

Development And Validation Of A Tamil Nadu–Specific Food Pyramid For Post-Oncology Patients Receiving Ryle’s Tube Feeding: A Prospective Mixed-Methods Study

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ABSTRACT

Background: Post-oncology patients, particularly those undergoing treatment for head and neck malignancies, may experience dysphagia, mucositis, impaired mastication and reduced oral intake, making enteral nutrition necessary during the postoperative period. ESPEN recommends that, when energy expenditure is not measured individually, cancer patients may generally be estimated to require 25–30 kcal/kg/day, with protein intake above 1 g/kg/day and, when possible, up to 1.5 g/kg/day. A culturally adapted framework is needed to translate these targets into practical foods that are familiar, accessible and feasible for tube administration.

Objective: To develop and validate a Tamil Nadu–specific food pyramid and practical enteral-feeding framework for post-oncology patients receiving Ryle’s tube feeding, incorporating locally consumed foods while maintaining nutritional adequacy and tube-feeding feasibility.

Methods: The study will comprise dietary mapping, food-pyramid formulation, multidisciplinary expert validation and pilot clinical evaluation. Eligible adult post-oncology patients requiring Ryle’s tube feeding will undergo baseline nutritional assessment, including anthropometry, dietary history and relevant clinical and biochemical parameters. Locally consumed foods will be mapped according to food group, nutritional contribution, availability, affordability, digestibility and suitability for blending and tube administration. The preliminary pyramid will be assessed for content validity and feasibility, followed by pilot implementation. Outcomes will include nutritional adequacy, feed tolerance, acceptability, adherence, tube-related events and selected nutritional parameters.

Conclusion: The study is designed to generate a culturally appropriate, clinically usable and nutritionally structured framework for individualized enteral nutrition in Tamil Nadu. The framework is intended to complement, not replace, individualized dietitian-led nutritional prescription.

Keywords: head and neck cancer; enteral nutrition; Ryle’s tube; Tamil Nadu diet; food pyramid; postoperative nutrition; nutritional rehabilitation.

1. INTRODUCTION

Malnutrition is a clinically important problem in patients with cancer and may result from inadequate intake, treatment-related toxicity, systemic inflammation and metabolic alterations. Patients with head and neck cancer are particularly vulnerable because disease and treatment can interfere directly with chewing and swallowing. Previous clinical trials have evaluated postoperative enteral and immunonutrition strategies in this population, with some studies reporting reductions in selected wound complications or length of stay, while other trials have shown less consistent effects. These findings support the importance of nutritional management while also emphasizing that the optimal formulation and delivery strategy require individualization.

Current cancer-nutrition guidance recommends early nutritional assessment and individualized nutritional targets. ESPEN's practical cancer guideline recommends an estimated energy requirement of approximately 25–30 kcal/kg/day when individual energy expenditure is not measured and protein intake above 1 g/kg/day, increasing toward 1.5 g/kg/day when feasible. These are clinical starting points rather than rigid prescriptions.

The ICMR–National Institute of Nutrition Dietary Guidelines for Indians 2024 provide a national dietary framework emphasizing dietary diversity and appropriate representation of cereals and millets, pulses and legumes, vegetables, fruits, dairy or alternatives, nuts and seeds, and fats and oils. A Tamil Nadu-specific food pyramid could translate these broad principles into a practical tube-feeding framework using foods familiar to patients and caregivers.

The present study therefore aims to develop and validate a locally adapted food pyramid for post-oncology patients receiving Ryle’s tube feeding, with explicit attention to nutritional adequacy, food safety, tube compatibility, affordability and acceptability.

2. RATIONALE AND RESEARCH GAP

Established enteral feeding protocols commonly rely on standardized commercial formulas or generalized dietary recommendations. A food-based model may improve cultural familiarity and feasibility for some patients and caregivers, but food-based tube feeding also introduces challenges including variable nutrient density, inadequate protein or energy delivery, viscosity, tube blockage and microbial contamination. The proposed study addresses the gap between generalized dietary guidance and a reproducible, nutritionally quantified and clinically validated Tamil Nadu-specific enteral framework.

3. AIM

To develop and validate a Tamil Nadu-specific food pyramid and practical dietary framework for post-oncology patients receiving Ryle's tube feeding.

4. OBJECTIVES

- To characterize dietary practices and commonly consumed foods relevant to post-oncology tube-fed patients in Tamil Nadu.
- To classify locally available foods according to their contribution to energy, protein, carbohydrate, fat, fibre and selected micronutrients.
- To develop a culturally appropriate food-pyramid framework that can be translated into individualized enteral feeding plans.
- To assess content validity, feasibility and safety through multidisciplinary expert review.
- To pilot the framework and evaluate nutritional adequacy, feed tolerance, acceptability, adherence and tube-related events.

5. MATERIALS AND METHODS

5.1 Study design

A prospective mixed-methods, multi-stage study will be conducted in a tertiary-care hospital. The study will include dietary mapping, development of the intervention framework, expert validation and pilot clinical evaluation.

5.2 Study population

Adults aged ≥ 18 years who have undergone oncological treatment, particularly for head and neck malignancy, and who require Ryle's tube feeding because of inadequate or unsafe oral intake will be considered. Patients requiring disease-specific nutritional prescriptions or with medical contraindications to the proposed food-based pathway will be excluded or managed separately according to standard clinical practice.

5.3 Study stages

Stage I—Dietary mapping: dietary histories and caregiver interviews will identify commonly used cereals, rice preparations, millets, pulses, legumes, vegetables, fruits, dairy products, eggs or other protein sources, fats and culturally familiar preparations. Food selection will consider seasonal availability, cost and household accessibility.

Stage II—Food-pyramid development: candidate foods will be grouped according to their principal nutritional role. Food combinations will be converted into standardized recipes with recorded raw weights, cooked weights, preparation method, final volume and estimated nutrient composition.

Stage III—Expert validation: an expert panel comprising clinicians, dietitians/nutritionists and nursing personnel will assess relevance, clarity, feasibility, cultural appropriateness and safety. Content validity indices will be calculated.

Stage IV—Pilot clinical evaluation: the finalized framework will be introduced under clinical supervision. Patients will receive individualized prescriptions based on their calculated requirements. Feed tolerance, gastrointestinal symptoms, tube patency, caregiver acceptability and adherence will be documented.

5.4 Nutritional prescription

The pyramid will not be used as a fixed prescription. Energy and protein requirements will be individualized. As a protocol reference, ESPEN recommends approximately 25–30 kcal/kg/day when individual energy expenditure is not measured and protein intake above 1 g/kg/day, with a target of up to 1.5 g/kg/day where feasible. Adjustment will be made for body composition, inflammatory state, renal/hepatic function, metabolic complications and treatment goals.

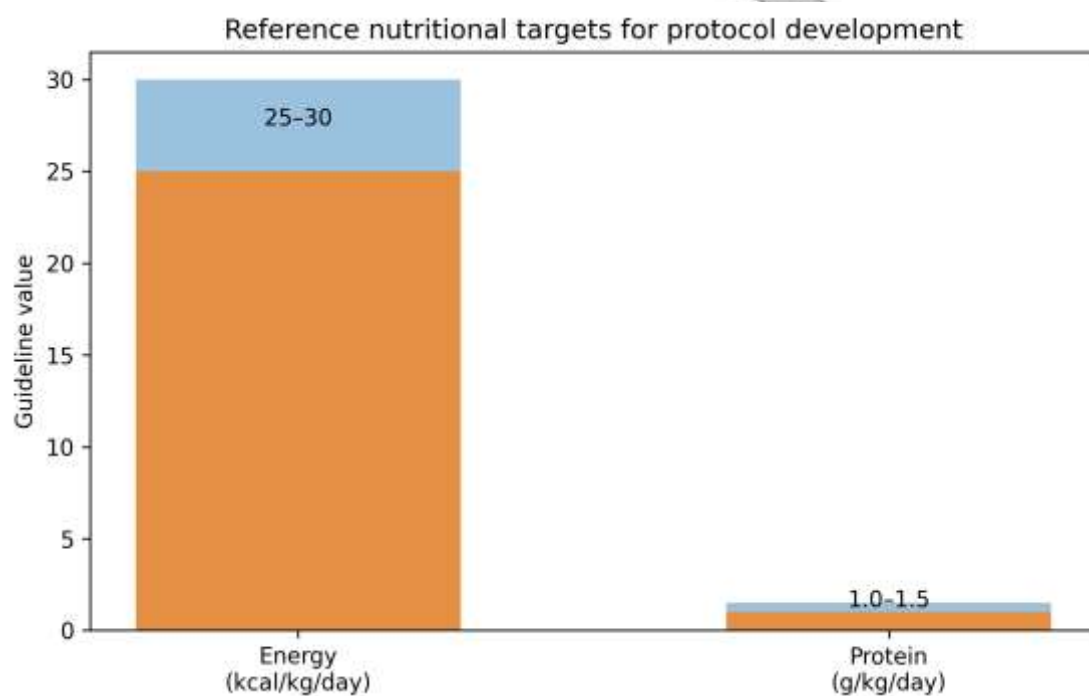


Figure 1. Guideline-derived nutritional targets used for protocol development. These are reference targets, not study results.

5.5 Tamil Nadu–adapted food framework

Tamil Nadu–adapted enteral food framework

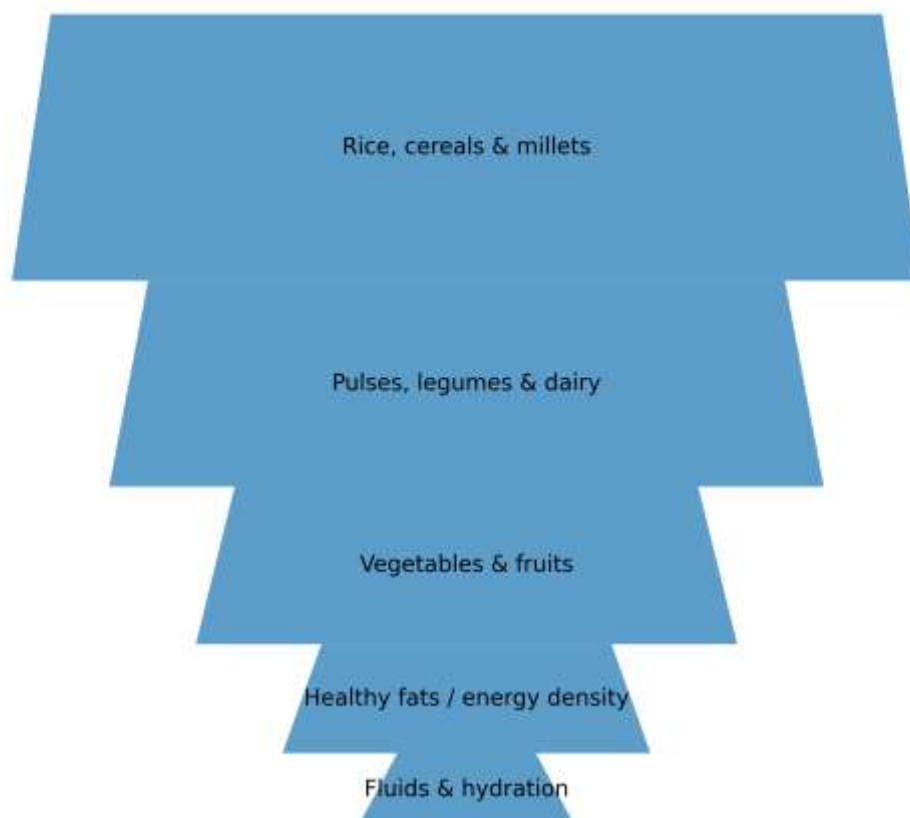


Figure 2. Conceptual Tamil Nadu–adapted food pyramid. Relative positioning is conceptual and does not represent fixed percentage intake.

Candidate foods may include rice and selected millets; dal and pulse preparations; cooked vegetables; suitable fruits; curd or milk where clinically appropriate; egg or other protein sources; and measured vegetable oils. These are candidate ingredients rather than universal prescriptions. Fibrous fragments, seeds, skins and coarse particles should not be administered through a feeding tube unless their safety and compatibility have been established.

5.6 Recipe standardization

Each recipe will be prepared using standardized kitchen scales and documented using raw ingredient weights, cooking method, final volume and dilution volume. The final preparation should be homogeneous and sufficiently fluid for the specific tube size and feeding method. Strict food hygiene, safe water, appropriate storage and timely administration will be required. Commercial formula should remain the preferred option when food-based feeding is unsafe, nutritionally inadequate or clinically inappropriate.

5.7 Outcome measures

Domain	Measure	Timing
Primary	Proportion of prescribed energy and protein achieved	Baseline/follow-up
Primary	Content validity of food-pyramid components	Expert validation
Secondary	Weight, BMI and selected anthropometric measures	Baseline/follow-up
Secondary	Feed tolerance and gastrointestinal symptoms	Daily during pilot
Secondary	Tube blockage, leakage or intolerance	Daily during pilot
Secondary	Caregiver acceptability and adherence	Follow-up
Exploratory	Selected biochemical markers when clinically indicated	Baseline/follow-up

5.8 Sample size

The final sample size should be calculated from the primary clinical outcome selected for the pilot phase and the expected effect size, alpha, power and anticipated attrition. If content validation is a principal objective, the expert-panel sample should be justified separately.

5.9 Statistical analysis

Continuous variables will be summarized as mean $\pm$ standard deviation or median with interquartile range according to distribution. Categorical variables will be summarized as frequencies and percentages. Paired comparisons may use paired t-test or Wilcoxon signed-rank test as appropriate. Repeated measurements may be analysed using repeated-measures ANOVA or a suitable mixed-effects model. Content validity will include item-level and scale-level content validity indices and, where appropriate, inter-rater agreement. Effect sizes and 95% confidence intervals should be reported.

5.10 Ethics and safety

Institutional ethics approval will be obtained before recruitment. Written informed consent will be obtained. Nutritional prescriptions will be individualized and supervised by the treating team and nutrition professional. The study will not delay medically indicated commercial enteral nutrition or other nutritional support. Patients with aspiration risk, metabolic instability or significant intolerance will be managed according to standard care.

6. STUDY WORKFLOW

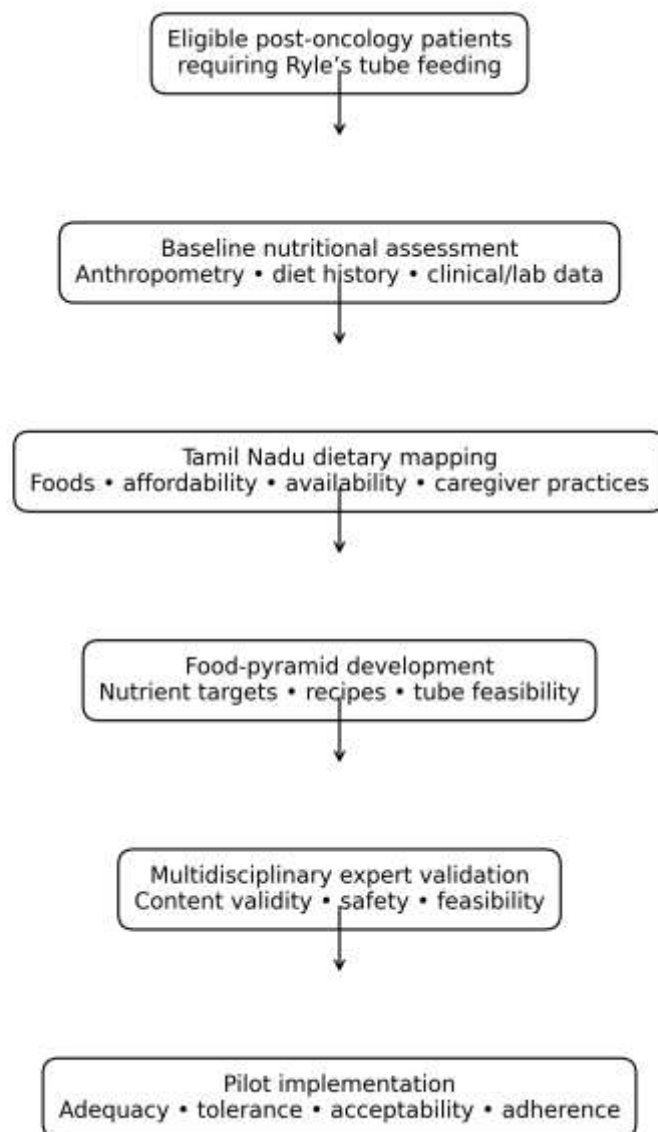


Figure 3. Proposed workflow for development, validation and pilot clinical evaluation.

7. PROPOSED DATA VISUALIZATION

The final manuscript should include graphs generated only from the actual study dataset. Recommended figures include: participant flow; baseline nutritional-risk distribution; prescribed versus achieved energy and protein intake; longitudinal change in weight/BMI or other nutritional measures; and frequency of feed intolerance and tube-related events. Graphs should display sample size and appropriate uncertainty measures.

No patient-outcome graph is presented as a result in this manuscript because no patient-level dataset has been supplied. This is deliberate: numerical clinical results should not be fabricated.

8. DISCUSSION

The proposed intervention addresses a practical gap in postoperative oncology nutrition: translating evidence-based nutrient requirements into foods that patients and caregivers recognize and can potentially prepare. Published head and neck cancer trials show that perioperative enteral strategies can affect selected outcomes, but effects vary with

formulation, dose and clinical context. A locally adapted framework therefore needs both nutritional quantification and clinical validation.

The principal innovation is the systematic development of a Tamil Nadu-adapted food framework rather than simply presenting a conventional food pyramid. Candidate foods will be assessed for nutritional contribution, affordability, preparation characteristics, viscosity, fibre content and tube compatibility. This allows the final product to function as a decision-support framework rather than a rigid diet chart.

Food-based tube feeding may be attractive where household foods are preferred or commercial formulas are difficult to access. Nevertheless, familiar foods do not automatically provide adequate protein or energy, and nutrient composition varies with preparation. Standardized recipes, safe preparation, clinical supervision and monitoring of adequacy are therefore essential.

9. STRENGTHS

- Local dietary adaptation.
- Integration of nutritional targets with tube-feeding feasibility.
- Multidisciplinary expert validation.
- Combination of objective nutritional outcomes with caregiver acceptability.
- Potential for subsequent multicentre validation.

10. LIMITATIONS

- Food-based enteral feeding has greater variability in nutrient composition than standardized formulas.
- Individual adjustment is required for renal, hepatic, metabolic and gastrointestinal conditions.
- A single-centre pilot may have limited generalizability.
- Clinical outcomes are influenced by tumour site, treatment intensity, reconstruction and systemic inflammation.
- Superiority over commercial enteral formulas cannot be claimed without a comparative trial.

11. CONCLUSION

This study proposes a structured approach to develop and validate a Tamil Nadu-specific food pyramid for post-oncology patients requiring Ryle's tube feeding. By combining local dietary practices with evidence-based nutritional targets, standardized recipes, multidisciplinary validation and prospective clinical assessment, the project aims to produce a practical framework for individualized nutritional rehabilitation.

12. DECLARATIONS

Ethics approval: To be obtained from the Institutional Ethics Committee before study commencement.

Consent to participate: Written informed consent will be obtained from eligible participants.

Competing interests: To be declared by the authors.

Funding: To be declared by the investigators.

Author contributions: To be completed according to the final authorship record.

Data availability: To be specified according to institutional policy and ethics requirements.

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APPENDIX: EXPERT VALIDATION DOMAINS

Domain	Suggested assessment	Rating
Relevance	Relevant to post-oncology tube feeding	1–4
Cultural appropriateness	Familiar and acceptable in Tamil Nadu	1–4
Nutritional adequacy	Contributes to energy/protein/micronutrient goals	1–4
Feasibility	Obtainable and realistically prepared	1–4
Tube compatibility	Can be safely prepared for the intended tube	1–4
Safety	Foreseeable preparation/feeding risks addressed	1–4