



# Health-Related Quality of Life and Related Factors in Patients with Fibromyalgia: A Cross-sectional Study

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## Abstract

**Background:** Fibromyalgia syndrome (FMS) is a chronic musculoskeletal condition, which can reduce the quality of life (QoL).

**Objectives:** This study aimed to evaluate the impact of FMS on health-related quality of life (HRQoL) and the possible related factors such as sociodemographic and psychological variables.

**Methods:** In this cross-sectional study, 150 women patients with FMS were included who visited a psychosomatic clinic at a referral center in northern Iran. The samples were selected in a consecutive procedure from April 2019 to March 2019. Sociodemographic variables, HRQoL score [36-Item Short Form (SF-36) Health Survey], and the Pittsburgh Sleep Quality Index (PSQI) were recorded. Data were analyzed using the SPSS Statistics software (ver. 24). The quantitative data were reported as mean  $\pm$  SD, and the qualitative variables were presented as frequency and percentage. Also, analysis was performed using analytical tests such as chi-square test ( $\chi^2$ ).  $P < 0.05$  was considered to be significant.

**Results:** The mean (SD) age was 42.35 (11.73) years. The mean physical and mental health scores were 33.45 (16.22) and 48.99 (18.19), respectively. Moreover, 88% of patients had moderate-to-severe sleep disorder, and those who did not, had a better physical and mental health status [42.7 (14.1) vs. 32.2 (16.1),  $P$ -value = 0.009 and 62.2 (16.3) vs. 47.2 (17.7),  $P$ -value = 0.001, respectively]. History of depression according to self-reporting was associated with worse mental health subscale scores [44.4 (16.8) vs. 52.4 (18.5),  $P$ -value = 0.007], and lower scores in social functioning and emotional well-being ( $P$ -value = 0.012,  $P$ -value = 0.001, respectively). Being post-menopausal was associated with a lower physical health quality ( $P$ -value = 0.049). Body Mass Index (BMI) reversely correlated with HRQoL subscales ( $r = -0.163$ ,  $P$ -value = 0.046), but the subscales were not affected by the level of income ( $P$ -value = 0.644,  $P$ -value = 0.170, respectively).

**Conclusions:** Patients with fibromyalgia report a considerable significant impact on their quality of life and impaired sleep quality. Assessment of sleep quality and QoL are needed in patients with fibromyalgia.

**Keywords:** Depression, Fibromyalgia, Health-Related Quality of Life, Sleep Disorders

## 1. Background

Fibromyalgia syndrome (FMS) is characterized by chronic widespread pain, stiffness, and tenderness of the muscles, tendons, and joints, unrefreshing sleep, fatigue, physical exhaustion, as well as cognitive difficulties (1). It is also presented with a decrease in pain threshold with excessive responses to painful stimuli (namely, hyperalgesia) and painful responses to non-painful stimuli (viz.

allodynia) (2). The prevalence rates of FMS are reported to be 0.7 - 13% in women and 0.2 - 3.9% in men worldwide (3, 4). In Iran, the total prevalence rate of FMS in women and men has been estimated at 3.98% (2.80 - 5.20) and 0.01% (0.04 - 0.06%), respectively (5). In this sense, approximately 3.1% of the general population suffers from FMS in Iran (5). This disorder can further lead to a decline in health-related quality of life (HRQoL) (6) and seriously affect daily functionality and QoL in patients. The impact of FMS on

HRQoL can even result in higher healthcare costs as well as significant economic consequences (7, 8). Despite the involvement of different body systems in FMS, pain has been introduced as the most important and disruptive symptom (7). More severe pain is thus associated with more HRQoL impairment, and evidence has established that relieving pain can diminish the effects of FMS over a three-month period and consequently moderate HRQoL (9). On the other hand, chronic pain is often linked with depression and anxiety and can lead to a decrease in QoL in patients with FMS (10, 11). Some studies have so far examined the impacts of sociodemographic, clinical, and psychological variables affecting HRQoL in such patients (12, 13). HRQoL in all components, especially physical ones, has been so far influenced by FMS (6, 7, 13, 14). In this respect, a systematic review by Samami et al. in 2021 showed that most of the psychological interventions improve the quality of life in women with fibromyalgia and the efficacy of these interventions are the increase of quality of life because decline of quality of life leads to many problems for women in the family, work, and community environment (15). Therefore, the baseline assessment of QoL, determination of health status, and patients' needs have become very important. Few studies have further reflected on the association between HRQoL and various factors related to FMS, including depression, sleep quality, obesity, and menopausal status (10, 11, 15). In addition, limited studies have been done on the psychosomatic aspects of this disorder. Assessing QoL in patients with FMS can thus elucidate problems facing these individuals and clarify solutions to improve their daily living and functionality.

## 2. Objectives

In this regard, the present study was conducted to evaluate HRQoL and the impact of FMS on various QoL components and to review the associated sociodemographic and psychological variables in women with FMS.

## 3. Methods

### 3.1. Design of the Study

Patients with FMS who visited a psychosomatic clinic at a referral center in northern Iran were included in this cross-sectional study. Women patients received a diagnosis of FMS from a rheumatologist based on the 1990 American College of Rheumatology criteria and were referred to a psychosomatic clinic and registered in <http://Reg.mazums.ac.ir>. The samples were selected in a consecutive procedure from April 2019 to March 2019.

### 3.2. Ethical Considerations

This research project was approved by the Ethics Committee of Mazandaran University of Medical Sciences (IR.MAZUMS.REC.1398.5053), Mazandaran University of Medical Sciences, Iran. Privacy and confidentiality of the patients' information were assured.

### 3.3. Study Population

A total number of 150 female patients with FMS were included in this cross-sectional study. The sample size was calculated according to Khatibi et al.'s study (16). Considering the 95% confidence interval (CI) ( $\alpha = 0.05$ ), estimation error of 1.25 ( $d = 1.25$ ), and the standard deviation (SD) of the HRQoL score ( $SD = 7.4$ ), 135 individuals were estimated. With respect to the 10% attrition rate of the recruited individuals, the minimum final sample size of 150 patients was considered.

### 3.4. Eligibility Criteria

The women patients were enrolled if they had been diagnosed with FMS based on the American College of Rheumatology (ACR) criteria in 1990 (17), with no other comorbid disorders, and at the age range of 18 - 75 years. They were excluded if physical or mental disabilities affecting their cooperation in completing the questionnaires had been deleted.

### 3.5. Data Collection

A sociodemographic characteristics information form, the SF-36 Health Survey, and the Pittsburgh Sleep Quality Index (PSQI) were used to collect the data in this study. Patients were asked to complete three validated questionnaires and a demographic questionnaire at the clinics when they were on a waiting list. Questionnaires for illiterate or illiterate people were completed by a psychiatrist. Privacy and confidentiality were assured. The response rate was 100% because psychiatrist approached the participants. Patients did not receive a reimbursement for their participation. Patients were free not to participate in the study. All patients were entered into the study after giving informed consent. Patients were informed by a psychiatrist and were assured of the confidentiality of the data.

### 3.6. Sociodemographic Characteristics Information Form

The sociodemographic characteristics of the participants included age, marital status, level of education, place of living, level of education, having child/children, number of children, residence status, occupational history, level of monthly income, and family of size.

### 3.7. SF-36 Health Survey

The 36-SF was administered to assess HRQoL (18, 19). This questionnaire consisted of 36 items, which were divided into eight dimensions, grouped into two components: physical and mental components. The final scores for each dimension could range from zero to 100, with the highest scores corresponding to a better condition. The physical component included the following dimensions, i.e., physical functioning, physical role functioning, bodily pain, and general health. The mental component could also be measured by the following dimensions: vitality, mental health, social functioning, and emotional role functioning (19). The reliability of Persian version of 36-SF had already been evaluated by Asghari et al., and the Cronbach's alpha coefficients of its subscales were between 0.70 and 0.85. Moreover, the test-retest method coefficients of the questionnaire subscales were between 0.43 and 0.79 (20).

### 3.8. PSQI

This questionnaire was comprised of seven subscales, namely, mental sleep quality, sleep delay, sleep duration, sleep efficiency, sleep disorders, use of sleeping pills, and daily functional disorders. In each subscale, the score will be between 0 and 3, which are interpreted as follows: (1) no sleep problem: score 0; (2) moderate sleep problem, score 1; (3) serious sleep problem, score 2; (4) very serious sleep problem, score 3. Achieving a total score higher than five in the whole questionnaire means poor sleep quality. Buysse et al. (1989), who first developed and introduced this questionnaire, also calculated its internal consistency with Cronbach's alpha coefficient of 0.83 (21). In another study, the reliability of the questionnaire was approved with Cronbach's alpha coefficient of 0.46 (22). In the Iranian version of this questionnaire, the validity and the reliability were reported to be 0.86 and 0.89, respectively (23).

### 3.9. Data Analysis

Statistical analysis was performed using the SPSS Statistics software (ver.24) (SPSS Inc., IBM Corp., USA). They were checked and cleaned before statistical analysis to identify the missing data. Accordingly, quantitative data were described as mean  $\pm$  SD, and the qualitative ones were illustrated as frequency and percentage. The student *t*-test was further utilized to compare the mean scores of the SF-36 Health Survey and its subscales as well as sleep quality scores between two independent groups. To compare between more than two independent groups, one-way analysis of variance (ANOVA) was also employed. Moreover, chi-square test and Fisher's exact test were used to evaluate the relationship between the qualitative variables. Pearson's

correlation coefficient was additionally practiced to examine the association between the quantitative variables and the HRQoL score. Ultimately, two-sided P-value  $\leq 0.05$  was considered significant in all statistical analyses.

## 4. Results

The study samples consisted of 150 women with a mean age of  $42.35 \pm 11.73$  years. The minimum age was 20, and the maximum age was 72 years. As well, 126 patients (84%) were married and had children, and 34 cases (22.67%) had high school diploma. Moreover, 132 patients (88%) had poor sleep patterns, and 64 cases (42.67%) had a history of depression. Baseline and sociodemographic characteristics of women with FMS are presented in Table 1.

The mean score of the main subscales of general health from the HRQoL score was  $38.20 \pm 18.42$ . In addition, physical and mental health scores were equal to  $33.45 \pm 16.22$  and  $48.99 \pm 18.19$ , respectively. The mean scores of the SF-36 Health Survey subscales are shown in Table 2.

Besides, the patients with appropriate sleep quality compared with poor sleep quality patients had significantly better physical and mental health ( $42.7 \pm 14.1$  vs.  $32.2 \pm 16.1$ , P-value = 0.009 and  $62.2 \pm 16.3$  vs.  $47.2 \pm 17.7$ , P-value = 0.001, respectively). Besides, those with no history of depression had higher scores on the mental health subscale ( $52.4 \pm 18.5$  Vs.  $44.4 \pm 16.8$ , P-value = 0.007). However, the scores of subscales of SF-36 were not significantly different between the patients with or without regular exercise (Table 3). Accordingly, patients with regular and irregular menstruation had significantly better physical health than the postmenopausal ones (P-value = 0.049). The subscales of general, physical, and mental health scores also did not show a significant difference between the patients with various levels of education and monthly income (P-value = 0.262, P-value = 0.404, P-value = 0.479). The relationship between general, physical, and mental health subscales and other five subscales of the SF-36 health survey in the patients with FMS based on sleep quality, a history of depression, regular exercise, menstrual status, level of education, and level of monthly income are presented in Tables 3 and 4. Likewise, the patients with a history of depression had lower scores on social functioning and emotional well-being. The patients who had diploma, and bachelor's degrees had also acquired higher physical functioning scores (P-value = 0.040) than illiterate cases or those with primary or secondary education and associate's degrees. Moreover, there was no significant difference in the HRQoL subscale scores between the patients with different levels of monthly income or exercise habits (P-value > 0.05). As well, a significant negative correlation was

**Table 1.** Baseline and Sociodemographic Characteristics of Women with FMS

Variables	No. (%)
<b>Marital status</b>	
Single	13 (8.67)
Married	126 (84)
Widowed	7 (4.67)
Divorced	4 (2.67)
<b>Level of Education</b>	
Illiterate	10 (6.67)
Primary school	24 (16)
Secondary school	26 (17.33)
High school diploma	34 (22.67)
Associate's degree	14 (9.33)
Bachelor's degree	33 (22)
Higher education	9 (6)
<b>Having child/children</b>	
Yes	126 (84)
No	24 (16)
<b>Number of children</b>	
1	32 (21.33)
2	44 (29.33)
3	28 (18.67)
4	13 (8.67)
5	6 (4)
6	3 (2)
<b>Living area</b>	
Urban	123 (82)
Rural	27 (18)
<b>Residence status</b>	
Living in a private home	127 (84.67)
Living in a rented house	20 (13.33)
Living in a donated house	3 (2)
<b>Family size</b>	
1	19 (12.67)
2	30 (20)
3	46 (30.67)
4	38 (25.33)
5	11 (7.33)
6	6 (4)
<b>Level of monthly income (Rials)</b>	
< 3,000,000	25 (6.67)
3,000,000 - 5,000,000	18 (12)
5,000,000 - 10,000,000	38 (25.33)
> 10,000,000	27 (18)
Unknown	42 (28)
<b>Occupational history</b>	
Employed/part-time	19 (12.67)
Employed/full-time	25 (16.67)
housewife	10 (70.67)
<b>Sleep quality</b>	
Poor	132 (88)
Appropriate	18 (12)
<b>Menstrual status</b>	
Regular	66 (44.00)
Irregular	37 (24.66)
Menopausal	47 (31.34)
<b>History of depression</b>	
Yes	64 (42.67)
No	86 (57.33)
<b>Regular exercise</b>	
Yes	18 (12)
No	132 (88)

**Table 2.** Mean Scores of the SF-36 Health Survey Subscales

SF-36 Health Survey Subscales	Mean $\pm$ SD
Physical functioning	46.17 $\pm$ 20.14
Physical role functioning	27.00 $\pm$ 32.58
Emotional role functioning	35.78 $\pm$ 36.45
Vitality	48.67 $\pm$ 20.61
Mental health	52.43 $\pm$ 19.46
Social functioning	59.08 $\pm$ 23.62
Bodily pain	22.45 $\pm$ 18.79
General health	38.20 $\pm$ 18.42

observed between BMI and HRQoL subscales ( $r = -0.163$ ,  $P$ -value = 0.046), so that the amount of physical functioning dropped as BMI increased.

## 5. Discussion

The main purpose of this study was to evaluate HRQoL and to investigate related factors such as sociodemographic and psychological variables shaping HRQoL in women with FMS, referred to a psychosomatic clinic at a referral center in northern Iran. In this study, FMS had strongly affected HRQoL in the patients concerned. Almost all patients reported moderate-to-severe sleep disorders. As well, those with appropriate sleep quality had significantly better physical and mental health. On the other hand, the patients with a history of depression had lower scores on social functioning and emotional well-being. It should be noted that FMS is a disorder characterized by chronic musculoskeletal pain that can lead to a decline in HRQoL (6, 24). The effects of FMS on HRQoL of patients are significantly important since they might result in considerable difficulties in performing daily living activities (7, 8). In a prospective observational study on patients with FMS in 2017, Lee et al. had found that HRQoL had been comparably affected by physical, social, and psychological variables. In these patients, higher levels of physical functioning and self-efficacy had helped improve HRQoL physical component summary (PCS), while lower levels of physical activity, depression, and anxiety had been observed with a negative effect on HRQoL mental component summary (MCS) (25), supporting the results of the present study. Based on the findings reported by Khatibi et al. on 59 patients with FMS, referred to a hospital in Iran, all cases had experienced low QoL. The data had further indicated that FMS had a negative impact on physical and mental health, and specific dimensions had been comprised of a particular focus on physical functioning. Social functioning and

bodily pain had been respectively the most and least relevant explanatory variables in terms of their impacts on HRQoL (16).

In the present study, there was no significant relationship between age and HRQoL subscales, while Khatibi et al. had established that HRQoL among patients with FMS had decreased with age ( $P$ -value = 0.010) (16). In a cross-sectional study, the SF-36 health survey standard scores had been also analyzed, and the HRQoL of each group of the patients had been compared with the general population of the same gender and age range. Although all groups had scored lower compared with the general population, the elderly patients had experienced lower HRQoL than younger ones, especially in physical and social functioning, which was consistent with the results of the present study. Moreover, patients over 60 years of age had been compared with those under 60, and a significant reduction in physical functioning, role physical, general health, and the SF-36 Health Survey scores had been observed ( $P$ -value < 0.05) (26).

The patients with higher BMI also had significantly lower physical functioning in the present study. Another research had also revealed that patients with higher BMI had lower HRQoL (16). According to Kim et al.'s study, patients with FMS and severe obesity ( $BMI > 35\text{kg/m}^2$ ) could be associated with more severe clinical symptoms and lower QoL (27), which was in line with the present study. The potential mechanisms explaining the association between FMS and obesity can thus include poor sleep quality (28, 29), higher levels of pain receptors in adipose tissues (28), elevated serum levels of pro-inflammatory cytokines (28, 30), thyroid dysfunctions (31), hypothalamic-pituitary-adrenal (HPA) axis and autonomic dysfunction (30), and increased mechanical loads associated with higher BMI (29). Although the causal relationship between obesity and FMS is unclear, the higher prevalence rate of obesity and the greater negative impact of obesity in patients with FMS than the general population may be attributed to pain and subsequent physical inactivity (29, 32). Therefore, FMS treatment programs should include weight loss strategies such as changes in lifestyle, proper diet, and increased physical activity.

In the present study, the patients with higher levels of education had also experienced better physical functioning. Recent studies have thus far paid less attention to the level of education as a variable involved in HRQoL in patients with FMS. A study showed there is no significant relationship between QoL and level of education in patients with FMS (32). In a cross-sectional study by Roshan et al., higher level of education correlated with less pain and better physical functioning (33). In this sense, there are two possible explanations for this relationship: first,

**Table 3.** Relationship Between Eight Subscales of the SF-36 Health Survey in Patients with FMS Based on Sleep Quality, History of Depression, Regular Exercise, Menstrual Status, Level of Education, and Level of Income<sup>a</sup>

Health Survey Variables and SF-36 Subscales	Physical Functioning*	Physical Role Functioning	Emotional Role Functioning	Energy or Fatigue	Emotional Well-Being	Social Functioning	Bodily Pain
<b>Sleep quality</b>							
Poor	57.2 ± 14.4	33.3 ± 32.1	55.6 ± 34.3	55.8 ± 17.7	59.1 ± 17.9	78.5 ± 17	34.6 ± 20
Appropriate	44.7 ± 20.4	26.1 ± 32.7	33.1 ± 36	47.7 ± 20.8	51.5 ± 19.5	56.4 ± 23.2	20.8 ± 18.1
P-value <sup>b</sup>	0.013	0.381	0.014	0.116	0.121	< 0.001	0.003
<b>History of depression</b>							
Yes	46.2 ± 21.5	29.3 ± 35.8	31.2 ± 34.1	46 ± 22.5	46.6 ± 18.7	53.5 ± 23.5	21.5 ± 16.6
No	46.2 ± 19.2	25.3 ± 30.1	39.1 ± 38	50.6 ± 18.9	56.7 ± 19	63.2 ± 23	23.1 ± 20.3
P-value <sup>b</sup>		0.988	0.470	0.190	0.175	0.001	0.012
<b>Regular exercise</b>							
Yes	48.1 ± 24.8	23.6 ± 31.5	46.3 ± 36.4	43.3 ± 21.8	55.6 ± 20.3	61.8 ± 22.5	21.7 ± 14.2
No	45.9 ± 19.5	27.5 ± 32.8	34.3 ± 6.4	49.7 ± 20.4	52 ± 19.4	58.7 ± 23.8	22.6 ± 19.4
P-value <sup>b</sup>		0.673	0.640	0.193	0.243	0.469	0.604
<b>Menstrual status</b>							
Regular	49.3 ± 15.9	25.8 ± 33.3	39.1 ± 37.4	48.7 ± 20.3	50.9 ± 20	61.7 ± 21	25.8 ± 20.3
Irregular	50.8 ± 23.1	33.8 ± 35	36 ± 38	49.3 ± 20.8	53.7 ± 19.1	58.8 ± 26.3	21.9 ± 19.8
Menopausal	39.1 ± 21.2	23.4 ± 29.7	32.6 ± 34.4	49.5 ± 20.7	54.4 ± 19	55.6 ± 25.1	19.1 ± 15.2
P-value <sup>c</sup>	0.009	0.326	0.658	0.977	0.614	0.406	0.173
<b>Level of education</b>							
Illiterate	34 ± 27.7	37.5 ± 31.7	40 ± 41	38.5 ± 29	47.6 ± 22.9	50 ± 28.9	20.8 ± 21.3
Primary school	40.8 ± 21.8	27.1 ± 25.4	34.7 ± 36.1	53.3 ± 19.7	57.7 ± 20.9	60.9 ± 17.4	24.1 ± 17.8
Secondary school	40.6 ± 16.2	23.1 ± 35.3	34.6 ± 34.6	49.2 ± 17.5	55.8 ± 19.4	59.6 ± 23	15.8 ± 15.9
High school diploma	52.8 ± 18.5	33.8 ± 35.8	38.2 ± 37.7	48.8 ± 20.2	50.1 ± 18.8	57.7 ± 25.6	25.5 ± 19.6
Associate's degree	45.4 ± 20.4	21.4 ± 32.3	33.3 ± 37	2.5 ± 19.8	54.3 ± 12.2	57.1 ± 23.4	20.4 ± 17
Bachelor's degree	50.5 ± 19.2	26.5 ± 35.3	41.4 ± 39.1	48.9 ± 19.8	51.6 ± 19.6	62.9 ± 25.7	24.5 ± 20.2
Higher education	50.6 ± 17	11.1 ± 13.2	1.1 ± 16.7	38.3 ± 25.5	42.7 ± 22.2	56.9 ± 22.6	23.3 ± 21.1
P value <sup>c</sup>	0.040	0.491	0.024	0.379	0.418	0.842	0.543
<b>Level of monthly income</b>							
Low	44.6 ± 17.7	33 ± 33.6	42.7 ± 39.1	50.8 ± 17.3	56.6 ± 17.3	65.5 ± 22	29.4 ± 26.1
Moderate	42.5 ± 21.5	22.2 ± 27	29.6 ± 36	40.6 ± 17.7	50 ± 16.4	54.9 ± 22.7	21.5 ± 20.2
Adequate	42.5 ± 15.5	30.9 ± 31	30.7 ± 32.3	47.5 ± 19.5	46 ± 18.6	54.9 ± 25.4	18.7 ± 14.7
High	49.4 ± 23.8	18.5 ± 27.4	39.5 ± 35.9	54.6 ± 23.2	56.7 ± 17.5	58.8 ± 22.4	21.9 ± 18.1
Unknown	49.9 ± 21.9	27.4 ± 38.2	36.5 ± 39.5	48.1 ± 22.3	54 ± 20.8	61 ± 23.9	22.5 ± 16.4
P-value <sup>c</sup>	0.389	0.464	0.661	0.243	0.124	0.427	0.287

<sup>a</sup> Values are expressed as mean ± standard deviation.<sup>b</sup> Independent-sample *t*-test.<sup>c</sup> One-way ANOVA.

patients with higher socioeconomic status are associated with higher QoL; second, it seems logical that the impact of FMS on individuals with a higher level of education is less due to access to more resources to deal with the disease. In this study, no significant relationship was observed between patients' level of monthly income and QoL. In this respect, Reisine et al. and Ubago et al. had reported similar results in agreement with the ones in the present study (12, 34). In addition, patients with regular and irregular menstruation in the present study had significantly better physical functioning and physical health than post-menopausal cases. In other words, QoL has decreased with

the onset of menopause. Studies have further shown that symptoms of premature or surgical menopausal hormone deficiency, as well as stress and mood swings, can lead to sleep disturbances and may be responsible for the onset or worsening of FMS-related symptoms and QoL (35, 36).

Although this study did not show a significant difference between regular exercise and HRQoL scales, a systematic review had established that exercise could diminish the symptoms of this disorder. Accordingly, the patients who had exercised had a better QoL, experienced fewer symptoms of depression, and had a better sense of well-being (37). In this study, 88% of the patients with FMS had



**Table 4.** Relationship Between General, Physical, and Mental Health Subscales in Patients with FMS Based on Sleep Quality, History of Depression, Regular Exercise, Menstrual Status, Level of Education, and Level of Monthly Income<sup>a</sup>

Variables and RQoL Subscales	General Health	Physical Health	Mental Health
<b>Sleep quality</b>			
Poor	45.8 ± 18.3	42.7 ± 14.1	62.2 ± 16.3
Appropriate	37.2 ± 18.3	32.2 ± 16.1	47.2 ± 17.7
P-value <sup>b</sup>	0.061	0.009	0.001
<b>History of depression</b>			
Yes	38 ± 20	33.8 ± 17.4	44.4 ± 16.8
No	33.3 ± 17.3	33.2 ± 15.4	52.4 ± 18.5
P-value <sup>b</sup>	0.930	0.009	0.007
<b>Regular exercise</b>			
Yes	39.7 ± 21	33.3 ± 17.3	51.7 ± 19.7
No	38 ± 18.1	33.5 ± 16.1	48.6 ± 18
P-value <sup>b</sup>	0.710	0.985	0.495
<b>Menstrual status</b>			
Regular	40.1 ± 18.5	35.2 ± 14.9	50.1 ± 18
Irregular	40.5 ± 18.6	36.8 ± 18.3	49.5 ± 18.3
Menopausal	33.9 ± 18.2	28.9 ± 15.6	48 ± 18.5
P-value <sup>c</sup>	0.155	0.049	0.836
<b>Level of education</b>			
Illiterate	24.5 ± 15.2	29.2 ± 19.4	44 ± 23.9
Primary school	35.4 ± 20.9	31.8 ± 14.4	51.7 ± 16.4
Secondary school	38.1 ± 18.6	29.4 ± 14.1	49.8 ± 17
High school diploma	39.9 ± 20.6	38 ± 19	48.7 ± 18.9
Associate's degree	39.3 ± 11.4	31.6 ± 12.8	49.3 ± 15
Bachelor's degree	41.5 ± 16.3	35.8 ± 16.8	51.2 ± 20.3
Higher education	41.1 ± 19.5	31.5 ± 13.2	37.3 ± 10.8
P-value <sup>c</sup>	0.262	0.404	0.479
<b>Level of monthly income (Rials)</b>			
< 3,000,000	37.2 ± 18	36.1 ± 15.9	53.9 ± 16.5
3,000,000 - 5,000,000	33.9 ± 15.4	30 ± 16.3	43.8 ± 17.4
5,000,000 - 10,000,000	34.6 ± 19.2	31.7 ± 13.8	44.8 ± 16.4
> 10,000,000	41.5 ± 18	32.8 ± 17.1	52.4 ± 16
Unknown	41.8 ± 19.1	35.4 ± 18	49.9 ± 21.5
P-value <sup>c</sup>	0.294	0.444	0.170

<sup>a</sup> Values are expressed as mean ± standard deviation.<sup>b</sup> Independent-sample *t*-test.<sup>c</sup> One-way ANOVA.

poor sleep quality. In a review study by Lawson in 2020, 90% of the patients with FMS experienced poor sleep quality (38). According to Andrade et al., the prevalence rate of sleep disorders in these patients has been reported to be 92.9%. On the other hand, patients with more symptoms had shown lower sleep quality (39). A systematic review also noted that sleep quality was strongly associated with many aspects of QoL and the severity of symptoms in patients with FMS, such as poor sleep quality, decreased physical functioning, lower social activity, as well as further psychiatric disorders and pain (40). Poor sleep quality was accordingly assumed as a risk factor for FMS; accordingly, correcting sleep problems could reduce the incidence of FMS

(38). As a result, it is recommended to evaluate sleep disorders in patients and seriously manage them if identified.

### 5.1. Limitations

This study had some limitations. In terms of gender, all the patients were female. Therefore, the results of this study could not be generalized to the whole community. Another limitation was the cross-sectional nature of the study, in a way that establishing a causal relationship or testing a statistical hypothesis was not possible. Further studies are thus suggested to include comparative groups with no FMS to assess differences or similarities. Moreover, more studies are needed in this field to compare two

groups with and without therapeutic interventions. For the purpose of an accurate diagnosis, it is recommended to interview and diagnose the patients by recruiting a neurologist as well.

## 5.2. Conclusion

Overall, FMS has a negative impact on HRQoL, which is affected by several factors such as BMI, menstrual status, level of education, history of depression, and sleep quality. Therefore, it is necessary to perform multidisciplinary interventions and to assess sleep quality and QoL in rheumatic disease clinics for FMS patients. Once the diagnosis of FMS is made, healthcare specialists are required to improve patients' functions and reduce their complaints.

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## Footnotes

**Authors' Contribution:** FE contributed to the conception of the work, data gathering, psychiatric evaluation of the patients following referring from a rheumatologist, FJ contributed to drafting the manuscript and editing the manuscript, MM rheumatologically evaluated patients and diagnosis and contributed to the conception of the work, editing the manuscript., SM contributed to statistical analyses and interpretation of data., SDD and IGH edited the manuscript. All authors read and approved the final manuscript.

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