RESEARCH PAPER

Efficacy of a High-Protein Nutritional Counseling Bundle for Pediatric Patients with Cystic Fibrosis and their Caregivers

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ABSTRACT

Background

Cystic Fibrosis (CF) is a genetic disorder causing pancreatic insufficiency, which leads to severe nutrient malabsorption and growth faltering in children. In pediatric care, therapeutic success relies heavily on primary caregivers who manage the complex daily dietary and medical needs of these patients. Intensive nutritional counseling targeting both patients and caregivers is essential to overcome malnutrition and improve clinical adherence.

Aim

To evaluate the efficacy of a high-protein nutritional counseling bundle for pediatric patients with cystic fibrosis and their caregivers.

Methods

Study Design: A quasi-experimental, pre-and-post interventional study. **Study Setting:** The Pediatric Outpatient Clinics at Sohag University Hospitals, Sohag Governorate, Egypt. **Sample:** A convenience sample consisting of 50 pediatric patients (aged 2–12 years) diagnosed with CF and their caregivers (N=50 caregivers). **Tools:** Caregiver Assessment Questionnaire: A structured tool, consisting of four distinct parts: Part 1: Socio-demographic and Clinical Baseline Data, Part 2: Nutritional Knowledge Score: Assessing understanding of CF-specific caloric and protein requirements, Part 3: Dietary Adherence Score: Evaluating compliance with prescribed high-protein dietary schedules, and Part 4: PERT Competence Scale: Measuring caregiver self-efficacy and correctness in administering and

adjusting Pancreatic Enzyme Replacement Therapy (PERT) dosages relative to fat and protein intake, Anthropometric Measurements, Biochemical Laboratory Panels, Clinical Outcome Records.

Results

Statistical analysis comparing post-intervention data to baseline (pre-intervention) values revealed significant improvements as Caregivers demonstrated a statistically significant increase in nutritional knowledge scores, dietary adherence scores, and confidence in managing PERT ($p < 0.05$). Children showed a significant increase in mean body weight and BMI Z-scores by the end of the 6-month period. Laboratory findings revealed a marked elevation in serum albumin and prealbumin levels, indicating corrected protein status. Enhanced caregiver compliance led to a noticeable reduction in children's acute pulmonary exacerbations.

Conclusion

The high-protein nutritional counseling bundle targeting both pediatric patients and their caregivers is highly effective. Empowering caregivers through structured education directly translates into optimized nutritional rehabilitation, catch-up growth, and better clinical outcomes for children with Cystic Fibrosis.

Keywords: Cystic Fibrosis; Caregivers; High-Protein; Nutritional Counseling Bundle; Pediatric Patients.

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Introduction:

Cystic Fibrosis (CF) is a life-limiting autosomal recessive genetic disorder caused by mutations in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. This genetic defect disrupts the normal transport of chloride and sodium ions across epithelial cell membranes **(Trimble et al.,, 2022).** As a result, the body produces abnormally thick, viscous mucus that accumulates within multiple organ systems, most notably the respiratory and gastrointestinal tracts **(Cutting, 2025).**

In the gastrointestinal tract, the thick secretions obstruct the pancreatic ducts, preventing essential digestive enzymes from reaching the duodenum. This condition, known as Pancreatic Insufficiency, affects approximately 85% to 90% of individuals diagnosed with CF. The absence of adequate lipase, protease, and amylase leads to severe maldigestion of macronutrients, particularly fats and proteins **(Wilschanski et al., 2024).**

The downstream consequence of pancreatic insufficiency is profound nutrient malabsorption, which induces chronic energy deficits **(Leonard et al., 2023).** Pediatric CF patients frequently suffer from steatorrhea, fat-soluble vitamin deficiencies, and severe protein-energy malnutrition. This state of malnutrition is exacerbated by the high metabolic demands triggered by chronic, recurrent pulmonary infections **(Mariotti Zani et al., 2023).**

In children, the combination of malabsorption and elevated energy expenditure leads to growth faltering, delayed puberty, and poor weight gain. Monitoring growth parameters, such as Body Mass Index (BMI) Z-scores, is a critical component of pediatric CF care. Poor nutritional status in early childhood is directly linked to a more rapid decline in lung function and shortened life expectancy **(Stephenson et al., 2023).**

Managing nutritional failure in CF requires aggressive therapeutic strategies, centered around a high-calorie, high-protein diet. Patients must also adhere to lifetime Pancreatic Enzyme Replacement Therapy to facilitate proper nutrient digestion. Weight maintenance and adequate protein status, reflected by biomarkers like serum albumin and prealbumin, are vital to support tissue repair and immune function **(Freswick et al., 2022)**.

Because the therapeutic regimen for pediatric CF is complex and demanding, the burden of daily management falls heavily on primary caregivers. Caregivers are responsible for calculating enzyme dosages, preparing specialized high-protein meals, and monitoring clinical symptoms. Consequently, the caregiver's health literacy and competence directly dictate the child's treatment adherence and overall health outcomes **(Daly et al., 2022**).

Despite the clear benefits of nutritional therapies, caregivers face significant barriers to adherence, including financial strain, lack of

structured education, and psychological burnout **(Shadi et al., 2026).** Misconceptions regarding PERT administration frequently lead to sub-optimal dosing, which perpetuates malnutrition **(Eaton et al., 2020)**.

Intensive nutritional counseling serves as a cornerstone intervention to bridge the gap between clinical guidelines and home-based care. Structured educational bundles that target both the patient and the caregiver have been shown to optimize dietary behaviors. By equipping families with practical skills, counseling enhances adherence to complex medical and dietary protocols **(Chatterjee & Nirgude, 2024).**

In developing nations like Egypt, managing CF presents unique challenges due to limited public awareness, delayed diagnosis, and constrained healthcare resources. At tertiary care centers such as Sohag University Hospitals, pediatric clinics encounter high patient volumes where structured educational resources are often scarce . Investigating localized, cost-effective counseling models is therefore critical to improving regional pediatric outcomes **(El-Falaki et al., 2021).**

The nurses play a fundamental role in executing high-protein nutritional bundles by conducting comprehensive assessments and empowering caregivers. Nurses routinely measure and monitor growth parameters—such as weight, height, and BMI percentiles—against cystic fibrosis-specific charts to detect any growth deceleration early. Beyond physical assessment, the nurse delivers vital education to families regarding the critical need for a high-calorie, high-protein diet to combat malabsorption. This includes providing structured training on Pancreatic Enzyme Replacement Therapy (PERT) administration, teaching caregivers how to adjust enzyme dosages based on protein intake, and instructing them on correct fat-soluble vitamin supplementation **(Wilschanski et al., 2024).**

In addition to clinical duties, the nurse provides essential behavioral support and manages interdisciplinary care to ensure long-term treatment adherence. Nurses actively assess family dynamics to address mealtime behavioral struggles and caregiver burden, reinforcing self-efficacy through practical tools like instructional recipe cards. As the central communication hub of the multidisciplinary team, the nurse collaborates closely with clinical dietitians and pulmonologists to update care plans based on laboratory findings and clinical progress. Through continuous monitoring, telephone follow-ups, and home visits, the nurse identifies economic or psychosocial barriers, ensuring the effective delivery of the nutritional bundle to optimize pediatric health outcomes **(Kalnins & Wilschanski, 2022).**

Significance of the Study

This study holds profound clinical and methodological significance as it provides a cost-effective, scalable strategy to combat severe protein-energy malnutrition and growth faltering among pediatric Cystic Fibrosis patients. By focusing on the pediatric patient and the caregiver, this research demonstrates that structured, high-protein nutritional counseling directly translates into improved caregiver literacy, enhanced dietary compliance, and increased confidence in managing complex Pancreatic Enzyme Replacement Therapy. The empirical evidence generated highlighted by significant post-intervention increases in children's BMI Z-scores, corrected protein biomarkers (serum albumin and prealbumin), and a marked reduction in acute pulmonary exacerbations validates caregiver empowerment as a critical clinical intervention. Ultimately, these findings offer a practical, resource-efficient framework for tertiary centers like Sohag University Hospitals to optimize pediatric rehabilitation, reduce hospital readmission rates, and mitigate the long-term healthcare burden of genetic disorders in developing nations.

Aim:

To evaluate the efficacy of a high-protein nutritional counseling bundle for pediatric patients with cystic fibrosis and their caregivers.

Research Hypotheses:

- **H_1:** Pediatric patients with Cystic Fibrosis whose caregivers participate in the high-protein nutritional counseling bundle will exhibit a statistically significant increase in mean body weight and BMI Z-scores post-intervention compared to baseline.
- **H_2:** Caregivers who receive the structured educational intervention will demonstrate a statistically significant increase in nutritional knowledge scores, dietary adherence scores, and confidence in managing Pancreatic

Enzyme Replacement Therapy at the 6-month follow-up.

- **H_3:** Pediatric patients will show a statistically significant elevation in biochemical markers of protein status, specifically serum albumin and prealbumin levels, following the implementation of the counseling bundle.
- **H_4:** Enhanced caregiver compliance achieved through the counseling intervention will result in a statistically significant reduction in the frequency of acute pulmonary exacerbations among the pediatric patients.

Subjects and Method:

Study Design

A quasi-experimental, pre-and-post test interventional study design was utilized to evaluate the efficacy of a structured, high-protein nutritional counseling bundle. This design allowed for the comparison of baseline (pre-intervention) data against post-intervention outcomes within the same subject group after a 6-month follow-up period, serving as its own control.

Study Setting

The study was conducted at the Pediatric Outpatient Clinics at Sohag University Hospitals, located in the Sohag Governorate, Egypt. This setting is a primary tertiary care referral center serving a high volume of pediatric patients from various urban and rural districts across Upper Egypt.

Sample:

A convenience sample consisting of 50 pediatric patients diagnosed with cystic fibrosis and their respective caregivers (N = 50) was recruited based on the following eligibility criteria:

- **Inclusion Criteria for Pediatric Patients:**
  - Confirmed clinical and laboratory diagnosis of Cystic Fibrosis.
  - Aged between 2 and 12 years.
  - Manifesting documented pancreatic insufficiency (PI).
- **Inclusion Criteria for Caregivers:**
  - Identified as the primary individual responsible for the child's daily medical and dietary management.
  - Willing to participate and commit to the full 6-month follow-up period.
- **Exclusion Criteria:** Patients with end-stage organ failure, severe intellectual disabilities in caregivers that preclude educational comprehension, or participation in concurrent nutritional trials.

Data Collection tools:

Data were collected using four distinct, comprehensive tools designed to evaluate the caregiver-patient dyad before and 6 months after the implementation of the high-protein nutritional counseling bundle.

Tool I: Structured Caregiver Assessment Questionnaire

This tool was developed by the researchers after an extensive review of literature **(Goodfellow et al., 2022; Hamed et al., 2022; Eaton et al., 2020)** and was translated into accessible Arabic to suit the local population. It consists of four distinct parts:

- **Part 1: Demographic and Clinical Baseline Data:**
  - *Caregiver Characteristics:* Age, maternal educational level, occupational status, and family income stability.
  - *Child Characteristics:* Age, sex, birth order, age at diagnosis, and history of hospital admissions.
- **Part 2: Caregiver Nutritional Knowledge Questionnaire:**
  - *Content:* 15 multiple-choice and true/false questions evaluating the caregiver's understanding of CF dietary requirements. Topics include: the definition of pancreatic insufficiency, elevated energy/caloric requirements (110–200% of normal), the importance of high-protein diets, identification of affordable local high-protein sources, and the role of fat-soluble vitamins (A, D, E, K).
  - *Scoring System:* Each correct answer is assigned a score of 1, and incorrect/unknown answers receive a score of 0. Total scores are categorized as: Poor (<50%), Fair (50%–75%), and Good (>75%).

- **Part 3: Caregiver Dietary Adherence Scale:**

  - *Content:* A 10-item self-report scale adapted from international cystic fibrosis behavioral checklists **(Leonard et al., 2023).** It measures the frequency of preparing fortified high-calorie meals, ensuring adequate daily protein portions, adding supplementary sodium/salt during hot weather, and consistency in offering snacks between main meals.

  - *Scoring System:* Items are scored on a 3-point Likert scale (2 = Always, 1 = Sometimes, 0 = Never). Higher cumulative scores indicate superior dietary compliance.

- **Part 4: Caregiver PERT Competence and Confidence Scale:**

  - *Content:* An 8-item index focusing on the precise administration of Pancreatic Enzyme Replacement Therapy (PERT) based on ESPEN-ESPGHAN-ECFS guidelines (**Wilschanski et al., 2024**). It assesses correct enzyme timing (before/during meals), avoiding destructive behaviors (crushing or chewing microspheres, mixing with hot/alkaline foods), dosage titration according to fat/protein intake, and tracking signs of malabsorption (steatorrhea, bloating).

  - *Scoring System:* Caregivers rate their subjective confidence using a 4-point scale (3 = Highly Confident, 2 = Confident, 1 = Neutral, 0 = Not Confident). Objective competence questions are scored as correct (1) or incorrect (0).

Tool II: Pediatric Anthropometric Measurement Sheet

- This objective sheet records physical growth metrics to calculate physical rehabilitation and catch-up growth (**Stephenson et al., 2023).**

  - *Absolute Body Weight:* Measured to the nearest 0.1 kg using a calibrated electronic digital scale with the child wearing light clothing and no shoes.

  - *Body Mass Index (BMI) Z-scores:* Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer. BMI was calculated using the standard formula (kg/m2). Absolute measurements were then converted into **BMI Z-scores** based on the World Health Organization (WHO) pediatric growth reference charts for age and sex.

Tool III: Biochemical Laboratory Analysis Panel

- Objective biomarkers were utilized to evaluate systemic protein status and verify the correction of malnutrition **(Kalnins & Wilschanski, 2022).**

  - *Serum Albumin:* Measured via venous blood samples using the bromocresol green (BCG) method to reflect long-term visceral protein stores (normal range: 3.5–5.0 g/dL).

  - *Serum Prealbumin (Transthyretin):* Analyzed via immunoturbidimetric assays to capture rapid, acute changes in nutritional restoration due to its short half-life of 2 days (normal range: 15–36 mg/dL).

Tool IV: Clinical Outcome Log (Pulmonary Exacerbation Record)

- **Content:** A retrospective and prospective tracking diary used to monitor the frequency of acute pulmonary exacerbations.

  - *Criteria for Exacerbation:* Defined based on the modified Fuchs' criteria, including increased cough frequency/severity, changes in sputum production, new-onset wheezing, respiratory rate elevation, or the acute clinical need for intravenous/oral antibiotic therapy **(Mariotti Zani et al., 2023).**

Validity of the tools:

The tools were submitted to a panel of five experts. This panel consisted of senior professors in pediatric medicine, pediatric nursing, community health nursing, and clinical nutrition. The experts reviewed the tools for clarity, relevance, linguistic appropriateness, and comprehensiveness. Based on their recommendations, no modifications were implemented.

Reliability of the tools:

To evaluate the internal consistency and stability of the subjective measurement tools, a reliability analysis was conducted. The Caregiver Assessment Questionnaire was administered twice to a small cohort of caregivers under identical conditions, with a two-week interval between tests. The internal consistency of the knowledge, adherence, and PERT competence subscales was calculated using Cronbach's alpha (alpha). The resulting alpha coefficients ranged from 0.82 to 0.87, demonstrating strong internal consistency and a high degree of reliability. Additionally, the test-retest reliability showed a high correlation

coefficient ($r > 0.80$), confirming the stability of the instrument over time.

Pilot Study

A pilot study was carried out on 10% of the total sample size (representing 5 pediatric patients and their caregivers) prior to the official commencement of data collection. The primary objectives of the pilot study were to test the feasibility of the research protocol, estimate the exact time required to complete the questionnaires, and identify any structural ambiguities in the educational bundle. The results of the pilot study indicated that filling out the assessment questionnaire took approximately 15 to 20 minutes per caregiver. The participants involved in the pilot study were included in the final research sample.

Ethical Considerations

The research protocol was reviewed and formally approved by the Research Ethics Committee of the Faculty of Nursing at Sohag University. Institutional administrative permission was obtained from the directors of the Pediatric Outpatient Clinics and Sohag University Hospitals before interacting with participants. The study was conducted in strict adherence to the ethical principles of the Declaration of Helsinki: Prior to enrollment, the primary researcher provided caregivers with a comprehensive verbal explanation regarding the study's aims, benefits, and data collection procedures. Formal, written informed consent was subsequently signed by each caregiver. Caregivers were explicitly informed that their participation was completely voluntary, and that they retained the right to withdraw from the study at any stage without facing any negative consequences or disruptions to their child's standard medical care. To protect participant privacy, a unique coding system was assigned to each patient-caregiver.

Data Collection Procedure

The data collection process was systematically executed over a 12-month period, encompassing the preparation, recruitment, implementation, and evaluation phases. The procedure was carried out through the following consecutive steps:

Step 1: Administrative and Preparatory Phase

- An official letter from the Faculty of Nursing/Medicine was directed to the authorities of Sohag University Hospitals. Formal administrative permission was secured from the director of the hospital and the head of the Pediatric Outpatient Clinics to conduct the study.
- The primary researchers established a dedicated schedule to visit the pediatric outpatient clinics three days per week (Sundays, Tuesdays, and Thursdays) during morning shift hours (9:00 AM to 2:00 PM), aligning with the designated days for reviewing children with chronic genetic disorders.

Step 2: Screening, Recruitment, and Ethical Consenting

- **Participant Screening:** The researchers screened the medical records of pediatric patients attending the outpatient clinic. Children who met the inclusion criteria (aged 2–12 years, confirmed Cystic Fibrosis with pancreatic insufficiency) were flagged.
- **Approach and Rapport:** When eligible patient-caregiver dyads arrived at the clinic, the researcher approached the primary caregiver individually in a private counseling room to build rapport and decrease any anxiety regarding hospital-based testing.
- **Informed Consent:** The researcher explained the study's scope, nature, voluntary participation, and expected clinical benefits. Caregivers who agreed to join formally signed the written informed consent form.

Step 3: Phase I - Baseline Assessment (Pre-Intervention)

- **Questionnaire Administration:** The researcher interviewed each caregiver individually to fill out **Tool I** (Socio-demographic data, Nutritional Knowledge, Dietary Adherence, and PERT Competence scales). This face-to-face interview lasted approximately 15 to 20 minutes per caregiver.
- **Anthropometric Baseline:** Following the interview, the child's absolute body weight and height were measured using standard calibrated hospital equipment to compute the baseline Body Mass Index (BMI) Z-scores.
- **Biochemical and Clinical Baseline:** The child was referred to the hospital laboratory for a baseline venous blood draw to analyze serum

albumin and prealbumin levels. Simultaneously, the frequency of respiratory relapses over the preceding months was retrieved from the child's hospital files and caregiver logs (**Tool IV**).

Step 4: Phase II - Implementation of the Nutritional Counseling Bundle

- **Educational Settings:** The counseling bundle was delivered to caregivers individually or in small focus groups (2–3 caregivers) within the clinic's educational unit to ensure safety and focused interaction.
- **Session Delivery:** The intervention was delivered across 3 main interactive sessions, each lasting between 30 to 45 minutes, utilizing a variety of teaching methods (e.g., face-to-face discussions, visual PowerPoint presentations, and practical modeling of enzyme administration).
- **Content Reinforcement:** Caregivers were trained on high-protein meal enrichment using affordable local Egyptian ingredients and precise PERT dosage timing. At the end of the sessions, each caregiver received a simplified, illustrated Arabic educational booklet to serve as a home-based reference guide.
- **Continuous Telephone Follow-up:** Over the 6-month intervention period, the researchers established bi-weekly telephone calls with the caregivers to provide ongoing psychological reinforcement, answer queries regarding PERT titration, and ensure adherence to the high-protein protocol.

Educational Content Points of the Counseling Bundle

Module 1: Understanding Cystic Fibrosis and the Pancreas

- **Disease Mechanism:** Simplified explanation of Cystic Fibrosis (CF) as a genetic condition causing thick, sticky mucus production.
- **Pancreatic Insufficiency (PI):** Visual mapping of how mucus blocks the pancreatic ducts, preventing natural digestive enzymes from reaching the small intestine.
- **The Cause of Malnutrition:** Explaining why children experience frequent steatorrhea (fatty stools), abdominal pain, poor weight gain, and muscle wasting despite having a normal or increased appetite.

Module 2: Caloric and High-Protein Dietary Requirements

- **Elevated Energy Needs:** Educating caregivers on why pediatric CF patients require 110% to 200% of the standard daily energy intake compared to healthy children.
- **The Power of Protein:** Stressing the critical role of protein in cellular repair, catch-up physical growth, immune defense, and the prevention of muscle wasting.
- **Locally Sourced Protein Options:** Identifying affordable, culturally familiar, and highly available Egyptian food sources:
  - *Animal Proteins:* Eggs, poultry, minced beef, fish, milk, and local cheese.
  - *Plant Proteins:* Fava beans (*Ful Medames*), lentils, chickpeas, and various legumes.
- **Caloric Fortification Strategies:** Practical techniques to enrich home-cooked meals without increasing food volume (e.g., adding dynamic fats like olive oil, butter, or cream to traditional Egyptian dishes).

Module 3: Mastery of Pancreatic Enzyme Replacement Therapy (PERT)

- **The Role of PERT:** Teaching caregivers that enzymes (e.g., Creon) are mandatory keys that unlock the nutrients in food, rather than standard medications.
- **Precise Timing and Administration:**
  - Enzymes must be taken immediately before or during the first few bites of *all* meals and snacks.
  - Capsules should never be crushed or chewed.
  - For younger children, demonstrating how to open capsules and mix microspheres with small amounts of acidic food (e.g., applesauce or yogurt).
- **Dosage Titration Self-Efficacy:** Training caregivers to safely adjust enzyme dosages based on meal size, fat content, and clinical signs (e.g., tracking stool consistency and bloating).
- **Prohibited Combinations:** Warning against mixing enzymes with hot foods or highly alkaline substances (like milk) which destroy enzyme activity before reaching the intestine.

Module 4: Management of Micro-nutrients and Hydration

- **Fat-Soluble Vitamin Supplementation:** Emphasizing the vital daily intake of prescribed Vitamins A, D, E, and K, and why they must be taken concurrently with PERT.
- **Salt and Electrolyte Balance:** Instructing caregivers on the necessity of adding extra table salt to foods, especially during hot summer months in Upper Egypt, to prevent dehydration and heat exhaustion.

Module 5: Clinical Monitoring and Prevention of Complications

- **Growth Tracking:** Teaching parents how to interpret basic growth parameters and understand the importance of consistent weight gain.
- **The Nutrition-Lung Link:** Explaining the direct biological relationship between a well-nourished body, strong respiratory muscles, and a reduced rate of acute pulmonary infections.
- **Red Flags:** Identifying signs of sub-optimal nutritional management that require immediate clinic visits (e.g., persistent weight loss, reoccurrence of greasy/foul stools, or early signs of respiratory distress).

Appendix A: High-Protein Nutritional Counseling Bundle Sessions Schedule

Session	Timing & Duration	Core Topics Covered	Teaching Methods	Educational Materials Used
Session 1: Introduction & Pathophysiology	**Month 0 (Baseline)** Duration: 30–45 mins	• Overview of Cystic Fibrosis (CF) as a genetic disorder. • Pathophysiology of Pancreatic Insufficiency (PI). • Mechanics of nutrient malabsorption and protein depletion. • Signs of gastrointestinal complications (e.g., steatorrhea).	• Face-to-face interactive lecture. • Visual mapping of the digestive tract. • Open Q&A session.	• Illustrated anatomical charts. • Introductory Arabic brochure. • PowerPoint slides.
Session 2: High-Protein Dietary Fortification	**Month 1 (Follow-up)** Duration: 45 mins	• Elevated caloric/energy demands in pediatric CF (110%–200%). • The biological importance of high-protein diets for catch-up growth. • Identifying affordable, local animal and plant protein sources. • Practical recipes to fortify meals without increasing volume.	• Interactive group discussion. • Practical modeling of meal formulation. • Peer-sharing of cooking experiences.	• Specialized Arabic Educational Booklet. • Food models and nutrient charts. • Sample meal-planning sheets.
Session 3: PERT Mastery & Clinical Monitoring	**Month 2 (Follow-up)** Duration: 45 mins	• Mechanism of Pancreatic Enzyme Replacement Therapy (PERT). • Timing rules (immediately before/during all meals/snacks). • Correct dosing	• Hands-on demonstration (opening capsules, mixing with acidic food). • Case-scenario problem solving. • Role-playing for dosage adjustment.	• Empty PERT capsules/placebos. • Visual dosage adjustment guide. • Home clinical outcome log/diary.

		titration and safe capsule administration rules. • Monitoring weight, hydration (salt intake), and respiratory red flags.		
Continuous Follow-up Phase	**Months 3 to 6** Duration: 10–15 mins per call	• Bi-weekly telephone reinforcement support. • Troubleshooting specific adherence barriers at home. • Reviewing home logs for pulmonary exacerbations and PERT titration.	• Semi-structured telephonic counseling. • Continuous individual psychological feedback.	• Standardized caregiver phone check-list.

Step 5: Phase III - Post-Intervention Evaluation (6-Month Follow-up)

- **Re-Assessment of Caregivers:** Exactly six months after the initiation of the counseling bundle, caregivers were recalled to the outpatient clinic during their scheduled follow-up visits. The researcher re-administered **Tool I** (Knowledge, Adherence, and PERT competence sections) to measure changes in scores.
- **Re-Evaluation of Pediatric Outcomes:** The children underwent identical post-test physical and clinical evaluations. Anthropometric parameters were re-measured to determine weight changes and catch-up growth (BMI Z-scores).
- **Biochemical and Exacerbation Re-Testing:** Follow-up venous blood samples were collected to re-evaluate serum albumin and prealbumin levels. The clinical outcome log was reviewed to record the total number of acute pulmonary exacerbations experienced by the child during the 6-month study window.

Statistical Analysis

Data were coded, entered, and analyzed using the Statistical Package for the Social Sciences (SPSS). Descriptive statistics were expressed as frequencies and percentages for categorical variables, and as means ± standard deviations for continuous variables. The Paired t-test was used to compare pre- and post-intervention scores, laboratory findings, and anthropometric metrics. Statistical significance was established at a p-value of less than 0.05 ($p < 0.05$).

Results:

Table 1: Demographic Characteristics of the Studied Caregivers (N = 50)

Caregiver Characteristics	Frequency (n)	Percentage (%)
Caregiver Age (Years)		
• < 25	6	12.0%
• 25 – 35	31	62.0%
• > 35	13	26.0%
Mean ± SD = 31.4 ± 5.2 years		
Maternal Educational Level		
• Illiterate / Read & Write	14	28.0%
• Basic / Secondary Education	26	52.0%
• University Education	10	20.0%
Occupational Status		
• Housewife	36	72.0%

• Working Mother	14	28.0%
Family Income Stability		
• Insufficient / Unstable	31	62.0%
• Sufficient / Stable	19	38.0%

Table 1 presents the demographic characteristics of the 50 studied caregivers. The data reveals that the majority of the caregivers (62.0%) fell within the 25–35 age cohort, with a mean age of 31.4 ± 5.2 years. Regarding education, 52.0% had completed basic or secondary education, whereas 28.0% were illiterate or could only read and write. Furthermore, a high proportion of caregivers were housewives (72.0%), and 62.0% reported having insufficient or unstable monthly family income.

Table 2: Demographic and Clinical Characteristics of the Studied Children (N = 50)

Child Characteristics	Frequency (n)	Percentage (%)
Child Age (Years)		
• 2 – 5	22	44.0%
• > 5 – 8	18	36.0%
• > 8 – 12	10	20.0%
Mean ± SD = 5.8 ± 2.9 years		
Sex		
• Male	27	54.0%
• Female	23	46.0%
Birth Order		
• First Child	12	24.0%
• Second Child	21	42.0%
• Third Child or Higher	17	34.0%
Age at Diagnosis		
• < 1 year	8	16.0%
• 1 – 3 years	29	58.0%
• > 3 years	13	26.0%
History of Hospital Admissions (Past Year)		
• 1 – 2 times	13	26.0%
• ≥ 3 times	37	74.0%

Table 2 outlines the clinical and demographic profiles of the pediatric patients with Cystic Fibrosis. The children's mean age was 5.8 ± 2.9 years, with the largest group falling between 2 and 5 years old (44.0%). Males represented 54.0% of the sample, and 42.0% were the second child in birth order. Notably, 58.0% of the children were diagnosed between 1 and 3 years of age. Critically, 74.0% of the cohort had a history of 3 or more hospital admissions during the preceding year.

Table 3: Comparison of Caregivers' Nutritional Knowledge and Dietary Adherence Levels Pre- and Post-Intervention (N = 50)

Variables	Pre-Intervention (n, %)	Post-Intervention (n, %)	Z value	p-value
Nutritional Knowledge Level				
• Poor (< 50%)	32 (64.0%)	2 (4.0%)		
• Fair (50% – 75%)	13 (26.0%)	8 (16.0%)	41.23	<0.001**
• Good (> 75%)	5 (10.0%)	40 (80.0%)		
Dietary Adherence Level				
• Low Adherence	28 (56.0%)	3 (6.0%)		

• Moderate Adherence	16 (32.0%)	10 (20.0%)	32.89	<0.001**
• High Adherence	6 (12.0%)	37 (74.0%)		

**Statistically highly significant at } $p < 0.01$.

Table 3 demonstrates a remarkable shifting and highly statistically significant improvement in caregivers' nutritional knowledge and dietary adherence levels after implementing the 6-month counseling bundle ($p < 0.001$). Prior to the intervention, the majority of caregivers exhibited poor nutritional knowledge (64.0%) and low dietary adherence (56.0%). Conversely, at the 6-month post-intervention follow-up, 80.0% of the caregivers achieved a "Good" knowledge level, and 74.0% advanced to the "High Adherence" category, reflecting the clinical efficacy of structured education.

Table 4: Comparison of Caregivers' Mean Scores of Knowledge, Adherence, and PERT Confidence Pre- and Post-Intervention (N = 50)

Caregiver Assessment Scales	Pre-Intervention Mean± SD	Post-Intervention Mean ±SD	Paired t-test	P -value
Total Nutritional Knowledge Score	5.12 ± 1.84	12.86 ± 1.62	18.45	<0.001**
Total Dietary Adherence Score	8.34 ± 2.11	17.12 ± 1.95	15.88	<0.001**
PERT Competence & Confidence Score	3.45 ± 1.22	7.18 ± 0.94	14.23	<0.001**

**Statistically highly significant at $p < 0.01$.

As illustrated in **Table 4**, there was a highly statistically significant increase in the mean scores of all caregiver behavioral metrics from baseline to the 6-month post-test ($p < 0.001$). The mean score of total nutritional knowledge surged from 5.12 ± 1.84 to 12.86 ± 1.62. Similarly, caregivers' self-efficacy and correctness in adjusting Pancreatic Enzyme Replacement Therapy dosages significantly doubled, with mean confidence scores rising from 3.45 ± 1.22 at pre-intervention to 7.18 ± 0.94 at post-intervention.

Table 5: Pediatric Anthropometric and Biochemical Parameters Pre- and Post-Intervention (N = 50)

Children Clinical Markers	Pre-Intervention Mean±SD	Post-Intervention Mean±SD	Paired t-test	\(p\)-value
Anthropometric Parameters				
• Mean Body Weight (kg)	16.42 ± 3.15	18.94± 2.88	8.12	<0.01*
• BMI Z-score	-2.41 ± 0.62	-1.15 ± 0.48	11.34	<0.001**
Biochemical Markers				
• Serum Albumin (g/dL)	3.12 ± 0.38	4.15 ± 0.42	9.67	<0.01*
• Serum Prealbumin (mg/dL)	11.45 ± 2.54	21.88 ± 3.12	16.21	<0.001**

*Significant at $p < 0.05$); **Highly significant at $p < 0.01$).

Table 5 validates that the improvements in caregiver compliance directly translated into optimized physical and physiological growth for children with CF. The mean BMI Z-scores significantly improved from a malnourished baseline of -2.41 ± 0.62 to a healthier mean of -1.15 ± 0.48 at 6 months ($p < 0.001$), proving catch-up growth rehabilitation. Objectively, visceral protein stores were successfully corrected; serum albumin increased significantly from (3.12± 0.38 \ g/dL) to (4.15 ± 0.42 \ g/dL), and rapid-turnover prealbumin levels safely elevated from a baseline of (11.45 ± 2.54 \mg/dL}) to a normal post-intervention level of (21.88 ± 3.12 \ mg/dL) ($p < 0.001$).

Table 6: Frequency of Children's Acute Pulmonary Exacerbations Over the 6-Month Period (N = 50)

Clinical Event	Pre-Intervention Rate Mean±SD	Post-Intervention Rate Mean±SD	Paired t-test	P-value
Number of Acute Pulmonary Exacerbations / 6 Months	3.24 ± 1.05	1.12 ± 0.68	10.95	<0.001**

**Statistically highly significant at $p < 0.01$.

Table 6 highlights the protective respiratory effect of proper nutritional rehabilitation. The mean frequency of acute pulmonary exacerbations per child over a 6-month period dropped significantly from (3.24 ± 1.05) at baseline to (1.12 ± 0.68) following the intensive nutritional counseling bundle ($p < 0.001$).

Table 7: Correlation Matrix Between Caregivers' Behavioral Scores and Children's Clinical Outcomes Post-Intervention (N = 50)

Study Variables	1. Knowledge Score	2. Dietary Adherence	3. PERT Confidence	4. BMI Z-score	5. Serum Albumin	6. Pulmonary Exacerbations
1. Nutritional Knowledge Score	1.00					
2. Dietary Adherence Score	0.68**	1.00				
3. PERT Confidence Score	0.59**	0.71**	1.00			
4. Children's BMI Z-score	0.48**	0.62**	0.55**	1.00		
5. Serum Albumin Level	0.42**	0.58**	0.64**	0.51**	1.00	
6. Pulmonary Exacerbations	-0.45**	-0.53**	-0.61**	-0.49**	-0.55**	1.00

**Correlation is significant at the 0.01 level (2-tailed).

Table 7 presents the correlation matrix evaluating the relationships between caregiver behaviors and pediatric clinical endpoints following the 6-month intervention. The data reveals a strong, statistically significant positive correlation between caregivers' nutritional knowledge and their dietary adherence ($r = 0.68$, $p < 0.01$), as well as their PERT confidence ($r = 0.59$, $p < 0.01$).

Crucially, higher caregiver dietary adherence and PERT confidence scores were strongly correlated with improved children's BMI Z-scores ($r = 0.62$) and ($r = 0.55$), respectively) and elevated serum albumin levels ($r = 0.58$) and ($r = 0.64$). Conversely, a highly significant negative correlation was observed between caregiver PERT confidence and the frequency of children's acute pulmonary exacerbations ($r = -0.61$, $p < 0.01$).

Table 8: Correlation Between Baseline Socio-Demographic Characteristics and Post-Intervention Improvement Scores (N = 50)

Baseline Characteristics	Caregiver Knowledge	Dietary Adherence	Children's BMI Z-score	Serum Albumin
Maternal Educational Level	0.54**	0.41**	0.35*	0.29*
Family Income Stability	0.21	0.48**	0.44**	0.38**

Child's Baseline Hospitalizations	-0.12	-0.26	-0.39**	-0.32*

*Correlation is significant at the 0.05 level; **Significant at the 0.01 level.

Table 8 displays the correlation between baseline sociodemographic profiles and the net improvement of key variables. Maternal educational level was significantly and positively correlated with the net gain in nutritional knowledge ($r = 0.54$, $p < 0.01$) and dietary adherence ($r = 0.41$, $p < 0.01$).

Family income stability exhibited a strong positive correlation with improvements in dietary adherence ($r = 0.48$) and children's BMI Z-scores ($r = 0.44$), highlighting that economic resource constraints can act as a barrier to optimal dietary fortification. Lastly, the child's baseline history of frequent hospitalizations was negatively correlated with the net improvement in BMI Z-scores ($r = -0.39$, $p < 0.01$).

Discussion:

Implementing a high-protein nutritional counseling bundle for pediatric patients with cystic fibrosis (CF) and their caregivers demonstrates significant clinical efficacy in improving growth outcomes and enhancing the quality of life. This structured intervention effectively combats CF-related malabsorption by equipping caregivers with practical knowledge regarding high-calorie, high-protein dietary planning and the precise optimization of Pancreatic Enzyme Replacement Therapy (PERT). Research indicates that such target-driven nutritional bundles lead to sustainable gains in weight, height, and body mass index (BMI) percentiles, which are directly linked to preserved pulmonary function and a reduced risk of respiratory exacerbations. Furthermore, by providing tailored behavioral strategies and supportive tools like educational recipe cards, the bundle successfully mitigates mealtime behavioral struggles and reduces caregiver anxiety, thereby promoting long-term dietary adherence and fostering a supportive home environment crucial for managing this chronic condition.

The demographic profile of the primary caregivers in the current study reflects the typical socioeconomic framework of Upper Egypt, which deeply influences the management of chronic, multi-system genetic disorders like Cystic Fibrosis. The findings revealed that more than three fifths of the caregivers were young mothers within the 25–35 age cohort (Mean age: 31.4 ± 5.2 years). This relatively young maternal age means that while these caregivers may possess the physical stamina required to manage the demanding daily routines of CF, they often lack sufficient clinical experience and developmental maturity, making structured healthcare counseling packages essential.

This age distribution is highly consistent with a regional study conducted in Egypt by **El-Falaki et al. (2021)**, who reported that the vast majority of primary caregivers managing pediatric chronic respiratory illnesses in tertiary university hospitals were young mothers under the age of 35. This alignment underscores the cultural reality in Middle Eastern societies, where the burden of intensive pediatric home care falls almost exclusively on young mothers.

Furthermore, the current study highlighted that less than three quarters of the caregivers were housewives and more than three fifths suffered from insufficient or unstable family incomes. This high rate of financial instability is in complete agreement with **Goodfellow et al. (2025)**, who investigated the clinical profiles of genetic diseases in Upper Egypt and confirmed that resource constraints and low household incomes are major socioeconomic barriers that directly restrict a family's ability to afford the high-calorie diets and specialized nutritional supplements required for pancreatic-insufficient patients.

Similarly, the educational distribution in our sample where more than half completed basic or secondary education and more than one quarters were illiterate mirrors the findings of **Eaton et al. (2020)**. They documented that a low-to-moderate maternal educational baseline is directly associated with decreased health literacy and a higher frequency of therapeutic non-compliance, particularly regarding the complex titration of Pancreatic Enzyme Replacement Therapy.

In contrast, these demographic and financial findings stand in sharp contradiction to a study by **Daly et al. (2022)** in a multi-center western clinical trial reported a much lower percentage of housewives and a significantly higher prevalence of paternal or shared

caregiving dynamics. This directly contradicts our findings from Sohag, where caregiving remains heavily localized and maternal-centric due to regional cultural norms.

The clinical and demographic parameters of the studied children highlight a vulnerable pediatric population characterized by delayed diagnosis and high baseline biological fragility. The data indicated that the children's mean age was 5.8 ± 2.9 years, with the largest proportion falling within the early childhood stage of 2 to 5 years. Males accounted for more than half of the sample, demonstrating a relatively balanced gender distribution. Crucially, more than half of the cohort were diagnosed late, between 1 and 3 years of age, and an alarming of about three quarters required three or more hospital admissions during the preceding year. This high frequency of hospitalization serves as an objective indicator of severe baseline morbidity and advanced protein-energy malnutrition

The high prevalence of delayed diagnosis and extensive hospitalization history is highly consistent with previous Egyptian research by **El-Falaki et al. (2024)**. They observed that pediatric CF patients in Egypt are rarely diagnosed during infancy due to the lack of universal mandatory newborn screening protocols for the *CFTR* gene. Consequently, children are often misdiagnosed with typical bronchial asthma or chronic diarrhea, delaying proper nutritional and enzyme intervention until significant growth faltering and tissue wasting have occurred.

This regional vulnerability is further supported by **Leonard et al. (2023)**, who documented that recurrent pulmonary infections and acute malabsorption crises are the leading causes of high readmission rates among pediatric CF cohorts in tertiary university hospitals. The high baseline admission rate in our study confirms that pancreatic insufficiency, when left unmanaged by trained caregivers, exposes children to a dangerous cycle of severe malnutrition, weakened respiratory muscles, and frequent, life-threatening pulmonary exacerbations.

Conversely, these clinical baselines stand in stark contrast to data from developed nations with advanced healthcare registries. In a multi-center study by **Stephenson et al. (2023)** using the Canadian Cystic Fibrosis Registry, the vast majority of CF infants were diagnosed within the first few weeks of life via mandatory newborn immunoreactive trypsinogen (IRT) blood screening. Early diagnosis allows for immediate initialization of Pancreatic Enzyme Replacement Therapy (PERT) and aggressive nutritional optimization, which minimizes early childhood growth failure.

Furthermore, epidemiological data published by the **Cystic Fibrosis Foundation (2022)** in the United States reported that less than one fifth of pediatric CF patients under 12 years old required three or more hospitalizations annually. This significantly lower admission rate directly contradicts our finding . This profound difference exists because Western healthcare infrastructures provide immediate access to highly effective modulator therapies, specialized home-care nursing networks, and proactive nutritional surveillance, which collectively maintain clinical stability and prevent acute exacerbations.

The baseline findings of this study revealed a critical vulnerability in the home-based management of pediatric Cystic Fibrosis (CF), characterized by widespread deficits in caregiver health literacy. Prior to the intervention, the majority of primary caregivers exhibited poor nutritional knowledge and low dietary adherence. This initial deficit can be attributed to the complex nature of CF dietary guidelines, combined with the lack of specialized, accessible educational resources within public outpatient clinics **(El-Falaki et al., 2021).**

However, following the implementation of the 6-month structured counseling bundle, a remarkable and highly statistically significant transformation was observed ($p < 0.001$). Post-intervention assessments demonstrated that the majority of the caregivers achieved a "Good" knowledge level, and less than three quarters advanced to the "High Adherence" category. This profound shift provides robust empirical evidence that interactive, culturally modified educational interventions can successfully bridge the gap between clinical theory and home execution.

The substantial baseline deficit and subsequent positive transformation observed in this study are highly consistent with international behavioral research in pediatric chronic disease management. A similar educational intervention conducted by **Chatterjee & Nirgude, (2024)** demonstrated that structured nutritional education programs targeting

families of children with complex chronic conditions yield a profound, immediate inflation in parental knowledge scores. Their study confirmed that when educational materials are simplified and delivered across multiple reinforcement sessions, caregivers show significantly higher retention and a greater willingness to alter traditional, sub-optimal dietary habits.

Furthermore, the post-intervention surge in dietary adherence closely mirrors the findings of **Hamed et al. (2022)**. They reported that intensive nutritional counseling delivered at tertiary pediatric clinics directly improves long-term dietary compliance trajectories. The alignment between our findings and those of **Hamed et al.** emphasizes that passive distribution of medical prescriptions is insufficient; behavior modification in caregivers requires active, structured educational scaffolding, continuous reassurance, and practical problem-solving strategies.

In contrast, the rapid and uniform success of this educational bundle stands in opposition to some behavioral research highlighting the persistent rigidity of caregiving practices. A longitudinal study by **Eaton et al. (2020)** focused on barriers to nutritional adherence in pediatric CF reported that simply increasing caregiver knowledge did not automatically translate into improved dietary adherence. Their findings indicated that deep-rooted socio-demographic barriers, maternal depression, and severe financial strain often neutralized the benefits of clinical education, leaving adherence scores stagnant despite improved knowledge.

This divergence can be explained by the specific methodological structure of our counseling bundle. While some traditional programs focus exclusively on theoretical disease mechanisms, our intervention was specifically tailored to address local socioeconomic constraints in Upper Egypt. By explicitly training mothers on how to utilize affordable, highly available local protein alternatives rather than expensive commercial nutritional formulas, the bundle successfully bypassed the financial barriers that typically cause educational interventions to fail in resource-limited settings.

The empirical data collected at baseline revealed that caregivers faced profound challenges in managing the complex, daily clinical demands of Pancreatic Enzyme Replacement Therapy (PERT) and high-protein dietary titration. The baseline mean scores for nutritional knowledge 5.12± 1.84 and PERT confidence 3.45 ± 1.22 were remarkably low, indicating that before the study, caregivers routinely administered therapies without a clear understanding of physiological mechanisms or correct dosage protocols. This lack of initial competence is a major driver of therapeutic failure, as sub-optimal enzyme dosing directly perpetuates fat and protein malabsorption regardless of food availability **(Freswick et a., 2022)**

Following the 6-month implementation of the high-protein counseling bundle, a highly statistically significant surge was achieved across all measured maternal behavioral metrics ($p < 0.001$). The total nutritional knowledge mean score more than doubled to 12.86± 1.62, and the PERT confidence and competence mean scores accurately doubled to 7.18 ± 0.94. This clinical breakthrough demonstrates that structured, interactive counseling transforms caregivers from passive implementers into active, analytical medical managers capable of tracking symptoms and adjusting treatments at home.

The post-intervention doubling of PERT competence and confidence scores observed in this study is highly consistent with international behavioral literature on pediatric parental training. A study by **Daly et al. (2022)** focusing on treatment adherence in pediatric CF cohorts confirmed that caregiver self-efficacy is a dynamic variable that can be radically optimized through targeted, systematic education. Their findings indicated that when parents are explicitly trained on the physiological relationship between enzyme dosage and macronutrient absorption, their clinical confidence increases, which leads to fewer dosing errors at home.

Similarly, the substantial clinical improvement mirrors the outcomes documented by **Shadi et al. (2026)** regarding the support needs of caregivers managing children with Cystic Fibrosis and noted that traditional medical clinics often overestimate a parent's intuitive understanding of complex enzyme protocols, which leads to high rates of unintended non-compliance. Their research proved that utilizing structured educational booklets, visual aids, and interactive hands-on simulations—identical to the methods utilized in our Sohag University Hospital intervention—successfully removes parental

confusion and creates a durable foundation of treatment competence.

Conversely, the rapid, uniform doubling of caregiver behavioral scores observed in our sample stands in contrast to specific behavioral studies that report persistent parental resistance to treatment modification. A behavioral tracking study by **Goodfellow et al., (2025)** regarding parental adherence to complex medical regimens showed that despite providing intensive educational interventions to parents, PERT adherence and dosage titration scores remained highly resistant to change. Their research highlighted that "treatment burnout" and the psychological stress of managing a multi-system chronic illness often act as powerful negative forces that prevent improved knowledge from translating into actual home competence.

The core clinical objective of the high-protein nutritional counseling bundle was to reverse the severe protein-energy malnutrition and growth faltering that traditionally plagues pediatric Cystic Fibrosis (CF) patients with pancreatic insufficiency. At baseline, the children's physiological status was highly compromised, evidenced by a severely wasted mean Body Mass Index (BMI) Z-score of -2.41 ± 0.62 and depleted visceral protein markers (serum albumin: 3.12 ± 0.38 g/d; prealbumin: 11.45 ± 2.54 mg/dL). This baseline depletion reflects an advanced state of malnutrition caused by uncorrected macronutrient malabsorption coupled with the high metabolic demands of chronic respiratory illness **(Wilschanski et al., 2024).**

Following the 6-month intervention, it was validates that optimizing caregiver home practices directly induced substantial catch-up growth and systemic physiological rehabilitation. The children's mean BMI Z-scores significantly shifted upward to -1.15 ± 0.48 ($p < 0.001$), successfully moving the cohort away from the critical threshold of severe acute wasting. Objectively, this physical growth was supported by the correction of internal visceral protein stores; serum albumin values normalized to 4.15 ± 0.42 g/dL, and rapid-turnover prealbumin levels safely elevated to 21.88 ± 3.12 mg/dL ($p < 0.001$). Because prealbumin has a very short biological half-life of only two days, its marked elevation serves as a highly sensitive, objective confirmation of consistent dietary compliance and successful protein assimilation over the course of the study **(Kalnins & Wilschanski, 2022).**

The post-intervention reversal of growth faltering and stabilization of protein biomarkers observed in this pediatric cohort are highly consistent with international clinical guidelines and nutritional trials. A multi-center study by **Hamed et al. (2022)** demonstrated that intensive, structured nutritional counseling in specialized pediatric CF clinics significantly improves growth velocity and shifts BMI Z-scores upward within a 6-to-12-month window. Their findings confirmed that proactive dietary behavioral changes, when combined with optimized enzyme titration, are fully capable of overcoming the intestinal malabsorptive barriers inherent to CF.

Furthermore, the significant elevation of visceral protein biomarkers is in complete agreement with research by **Leonard et al. (2023)** regarding evidence-based practice recommendations for nutrition in cystic fibrosis care and emphasized that serum albumin and prealbumin are not merely indicators of muscle mass, but are vital metabolic surrogates for systemic immune health and cellular repair. The successful normalization of these markers in our Upper Egypt cohort confirms that the caregivers accurately implemented the caloric and high-protein fortification techniques learned during the counseling sessions, directly correcting the children's cellular protein deficiencies.

The ultimate clinical justification for aggressive nutritional interventions in Cystic Fibrosis (CF) lies in its direct biological impact on preserving lung function and preventing respiratory failure. At baseline, the studied children exhibited severe clinical fragility, experiencing a high mean frequency of acute pulmonary exacerbations (3.24 ± 1.05) over a 6-month period). This high baseline relapse rate reflects a well-documented pathophysiological cycle in CF, where chronic protein-energy malnutrition weakens the diaphragm and intercostal respiratory muscles, leading to sub-optimal cough clearance, retained thick secretions, and subsequent opportunistic bacterial colonization.

Following the implementation of the high-protein counseling bundle, it was highlighted that a highly statistically significant clinical breakthrough, with the mean frequency of acute pulmonary exacerbations dropping sharply to 1.12 ± 0.68 ($p < 0.001$). This profound reduction provides clear empirical evidence of the "nutrition-lung link" in pediatric CF care. By correcting visceral protein stores and reversing physical wasting,

the intervention successfully bolstered the children's cell-mediated immune responses and enhanced respiratory muscle contractility, thereby breaking the destructive cycle of chronic inflammation and recurrent infection.

Furthermore, this clinical outcome is in complete agreement with the findings of **Wilschanski et al. (2024)** in the *ESPEN-ESPGHAN-ECFS guidelines*. They emphasized that intensive nutritional rehabilitation is not merely an auxiliary support mechanism, but a core disease-modifying therapy. The guidelines state that maximizing protein intake and ensuring strict adherence to Pancreatic Enzyme Replacement Therapy (PERT) reduces systemic circulating inflammatory cytokines, which directly stabilizes the airway microenvironment and lowers the frequency of acute pulmonary relapses.

The correlation matrix revealed that the intricate behavioral and physiological mechanisms through which the high-protein nutritional counseling bundle achieved its therapeutic success. Rather than viewing caregiver knowledge, dietary adherence, and clinical markers as isolated variables, the statistical analysis confirms a powerful, interconnected cascade. Enhanced maternal health literacy serves as the initial catalyst, which directly drives home-based compliance, optimizes digestive physiology, and ultimately culminates in systemic clinical and respiratory stabilization for the pediatric patient.

The strong, statistically significant positive correlation between caregivers' nutritional knowledge and their dietary adherence. This is reflected when primary caregivers understand the "why" behind dietary protocols, they experience a psychological shift that increases their competence and confidence to execute rigorous therapies consistently at home.

The significant positive correlation between maternal educational level and the net gain in nutritional knowledge and dietary adherence is highly consistent with international literature on health literacy. A study by **Chatterjee & Nirgude, (2024)**confirmed that formal maternal education is a powerful facilitator of cognitive reception during medical counseling. Mothers with a basic or secondary education baseline possess superior familiarity with structured learning, allowing them to rapidly master complex clinical directives, such as the physiological rationale behind high-protein adjustments and the technical calculations required for pancreatic enzyme replacement titration.

Additionally, the negative correlation between a child's baseline history of frequent hospitalizations and their net improvement in BMI Z-scores is highly consistent with research by **Mariotti Zani et al. (2023)**. Their study demonstrated that children with a high initial disease burden and severe tissue wasting require far more aggressive, intensive, or prolonged nutritional rehabilitation pathways to overcome baseline cellular catabolism and successfully achieve physical catch-up growth.

Limitations of the Study

1. The use of a convenience sample consisting of 50 patient-caregiver limits the statistical power of the study. This non-randomized approach introduces potential selection bias, which may restrict the generalization of the findings to the broader population of pediatric Cystic Fibrosis patients across Egypt.
2. Due to the quasi-experimental, pre-and-post test design, this study lacked a parallel, randomized control group. Consequently, history and maturation effects such as the natural growth of the children over the 6-month period or changes in standard clinical management at the hospital—cannot be entirely isolated from the direct impact of the counseling intervention.

Conclusion

In conclusion, this study demonstrates that a structured, high-protein nutritional counseling bundle targeting both pediatric patients with Cystic Fibrosis and their primary caregivers is highly effective. By transitioning caregivers from passive observers to active, informed clinical managers, the intervention directly addresses the root complications of pancreatic insufficiency and nutrient malabsorption.

The empirical evidence generated over the 6-month follow-up period confirms that intensive, localized education yields a statistically significant increase in caregivers' nutritional knowledge, dietary adherence, and PERT administration competence. More importantly, this empowerment directly translates into optimized clinical and physiological rehabilitation for the children, evidenced by significant catch-up growth (improved body weight and BMI Z-scores), corrected protein statuses (elevated serum

albumin and prealbumin levels), and a noticeable reduction in acute pulmonary exacerbations. Ultimately, this research underscores that investing in caregiver literacy is a highly sustainable, cost-effective strategy capable of maximizing therapeutic adherence, optimizing pediatric outcomes, and reducing the acute healthcare burden within resource-constrained clinical settings.

Recommendations

Based on the significant findings and clinical outcomes of this study, the following recommendations are proposed :

- The high-protein nutritional counseling bundle should be integrated as a standard, mandatory component of routine protocol for all pediatric CF patients and their families attending outpatient clinics at Sohag University Hospitals and similar tertiary centers.
- Specialized, multidisciplinary care teams—consisting of pediatric pulmonologists, clinical nutritionists, pediatric nurses, and social workers—should be formed to provide continuous, coordinated medical and dietary surveillance.
- Culturally tailored, illustrated Arabic booklets, mobile applications, and visual media demonstrating correct Pancreatic Enzyme Replacement Therapy (PERT) titration and affordable high-protein meal formulation must be distributed freely to all newly diagnosed families.
- Serial monitoring of rapid-turnover protein biomarkers, specifically serum prealbumin, should be performed routinely alongside standard anthropometric checks to detect early sub-clinical malnutrition before physical growth faltering occurs.
- Continuous educational workshops should be conducted for nurses to upgrade their counseling skills and update their knowledge on modern international CF nutritional guidelines.
- Healthcare policymakers should work towards expanding the health insurance umbrella to fully subsidize the cost of high-potency PERT micro-tablets and required fat-soluble vitamin supplements, eliminating financial barriers to adherence for low-income families.
- Future studies should replicate this intervention utilizing large-scale, multi-center randomized controlled trials (RCTs) across different geographic regions in Egypt to enhance the generalizability of the findings.
- Longitudinal research with an extended follow-up duration (e.g., 2 to 5 years) is strongly recommended to evaluate the long-term sustainability of caregiver dietary compliance and its permanent protective impact on stabilizing children's lung function.
- Further research should explore the efficacy of telehealth models, including text-message reminders or dedicated mobile health (mHealth) applications, in maintaining caregiver self-efficacy and reducing hospital readmissions.

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