A COMPARISON OF THE EFFECTS OF BALANCE–PROPRIOCEPTION AND AEROBIC EXERCISES ON FUNCTIONAL STATUS, PAIN, AND BALANCE IN PATIENTS WITH FIBROMYALGIA SYNDROME - A RANDOMIZED CONTROLLED STUDY

FİBROMİYALJİ HASTALARINDA DENGÊ-PÔRÎÖPOSEŞİYON VE AEROBİK EGZERSİZ UYGULAMALARININ FONKSİYONEL DURUM, AĞRI VE DENGE ÜZERİNE ETKİSİ-RANDOMİZE KONTOLLÜ ÇALIŞMA

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ABSTRACT

Objective: Difficulty in performing daily activities and loss of balance are common complaints in addition to generalized pain in fibromyalgia syndrome (FMS) patients. Exercise is an effective treatment for fibromyalgia. There are a variety of forms of exercise used to treat fibromyalgia. This study aimed to compare the effects of aerobic and balance-proprioception exercises on pain, functional status, and balance in female patients with fibromyalgia.

Material and Method: Female patients with fibromyalgia syndrome who applied to the university physical medicine and rehabilitation department clinic were evaluated for eligibility. Patients were allocated into two groups: the aerobic exercise group and balance-proprioception group. These two groups exercised under the supervision of a physiotherapist three days a week for a total of 6 weeks. Visual Analogue Scale (VAS) was used for pain severity, Fibromyalgia Impact Questionnaire (FIQ) was used for functional status assessment, and balance-stability measurement was performed using the Biodex Balance System.

ÖZET

Amaç: Fibromiyalji sendromunda yaygın ağrıya ek olarak günlük aktiviteleri gerçekleştirmede güçlük ve denge kaybı sık görülen şikayetlerdir. Çalışmamızda fibromiyaljijdeki bu şikayetler üzerine etkili olabileceğini düşündüğümüz farklı tip egzersiz programlarının (aerobik ve denge-propriyosepsiyon) ağrı, fonksiyonel durum ve denge parametreleri üzerine etkilerini karşılaştırmaya amaçladık. Bu nedenle randomize kontrol, paralel gruplar içeren, tek merkezli ve tek kör bir çalışma tasarladık.

Gereç ve Yöntem: Üniversitelerin fizik tedavi ve rehabilitasyon bölümü kliniğine başvuran fibromiyalji sendromlu kadın hastalar uygulanan açıdan değerlendirildi. Hastalar aerobik egzersiz grubu ve denge-propriyosepsiyon grubu olarak iki gruba ayrıldı. Bu iki grubu haftada 3 gün fizyoterapist yönetiminde program 6 hafta egzersiz yaptı. Ağrı şiddeti için Visual Analogue Scale (VAS), fonksiyonel durum değerlendirilmesi için Fibromiyalji Etki Anketi (FEA), denge durumu değerlendirilmesi için denge-stabilite sistemleri (Biodex Balance System) kullanıldı. Her ölçüm teda-
INTRODUCTION

Fibromyalgia syndrome (FMS) is a chronic disease characterized by generalized pain, fatigue, sleep disorder, cognitive impairment, and other physical symptoms that negatively affect physical and sensory functions while lowering quality of life (1). The prevalence of FMS is 2%-4% in the population, with a female/male ratio of 9:1. People between the ages of 45 and 60 are most commonly affected (2). It is believed that numerous mechanisms contribute to the development of FMS. There is evidence of biochemical, neurohormonal, central nervous system, immunological, psychological, and environmental factors (3).

Fibromyalgia significantly affects the health-related quality of life of patients by restricting their ability to perform daily activities including walking, lifting, and carrying objects (4,5,6). Patients with FMS have reduced functional abilities, poor health status, and lower quality of life in comparison to both healthy individuals or those with other chronic conditions (7,8). These patients tend to maintain a sedentary lifestyle due to their impaired physical fitness, which exacerbates symptoms and increases the risk of other morbidities (9-11).

There are two options for the treatment of FMS: pharmacological and non-pharmacological. Education, cognitive behavior therapy, exercise, and complementary and alternative medicine are the four most effective non-pharmacological treatment approaches commonly used and have a 1A level of evidence (12). Exercise training is a non-pharmacological management strategy for FMS that is effective and affordable. Exercise improves the quality of life, cognitive function, anxiety, depression, pain, sleep quality, and stress responses by increasing the “status of energy” (13). Despite these effects, studies demonstrate that women with FMS spend 48%-71% of their time in sedentary behaviors and engage in activities that do not require elevated energy expenditure (14-16).

The literature indicates that various exercise programs have positively impacted pain and functionality, with no significant adverse effects reported in individuals with FMS (17). Research on the type, intensity, and frequency of exercise has increased significantly in recent times. Aerobic exercise (AE) is frequently suggested as the predominant modality of exercise for the management of FMS. Many exercise programs involve both strengthening and flexibility types of exercise. Approximately 80% of the studies investigated the effects of AE or a combination of exercises including aerobic, flexibility, and strength (13).

Balance problems are another prominent functional symptom of FMS, in addition to pain and chronic fatigue. It is reported that 45%-68% of the FMS cases have balance problems. Jones et al. reported that individuals diagnosed with FMS exhibit balance problems and are susceptible to falls. The authors emphasize the importance of developing protective measures for postural stability, given that the dis-
ease affects the mechanisms that regulate postural control (18). It is shown that exercise programs improving balance increase postural stability and decrease the fall risk in patients with FMS (19). In the literature, the number of studies testing the efficacy of different exercise programs on balance disorders is limited. Furthermore, there is not much data on the influence of various exercise types on balance and the possible pain-balance relationship. Therefore, the goal of our study was to evaluate and compare the effects of aerobic and balance-proprioception exercises on pain, functionality, and balance parameters in patients with FMS.

MATERIAL AND METHODS

This randomized controlled, double-center, single-blinded, parallel-group study was approved by the local research ethics committee (Clinical Research Ethics Committee of Istanbul University Faculty of Medicine (Date: 22.09.2017, No: 15)) and registered on the ClinicalTrials.gov website (registration number NCT04437524). The study has been performed in accordance with the ethical standards laid down in the Declaration of Helsinki. Patients included in the study were verbally informed regarding the study’s objective, the process, the methods to be used, and any potential side effects. Their written consent was obtained by having them sign the “Informed Consent Form.”

Eligibility criteria

The study comprised 62 female FMS patients admitted to our physical medicine and rehabilitation department outpatient clinic and met the study requirements. The test and rehabilitation programs of the patients were completed in the exercise test laboratories of the Istanbul Faculty of Medicine, Department of Sports Medicine. The following were the inclusion criteria: patients aged between 18 and 60 years old, patients whose symptoms lasted more than three months, and patients who agreed to undergo treatment for six weeks, three days per week. Additionally, there was no anticipated possibility of any changes in the medical treatment they received for FMS during the study process. Another criterion for inclusion was that the patient had a Pain Location Inventory (PLI) score of 17 or higher and a Symptom Impact Questionnaire (SIQR) score of 21 or higher, as defined by the 2011 American College of Rheumatology (ACR) criteria (20). The exclusion criteria were: the presence of a central or peripheral nervous system disease, progressive neurological damage, severe cardiovascular pathology, loss of sensation or position sense, unhealed fractures or surgical wounds, uncontrolled hypertension, and the inability to understand or follow simple commands.

Randomization

The cases were randomized using a simple random-number drawing procedure. Those who picked odd numbers from the bag of odd and even numbers were assigned to the aerobic exercise group (AEG), whereas those who picked even numbers were assigned to the balance-proprioception exercise group (BPEG).

Group assignment

Exercise therapy programs were designed independently for each group and were performed three days a week under the supervision of a physiotherapist for six weeks in the study. Exercise programs were conducted in the Department of Sports Medicine’s exercise laboratory.

The AEG’s exercise program was thoroughly explained to the patient, and documentation was provided in both written and graphic form. Each exercise session was carried out under the supervision of a physiotherapist in a clinical environment. Total exercise time ranged from a minimum of 30 minutes to a maximum of 60 minutes, including warm-up (low-intensity foot ergometer followed by short-duration stretching of major muscle groups) and cool-down (heart rate was gradually decreased following treadmill use, followed by stretching and abdominal breathing exercises). The patients began with a low-intensity walk on a treadmill at 55%-60% of maximal heart rate (calculated using the formula 220–age in years). The intensity and duration of walking on the treadmill were gradually increased to a moderate level. Subjective exertion was assessed using the Borg Scale of perceived exertion. The intensity level was kept at a moderate level for each individual once they had reached moderate intensity during the exercise program (21). The duration was increased by 5 minutes in each exercise session of the first two weeks to reach 60 minutes of exercise duration (22).

The BPEG’s exercise program was thoroughly explained to the patient, and documentation was provided in both written and graphic form. Each exercise session was carried out under the supervision of a physiotherapist in a clinical environment. Total exercise time ranged from 30 minutes to a maximum of 60 minutes, including warm-up (low-intensity foot ergometer followed by short-term stretching of large muscle groups) and cool-down (short-term stretching exercises followed by abdominal breathing exercises). Balance exercises included exercises on fixed surfaces and progressed to those on mobile surfaces (balance board, Pilates ball). Furthermore, if the patients successfully completed the exercises, they were asked to perform the exercises with their eyes closed to make the exercises more challenging. The proprioception exercise program included: standing on one leg, bending forward-backward-two sides with eyes open, bending forward-backward-two sides with eyes closed, and sitting on the Pilates ball with arms open and one leg extended. As the patients progressed, they were asked to do the same exercises on balance pads while holding a small exercise ball.

Outcome measures

First, demographic data on the study’s participants were obtained. The patients’ pain intensity was assessed using the Visual Analogue Scale (VAS), their functional status...
Effects of different exercise types in fibromyalgia

was assessed using the Fibromyalgia Impact Questionnaire (FIQ), and their balance was assessed using the “Biodex Balance System” (Biodex, Inc., Shirley, New York) device, which was found to be valid and reliable (23,24).

The balance test was applied on the platform of the device in a standing position with both feet for 20 seconds, in triplicate. The mean score of these three times was calculated and recorded as the result. The rest period between repetitions was 60 seconds (25). Overall Stability Index (OSI), Anterior/Posterior Stability Index (APSI), and Medial/Lateral Stability Index (MLSI) data were obtained as test parameters (26).

A blinded physiotherapist who aggregated the outcome data into a specialized database evaluated all the aforementioned scales on the first and last days of the six-week exercise program.

**Statistical analysis**

G*Power (v3.1.9) software was used to do a power analysis to calculate the number of samples. Repeated measures analysis of variance was used to determine the minimal clinically significant difference (MCID=14%) in the FIQ, the study’s main outcome measure based on values acquired from the literature (27,28). The probability of Type 1 error (significance level) was 0.05, and the power of the test was 80% (Type 2 error: 20%). The total number of cases for each group was calculated as 26 and was determined by assessing the likelihood of participants dropping out of the study. A total of 72 patients were evaluated, with 10 of them being excluded because they did not meet the inclusion criteria. As a result, 62 patients participated in the study. The CONSORT flowchart is shown in Figure 1. SPSS ver. 21.0 (IBM Corp., Armonk, NY) was used to analyze the data in the study. Shapiro-Wilk test was used to assess the data’s conformity to the normal distribution. The Chi-square test was used to analyze independent qualitative data, whereas the Pearson Chi-Square likelihood ratio was used to evaluate the predicted values of the data in the cross tables. Independent samples t-test was used to examine independent (between-group) two-group normally distributed quantitative data, whereas the paired samples t-test was used to compare two dependent (within-group) quantitative variables. A value of p<0.05 was accepted as the statistical significance threshold.

**RESULTS**

A total of 11 of the 62 patients dropped out of the study during the treatment due to the fact that five patients refused to continue treatment, and six of them resided far away from the treatment center and were unable to continue treatment. Twenty-six out of 31 patients in the AEG, and 25 out of 31 patients in the BPEG completed their exercise programs successfully in the study, and the data of 51 patients were analyzed. Table 1 shows the baseline demographic (age, weight, body mass index, etc.) characteristics of the groups. In our study, all the participants were female. There was no statistically significant difference between the demographic characteristics of the groups (p>0.05).

At the beginning of the study, there was no statistically significant difference between the FIQ, VAS, and balance assessment values of the groups (p>0.05) (Table 2).

Similar to before-treatment findings, there was no statistically significant difference between groups in the evaluation of the FIQ, VAS, and balance scores after treatment (p>0.05) (Table 3).

The difference between the before-treatment and after-treatment FIQ and VAS scores was statistically significant in both the groups (p<0.001 each) on within-group comparison. After treatment, the FIQ and VAS scores of the groups decreased (Table 4). The results of the within-group comparison showed that values of the Eyes Open Overall Stability Index (EO-OSI) and Eyes Open Anteroposterior Stability Index (EO-APSI) parameters in the BPEG after treatment were decreased and statistically significant (p=0.008 and p=0.043, respectively), whereas there was no significant difference in the same parameters in the AEG compared with the before-treatment values (p>0.05). The changes in Eyes Open Mediolateral Stability Index (EO-MLSI), Eyes Closed Overall Stability Index (EC-OSI), Eyes Closed Anteroposterior Stability Index, and Eyes Closed Mediolateral Stability Index parameters were statistically significant in both the AEG (respectively; p=0.019, p=0.001, p=0.001, p=0.039) and BPEG (respectively; p=0.002, p<0.001, p=0.002, p<0.001). The results of balance parameters improved following treatment in both the groups (Table 4).
### Table 1: Demographic characteristics of the patients

<table>
<thead>
<tr>
<th></th>
<th>AEG (n=26) (mean±SD)</th>
<th>BPEG (n=25) (mean±SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>38.12±9.02</td>
<td>41±5.81</td>
<td>0.180</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td>70.77±14.16</td>
<td>66.36±11.29</td>
<td>0.226</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>27.40±5.64</td>
<td>26.43±3.77</td>
<td>0.469</td>
</tr>
<tr>
<td>Occupation status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>10 (38.5)</td>
<td>12 (48.0%)</td>
<td>0.206</td>
</tr>
<tr>
<td>Unemployed</td>
<td>13 (50.0%)</td>
<td>13 (52.0%)</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>3 (11.5%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

AEG: Aerobic Exercise Group, BPEG: Balance-proprioception Exercise Group, SD: Standard deviation, n: Number of samples, %: percentage

### Table 2: Comparison of the FIQ, VAS, and balance parameters of the groups before treatment

<table>
<thead>
<tr>
<th></th>
<th>AEG (n=26) mean±SD</th>
<th>BPEG (n=25) mean±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIQ</td>
<td>72.01±9.31</td>
<td>67.46±13.00</td>
<td>0.156</td>
</tr>
<tr>
<td>VAS</td>
<td>8.03±1.37</td>
<td>8.06±1.32</td>
<td>0.955</td>
</tr>
<tr>
<td>EO-OSI</td>
<td>0.43±0.14</td>
<td>0.44±0.14</td>
<td>0.817</td>
</tr>
<tr>
<td>EO-APSI</td>
<td>0.32±0.14</td>
<td>0.32±0.12</td>
<td>0.912</td>
</tr>
<tr>
<td>EO-MLSI</td>
<td>0.21±0.10</td>
<td>0.23±0.12</td>
<td>0.582</td>
</tr>
<tr>
<td>EC-OSI</td>
<td>1.29±0.58</td>
<td>1.36±0.49</td>
<td>0.671</td>
</tr>
<tr>
<td>EC-APSI</td>
<td>0.97±0.51</td>
<td>0.95±0.49</td>
<td>0.911</td>
</tr>
<tr>
<td>EC-MLSI</td>
<td>0.63±0.34</td>
<td>0.71±0.38</td>
<td>0.432</td>
</tr>
</tbody>
</table>


### Table 3: Comparison of the FIQ, VAS, and balance parameters of the groups after treatment

<table>
<thead>
<tr>
<th></th>
<th>AEG (n=26) mean±SD</th>
<th>BPEG (n=25) mean±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIQ</td>
<td>34.63±11.85</td>
<td>29.60±12.77</td>
<td>0.152</td>
</tr>
<tr>
<td>VAS</td>
<td>4.54±1.83</td>
<td>4.28±1.92</td>
<td>0.626</td>
</tr>
<tr>
<td>EO-OSI</td>
<td>0.39±0.17</td>
<td>0.34±0.13</td>
<td>0.208</td>
</tr>
<tr>
<td>EO-APSI</td>
<td>0.31±0.16</td>
<td>0.25±0.12</td>
<td>0.177</td>
</tr>
<tr>
<td>EO-MLSI</td>
<td>0.15±0.07</td>
<td>0.14±0.05</td>
<td>0.823</td>
</tr>
<tr>
<td>EC-OSI</td>
<td>0.85±0.53</td>
<td>0.80±0.33</td>
<td>0.692</td>
</tr>
<tr>
<td>EC-APSI</td>
<td>0.65±0.32</td>
<td>0.62±0.29</td>
<td>0.701</td>
</tr>
<tr>
<td>EC-MLSI</td>
<td>0.41±0.43</td>
<td>0.35±0.19</td>
<td>0.537</td>
</tr>
</tbody>
</table>

DISCUSSION

AE and BPE programs were found to be effective in improving the functional status, pain, and balance of patients with FMS in our study. However, it was shown that there was no difference between the exercise programs in terms of reducing pain and improving functionality. Whilst the EO-OSI and EO-APSI balance parameters improved in both groups, the improvement in the AEG was not statistically significant. On the other hand, the improvement was statistically significant in the BPEG.

The implementation of diverse exercise modalities, encompassing aerobics, stretching, strengthening, balance, and flexibility has been observed to yield superior outcomes in pain reduction, quality of life enhancement, and functional status improvement among FMS patients, as compared to exercise programs that do not incorporate therapeutic exercises (29-34). This study indicated that both AE and BPE statistically significantly improved the pain and functional status of female patients with FMS. However, we could not find any statistically significant difference between two exercise programs, consistent with the findings of Demir-Göçmen et al. (35). In this context, our findings emphasize the need for individuals with FMS to participate in an exercise program that is appropriate for them to live a pain-free life with high levels of function.

In a study conducted by Duruturk et al., it was shown that the aerobic exercise program had no significant effect on balance parameters, whilst the balance exercise program showed considerable improvements in two of the eight parameters tested (balance on a pad with eyes open and balance in head-up position with eyes closed) (1). In this study, four balance parameters improved in the AEG, whereas all the balance parameters improved in the BPEG. This difference could be attributed to the use of a different balance exercise program in this study compared to Duruturk et al (1). An exercise program that comprised both static and dynamic balance and proprioceptive exercises was used in this study. Moreover, the level of difficulty of the exercises was gradually increased based on the performance of the individual. On the other hand, Colledge et al. examined the relative contributions of proprioceptive, visual, and vestibular components of balance ability in different age groups. The authors argued that the maintenance of balance across all age groups is more dependent on proprioception than vision (36). In this context, we believe that the proprioception exercises performed in this study may have additional contribution balance results. In addition, the younger mean age of the patients in the groups could play a role in the different balance outcomes achieved as young people, by definition, have better physical performance than the elderly in terms of muscle strength, endurance, and reaction time (37). These factors may also have a favorable impact on exercise program compliance and gains, explaining why patients in our study showed significant improvements in numerous parameters.

Eleven of the 62 patients dropped out of the study during the treatment; 6 of them stated residing far away from the treatment center as the reason. A recent study investigating the effects of a Telerehabilitation-based aerobic exercise program on pain intensity, mechanical pain sensitivity, and psychological stress in patients with FMS noted significant improvements, similar to previous face-to-face studies (38). This method could be an appropriate solution for patients with FMS to continue their exercise programs from home, also considering the COVID-19 pandemic conditions, to prevent loss of motivation and interruption of treatment.
The strength of this study arises from the evaluation techniques and equipment utilized for evaluation which were regularly calibrated and had a high level of sensitivity and reliability. Thus, we can confidently state that our study findings are objective and valuable. Furthermore, regular patient follow-up and the supervised implementation of exercise programs in clinical settings provided appropriate exercise performance and safety in terms of any adverse effects.

The limitations of this study include the small number of participants, the lack of a non-exercising control group, and the inability to investigate the long-term effects of exercise.

**CONCLUSION**

As the outcomes of the two exercise programs assessed for their efficacy on FMS were similar, we believe both exercise regimens can be recommended. Furthermore, we assume that an exercise model tailored to an individual’s preferences will be more practical and will help in exercise program adherence over a long-term period. In this context, we suggest that exercises should be incorporated into the treatment of FMS. As a matter of fact, the balance proprioception exercises, apart from the AE models that are often prescribed today, can also be a preferable option.

**Ethics Committee Approval:** This study was approved by Istanbul Faculty of Medicine Clinical Research Ethics Committee (Date: 22.09.2017, No: 15).

**Peer Review:** Externally peer-reviewed.


**Conflict of Interest:** The authors have no conflict of interest to declare.

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