

## **Informed Consent Form (ICF)**

### **Official Study Title:**

The Effect of Structured Breathing Exercises on Pain, Dyspnea, and Functionality in Terminal Stage Cancer Patients Receiving Palliative Care

### **NCT Number:**

Pending

### **Document Type:**

[Informed Consent Form]

### **Principal Investigator:**

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Istanbul Atlas University, Turkey

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### **Date of the Document:**

August 07, 2025

### **Study Site:**

Eyupsultan State Hospital, Istanbul, Turkey

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### **Dear Participant,**

You are invited to participate in a clinical research study conducted at Eyupsultan State Hospital, Palliative Care Unit, under the supervision of Physiotherapist Fatma Nur Yildiz.

This study aims to investigate whether structured breathing exercises can help reduce pain, dyspnea, fatigue, and anxiety, improve overall functional status, and enhance quality of life in terminal-stage cancer patients receiving palliative care.

Before you decide, please read the following information carefully. You are encouraged to ask any questions regarding the study procedures, benefits, and potential risks.

### **Purpose of the Study**

The purpose of this study is to evaluate the effects of multi-modal breathing exercises on:

- Reducing pain and shortness of breath
- Improving functional capacity
- Supporting better psychological and physical well-being

### **Study Procedures**

If you agree to participate, you will be randomly assigned to one of two groups:

1. Intervention group → Will receive structured breathing exercises under the supervision of a physiotherapist.
2. Control group → Will receive standard palliative care only.

Breathing exercises will be performed once daily for five (5) consecutive days.

Questionnaires and assessments will be conducted before and after the intervention.

Symptom scores, oxygen saturation, and other physiological data will be collected and recorded.

### **Potential Risks and Discomforts**

- Breathing exercises are considered safe.
- There are no known long-term risks associated with these exercises.
- If you experience any discomfort, please inform the physiotherapist immediately.

### **Potential Benefits**

- Possible reduction in pain, dyspnea, fatigue, and anxiety
- Improvement in oxygen saturation and daily functional capacity
- Contribution to medical knowledge that may benefit future patients with similar conditions

### **Confidentiality**

- All personal information and collected data will remain strictly confidential.
- Your name will not appear in any publications, reports, or ClinicalTrials.gov records.
- Data will be securely stored and used only for scientific purposes.

### **Voluntary Participation and Right to Withdraw**

- Participation in this study is entirely voluntary.
- You may refuse to participate or withdraw at any time without affecting your medical treatment or care.
- Withdrawing will not result in any penalties or loss of benefits to which you are otherwise entitled.

### **Ethics and Contact Information**

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This study has been reviewed and approved by the Istanbul Atlas University Non-Interventional Research Ethics Committee (Approval No: 44948, July 4, 2024).

If you have any concerns, questions, or experience any adverse effects during the study, you may contact:

Fatma Nur Yildiz Yildirim, PT, MSc

☎ Phone: +90 507 819 52 89

✉ Email: yildiz.fatmanur@hotmail.com

### Consent Statement

I have read and understood the information provided above. I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study.

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### Participant Information

- Full Name: \_\_\_\_\_
- Signature: \_\_\_\_\_
- Date: \_\_\_\_\_

### Witness Information (if required)

- Full Name: \_\_\_\_\_
- Signature: \_\_\_\_\_
- Date: \_\_\_\_\_

### Investigator Declaration

I confirm that I have explained the study procedures, benefits, and potential risks to the participant and obtained informed consent.

- Investigator Name: Fatma Nur Yildiz Yildirim, PT, MSc
- Signature: \_\_\_\_\_
- Date: \_\_\_\_\_