STATISTICAL ANALYSIS PLAN

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

1. Purpose

This SAP outlines the pre-specified statistical methods for analyzing the impact of a mild exercise intervention on state anxiety levels among cancer patients undergoing chemotherapy.

2. Study Objectives (Statistical)

- Assess the change in STAI-Y1 anxiety scores before and after the intervention.

- Explore associations between age, gender, and anxiety score changes.

3. Study Variables

- **Primary Outcome:**
  Change in STAI-Y1 scores (post-intervention minus baseline)

- **Covariates:**
  Age, gender

4. Statistical Methods

- **Descriptive Statistics:**
  Summary statistics (mean, SD, median, IQR) will be calculated for all variables.

- **Inferential Tests:**

  o Wilcoxon signed-rank test to compare pre- and post-intervention anxiety scores (due to expected non-normal distribution).

  o Cohen's D for paired samples to assess effect size.

  o Spearman's rank correlation to explore relationships between demographics and anxiety change.

5. Sample Size Estimation

Based on similar studies (e.g., Moraes et al., 2021), a minimum of 45 participants is estimated to provide 80% power to detect significant differences ($\alpha = 0.01$).

6. Handling of Missing Data

Any missing questionnaire responses will be evaluated. If fewer than 5% of responses are missing, listwise deletion will be used. Otherwise, imputation methods may be considered.

7. Software

All analyses will be conducted using SPSS v29.