

EFFECTIVENESS OF INDIVIDUALIZED
DIETARY COUNSELING AND
NUTRITIONAL MONITORING IN
REDUCING CANCER-ASSOCIATED
CACHEXIA AMONG FEMALE BREAST
CANCER PATIENTS

Submitted by

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Effectiveness of Individualized Dietary Counseling and Nutritional Monitoring in Reducing Cancer-Associated Cachexia among Female Breast Cancer Patients

INTRODUCTION

Background of the Study

Cancer-associated cachexia (CACS) is a multifactorial syndrome marked by involuntary weight loss, muscle wasting, systemic inflammation, and metabolic abnormalities. Among patients with advanced-stage breast cancer, CACS significantly impacts quality of life, treatment tolerance, and survival. In low- and middle-income countries like Pakistan, cachexia often remains underdiagnosed and poorly managed due to limited supportive care resources. This study aims to assess the effectiveness of personalized dietary counseling and regular nutritional monitoring in reducing cachexia severity using the validated Mini-CASCO tool.

Objectives of the Study

Primary Objective:

- To evaluate whether individualized dietary counseling combined with monthly nutritional monitoring reduces cachexia severity over six months in female patients with advanced breast cancer.

Secondary Objectives:

- To assess changes in body composition, appetite, physical performance, inflammatory markers, and quality of life.
- To determine the adherence and feasibility of implementing nutrition-sensitive supportive care in an oncology setting.

METHODOLOGY

Study Design

This is a two-arm; parallel-group, randomized controlled trial (RCT) conducted over a six-month intervention period at Fauji Foundation Hospital, Rawalpindi, Pakistan. Participants will be randomly assigned (1:1) to receive either standard oncological care alone (control group) or standard care plus tailored nutritional counseling and monthly monitoring (intervention group). Randomization will be block-stratified with allocation concealment using opaque, sealed envelopes.

Patient Selection and Enrollment

Inclusion Criteria:

- Female patients aged 20–60 years.
- Histologically confirmed advanced-stage breast cancer.
- $\geq 5\%$ unintentional weight loss in the previous 6 months.
- Hemoglobin < 12 g/dL or energy intake < 1500 kcal/day.

Exclusion Criteria:

- Concurrent non-cancer-related malnutrition.
- Pregnancy or lactation.
- GI/endocrine disorders affecting nutrition.
- Enrollment involved screening for eligibility, obtaining informed consent, and randomization using sealed, opaque envelopes.

Baseline data were collected before group assignment.

Eligible patients will undergo informed consent. Those consenting will be randomized using a block randomization method. Baseline data will be collected prior to group assignment.

Intervention

Intervention Group:

- Individualized dietary counseling based on baseline nutritional status
- Monthly monitoring (every 15–21 days) of weight, intake, and biochemical parameters
- Light physical activity guidance and psychosocial support
- Dietary goals: 25–30 kcal/kg/day and 1.2–1.5 g/kg/day protein
- Compliance tracked through food intake records and goal adherence checklists

Control Group:

Standard oncological care without structured nutritional intervention

Ethical Considerations

This study will be approved by the Ethical Review Board of Fauji Foundation Hospital, Rawalpindi. All participants will provide written informed consent prior to enrollment. The study adheres to the ethical principles outlined in the Declaration of Helsinki. Confidentiality will be ensured through unique patient identifiers and restricted data access.

Protocol Amendments

No protocol amendments have been made to date. Any future amendments will be reviewed and approved by the Ethical Review Board and documented accordingly in the PRS system.

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