

OFFICIAL STUDY PROTOCOL

Study Title: Investigation of the Effectiveness of Mindfulness-Based Yoga Training in Individuals With

Fibromyalgia: A Randomized Controlled Trial

ClinicalTrials.gov Identifier: NCT07439900

Document Date: 22 September 2023

Protocol Version: Version 1.2 – Updated for ClinicalTrials.gov posting on 27 February 2026

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1. Background and Rationale

Fibromyalgia is a chronic condition characterized by widespread musculoskeletal pain, fatigue,

sleep disturbances, mood disorders, and psychosocial dysfunction. This randomized controlled trial

was designed to evaluate the effectiveness of mindfulness-based yoga (MBY) training delivered via

telerehabilitation on pain, pain-related problems, fibromyalgia symptoms, kinesiophobia, biopsychosocial status, and mindfulness levels.

2. Ethical Approval

Ethical approval was granted by the Istanbul Gelisim University Ethics Committee (Decision No:

2023-07-129, dated September 22, 2023). The study was conducted in accordance with the

Declaration of Helsinki. All participants provided written informed consent prior to enrollment.

3. Study Design

This study is a parallel-group randomized controlled trial. Participants were randomly allocated to

either the intervention group (MBY via telerehabilitation) or the active control group.

4. Participants

Inclusion Criteria:

- Native Turkish speakers who are literate.
- Aged 18 years and older with a confirmed diagnosis of fibromyalgia.
- Stable fibromyalgia medical treatment for at least 3 months.
- No planned medication changes during the study.
- Access to a computer/tablet/smartphone with active internet connection.
- Able to participate in video conferencing or having assistance from a relative.
- Voluntary agreement to participate.

Exclusion Criteria:

- Uncontrolled or clinically significant comorbidities (e.g., COPD, congestive heart failure, endocrine disorders, neurological or psychiatric disorders).
- Malignancy.
- History of spinal or extremity surgery resulting in functional loss.
- Pregnancy.
- Participation in another rehabilitation program.
- Any medical condition preventing safe exercise.
- Refusal to participate.

5. Sample Size

Based on previous studies and power analysis, the study was planned with a 95% confidence level

and 80% statistical power.

6. Interventions

Intervention Group: Participants received an 8-week mindfulness-based yoga program delivered

via telerehabilitation. Sessions lasted 60–75 minutes, conducted twice weekly through exercise logs

and once weekly via Zoom-based group sessions under the supervision of a certified physiotherapist.

Active Control Group: Participants received 10 sessions of conventional physiotherapy and were

prescribed 20-minute walking exercises three times per week. Participants were encouraged and

monitored via phone calls or messages.

Patient Education: At the first treatment session, participants in both groups received standardized

patient education regarding fibromyalgia and the intervention process.

7. Outcome Measures

Assessments were performed at baseline and at Week 8.

Primary and secondary outcomes included:

- Fibromyalgia symptoms: Fibromyalgia Impact Questionnaire (FIQ)
- Mindfulness: Mindful Attention Awareness Scale (MAAS)
- Anxiety and Depression: Hospital Anxiety and Depression Scale (HADS)
- Sleep Quality: Pittsburgh Sleep Quality Index (PSQI)
- Fatigue: Fatigue Severity Scale (FSS)
- Pain-related factors: Pain Catastrophizing Scale (PCS) and Central Sensitization Inventory (CSI)
- Kinesiophobia: Tampa Scale of Kinesiophobia (TSK)
- Biopsychosocial status: Cognitive Exercise Therapy Approach Scale

All instruments have validated Turkish versions.