Statistical Analysis Plan (SAP)

Effectiveness of Individualized Dietary Counseling and Nutritional Monitoring in Reducing Cancer-Associated Cachexia among Female Breast Cancer Patients: A Randomized Controlled Trial

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Introduction

This SAP outlines the pre-specified statistical methodology used to evaluate the effectiveness of individualized dietary counseling combined with regular nutritional monitoring in reducing cancer-associated cachexia among female breast cancer patients. The protocol adheres to the CONSORT guidelines.

Objectives

Primary Objective:

To assess the effect of individualized dietary counseling and regular nutritional monitoring on cachexia severity using the Mini-CASCO tool after six months.

Secondary Objectives:

To evaluate changes in:

- Body composition
- Inflammatory and metabolic markers
- Physical performance
- Appetite levels
- Quality of life (QoL)

Study Design

- **Design:** Prospective, parallel-arm, randomized controlled trial
- **Randomization:** 1:1 ratio with block-stratified randomization (block size = 4)
- **Blinding:** Outcome assessors and statisticians were blinded

Sample Size Determination

Using G*Power for repeated-measures ANCOVA:

- Effect size (Cohen's d): 0.5
- Power: 80%
- Alpha: 0.05
- Estimated N: 64 per group (total 128)
- Final enrollment: 134 randomized; 130 completed (65 per group)

Handling of Missing Data

- Missing data (<5%) addressed via Multiple Imputation (Chained Equations, 10 iterations)
  Assumed Missing At Random (MAR)
  Sensitivity analyses compared results with and without imputation

Effect Size Estimations

- Cohen's d: within-group effect size
- Partial eta squared (η^2): between-group comparisons
- Interpretation thresholds:
  - $d \geq 0.8$ = large
  - $\eta^2 \geq 0.14$ = large

Software

- Statistical analyses were performed using IBM SPSS Statistics v25.0
- Graphs and tables created using Excel and SPSS

Validation and Sensitivity Analyses

Key assumptions for ANCOVA validated:

- Normality via Shapiro-Wilk test
- Homogeneity of variance via Levene's test
- Sphericity via Mauchly's test
- Sensitivity analysis excluding imputed data showed similar trends

Appendix A: List of Variables

Outcome Measures Table

Outcome	Type	Statistical Test	Covariates	Assumption Checks
Change in total Mini-CASCO score	Primary	Repeated-measures ANCOVA	Baseline score	Normality, sphericity (Mauchly's test)
Domain-specific Mini-CASCO changes	Secondary	Repeated-measures ANCOVA	Baseline scores	Same as above
Within-group differences	Secondary	Paired t-tests		Normality
Between-group effect size	Secondary	Partial eta squared (η^2)		
Compliance/adherence	Secondary	Frequency, percentage		

List of Variables Table

Variable	Type	Tool/Scale
Weight	Continuous	Digital scale
Lean body mass	Continuous	Bioelectrical impedance analysis
CRP, Albumin, Hb, TLC	Continuous	Blood test
ECOG performance	Ordinal	ECOG Scale
Appetite	Ordinal	Simplified Nutritional Appetite Questionnaire (SNAQ)
QoL	Continuous	EORTC QLQ-C30 (Urdu version)
Total Mini-CASCO	Composite score	0–100 scale