

## **INFORMED CONSENT FORM**

**Study Title: Effectiveness of Mindfulness-Based Yoga Training in Individuals with Fibromyalgia: A Randomized Controlled Trial**

Ethics Committee Approval:

Approved by Istanbul Gelisim University Ethics Committee

Approval Date: 22.09.2023

Approval Number: 2023-07-129

Principal Investigator:

Ebru DURUSOY

### **1. Invitation to Participate**

You are invited to participate in a research study investigating the effects of mindfulness-based yoga training in individuals diagnosed with fibromyalgia. Participation in this study is entirely voluntary. You may choose not to participate or withdraw from the study at any time without any penalty or loss of benefits.

### **2. Purpose of the Study**

The purpose of this study is to examine the effects of an 8-week mindfulness-based yoga program delivered via telerehabilitation on pain, fatigue, sleep quality, emotional state, fear of movement, pain-related thoughts, biopsychosocial status, and mindfulness levels in individuals with fibromyalgia.

### **3. Study Procedures**

If you agree to participate, you will complete questionnaires at the beginning of the study and at the end of the 8th week. Information about your demographic characteristics, medications, and lifestyle habits will be recorded.

Participants will be randomly assigned to one of two groups:

Group 1 – Mindfulness-Based Yoga Group:

- 8-week program
- Two individual exercise recordings per week
- One 75-minute live online group session per week
- Supervised by a certified physiotherapist

Group 2 – Active Control Group:

- 10 sessions of conventional physiotherapy provided by the hospital
- 20-minute walking exercise three times per week

All participants will receive patient education at the beginning of the study.

#### **4. Duration of Participation**

Each participant will be involved in the study for 8 weeks.

Study Period: 14.03.2024 - 30.12.2024

#### **5. Potential Risks**

You may experience mild muscle soreness, fatigue, or temporary discomfort during exercise. No serious risks are anticipated. You may stop exercising at any time if you feel discomfort.

#### **6. Potential Benefits**

You may experience improvements in pain, sleep quality, fatigue, and overall well-being. However, these benefits cannot be guaranteed.

#### **7. Costs and Compensation**

There is no cost to participate in this study. You will not receive any financial compensation.

#### **8. Confidentiality**

Your identity will remain confidential. All collected data will be coded and stored securely. Your name will not appear in any publication or presentation resulting from this study.

#### **9. Voluntary Participation and Withdrawal**

Your participation is voluntary. You may withdraw from the study at any time without giving a reason, and this decision will not affect your medical care.

#### **10. Contact Information**

If you have any questions regarding this study, please contact:

Ebru DURUSOY

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

#### **Participant Statement**

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study. I understand that I may withdraw at any time without penalty.

Participant Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Researcher Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_