



Association of Kinesiophobia with Core Muscle Endurance, Functional Mobility and Physical Activity Level in Patients with Fibromyalgia Syndrome: A Cross-Sectional Study

Fibromiyalji Sendromlu Hastalarda Kinezyofobinin Kor Kas Dayanıklılığı, Fonksiyonel Hareketlilik ve Fiziksel Aktivite Düzeyi ile İlişkisi: Kesitsel Bir Çalışma

 Yasemin Mirza¹,  Adem Kucuk²

ÖZET

Amaç: Bu çalışmada FMS hastalarında kinezyofobi düzeyini analiz etmek ve kinezyofobi ile ağrı, hastalık aktivitesi, yorgunluk, fiziksel aktivite düzeyi, fonksiyonel mobilite ve kor kas dayanıklılığı süreleri arasındaki olası ilişkiyi araştırmak amaçlanmıştır.

Gereçler ve Yöntem: Bu çalışmaya FMS'li 41 kadın katılmıştır. Hastalar kinezyofobi için Tampa Kinezyofobi Skalası, ağrı düzeyi için görsel analog skala, hastalık aktivitesi için Fibromiyalji Etki Anketi, fiziksel aktivite düzeyi için Uluslararası Fiziksel Aktivite Anketi-Kısa Form ve yorgunluk için Yorgunluk Şiddeti Ölçeği kullanılarak değerlendirildi. Kor kas dayanıklılık ve fiziksel uygunluk testleri uygulandı. İstatistiksel analiz için Spearman korelasyon katsayıları ve Mann-Whitney U testi uygulandı.

Bulgular: Hastaların hastalık durasyonu 3 (2/10) yıldır ve 25'inde (%60.9) yüksek düzeyde kinezyofobi vardı. Kinezyofobi ile ağrı düzeyi ($p<0.001$), fiziksel aktivite düzeyi, yorgunluk, fiziksel uygunluk testleri ve gövde fleksör kas dayanıklılık süresi ($p<0.05$) arasında anlamlı ilişkiler tespit edildi. Ancak kinezyofobinin hastalık aktivitesi ve diğer kor kas dayanıklılık testleri ile ilişkisi yoktu ($p>0.05$). Ağrı, yorgunluk ve fiziksel aktivite düzeyi, fiziksel uygunluk testleri, gövde ekstansör testi dışındaki kor kas dayanıklılık testleri yüksek kinezyofobi ve düşük kinezyofobi grupları arasında farklılık gösterdi ($p<0.05$). Ancak yüksek kinezyofobi ve düşük kinezyofobi grupları arasında hastalık aktivitesi benzerdi ($p>0.05$). **Sonuç:** Kinezyofobinin ağrı, fiziksel aktivite düzeyi, yorgunluk, gövde fleksör kas dayanıklılığı ve fonksiyonel hareketlilik ile ilişkili olduğu görülmektedir. FMS hastalarında kinezyofobi ve ilişkili faktörlerin değerlendirilmesi rehabilitasyon programının oluşturulmasına yardımcı olabilir.

Anahtar Kelimeler: Fibromiyalji, kinezyofobi, kor kas dayanıklılığı, fiziksel uygunluk, ağrı.

ABSTRACT

Aim: Present study analyzes kinesiophobia level in FMS patients and investigates the possible relationship between kinesiophobia and pain, disease activity, fatigue, physical activity level, functional mobility and core muscle endurance (CME) times.

Materials and Methods: Forty-one female patients were participated in present study. Patients were assessed performing Tampa Scale for Kinesiophobia for kinesiophobia, a visual analog scale for pain level, the Fibromyalgia Impact Questionnaire for disease activity, the International Physical Activity Questionnaire- Short Form for physical activity (PA) level and Fatigue Severity Scale for fatigue. Core muscle endurance and physical fitness tests were applied. For statistical analysis were performed Spearman correlation coefficients and Mann-Whitney U test.

Results: Of the patients, disease duration was 3 (2/10) years and 25 (60.9%) had a high level of kinesiophobia. Significant relationships were detected between kinesiophobia and pain level ($p<0.001$), PA level, fatigue, physical fitness tests and trunk flexor endurance time ($p<0.05$). However, kinesiophobia were not related to disease activity and other CME tests ($p>0.05$). Pain ($p<0.001$), fatigue and PA level, physical fitness tests, CME tests except trunk extensor test differed between high- kinesiophobia and low-kinesiophobia groups ($p<0.05$). However, disease activity was similar between high- kinesiophobia and low- kinesiophobia groups (>0.05).

Conclusions: Kinesiophobia seems to be associated with pain, PA level, fatigue, trunk flexor endurance and functional mobility. Evaluating kinesiophobia and associated factors in FMS patients may help in creating rehabilitation program.

Key words: Fibromyalgia, kinesiophobia, core muscle endurance, physical fitness, pain.

¹Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya Türkiye

²Necmettin Erbakan University, Faculty of Medicine, Department of Internal Medicine, Division of Rheumatology, Konya, Türkiye

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Sorumlu Yazar/Corresponding Author:

Yasemin Mirza,

Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya, Türkiye

e mail: yakkubak@gmail.com

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INTRODUCTION

Fibromyalgia syndrome (FMS) is a chronic and complex disease accompanied by widespread and persistent pain, poor sleep quality, fatigue, cognitive and mood disorders (1). The etiology of FMS is complex and unclear, and biological, genetic and psychological factors are effective in the development of the disease (2, 3). FMS also has an adverse impact on daily activities and quality of life. Especially, it has been frequently reported that severe fatigue and pain in FMS may reduce physical activities and lead to a sedentary lifestyle by reducing functional mobility and increasing disability risk (4). It has also been shown that loss of function in these patients may be strongly associated with work disability (5).

Movement-related fear is highly associated with disability in individuals with chronic musculoskeletal complaints (6, 7). Fear of movement, frequently called “kinesiophobia,” is an irrational, debilitating and excessive fear of physical movement that can cause painful injuries and re-injury (8). Research states that kinesiophobia is related to reduced physical mobility and higher pain severity in FMS patients (9-11). Kinesiophobia causes activity limitation by reducing mobility, strength and stability and activity limitation reduces tolerance to activity, which turns into a vicious circle (10, 12). Furthermore, activity limitation restricts successful activity opportunities, diminishing opportunities for positive reinforcement (13). Negative emotions such as fear and anxiety also increase the perception of pain.

Anatomically, the core muscles consist of the muscles surrounding the lumbopelvic-hip complex. These muscles have an important place in the stabilization of the lumbopelvic region and spine (14). Core muscle endurance (CME) indicates the capacity of core muscles to maintain their activity in long periods of time (15). It has been reported that core muscles are accountable for spinal stability; thus lack of endurance may cause deterioration of functional mobility and spinal stabilization (16). Previous studies reported that the strength of lower extremity and trunk muscles in FMS patients is reduced compared to healthy individuals (17, 18). Furthermore, CME has been demonstrated to be associated with posture disorders, lower back pain, deterioration of functional mobility and balance in FMS patients (17).

Although the effect of kinesiophobia on mobility, fear of falling and postural control has been studied in FMS patients, there is no evidence on how kinesiophobia influences CME in patients with FMS (9-11). Therefore, the aims of present study is to define kinesiophobia level in FMS patients and to investigate the correlation between kinesiophobia and pain, disease activity, fatigue, physical activity level, functional mobility and CME times.

MATERIALS AND METHODS

A total of 41 female FMS patients who came to rheumatology clinic at Necmettin Erbakan University, participated in this prospective and cross-sectional study. Patients were participated if they met the following criteria: (a) were from 18 to 65 ages, (b) were diagnosed with FMS by a rheumatologist, (c) met the American College of Rheumatology's 2010 diagnostic criteria (19). Patients were excluded if they had musculoskeletal surgery, neurological deficits, fracture, osteoporosis, vestibular system disorder, inflammatory joint disease, psychiatric disorders with psychotic symptoms, and/or being pregnant. Necmettin Erbakan University Ethics Committee approved the study protocol (approval number: 2023/4664). The patients were first informed about the study and then their written consent was received. The study was administered in regarding the Declaration of Helsinki's principles.

Participants completed a sociodemographic information form consisting of body mass index, age, marital status, current opioid use, years since diagnosis. To assess self-reported pain severity was performed visual analog scale (VAS) (20). It consists of a solid line defined as 0 = “no pain” and 10 = “worst pain”. Participants described their pain level on a line. There were no negative situations during the evaluation process. No medication changes were made in the patients.

Core Muscle Endurance

McGill's trunk muscle endurance tests were performed to evaluate CME times (15). These consist of the trunk extension and flexion, and right/left side bridge tests. Patients were asked to continue isometric postures for as long as possible for each test position. The time that the patients were able to continue the correct test position was documented in seconds. Previously, it has been reported that these four CME assessment have excellent reliability: trunk extensor test intraclass correlation coefficient (ICC) = 0.97, trunk flexor test, ICC = 0.97, and right/left side bridge tests ICC = 0.99 (15).

Physical Fitness Tests

- Timed Up and Go (TUG): It was performed to measure functional mobility. According to the test instructions, the patient stands up from a chair without armrests, walks 3 m, turns and sits down. Using a manual stopwatch, time was recorded. The test period starts when the patient gets up from the chair and ends when the patient sits down. This test has shown excellent reliability (ICC = 0.935) in previous study in women with FMS (21).

- 30-s chair stand test: The test was performed to measure lower body muscle strength. This test includes counting the number of times an individual rises from a sitting position to a full standing position in 30 seconds (22).

Kinesiophobia

The Turkish version of the Tampa Scale of Kinesiophobia (TSK) was performed to evaluate kinesiophobia (23). This scale includes 17 questions. A 4-point Likert scoring is used in the scale (1=completely disagree, 4=completely agree). The subject receives a total score ranging from 17 to 68. High scores from the questionnaire indicate a high kinesiophobia level. The cut-off score of the scale was determined as 37; a total score of 37 and above presents high kinesiophobia level, and a score below 37 presents low level kinesiophobia.

Physical Activity Level

To assess physical activity level was performed The Turkish version of the International Physical Activity Questionnaire-Short Form (IPAQ-SF) (24). The questionnaire includes information on daily sitting time and time spent on walking and moderate and vigorous physical activities in the last week. It evaluates the days and minutes of physical activities done in the past seven days. According to total score, subjects

are classified as physically very active, minimally active and inactive (7).

Disease Activity

The Turkish version of Fibromyalgia Impact Questionnaire (FIQ) was performed to evaluate disease activity of the patients (25). FIQ consists of ten different parameters containing daily activity, inability to occupation, difficulty doing occupation, fatigue, morning stiffness, pain well-being, anxiety and depression. According to the total score, the disease effect varies between 0 and 100 points. High scores from the questionnaire indicate a high disease activity.

Fatigue

To assess fatigue was used The Turkish version of the Fatigue Severity Scale (FSS) (26). It consist of 9 items that assess the severity of fatigue. Likert-type scoring is used in the scale (1= completely disagree, 7= completely agree). Total score is obtained by adding up all scores and dividing by 9. The cut-off score of the scale was determined as 4; a total score of 4 and above presents high fatigue level, and a score below 4 presents low fatigue level.

Statistical Analysis

Using G*Power package software program (G*Power, Ver.3.1.9.2 Universitat D sseldorf Germany) was calculated the required sample size for present study. Regarding the results of relationship between kinesiophobia and disease activity from Leon-Llamas et al (27). (correlation coefficient: 0.458), a total of 37 patients was necessary to acquire 85% power with $d = 0.45$ effect size, $\alpha = 0.05$ type I error. The participant rate was calculated to be 10% higher in order to compensate for data losses in research process or statistical analysis process. As a result, 41 patients was participated in this study.

The Statistical Package for the Social Sciences (SPSS Inc.,

Table 1. Characteristics of patients

| Characteristic | Median (IQR 25/75) or n (n = 41) |
|--------------------------------|----------------------------------|
| Age (years) | 46 (40/50.5) |
| Height (cm) | 160 (155.5/164.5) |
| Weight (kg) | 71 (63/83.5) |
| BMI (kg/m ²) | 28.51 (25.36/31.19) |
| Disease duration (years) | 3 (2/10) |
| Pain (VAS 0–100 mm) | 6 (5/8) |
| Drug use | |
| Analgesic | 15 |
| Anti-depressant | 7 |
| No drugs | 15 |
| Family history of FMS (yes/no) | 23/18 |

IQR 25/75: Interquartile range 25/75, BMI: Body mass index, VAS: Visual analog scale. FMS: Fibromyalgia syndrome

Table 2. Test results of patients

| Test | Median (IQR 25/75) |
|------------------------------|---------------------|
| Core Muscle Endurance | |
| Trunk flexor endurance (s) | 8.83 (5.67/13.42) |
| Trunk extensor endurance (s) | 9.38 (6.84/13.7) |
| Right side bridge (s) | 11.59 (8.22/17.2) |
| Left side bridge (s) | 10.68 (6.88/16.42) |
| Physical Fitness Tests | |
| TUG (s) | 7.86 (7.28/8.19) |
| 30-s chair stand test (rep) | 11 (10/13) |
| TSK (score) | 38 (34/44.5) |
| IPAQ (MET-min/wk) | 198 (41.48/396) |
| FIQ (score) | 56.43 (46.15/61.78) |
| FSS (score) | 4.88 (3.82/5.6) |

IQR 25/75: Interquartile range 25/75, TUG: Timed Up and Go, TSK: Tampa Scale for Kinesiophobia, IPAQ: International Physical Activity Questionnaire, FIQ: Fibromyalgia Impact Questionnaire, FSS: Fatigue Severity Scale.

Table 3. Relationship between TSK scores and explanatory variables (n = 41).

| Explanatory Variables | Kinesiophobia | |
|------------------------------|---------------|----------|
| | rho | p-Value |
| Pain (VAS) | 0.669 | <0.001** |
| Trunk flexor endurance (s) | -0.389 | 0.012* |
| Trunk extensor endurance (s) | -0.052 | 0.746 |
| Right side bridge (s) | -0.187 | 0.242 |
| Left side bridge (s) | -0.146 | 0.362 |
| TUG (s) | 0.357 | 0.022* |
| 30-s chair stand test (rep) | -0.402 | 0.009* |
| IPAQ (MET-min/wk) | -0.454 | 0.003* |
| FIQ (score) | 0.195 | 0.222 |
| FSS (score) | 0.433 | 0.005* |

VAS: Visual analog scale, TSK: Tampa Scale for Kinesiophobia, TUG: Timed Up and Go, IPAQ: International Physical Activity Questionnaire, FIQ: Fibromyalgia Impact Questionnaire, FSS: Fatigue Severity Scale, rho: Spearman's rank correlation coefficient, * $p < 0.05$, ** $p < 0.001$.

Table 4. Comparison of clinical parameters between low- and high-level kinesiophobia groups

| | Low-level kinesiophobia group (n=16) Median (IQR 25/75) | High-level kinesiophobia group (n=25) Median (IQR 25/75) | p-Value |
|------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------|
| Pain (VAS) | 5 (4/5) | 8 (6/8) | <0.001 ^b |
| Trunk flexor endurance (s) | 13.42 (8.95/18.24) | 6.76 (4.92/10.2) | 0.001 ^a |
| Trunk extensor endurance (s) | 11 (7.43/14.96) | 8.92 (5.66/13.7) | 0.419 |
| Right side bridge (s) | 14.97 (10.04/27.72) | 10.36 (4.8/14.8) | 0.046 ^a |
| Left side bridge (s) | 14.48 (9.73/27.92) | 10.35 (5.67/11.96) | 0.026 ^a |
| TUG (s) | 7.43 (7.05/7.91) | 8.05 (7.41/9.44) | 0.011 ^a |
| 30-s chair stand test (rep) | 13 (10.25/14.75) | 11 (9.5/12) | 0.035 ^a |
| IPAQ (MET-min/wk) | 214.5 (173.25/486.75) | 132 (0/247.5) | 0.040 ^a |
| FIQ (score) | 54.93 (46.86/62.13) | 57.22 (43.85/61.8) | 0.905 |
| FSS (score) | 3.94 (2.85/4.74) | 5.22 (4.71/5.88) | 0.002 ^a |

IQR 25/75: Interquartile range 25/75, VAS: Visual analog scale, TUG: Timed Up and Go, IPAQ: International Physical Activity Questionnaire, FIQ: Fibromyalgia Impact Questionnaire, FSS: Fatigue Severity Scale, ap < 0.05, bp<0.001, Mann-Whitney U test.

version 21; IBM, Raleigh, NC) was used to calculate data analysis. $p < 0.05$ was accepted for statistical significance level. Analytical (Shapiro–Wilk test) and visual (probability plots, histograms) methods were performed to find the distribution of the variables. Nonparametric methods were determined more convenient to represent the results. To evaluate the relationship between kinesiophobia and pain, CME times, functional mobility, physical activity level, disease activity and fatigue in FMS patients was performed Spearman correlation coefficient (ρ). The correlation coefficient was interpreted as following, high; between 0.90 and 0.71, good; between 0.70 and 0.51, moderate; 0.50 and 0.31, negligible; 0.3 or less (28). Mann-Whitney U test was performed to determine between group differences.

RESULTS

Forty-one patients with FMS were completed this study. Fifteen patients were excluded due to various reasons (11: musculoskeletal disorders, 3: non-volunteer to participate, 1: severe psychological disorders). Patients' demographic characteristics are showed in Table 1. Patients' pain level was 6 (5/8) cm. Fifteen patients (35.5%) used analgesic medicine, eleven patients (26.8%) used anti-depressant, and fifteen patients (37.7%) don't used any medicine prior to the study. Twenty three patients (56%) have family history of FMS. The results of CME times, physical fitness tests, TSK, IPAQ, FIQ and FSS evaluations are listed in Table 2. Regarding patients' TSK scores, 16 patients had low-level kinesiophobia and 25 patients had high-level kinesiophobia.

Relationship between TSK scores and explanatory variables were presented Table 3. Good correlation between TSK and pain level was found ($p < 0.001$). Moderate correlations between TSK and TUG, 30-s chair stand test, IPAQ, FSS were found by using spearman correlation test ($p < 0.05$). Regarding

relationship between TSK score and CME tests, Moderate correlation between kinesiophobia level and trunk flexor endurance test was obtained ($p < 0.05$). However, significant correlation were not obtained between TSK and FIQ ($p > 0.05$) (Table 3).

Participants were separated two groups as high level kinesiophobia (n=25) and low level kinesiophobia (n=16) regarding their kinesiophobia level. The patients' trunk flexor and right/left lateral bridge tests were significantly greater in the low-level kinesiophobia group ($p < 0.05$) (Table 4). Pain level was significantly higher in the high-level kinesiophobia group ($p < 0.001$). While the TUG duration and FSS score were higher in high-level kinesiophobia group; the 30-s chair stand test result and IPAQ score were lower ($p < 0.05$). No other significant differences were obtained between groups for trunk extensor test and FIQ score ($p > 0.05$) (Table 4).

DISCUSSION

This study was designed to determine kinesiophobia level in patients with FMS. In addition, it assessed relationship between kinesiophobia and CME times, physical fitness tests (TUG and 30-s chair stand test), pain, disease activity, fatigue, physical activity level. As we hypothesized, results revealed that 60.9% of FMS patients had high levels of kinesiophobia. Furthermore, kinesiophobia are associated with trunk flexor endurance, physical fitness tests, physical activity level and fatigue, where as significant relationship was not obtained between pain, disease activity and other CME times.

In most studies on kinesiophobia in chronic musculoskeletal diseases, high level kinesiophobia was reported with a prevalence of 56% (29). Our results indicated that women with FMS had high level kinesiophobia. Similar to our result, Koçyiğit et al. reported that the rate of high-level kinesiophobia in FMS patients was 71.5%, and Russek

et al. showed that this rate was 72.9% in patients with FMS (9, 10). On the other hand, few studies have demonstrated that a lower percentage of FMS patients have kinesiophobia. Turk et al. showed that 38.6% of FMS patients had the high level kinesiophobia and other previous study also revealed that 40% of FMS patients had kinesiophobia (30, 31). Cultural differences and ethnicity may influence kinesiophobia level of FMS patients. In addition, differences in disease duration, educational status, psychiatric diseases and management of the disease process may have affected the results.

It has been reported that the main cause of decreased CME in different populations is atrophy of the lumbar region muscles (15, 32, 33). Previous researches have shown that common symptoms of FMS patients, such as chronic pain, fatigue, immobility and cytokines may cause muscle atrophy. These researches generally include evaluations of strength of upper and lower extremity muscles and grip strength (34-36). Previously, it has been reported that CME in FMS patients is lower than compared to healthy subjects (17). It has been known that trunk muscles are especially important in maintaining physical activity and balance during daily life, improving extremity functions and protecting spine health (37-39). Therefore, in our study, we evaluated the possible relationship between CME and kinesiophobia in FMS patients. Our study showed that trunk flexor endurance was associated with kinesiophobia in FMS patients. There is no study assessing relationship between CME and kinesiophobia in FMS patients, hence, it is difficult to discuss the amount of relationship. Therefore, more studies are needed to understand the possible reasons of kinesiophobia in FMS patients. On the other hand, we think that it will be important for clinicians to consider protective exercise approaches for trunk muscle groups in the rehabilitation programs of FMS patients in terms of reducing kinesiophobia.

It has been reported that physical impairment in FMS patients may decline their ability to perform daily living activities (40, 41). Furthermore, some studies have found that kinesiophobia is related to physical performance (5, 27). In line with above studies, in our study, kinesiophobia was found to be associated with physical activity level, TUG 30-second chair stand test. Furthermore, these performance tests are relatively close to the activities that people with FMS have difficulty performing in daily life. Regarding association between kinesiophobia and performance tests in present study, these relationship may be interpreted with the Fear Avoidance Model (42, 43). Chronic and widespread pain FMS patients may lead to changes in central pain networks that cause central sensitization (44). Additionally, these relationships may be due to kinesiophobia causing fear of physical activity, triggering a vicious cycle that promotes to disease development. Moreover, increase in the disease activity may

be one of the factors affecting kinesiophobia. In this regard, previous studies reported relationship between kinesiophobia and disease activity (10, 27). Therefore, what was expected as a result of this study was that kinesiophobia would be associated with an increase in disease activity. However, in our study, kinesiophobia did not have a significant correlation with disease activity, but kinesiophobia was associated with self-reported pain, suggesting that kinesiophobia in FMS patients is a direct result of body pain. Additionally, cultural differences, disease duration, educational status and comorbid psychiatric diseases may influence perception of disease.

Fatigue has been widely researched because it is one of the main symptoms of FMS. Because of physical and psychological impairments and the disease progression, most of patients with FMS experience chronic fatigue (45, 46). Previous researches have reported that fatigue in FMS is closely associated with chronic inflammation with increased levels of oxidative stress, pain intensity, decreased physical activity and function, impairment sleep quality and psychological disease (46, 47). In this study, moderately significant relationships were obtained between fatigue and kinesiophobia. A previous study has also shown that fatigue is a significant exercise barrier in FMS patients (48). Thus, reducing fatigue may be useful in coping with the adverse impact of kinesiophobia. In this regard, the appropriate rehabilitation program should be determined in following research.

In this study, it was observed that patients with high levels kinesiophobia presented more pain and fatigue, and their CME duration, functional mobility and physical activity levels decreased. In line with our results, Turk et al. indicated that FMS patients with high level kinesiophobia presented higher pain, and lower mobility (30). Kocyigit et al. also found pain and disease activity were significantly greater in the high level kinesiophobia group (9). On the other hand, it was found no significant difference between the groups regard to disease activity. Kinesiophobia, as its definition suggests, arises and develops from a reaction to a movement that previously caused pain. Thus, learned pain experiences may cause kinesiophobia scores to increase.

In this sense, kinesiophobia significantly affects physical activity levels and daily living activities in FMS patients (49). Moreover in patients with FMS, kinesiophobia leads to a sedentary lifestyle, triggering a vicious cycle that can lead to disability (50, 51). Therefore, physical activity applications are significant as they are an effective way to break the vicious cycle, reduce perceived pain, and improve health-related quality of life in this population (52). Evaluation of kinesiophobia seems to be very important in clinical settings as it can be a barrier to exercise applications (53). In this respect, best to our knowledge, the relationship CME times and kinesiophobia was not evaluated previously. Therefore, we believe that we

have contributed to the literature in terms of kinesiophobia and related factors for FMS patients. Furthermore, future studies need to be investigate factors such as related to pain acceptance and pain catastrophizing in FMS patients.

First limitation of current study is that the sample size was small and included only women patients, thus it cannot be generalized to all FMS patients. Self-reported questionnaires were performed for the evaluation and was not assess psychological state of the patients. Another limitation is lack of control group. Lastly, current study was designed cross-sectional study so it does not allow us to establish causality.

CONCLUSION

In conclusion, we found that the increase in kinesiophobia level in patients with FMS is related to low physical activity level, mobility, trunk flexor endurance and increased pain and fatigue level. Exercise is a important treatment application in the management of FMS, and as mentioned aboved, kinesiophobia may affect participation in exercise in FMS patients. Therefore, we believe that these results will be useful when designing a rehabilitation program for FMS patients.

Etik Kurul: Ethical approval was obtained for this study from the local ethics committee (approval number: 2023/4664).

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Sorumlu Yazar: Yasemin Mirza, Necmettin Erbakan University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Konya, Türkiye

e-mail: yakkubak@gmail.com

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