

# BANDIRMA ONYEDİ EYLÜL ÜNİVERSİTESİ SAĞLIK BİLİMLERİ VE ARAŞTIRMALARI DERGİSİ BANU Journal of Health Science and Research

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Original Research / Özgün Araştırma

Effectiveness of Different Exercise Approaches for Individuals with Chronic Low Back Pain Providing Primary Care to Multiple Sclerosis Patients

Multiple Skleroz Hastalarına Primer Bakım Veren Kronik Bel Ağrılı Bireylere Uygulanan Farklı Egzersiz Yaklaşımlarının Etkinliğin İncelenmesi

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ABSTRACT

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This study was produced from the master's thesis titled "Multiple Skleroz Hastalarına Primer Bakım Veren Bireylerde Farklı Egzersiz Yaklaşımlarının Etkinliğinin İncelenmesi.

Aim: Multiple Sclerosis need help with personal care due to symptoms like weakness, stiffness, and fatigue. Chronic low back pain often affects primary caregivers of MS patients. Our study aims to assess exercise efficacy in caregivers with chronic low back pain caring for MS patients.

*Material and Method:* Forty-one participants with low back pain for 12 weeks who were primary caregivers of MS patients were randomly divided into Pilates (n=20) and home exercise program (n=21). Visual Analogue Scale, Algometer, Oswestry Disability Index, Bakas Caregiver Outcome Scale, fingertip-to-floor test, 30-second sit-stand test and Beck Anxiety Inventory parameters were used on the participants. Assessments were conducted both prior to initiating treatment and following six weeks of exercise intervention.

**Results:** As a result of the applied treatment program, for both groups in the evaluation results; pain tolerance(p=0.001), bakas score (p=0.00), functionality (p=0.00) and anxiety (p=0.00) were also found to be improved. However, there was no statistically significant difference between the two groups when the groups were compared (p≥0.005).

**Conclusion:** Pilates exercise and the McKenzie home exercise program were shown to improve patients' pain and pain tolerance, functioning and anxiety. Moreover, these results underscore the importance of considering the individual preferences and needs of caregivers with chronic low back pain when making clinical treatment plans.

Keywords: Pilates training, L back pain, Exercise, caregivers, Multipl sclerosis

#### ÖZET

**Amaç:** Halsizlik, tutukluk ve yorgunluk gibi semptomlar genellikle Multipl Skleroz hastalarının kişisel bakımına yardımcı olmayı gerekmektedir. Ayrıca, kronik bel ağrısı MS hastalarının birincil bakıcılarını da sıklıkla etkilemektedir. Çalışmamız, bu bakıcılarda kronik bel ağrısına yönelik egzersiz müdahalelerinin etkinliğini değerlendirmeyi amaçlamaktadır.

Gereç ve Yöntem: MS hastalarına primer bakım veren 12 haftadır bel ağrısı yaşayan 41 katılımcı randomize olarak pilates (n=20), ev egzersiz programı (n=21) olarak ikiye ayrıldı. Katılımcılara, hasta tanıma formu, Vizüel Analog Skala, Algometre cihazı, Oswestry Disability İndeksi, Bakas Bakım Veren Etki Ölçeği, elparmak zemin mesafesi testi, 30 saniye otur-kalk testi, Beck Anksiyete Ölçeği parametreleri kullanıldı. Değerlendirmeler hem tedaviye başlamadan önce hem de altı haftalık egzersiz müdahalesinin ardından yapılmıştır.

**Bulgular:** Uygulama sonrası tüm katılımcılarda iyileşmeler kaydedildi. Uygulanan tedavi programı sonucunda, grup içi değerlendirme sonuçlarında her iki grup için; ağrı toleransı(p=0,001), bakas skoru (p=0,00), fonksiyonellik (p=0,00) ve anksiyete (p=0,00) üzerinde iyileşme olduğu saptandı. Ancak gruplar arası karşılaştırmada istatistiksel olarak iki grup arasında üstünlük gözlemlenmedi ( $p\ge 0.005$ ).

**Sonuç:** Pilates egzersizi ve ev egzersiz programının hastaların ağrı ve ağrı toleransı, fonksiyonellik ve anksiyete üzerinde iyileşme görüldüğünü ancak birbirleri üzerinde iyileşme bulunmadığı görüldü. Ayrıca, bu sonuçlar, kronik bel ağrısı olan bakım verenlerin tedavi seçimlerinde bireysel tercihlerinin ve ihtiyaçlarının göz önünde bulundurulmasının klinik planlamada önemli olduğunu göstermektedir.

Anahtar Kelimeler: Pilates Eğitimi, Bel Ağrısı, Egzersiz, Bakım Veren, Multipl Skleroz



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### INTRODUCTION

An immune system-mediated demyelinating illness that causes depressive, cognitive, and physical symptoms is known as multiple sclerosis (MS) (Tolar et al., 2020). In the first 15 years after receiving an MS diagnosis, it has been observed that, depending on how the disease progresses, 50% of patients are unable to walk without assistance, and 25% require a wheelchair to go around. Due to the difficulties they have in their everyday lives, people with MS are often unable to take care of themselves. As a result, they require lifelong care and a caregiver (Dibley et al., 2017).

According to studies, the concept of burden, refers to "negative objective and subjective consequences caused by the care provided by the caregiver, such as psychological problems, physical health problems, economic problems, social problems, negative effects on family relationships, and fear of losing control. (Mishra et al., 2021; Öztürk et al., 2019). Giving long-term care involves emotional, financial, and physical difficulties. Caretakers struggle with social activity restriction, sadness, anxiety, tension, routinely bringing patients to medical facilities, and providing essential equipment. Over the years, transfers of MS patients have led to longterm improper posture in caregivers (Benini et al., 2023; Haase et al., 2021). These challenges result in recurring musculoskeletal issues. Typically, family members are responsible for the care of MS patients. Because of this, carers frequently experience musculoskeletal pain (Mishra et al., 2021).

The most prevalent musculoskeletal problem affecting carers is low back pain, which limits people's mobility and makes their lives more difficult (Gunay Uçurum et al., 2019). A person with low back pain experiences physical, mental, and psychological effects as well as physical function limitations. Low back pain patients may find it difficult to get involved with social activities and may have depression symptoms as a result of their discomfort (Coşkun et al., 2012; Adıgüzel, 2021). Exercise is regarded as a preventive treatment for enhancing quality of life, ensuring functionality, and maintaining posture (Özsoy et al., 2019).

Although there are research in the literature looking at different exercise efficacy in chronic pain on various groups, no studies have been found on this topic for people who care for patients with MS. It is expected that people will frequently exercise and incorporate it into their everyday routines in order to live longer, healthier lives free from pain. The aim of this research is to evaluate the efficacy of exercise programs supervised by a physiotherapist and home programs designed to be completed in participants' homes for chronic pain experienced by MS caregivers.

### MATERIALS AND METHODS

### **Research Type**

The type of this study was randomized controlled.

### **Study Population and Sample**

The study was conducted at the Uzay Rehabilitation Center between May 1, 2023, and July 7, 2023. Pilates with a physiotherapist (n= 20) and home exercise program group (n= 21) were allocated at random to the 41 participants who provided primary care to MS patients in the trial. The random.org website was used for the randomization.

Participants assessment and therapy were carried out (single blind) by various physiotherapists. Six weeks following application, the impact was evaluated for our investigation. Participants must have a diagnosis of chronic low back pain that has persisted for at least six months. They must be professionally involved in providing primary care to patients with multiple sclerosis. The age range for participants is between 18 and 60 years. Additionally, participants should not have engaged in any regular exercise program for at least three months prior to joining the study. They must be free of serious cardiovascular, pulmonary, neurological, or other systemic diseases. Furthermore, participants should not be using analgesics, anti-inflammatory drugs, or muscle relaxants that could significantly impact the study's outcomes.

Exclusion criteria for the participants included a lack of cognitive impairment (delirium, dementia, amnesia), exercise contraindications (uncontrolled medical conditions), caring for people with unclear MS diagnoses, disagreeing with the measurements to be taken or giving evasive answers, prior spinal surgery, excluding lumbar disc herniation, and other spinal and joint disorders.

The number of patients required to be recruited

was calculated using the G Power program (version 3.1.9.2) with 80% power, 0.05 type 1 error was calculated as 20 for each group, and the effect size value was calculated as 0.9 based on the difference between the survey results (Özsoy et al., 2019).

### **Data Collection Tools**

The participants in the study's demographic data were collected. Evaluation techniques include the MSQOL-54 for measuring MS patients' quality of life, the ODI for measuring disability, the Beck Anxiety Scale for measuring anxiety, the Bakas Caregiver Outcome Scale for assessing the impact on the caregiver's process, the VAS and algometer for pain tolerance, and the sit-to-stand activity. For lower extremity strength and dynamic balance, the 30 Second Sit-Rise Test was performed, and finger to floor distance (FTF) was employed to assess lumbar range of motion. MS-54 and EDDS were applied to the patient and other tests were applied to the patient's relatives.

*Multiple Sclerosis Quality of Life-54 (MSQOL-54):* Consists of 54 items, 2 main groups as composite physical health and composite mental health, 12 subgroups and 2 independent items and is scored between 0-100. The high score obtained from the scale determines the good quality of life level (Baker et al., 2019).

*The Expanded Disability Status Scale (EDSS):* EDSS is an important scale that examines the increase in disability status, which is widely used in the evaluation and follow-up of neurological examinations of patients with demyelinating diseases such as MS. The scale covers 8 functional systems including pyramidal, cerebral, cerebellar, brainstem, bladder and bowel, sensory, visual, and ambulatory positions. A score of 0 on the scale indicates normal neurologic status, while a score of 10 indicates death caused by MS (Meyer-Moock et al., 2014).

**Bakas Caregiver Outcome Scale:** It is used to measure the impact of individuals caring for patients with MS. It assesses the impact and difficulty of caregiving on caregivers. The scale identifies both positive and negative effects. The scale includes a total of 15 questions scored from +3 (for the best) to -3 (for the worst). In the scale, the worst affected individual can score 15 points and the best affected individual can score 105 points. The higher the score, the "better affected" and the lower the score, the "worse affected (Bakas et al., 2006). **Beck Anxiety Inventory:** It is a frequently preferred scale to interpret the mental problems of the individuals included in the study. It consists of 21 questions, each of which is scored between 0-3 points. The maximum score is 63. The scale evaluates the symptoms that occur as a result of the reactions of anxiety to the body (tingling, weakness, hot flashes, heart palpitations, stomach upset, trembling, fainting, etc.) and thoughts that include anxiety (fear of something very bad happening, fear of death, fear of losing control, being terrified, etc.). The higher the score, the more severe the anxiety (Toledano- Toledano et al., 2020).

*Visual Analog Scale (VAS):* Pain intensity was evaluated with VAS. A score of 0 was defined as "no pain" and a score of 10 was defined as "very much pain". Participants were asked to indicate the score according to the degree of pain sensation at rest.

*Oswestry Disability Questionnaire (ODI):* Provides information about how much low back pain affects daily life. It consists of 10 questions. There are 5 options for each question. It is stated that the intensity of pain increases from 0 to 5. When the total score is calculated, it is multiplied by two and expressed as a percentage. The maximum score is "100" and the minimum score is "0". The higher the total score, the higher the level of disability (Yakut et al., 2004).

*Algometer:* Manual algometer device, which is an objective method to evaluate pain sensitivity to pressure, was used. "Baseline Dolorimeter" was preferred in this study. The unilateral Iliocostalis Lumborum muscle on the dominant side was targeted in the measurement. Individuals were asked to report when the pressure sensation turned into pain sensation (Imamura et al., 2016).

*Finger to Floor Distance (FTF):* In standing position, the distance between the middle finger and the floor is measured with a tape measure using active trunk flexion without knee flexion. This distance is considered normal up to 0 cm in women and 10 cm in men (Perret et al., 2001).

**30sn Sit to Stand Test:** This test, which was preferred to evaluate lumbar leg functionality and balance in daily activities, was performed on a chair with an average height of 44 cm, leaning against a wall and without arms, with the individual sitting upright with his/her feet on the floor and arms crossed in front of the chest. First, a few attempts were made and then the individual

was given a command to sit up and sit down for 30 seconds. As the number of sit-ups in 30 seconds increased, an increase in the individual's functionality was observed (Kahraman et al., 2016).

### Exercise program

All exercises were explained to the participants by the physiotherapist and they were asked to do them regularly. They were also given brochures of the exercises.

*Group 1:* The first group did Pilates exercises with a physiotherapist and continued McKenzie exercises in a home program. Extension in lying, flexion in lying, extension in standing, flexion in standing, extension in sitting, flexion in sitting, prone press-ups, and core stabilization exercises within the McKenzie exercise framework.

*Group 2:* The second group completed Pilates and McKenzie exercises as a home program. pilates exercises were the same as the exercises performed in the first group, but the difference was that these patients were asked to perform the exercises at home. Each exercise consisted of two sets of 5-10 repetitions with 30 seconds rest time between sets. The total exercise time reached an average of 30 minutes. Exercises were performed twice a week in their own living spaces. Face-toface meetings were held with physiotherapists once a week and verbal general information about exercise continuity and health status of the individuals were obtained.

In Weeks 1 and 2, the focus was on foundation and stability exercises. The exercises for these weeks included Supine Flexion (Forward Bend), Standing Extension (Backward Bend), Breathing Exercise, Pelvic Clock Exercise, Dead Bug Exercise, and Cat-Cow Stretch.

In Weeks 3 and 4, the program progressed to strengthening and endurance exercises. The exercises for these weeks included Supine Flexion (Forward Bend), Standing Extension (Backward Bend), Prone Position Push-Up, Plank on Elbows, Quadruped Exercise, Bridge Exercise, and Bird Dog Exercise.

In Weeks 5 and 6, the program advanced to coordination and flexibility exercises. The exercises for these weeks included Supine Flexion (Forward Bend), Standing Extension (Backward Bend), Prone Position Push-Up, Plank on Elbows, Quadruped Exercise, Dead Bug Exercise, Bridge Exercise, Mermaid Exercise, Book Opening Exercise, Spine Twist Exercise, Single Leg

Stretch, Double Leg Stretch, and Rolling Like a Ball.

### **Ethics Consideration**

Our study's registration number in the clinical trials database is NCT05896995. Ethical approval was retrieved from the university human ethics committee (Date: 05.04.2023 and Approvel Number: 2023-07/02). The Helsinki declaration was followed in the design of our study.

### Data Analysis

Data were analyzed using SPSS 25.0 software. Categorical data were presented as frequency (N) and percentage (%) and numerical data were presented as mean and standard deviation values. The normality assumption was examined using the "Shapiro-Wilk" test. Intragroup comparisons were examined using Wilcoxon Test and Student t test, and intergroup comparisons were done using Mann-Whitney U and Independent t Test. The significance level was defined as  $p \le 0.05$  for all tests.

## RESULTS

Forty-five participants who could be included in the study were evaluated for eligibility for inclusion. In total, three people did not meet the inclusion criteria. 42 people were randomly divided into two groups. One person dropped out of the study due to health problems. Data were collected from 41 participants before and after treatment (Figure 1).

There were no significant differences between the groups in terms of age (p=0.112) and BMI (p=0.164). The fact that the results were not significant indicates that the demographic data of the groups were homogeneously distributed (Table 1).

The MS54 physical (p=0.142) and mental scores (p=0.604) and EDSS scores (p=0.331) of individuals with MS for whom relatives were responsible were similar between the first group and the second group (Figure 2). MS 54 and EDDS were administered to MS patients. Other tests were administered to primary care to Multiple Sclerosis patients.

VAS score was p=0.59 in group 1. In the second group, p=0.00 and p=0.278 between both groups. Algometer score was p=0.001 for group 1. In the second group, p=0.012 and the evaluation result between both groups was p=0.671. The ODI score was p=0.00 in group 1 and p=0.00 in the second

group, yielding a significant result and p=0.347 between both groups. BCOS score was observed as p=0.00 in group 1 as a result of evaluation of the data. In the second group, p=0.006 and p=0.129 between both groups. FTF score was p=0.003 in group 1, p=0.01 in the second group and p=0.185 in the statistical analysis between

both groups. The sit-to-stand score was significant as p=0.00 in group 1 and p=0.00 in the second group. The result of the analysis between both groups was p=0.711. Beck score was expressed as p=0.00 in group 1 and p=0.00 in the second group and the evaluation score between both groups was analyzed as p=0.186 (Table 2).



Figure 1. Consort 2010 Flow Diagram

	Group 1 Average ± SD	Group 2 Average ± SD	Р
Age (years)	$43.63 \pm 11.80$	37. 57 ± 13.75	0.112
BMI (kg/m <sup>2</sup> )	$26.95\pm5.24$	$25.67 \pm 5.23$	0.164
Gender	11 Female	16 Female	0.160
	9 Male	5 Male	
MS54 PHYSIO TOTAL	$52.08 \pm 11.90$	$65.90 \pm 30.51$	0.142
MS54 MENTAL TOTAL	$53.14 \pm 15.30$	$55.90 \pm 18.26$	0.604
EDSS	$10.70\pm5.14$	$9.00\pm5.86$	0.331

#### Table 1. Anthropometric Measurements

BMI: Body Mass Index, P-value < 0.05 SD - standard deviation, MS: Multiple Sclerosis, EDSS: Expanded Disability Status Scale, kg: kilograms, m:meter



### Figure 2. MS-54 and EDSS score

MS: Multiple Sclerosis, EDSS: Expanded Disability Status Scale

#### DISCUSSION

In this randomized controlled study, we have found the effectiveness of both exercise programs in individuals with low back pain who care for patients with MS in our program consisting of McKenzie and Pilates exercises. However, we found that there was no difference between the groups when the program accompanied by a physiotherapist and home exercise program applications were compared.

The relatives of patients with MS included in our study may experience musculoskeletal problems due to the problems they experience during caregiving. Chronic low back pain is one of the most common problems in the general population. Chronic low back pain is also frequently encountered in relatives of patients with MS. Exercise is one of the treatment approaches with the highest level of evidence in the rehabilitation

#### of chronic low back pain.

In a study, positive results were obtained for pilates exercises to improve pain, functionality and quality of life in individuals with non-specific low back pain (Taşpınar et al., 2023). In our study, exercise programs were prescribed to the patients as a result of one-to-one interviews under the supervision of a physiotherapist. In this way, improvement was achieved in both groups in our study.

In people with low back pain, the McKenzie method has been reported to be significantly effective in relieving pain and disability in a shorter time compared to other treatment methods (Clare et al., 2004). We included the McKenzie exercise prescription in our program, aiming to relieve muscle tension and prevent functional limitation in chronic low back pain. We obtained a significant difference in the six-week evaluation

of our study (Owen et al., 2020). Found that the level of evidence for exercise applications in low back pain was insufficient. For this reason, they recommended exercises under the supervision of physiotherapist. Similarly, Pilates a and McKenzie were applied to the first and second groups in our study. The first group was accompanied by a physiotherapist. As a result of the study, improvement was observed in both groups.

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	Group 1			Group 2			P**
	Before	After	Р	Before	After	Р	-
	Treatment	Treatment		treatment	Treatment		
VAS	$6.80\pm2.30$	$4.40\pm2.21$	0.59	$4.80\pm2.70$	$3.00\pm2.30$	0.00*	0.278
Algometer	$8.67\pm2.40$	$9.58\pm2.02$	0.001*	$9.08\pm2.40$	$9.89 \pm 1.72$	0.012*	0.671
ODI	$32.62\pm16.64$	$21.32\pm16.40$	0.00*	$29.83\pm12.83$	$20.70\pm12.09$	0.00*	0.347
BCOS	$52.65\pm14.83$	$70.20\pm13.05$	0.00*	$58.71 \pm 14.40$	$70.71\pm13.60$	0.006*	0.129
FTF	$-10.22 \pm 8,56$	$-6.11 \pm 5.83$	0.003*	$\textbf{-5.33} \pm 7.16$	$-2.67 \pm 5.14$	0.01*	0.185
30sn sit to	$9.65\pm3.73$	$11.60\pm4.30$	0.00*	$14.33\pm4.93$	$16.52\pm4.97$	0.00*	0.711
stand test							
BAI	$20.10 \pm 11.70$	$10.70 \pm 8.30$	0.00*	$19.30 \pm 10.53$	$12.30 \pm 8.45$	0.00*	0.186

VAS: Visual Analog Scale, ODI: Oswestry Disability Index, BCOS: Bakas Caregiver Outcome Scale, Finger to Floor Distance (FTF),

BAI:Beck Anxiety Inventory, \*p-value < 0.05

The review, which also compared Pilates and McKenzie exercises, found evidence of highly beneficial returns from other types of exercise therapy in reducing functional improvement, pain severity and functional limitations (Hayden et al., 2021; Kwok et al., 2021). In our study, the effectiveness of exercise programs on pain relief, increased functionality and flexibility was determined.

In their review, found that pilates exercises are one of the most meaningful exercises for pain relief among different exercise applications. The appropriate exercise program most is recommended to be 1-2 weekly sessions for 3-9 weeks (Ruben et al., 2022). In our study, we combined McKenzie and Pilates exercises and obtained significant results in our 6-week followup period.

The applicability of specific physical assessment and home exercise prescription in individuals with subacute and chronic non-specific pain has gained importance. In the study, muscle strength, flexibility and trunk range of motion were evaluated. Pain and ODI assessment methods were preferred at the end of six weeks. Individualized exercise prescription is recommended for clinicians instead of frequently used exercises (Descarreaux et al., 2002). In our study, the home exercise program was given a clear exercise program brochure that caregivers could apply at any time in their own living spaces without being tied to a specific clinic or time for exercise due to social activity and time constraints. Accordingly, while significant

improvements were observed in both of our studies, there was no significant difference between the home exercise program and the physiotherapist-guided exercise program. The individuals included in our study are under a psychologically difficult process due to primary caregiving. During the study process, time management of the patients was encountered difficulties while exercising with a physiotherapist. For this reason, since the home program allows patients to exercise at any time and place they wish, there was no superiority of the exercise program under the supervision of a physiotherapist compared to the home exercise program.

When pain, functional impairments and quality of life of individuals with chronic low back pain were examined, it was found that Pilates improved pain reduction by eliminating functional impairments, but it was stated that there was not a very effective change in the living standards of individuals (Yuz et al., 2023). In contrast to this study, our study showed a significant difference in the quality of life of individuals with increased functionality.

In other studies comparing and evaluating exercise therapies, it was observed that exercise therapy was less effective in chronic low back pain. Within the scope of the study, strengthening and stretching exercises were applied for 14 days and the effects of pain, FTF and Modified Schober test and ODI were analyzed (Yılmaz et al., 2015). In our study, we think that the 6-week duration of the application was effective in

finding improvement in all the parameters we preferred.

It was determined that caregivers were negatively affected by the care process (42.9%) and the individuals who thought that the care process did not affect their lives (48.6%) (Sağlam et al., 2016). Similar to this study, in our study; in the pre-treatment evaluation parameters, the "bad influence" score of individuals in the caregiving process was higher, but improvement was observed after treatment. We think that musculoskeletal problems accompany stress due to increased stress with the restriction of social life of individuals during the caregiving process and restriction of mobility in the long term. We think that our study was beneficial because it was in the individuals' own living space and provided stress, pain and functionality by providing mobility to the individuals.

The gender factor, the effectiveness of which varies in many diseases, has been reported in some studies that low back pain is more common in women (Çelenk et al., 2022). In the researches conducted, it has been observed that the fact that it is mostly women in the family to undertake care and that the individuals hired as caregivers are mostly female individuals causes an increase in the role of women in life; It has been observed that it is negatively affected socially, professionally and psychologically (Benini et al., 2023; Haase et al., 2021).

A study aims to evaluate pain and active range of motion in chronic low back pain with core exercises. The core group was exercised three days a week for four weeks. The control group did not exercise. VAS was used for pain and algometer device was preferred to evaluate pain tolerance. The results showed a significant increase in pain tolerance (Cho et al., 2014). In our study, we preferred algometer device to evaluate pain tolerance in chronic low back pain. As a result of our study, we found that pain tolerance increased after exercise programs.

### Limitation

The limitation of our study is that the follow-up period was limited to six weeks and we could not do follow-up in the advanced period. This limitation is our target for future studies.

## CONCLUSION

Studies have shown that caregivers frequently encounter musculoskeletal problems and stressinduced anxiety disorder. In our study, we found that musculoskeletal problems and anxiety decreased with exercise and accordingly, the relationship with the patient was positively affected. We believe that extending our study with longer-term exercise programs would yield more comprehensive insights. Our findings suggest that exercise exerts a significant positive effect on chronic low back pain and should be integrally included in treatment programs.

### **Ethics Committe Approval**

Ethics committee approval was received for this study from the Istanbul Bahçeşehir University Ethics Committee (Date: 25.01.2023, Approval Number: 2023/01).

#### Author Contributions

Idea/Concept: S.K., H.G.; Design: S.K.; Supervision/Consulting: H.G.; Analysis and/or Interpretation: S.K., H.G.; Literature Search: S.K., H.G.; Writing the Article: S.K., H.G.; Critical Review: H.G.

#### Peer-review

Externally peer-reviewed.

#### **Conflict of Interest**

The authors have no conflict of interest to declare.

#### **Financial Disclosure**

The authors declared that this study has received no financial support.

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