STUDY DOCUMENT COVER PAGE

Official Title:

Effects of Home-Based Exercise Program on Pain, Fatigue, Quality of Life, Depression, and Exercise Perception in Fibromyalgia Patients: A Randomized Controlled Trial

NCT Number:

Not yet assigned

Document Date:

March 31, 2021

Study design and participants

This prospective, randomized, and controlled study was conducted between June 2021 and June 2022 at the Department of Physical Medicine and Rehabilitation (PMR), University Hospital. Patients diagnosed with FM according to the 2016 ACR diagnostic criteria were evaluated for eligibility. In accordance with the ACR diagnostic criteria, three conditions are required to be met: 1) The presence of symptoms of similar severity for at least 3 months; 2) A widespread pain index (WPI) ≥7 and a symptom severity scale (SSS) score ≥5, or a WPI of 4–6 and an SSS score ≥9; 3) Generalized pain in at least 4 out of 5 regions [7]. The inclusion criteria were as follows: age between 18 and 65 years; voluntary participation in the study; diagnosis of fibromyalgia according to the 2016 ACR criteria; female gender; and a pain severity score of ≥4/10 on the Visual Analog Scale (VAS). The exclusion criteria included pregnancy, a history of malignancy, pre-existing neurological, endocrine, infectious, or inflammatory rheumatic diseases, severe psychiatric disorders, advanced cardiac, respiratory, or musculoskeletal conditions that would prevent exercise, participation in an exercise or physical therapy program within the last 6 months, and any changes to current medical treatment during the study period. A written informed consent was obtained from each patient. The study protocol was approved by the Interventional Research Ethics Committee (Date: 31/05/2021, Number: 2021/02). The study was conducted in accordance with the principles of the Declaration of Helsinki.

A total of 60 female patients (mean age: 48.0±9.7 years; age range: 28 to 65 years) participated in the study. The patients were randomly assigned to the exercise group or the control group using a computer program (https://www.random.org). Seven patients (three from the exercise group and four from the control group) did not complete the follow-up. The study flowchart is presented as shown in Figure 1. **Intervention**

During the study, the patients' pre-existing medical treatments were not altered. The exercise group was provided with a home-based exercise program. We did not prohibit the control group from exercising, although they did not receive any specific exercise recommendations. The home-based exercise program was instructed by the researcher physician in the PMR outpatient clinic, and a visual and descriptive brochure of the exercises was provided to the patients. The home-based exercise program, which included stretching and strengthening exercises, was followed at home for 12 weeks. The program consisted of stretching exercises targeting the neck, back, chest, and thigh muscles, as well as strengthening exercises focused on the back, shoulders, abdomen, and thigh muscles. The home-based exercise program was adapted from the Fibromyalgia Syndrome Patient Handbook, developed by the Turkish Society of Physical Medicine and Rehabilitation (available at:https://www.tftr.org.tr/uploads/fibromiyalji-sendromu-hasta-kitapcigi.pdf**).** Patients were advised to perform the exercises daily, if possible. If daily adherence was not feasible, they were recommended to exercise at least three days per week. To promote adherence in the exercise group, patients were contacted by phone every three weeks. During the final phone call, patients were invited to the outpatient clinic for their week 12 follow-up assessments. Patients in the control group were also contacted and invited for their evaluations at week 12.

Outcome measures

The data were collected through face-to-face interviews with patients, using their self-reports. The patients' age, body mass index (BMI), smoking status, disease duration (in years), and exercise habits were recorded. The survey primarily encompassed demographic characteristics, pain severity, fatigue, depressive symptoms, exercise perception, and quality of life measures. All participants were required to complete the questionnaires at baseline and at the 12-week follow-up.

Pain and fatigue were evaluated using the VAS score, whose reliability was confirmed by Clark et al. [16]. This scale consists of a 10 cm horizontal line where "0" represents "no pain"

and “10” signifies “unbearable pain” for pain measurement, “0” indicates “no fatigue” and “10” represents “intolerable fatigue” for fatigue evaluation. Patients were instructed to indicate the severity of their pain and fatigue on the horizontal line.Quality of life was evaluated using the Turkish version of the Fibromyalgia Impact Questionnaire (FIQ) [17]. This tool consists of 10 subscales, each scored from 0 to 10, covering areas such as "physical impairment," "days feeling well," "missed work," "work-related impairment," "pain," "fatigue," "morning fatigue," "stiffness," "anxiety," and "depression." The total FIQ score can range from 0 to 100, with higher scores reflecting a greater impact of the condition on the patient’s well-being [18].

The Exercise Benefits and Barriers Scale (EBBS) was used to assess patients' exercise perceptions. This scale consists of 44 items, and patients are asked to select the most appropriate option on a 4-point Likert scale. Items 4, 6, 9, 12, 14, 16, 19, 21, 24, 28, 33, 38, 40, and 42 represent perceived barriers to exercise, whereas the remaining items reflect perceived benefits. Scores for the benefits and barriers subscales are calculated separately. Higher scores on the benefits subscale indicate a more positive perception of exercise, while higher scores on the barriers subscale suggest a greater perception of obstacles to engaging in exercise. The Turkish validity and reliability study of this scale has been conducted [19].

Beck Depression Inventory (BDI) was used to assess the patients’ depressive symptoms. The validity and reliability of the Turkish version of this scale have been established [20].

Statistical analysis

Descriptive statistics of the data are presented as mean, standard deviation, median, minimum, maximum, frequency, and percentage values. The normality assumption of quantitative data was checked using the Shapiro-Wilk test. Differences between exercise and control groups in terms of demographic variables were analyzed. For variables showing normal distribution, the Independent Samples t-test was used, while the Mann-Whitney U test was used for variables that did not meet the normality assumption. Relationships between categorical variables were examined using the Pearson Chi-square test. For VAS, EBBS, BDI, and FIQ, the BrunnerLanger F1-LD-F1 model (One independent factor: Group. One dependent factor: Time) was used. After significant interaction, within-group and between-group comparisons were made. Differences between time points within each group were analyzed using the Brunner-Langer analysis with LD-F1 design. Mann-Whitney U test was used for between-group comparisons at each time point.Statistical analyses were performed using R software (R

Foundation for Statistical Computing, version 4.4.1, packages: nparLD, Vienna, Austria; http://r-project.org) and IBM SPSS Statistics 25.0 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). The significance level was set at 0.05 for all analyses, except for interactions, where $p < 0.1$.