STUDY PROTOCOL

Title: The Effect of Mild Exercise While Receiving Chemotherapy on the Psychology of the Cancer Patient
NCT Number: NCT06943638
Date: 31 July 2025

1. Background and Rationale

Cancer patients undergoing chemotherapy often experience heightened levels of anxiety. Non-pharmacological interventions such as mild physical activity may alleviate these symptoms. This study investigates whether a short, tailored exercise program can reduce anxiety levels in adult cancer patients.

2. Objectives

- **Primary Objective:**
  To assess the effect of a mild, individualized exercise program on state anxiety levels in cancer patients undergoing chemotherapy.

3. Study Design

This is a prospective observational cohort study conducted at the General Oncology Hospital of Kifissia "Agioi Anargyroi" in Athens, Greece.

4. Study Population

- **Inclusion Criteria:**
  - Age ≥ 18 years
  - Receiving chemotherapy
  - Ability to understand and provide informed consent
- **Exclusion Criteria:**
  - Refusal to participate
  - Cognitive or sensory impairment affecting ability to engage
  - Inability to mobilize independently

5. Intervention

Participants receive 20-minute sessions of mild physical exercises designed by a licensed physiotherapist, including warm-up, upper limb, lower limb, and stretching routines. Sessions are tailored to each participant's physical condition and conducted in person.

6. Outcome Measures

- **Primary Outcome:**
  Change in state anxiety level as measured by the Spielberger State-Trait Anxiety Inventory (STAI-Y1) before and after the intervention.

7. Data Collection

The STAI-Y1 will be administered pre- and post-intervention. Demographic data including age and gender will be collected at baseline.

8. Ethical Considerations

Ethics approval was granted by the Ethics Committee of the General Oncology Hospital of Kifissia (Protocol #779/15-1-2024). Written informed consent will be obtained from all participants.

9. Data Management and Confidentiality

Data will be anonymized and stored securely. Only study investigators will have access to identifiable information. All analyses will use coded identifiers.

10. Study Timeline

- **Start Date:** 02 December 2024
- **End Date:** 24 March 2025