depression, stiffness and wellbeing. The scores range from 0 to 100, and a higher score indicates a greater impact on the individual.

Anthropometric measurements such as height (to the nearest 0.1 cm), weight (to the nearest 0.1 kg; Seca 780, Hamburg, Germany) and BMI were recorded using standard procedures. Skinfold thicknesses (biceps, triceps, subcapular, supra-iliac, calf and medium thigh) were measured to the nearest millimetre using calipers (Holtain, Crymich, UK) on the right-hand side of the body (Lohman et al., 1988). The sum of the six skinfold thicknesses was used as an indicator of total body fat. All skinfold measurements were repeated three times, and the three values were averaged.

Sociodemographic and additional clinical information, including duration of symptoms, age and educational level, were collected by self-report. Subjects also reported on prescribed medications.

Statistical analyses

Data are expressed as the means with the corresponding standard deviations. We used the Student’s t-test and the Mann–Whitney U-test to compare the measures between the healthy subjects and patients with FS. The Pearson and Spearman correlation coefficients were used to quantify the relationships between sleep quality and each potential predictor variable.

A multivariate linear model was utilized to establish the factors that determined the difference in overall sleep quality between the patients and healthy women. For the patients, a series of hierarchical multiple regression analyses were computed to test the importance to sleep quality of disease-related, physical activity, psychological and anthropometric factors (tested in sets), after controlling for demographics factors. A standard multiple regression analysis was then performed with all the variables entered simultaneously into the model to determine the relative contributions of these variables to sleep quality. The selection of variables was based on theoretical relevance, a pattern of correlation with the outcome variable and other potential predictor variables, and the assumptions underlying multiple regression analyses. Statistical significance was set at P < 0.05.

RESULTS

Sample characteristics

Of the 75 women with FS who agreed to participate in this study, 66 (88%) returned completed questionnaires. Of the nine patients who failed to return their questionnaires, six were no longer interested in participating, and three felt too ill to complete the questionnaires. All the questionnaires were correctly completed by the 48 healthy women.

Table 1 summarizes the demographic and clinical characteristics of the 66 patients and 48 healthy women. All of the subjects were female, white and born in Spain. No differences

| Table 1 Demographic and clinical characteristics in patients with FS (n = 66) and healthy persons (n = 48)* |
|----------------------------------------------------------|---------------------------------|------------------|---|
| Demographics                                             | FS group                        | Healthy group    | P-value |
| Age, years                                               | 48.6 (8.4)                      | 46.9 (6.4)       | 0.130 |
| Education, years                                         | 8.3 (3.6)                       | 9.7 (3.1)        | 0.206 |
| Gender (female)                                          | 100                             | 100              | NA    |
| Ethnicity (white)                                        | 100                             | 100              | NA    |
| Clinical                                                 |                                 |                  |       |
| BMI, kg m⁻²                                              | 27.9 (4.8)                      | 26.7 (3.8)       | 0.149 |
| Sum of skinfold thickness, mm                            | 226.7 (55.9)                    | 215.8 (59.2)     | 0.324 |
| FIQ total score, 0–100                                   | 51.6 (19.4)                     | 18.3 (18.0)      | 0.000 |
| Duration of symptoms, years                              | 18.0 (10.9)                     | NA               | NA    |
| SAI score, 20–80                                         | 42.3 (10.3)                     | 37.4 (11.6)      | 0.008 |
| TAI score, 20–80                                         | 50.4 (10.9)                     | 42.2 (10.9)      | 0.000 |
| BDI-II score, 0–63                                       | 16.9 (8.7)                      | 9.2 (8.3)        | 0.000 |
| Active time (> 3 METs), h                                | 22.2 (17.3)                     | 18.3 (12.7)      | 0.335 |
| Drugs                                                    |                                 |                  |       |
| Simple analgesics, mg week⁻¹                              | 1461.3 (2286.7)                 | 433.6 (1093.3)   | 0.003 |
| Antidepressants, mg week⁻¹                               | 17.0 (59.6)                     | 5.2 (25.3)       | 0.073 |

BDI-II, Beck Depression Inventory-II; BMI, body mass index; FIQ, Fibromyalgia Impact Questionnaire; FS, fibromyalgia syndrome; MET, metabolism equivalent; NA, not applicable; SAI, State Anxiety Inventory; TAI, Trait Anxiety Inventory.

*Values are the mean (SD), 95% confidence interval.
were observed between the healthy women and the patients with FS in terms of age, educational level, BMI, sum of skinfold thickness and physical activity level \((P > 0.05)\). The patients with FS had significantly poorer scores than the healthy subjects on the FIQ, State Anxiety Inventory (SAI), Trait Anxiety Inventory (TAI) and BDI \((P < 0.001)\), and also reported taking more analgesics during the previous month \((P = 0.003)\). For the patients, the mean FIQ score was \(51.6 \pm 19.4\), indicating mild to severe disease activity.

### Sleep quality

Table 2 shows the global score and the component scale scores for the PSQI for our sample. The mean ± SD global PSQI score for the patients with FS was \(11.6 \pm 3.7\) (range 3–19), with 65 patients with FS (96%) classified as ‘poor sleepers’ (global PSQI ≥ 6). Meanwhile, the mean ± SD global PSQI score for the healthy controls was \(7.2 \pm 4.8\) (range 1–19), with 22 healthy controls (46%) classified as ‘poor sleepers’. Patients with FS had significantly poorer scores on the global score and all the component scores when compared with healthy persons, except in terms of sleep duration.

### Bivariate associations

Pearson and Spearman coefficients were computed to identify correlates of sleep quality in patients with FS. As shown in Table 3, the duration of symptoms, symptom severity (pain, fatigue, tiredness, stiffness, anxiety, depression), use of antidepressants, state of anxiety and sum of skinfold thickness were positively correlated with poorer sleep quality, although a trend was also observed for a depressed mood as assessed with the BDI and BMI \((P = 0.054\) for both). Higher levels of physical activity participation negatively correlated with poorer sleep quality.

### Determinants of sleep quality

The differences in sleep quality between the healthy subjects and patients with FS were associated with the FIQ \((R^2 = 0.43, P < 0.001)\), SAI \((R^2 = 0.29, P = 0.001)\), TAI \((R^2 = 0.28, P = 0.004)\) and BDI \((R^2 = 0.36, P < 0.001)\) scores. When the relationships among these variables were controlled, only FIQ \((43\%, P < 0.001)\) and BDI \((3\%, P = 0.011)\) contributed to explaining the differences in sleep quality between the two groups.

For the patients, the results of the hierarchical multiple regression analyses are shown in Table 4. The first model that tested the contribution of demographic variables to sleep quality was not statistically significant \((F_{2,63} = 1.75, R^2 = 0.05, P = 0.118)\). The addition of disease-related variables (model 2) resulted in a significant increase in the \(R^2\)-value \((F_{4,61} = 9.84, R^2 = 0.24, P < 0.001)\). The duration of symptoms and symptom severity contributed to poor sleep quality \((P = 0.018\) and \(P = 0.014\), respectively). In model 3, the addition of physical activity participation significantly added to the demographic set \((F_{3,62} = 17.79, R^2 = 0.22, P < 0.001)\). A physical activity intensity of > 3 METs contributed to good sleep quality \((P < 0.001)\). The addition of psychological symptoms also significantly added to the demographic set \((F_{4,61} = 5.91, R^2 = 0.09, P = 0.018)\). In this model, only the state of anxiety contributed significantly to poor sleep quality \((P = 0.018)\). In model 5, the addition of

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important determinants of sleep quality (duration of symptoms and symptom severity remained significant). Physical activity of an intensity higher than three METs, the self-rated questionnaires (Osorio et al., 2006), have shown that patients with FS suffer from a poorer quality of sleep than the general population. The prevalence of poor sleep quality in our patients with FS was 96%, whereas it was 46% for our healthy controls. The mean scores on the subscales of the sleep quality questionnaire, we conducted a more exhaustive analysis of sleep quality between the two groups. Our results on depression strengthen findings from previous studies with non-clinical subjects (Isaac and Greenwood, 2011) and other diseases (Chandrasekhara et al., 2009; Hawker et al., 2010). This finding suggests that multi-disciplinary treatments that have proven the most effective in improving the wide range of symptoms associated with FS (Arnold and Clauw, 2010; Scascighini et al., 2008) will also probably be the most effective in improving sleep quality in these patients. The inclusion of the FIQ score in the analysis prevents the identification of the specific symptoms that are most strongly associated with sleep quality in patients with FS.

**DISCUSSION**

This study is one of the best efforts to date to establish the determinants of sleep quality in middle-aged women with FS. The results obtained here deserve discussion from several different perspectives.

The results of this study give support to the numerous studies that, using polysomnography (Burns et al., 2008) or self-rated questionnaires (Osorio et al., 2006), have shown that patients with FS suffer from a poorer quality of sleep than the general population. The prevalence of poor sleep quality in our patients with FS was 96%, whereas it was 46% for our healthy controls. The mean scores on the subscales of the sleep quality measure support previous findings, indicating that FS patients reported having difficulties both falling asleep initially and going back to sleep after waking during the night (Osorio et al., 2006). Our comparison of patients with FS and control subjects failed to show differences in sleep duration. This observation is similar to findings from several studies that have examined sleep in FS (Chervin et al., 2009). This finding is further supported by literature indicating that, despite receiving between 6 and 8 h of sleep, patients with FS wake up stiff, fatigued and in pain (Moldofsky, 1989). This result suggests that the focus of sleep research in patients with FS should be on the quality rather than the quantity of sleep.

Importantly, our results indicate that the poor quality of sleep in patients with FS compared with healthy subjects was mainly associated with the FIQ score. This result is not surprising because the FIQ score is indicative of the severity of a variety of symptoms, including worsened physical function, anxiety, pain, fatigue, poor sleep quality, depression, stiffness and lack of well-being. Studies of patients with other chronic pain diseases (e.g. osteoarthritis and systemic lupus erythematosus) have also highlighted that the severity of illness is an important determinant of sleep quality (Chandrasekhara et al., 2009; Hawker et al., 2010). This finding suggests that multi-disciplinary treatments that have proven the most effective in improving sleep quality in these patients. The inclusion of the FIQ score in the analysis prevents the identification of the specific symptoms that are most strongly associated with sleep quality in patients with FS. For this reason, out of the variety of symptoms included in the FIQ questionnaire, we conducted a more exhaustive analysis of anxiety and depression using more specific questionnaires. Both symptoms were more acute in patients with FS than in healthy women, and were associated with the difference observed in sleep quality between the two groups. Our results on depression strengthen findings from previous studies with non-clinical subjects (Isaac and Greenwood, 2011) and patients with FS (Lange and Petermann, 2010) and other diseases (Chandrasekhara et al., 2009; Hawker et al., 2010). Our results on anxiety extend to patients with FS where the observations of previous studies showed a relationship between sleep disturbances and anxiety status in community

| Table 4 Results of regression models predicting sleep quality |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                                | Model 1         | Model 2         | Model 3         | Model 4         | Model 5         | Full model      |
|                                | demographic    | disease-related | physical activity | psychological | anthropometry  |                 |
|                                | β               | P               | β               | P               | β               | P               |
| Age                            | 0.23            | 0.087           | 0.11            | 0.362           | 0.18            | 0.104           |
| Education                      | −0.01           | 0.944           | −0.09           | 0.425           | −0.01           | 0.392           |
| Duration of symptoms           | 0.29            | 0.018           | 0.20            | 0.096           | 0.15            | 0.244           |
| FIQ total score                | 0.30            | 0.014           | −0.47           | 0.000           | 0.23            | 0.038           |
| Active total time (>3 METs)    |                 |                 |                 |                 |                 |                 |
| SAI                            | 0.29            | 0.018           | 0.09            | 0.373           |                 |                 |
| BDI-II                         | 0.18            | 0.155           | 0.14            | 0.202           |                 |                 |
| BMI                            | 0.12            | 0.467           | 0.06            | 0.540           |                 |                 |
| Sum of skinfold thickness      | 0.26            | 0.037           | 0.13            | 0.221           |                 |                 |
| $R^2$                          | 0.05            | 0.29            | 0.22            | 0.09            | 0.07            | 0.40            |
| Adjusted $R^2$                 | 0.02            | 0.26            | 0.21            | 0.07            | 0.05            | 0.37            |

BDI-II, Beck Depression Inventory-II; BMI, body mass index; FIQ, Fibromyalgia Impact Questionnaire; MET, metabolic equivalents; SAI, State Anxiety Inventory.
samples (Ramsawh et al., 2009) and in other chronic pain patients (Tang et al., 2007; Widerström-Noga et al., 2001). A detailed analysis of other symptoms, such as worsened physical function, pain, fatigue and stiffness, deserves to be considered for future studies. The body fat and physical activity levels were comparable in patients with FS and healthy women, and therefore were not associated with the difference observed between these groups in sleep quality. However, we cannot exclude the possibility that, among subjects who differ significantly in physical activity level and body fat, both variables might influence the quality of sleep.

Among patients with FS, we found support for a biopsychosocial model in understanding sleep quality. Our results support previous findings that poor sleep quality is strongly associated with pain, fatigue, greater psychopathology and other health outcomes in FS (Nicassio et al., 2002), whereas satisfactory sleep quality, more than sleep quantity, has been correlated with improved health and life satisfaction (Pilcher and Ott, 1998). Again, the severity of symptoms was an important determinant of sleep quality. In fact, bivariate analyses indicated a significant relationship between sleep disturbances, with the majority of symptoms assessed by the FIQ (see Table 3). This finding again suggests that treatments that influence the totality of the symptoms of FS may be the most effective in improving sleep quality. The duration of symptoms was another factor significantly associated with poor sleep quality, which may suggest that, for our sample, sleep quality does not improve with time as patients adapt to living with the condition. This finding, however, requires further analysis, including the study of the treatments prescribed to these patients. Importantly, the most significant determinant of sleep quality among patients with FS in this study was their physical activity level. This finding is consistent with studies that have demonstrated a useful role for exercise in sleep quality in healthy individuals (King et al., 1997), patients with FS (Munguia-Izquierdo and Legaz-Arrese, 2008) and other populations (Sprod et al., 2010). There is some evidence to suggest that physiological pathways, including muscular relaxation, decrease in sympathetic tone or that the thermal changes induced by exercise may promote sleep (O’Connor and Youngstedt, 1995). Exercise has also been associated with improvements in depressed mood and anxiety levels (Blumenthal et al., 1999), pain, fatigue, physical fitness and FIQ score (Munguia-Izquierdo and Legaz-Arrese, 2008), which are all factors that can influence sleep quality. Future studies need to examine the influence on sleep quality of the intensity and duration of exercise, the type of exercise and the time of day when exercise is performed. Our skinfold thickness results reflected previous findings that obesity is related to a poorer quality of sleep in patients with FS (Okifuji et al., 2010). However, skinfold thickness did not remain significant in the multiple regression model, suggesting that its importance in the quality of sleep in patients with FS is weak and can be explained by its interaction with other variables. Bivariate analysis also showed that patients taking antidepressants had a worse quality of sleep. This association was weak and limited by the number of patients (15) who reported taking antidepressants. Therefore, controlled studies are needed to determine the interrelations among the use of antidepressants, severity of symptoms and sleep quality in patients with FS.

The present study has several limitations. For instance, sleep quality was assessed by self-reporting. This measure may not reflect the symptoms as accurately as objective measures (e.g., polysomnography). We did, however, select a sleep measure that has previously been validated and compared with polysomnography (Osorio et al., 2006). In our final model, 46% of the variance in sleep quality between patients with FS and healthy women was explained. Similar variance (40%) was explained among patients with FS. This result suggests that other variables not assessed in our study contribute to sleep quality in patients with FS. In addition, the study was restricted in terms of age, sex and size. As such, these patients do not represent the larger population of community-dwelling individuals of all ages who suffer from FS. The relatively small size of our sample makes the results mainly indicative. The cross-sectional design of the present study does not allow us to determine the direction of the relationship found. However, if there is a bidirectional relationship between sleep and the severity of symptoms in FS, interventions that focus on improving sleep in FS may be needed to successfully manage the condition. Future multivariate, prospective studies are needed to expand our understanding of sleep disturbances among patients with FS. Because there is currently no recognized effective treatment for this condition, further research on the role of sleep in FS and on effective interventions to improve patients’ quality of life is urgently needed.

In conclusion, as a consequence of the severity of the symptoms associated with FS, patients with FS showed impaired sleep quality when compared with healthy women, and the majority of patients with FS exhibited sleep disturbances. Our results also suggest that, in addition to symptom severity, the duration of symptoms and, especially, a sedentary lifestyle contribute to decreased sleep quality in patients with FS. Modifiable determinants of sleep quality, such as depressed mood, anxiety and lack of regular exercise, may be important areas to target in interventions aimed at promoting sleep in patients with FS. Increasing knowledge will likely help improve the multidisciplinary treatment, and thus the quality of life, of patients with FS.

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