Study Protocol and Statistical Analysis Plan on Palliative Study

Official Study Title:

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

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Pending

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[Study Protocol and Statiscal Analysis]

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Study Site:

Eyupsultan State Hospital, Istanbul, Turkey

Study Design:

- Interventional, randomized controlled trial (RCT)
- Two-arm parallel design (Intervention vs. Control)
- Single-blinded (evaluator)

Study Population:

- Total of 39 terminal-stage cancer patients receiving palliative care
- Intervention group (n = 22), Control group (n = 17)

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Inclusion Criteria:

- Age >18 years
- Terminal stage cancer diagnosis
- Receiving inpatient palliative care
- Able to provide consent or have a legal representative

Exclusion Criteria:

- Cognitive impairment preventing exercise compliance
- Severe respiratory instability

Intervention Description:

-The intervention group received structured breathing exercises consisting of pursed-lip breathing, diaphragmatic breathing, respiratory control, relaxation breathing exercises, and slow, deep breathing, once a day for 5 days, for an average of 15 minutes.

Exercises administered by a physiotherapist. Conducted once daily for 5 consecutive days

Control Group:

- Receives standard palliative care and an informational booklet that describing breathing exercises.

Primary Outcomes:

1. Pain level (measured by Visual Analog Scale - VAS)
2. Dyspnea (measured by Cancer Dyspnea Scale - CDS)
3. Functionality (measured by ESAS-r functional subscale)

Secondary Outcomes:

- SpO2, pulse rate, hemoglobin, leukocyte, platelet, CRP levels

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Data Collection Time Points:

- Baseline (Day 0)

- Post-intervention (Day 5)

Data Analysis:

- Data analyzed using SPSS Statistics v27

- Kolmogorov-Smirnov test for normality

- t-tests, Wilcoxon signed-rank test, and Mann-Whitney U test as appropriate

- Effect size reported using Cohen's d

Ethical Considerations:

- Study approved by local ethics committee (IRB)

-Informed consent was obtained from all participants or their legal representatives.

-University Ethics Committee was approved this study (# 44948; July 4, 2024).

Study Timeline:

- Start Date: October 2024

- Completion Date: May 2025