PediaSure

COMPRENDIUM OF ABBOTT STUDIES

This is an interactive pdf. Use the Table of Contents (TOC) to navigate to specific pages within the document or use the forward arrow, back arrow, TOC button, or Bibliography button found at the bottom of every page.
TABLE OF CONTENTS

INTRODUCTION ................................................................................................................. 4

SUMMARY TABLE OF CLINICAL STUDIES ................................................................. 5

PEDIASURE STUDIES

Outpatient/Community Setting

Oral Nutritional Supplementation Improved Physical Growth and Micronutrient Deficiencies in Stunted Children (Ninh N et al., 2018) .......... 8

High-Fibre Enteral Feeding Results in Improved Anthropometrics and Favourable Gastrointestinal Tolerance in Malnourished Children With Growth Failure (Kansu A et al., 2018) ......................................................... 9

Effect of Oral Nutritional Supplementation on Growth and Recurrent Upper Respiratory Tract Infections in Picky Eating Children at Nutritional Risk: A Randomized, Controlled Trial (Ghosh AK et al., 2018) ............................................................................. 10

Continuation of Oral Nutritional Supplementation Supports Continued Growth in Nutritionally At-Risk Children With Picky Eating Behavior: A Post-Intervention Observational Follow-Up Study (Ghosh AK et al., 2018) ............................................................... 11

Growth and Mealtime Stress Levels in Spanish Children Receiving Oral Nutritional Supplementation (ONS) (Bodas PA et al., 2016) ........................................................................................................ 12

Impact of Long-Term Use of Oral Nutritional Supplement on Nutritional Adequacy, Dietary Diversity, Food Intake and Growth of Filipino Preschool Children (Huynh DTT et al., 2016) ......................... 13

Longitudinal Growth and Health Outcomes in Nutritionally At-Risk Children Who Received Long-Term Nutritional Intervention (Huynh DTT et al., 2015) ................................................................. 13

Benefits of Oral Supplementation With and Without Synbiotics in Young Children With Acute Bacterial Infections (Schrezenmeir J et al., 2004) ........................................................................................................ 14

Tolerance and Safety of Energy-Dense Enteral Formulae for Young Children (Van Aerde J et al., 2003) ................................................................. 15

Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters (Alarcón PA et al., 2003) ................................................................. 16

Effect of Oral Nutritional Supplementation With or Without Synbiotics on Sickness and Catch-Up Growth in Preschool Children (Fisberg M et al., 2002) ................................................................. 17
<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect of Nutritional Intervention on Physical Growth in Children at Risk of Malnutrition (Fiore P et al., 2002)</td>
<td>18</td>
</tr>
<tr>
<td>Gastrointestinal Tolerance of a Pediatric Fiber Formula in Developmentally Disabled Children (Tolia V et al., 1997)</td>
<td>19</td>
</tr>
<tr>
<td>A Randomized Trial of Nutritional Intervention in Children With Failure to Thrive (Casey PH et al., 1997)</td>
<td>20</td>
</tr>
<tr>
<td>Very Early Onset Nonorganic Failure to Thrive in Infants (Tolia V 1995)</td>
<td>21</td>
</tr>
<tr>
<td>Use of a Pediatric Enteral Product As Supplemental Nutrition in Malnourished Children. Presented at the Third Commonwealth Conference on Diarrhoea and Malnutrition (Lai HS et al., 1994)</td>
<td>22</td>
</tr>
<tr>
<td>The Effect of PediaSure on the Growth of Developmentally Disabled Children (Sharrett MK et al., 1993)</td>
<td>23</td>
</tr>
<tr>
<td>Safety and Efficacy of a New Pediatric Enteral Product in the Young Child (Ramstack M et al., 1991)</td>
<td>24</td>
</tr>
<tr>
<td>Hospital Setting</td>
<td></td>
</tr>
<tr>
<td>Effects of Nutritional Supplementation on Prealbumin Concentrations in Pediatric Burn Patients: A Randomized, Controlled Trial (Williams JA et al., 2013)</td>
<td>25</td>
</tr>
<tr>
<td>PediaSure in the Treatment of Severe Malnutrition in Pakistani Children (Akram et al., 2000)</td>
<td>26</td>
</tr>
<tr>
<td>Early Enteral Feeding in the Pediatric Intensive Care Unit (Chellis MJ et al., 1996)</td>
<td>27</td>
</tr>
<tr>
<td>Dietary Management of Malnourished Children With a New Enteral Feeding (Morales E et al., 1991)</td>
<td>28</td>
</tr>
<tr>
<td>BIBLIOGRAPHY</td>
<td></td>
</tr>
<tr>
<td>Alphabetical by Author</td>
<td>30</td>
</tr>
<tr>
<td>APPENDIX</td>
<td></td>
</tr>
<tr>
<td>Timeline of Clinical Studies</td>
<td>32</td>
</tr>
</tbody>
</table>
INTRODUCTION

The efficacy and safety of PediaSure has been shown in 21 studies conducted over more than 25 years.

- 17 studies showed efficacy in terms of weight gain or catch-up growth.
- 3 studies reported improved immune status in terms of fewer sick days and upper respiratory tract infections.
- 6 studies showed that PediaSure helps improve nutritional status.
- 12 studies reported that PediaSure was safe and well tolerated.

The 21 summarized studies include published papers, abstracts and posters. Each article summary contains a brief description of the objectives, study design, results and conclusions.
## SUMMARY TABLE OF KEY PEDIASURE CLINICAL STUDIES*

<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Publication</th>
<th>Promote Weight and/or Height Gain</th>
<th>Improves Nutritional Status or Intake</th>
<th>Supports Immune Health (Reduced Infection and/or Sick Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ninh et al 2018</td>
<td><em>International Congress on Nutrition &amp; Growth</em></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Kansu et al 2018</td>
<td><em>Acta Paediatr</em></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ghosh et al 2018</td>
<td><em>J Int Med Res</em></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Bodas et al 2016</td>
<td><em>International Congress on Nutrition &amp; Growth</em></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Williams et al 2013</td>
<td><em>Open Nutr J</em></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Schrezenmeier et al 2004</td>
<td><em>Clin Pediatr</em></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Van Aerde et al 2003</td>
<td><em>Int Pediatr</em></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarcon et al 2003</td>
<td><em>Clin Pediatr</em></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fisberg et al 2002</td>
<td><em>Int Pediatr</em></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Fiore et al 2002</td>
<td><em>Int Pediatr</em></td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

*Studied in various PediaSure formulations

PediaSure Compendium of Abbott Studies
### SUMMARY TABLE OF KEY PEDIASURE CLINICAL STUDIES

<table>
<thead>
<tr>
<th>Author and Year</th>
<th>Publication</th>
<th>Promote Weight and/or Height Gain</th>
<th>Improves Nutritional Status or Intake</th>
<th>Supports Immune Health (Reduced Infection and/or Sick Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Akram et al 2000</td>
<td>JPMA</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Tolia et al 1997</td>
<td>J Pak Med Assoc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Casey et al 1997</td>
<td>American Pediatric Society meeting</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chellis et al 1996</td>
<td>J Pak Med Assoc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tolia 1995</td>
<td>J Pediatr Gastroenterol Nutr</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lai 1994</td>
<td>Commonwealth Conference on Diarrhea and Malnutrition</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sharrett MK and Li BUK 1993</td>
<td>FNCE meeting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ramstack and Listernick 1991</td>
<td>J Pediatr Gastroenterol Nutr</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Morales et al 1991</td>
<td>J Am Diet Assoc</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
PEDIASURE STUDIES
OBJECTIVE
To evaluate the effects of oral nutritional supplementation (ONS) on physical growth and micronutrient deficiencies of stunted children.

STUDY DESIGN
Study type: Prospective, single-arm study.

Study population: Children aged 24-48 months who had height-for-age Z-score <-2SD and weight-for-height Z-score <-1SD (WHO Growth Standards).

Intervention: One group. Children received 2 oral servings of PediaSure* on a daily basis for 6 months. 140 subjects were recruited.

Outcomes measured: Anthropometrics, blood tests were conducted to measure blood concentrations of hemoglobin, albumin, zinc, C reactive protein and α1-acid glycoprotein at baseline and 6 months of intervention.

RESULTS
Significant increases in height-for-age and weight-for-age Z-scores were observed after 6 months of supplementation (P<0.05). At the end of the study period, 40% of the children had normal height-for-age Z-scores (>2SD). The prevalence of anemia, low albumin and zinc deficiency was significantly reduced at the end of the study.

CONCLUSION
PediaSure supplementation over 6 months significantly improved physical growth, reduced stunting, underweight and micronutrient deficiencies in stunted children. ONS supplementation may be an effective strategy to reduce stunting in children who are malnourished.

*Reconstituted PediaSure TripleSure 1kcal/ml powder

PediaSure Compendium of Abbott Studies
**OUTPATIENT/COMMUNITY SETTING**

High-Fibre Enteral Feeding Results in Improved Anthropometrics and Favourable Gastrointestinal Tolerance in Malnourished Children With Growth Failure


**OBJECTIVE**

To determine typical usage of high-fiber enteral feeding and its effects on gastrointestinal tolerance, anthropometrics and safety in malnourished children with growth failure.

**STUDY DESIGN**

**Study type:** Post-marketing, observational, multicenter study.

**Study population:** Children aged 1-10 years with malnutrition-related growth failure, with a weight and height below 2 SD percentiles for their age.

**Intervention:** One group. 345 subjects had been prescribed isocaloric or hypercaloric high-fibre oral or tube-fed enteral feeding regimens. Feeding was used as a supplement (99.7%) and provided orally (99.1%) for the majority of patients. Children received an average of 2 servings daily for 6 months. 93.6% of patients received PediaSure Fiber formula* (55% receiving 1.0 kcal/ml formula; 38.5% 1.5kcal/ml formula). The remaining 6.4% patients received another 1kcal/ml fiber containing formula.

**Outcomes measured:** Anthropometrics, gastrointestinal symptoms, defecation habits and safety data relating to adverse events were analyzed.

**RESULTS**

Significant increases were found for the Z scores of height for age, weight for age, weight for height and body mass index for height in four months to six months (p<0.001 for each). The percentage of patients with normal defecation frequency significantly increased at the four months to six months visit (p=0.004).

**CONCLUSION**

Use of a high fiber enteral feed for 6 months was associated with favorable outcomes in anthropometrics, appetite, gastrointestinal tolerance and safety in malnourished children.

*PediaSure Fiber1kcal/ml, PediaSure Fiber 1.5kcal/ml liquid products
**OBJECTIVE**
To evaluate the effect of oral nutritional supplementation (ONS) plus dietary counselling (DC) versus DC alone on growth and recurrence of upper respiratory tract infection (URTI) in nutritionally at-risk, picky eating children.

**STUDY DESIGN**

**Study type:** Prospective, randomized, multicenter, controlled trial.

**Study population:** Children aged 24–72 months (2–6 years) who had picky eating behaviour, a weight-for-age between the 3rd and 15th percentiles (WHO Child Growth Standards) and were diagnosed with URTI.

**Intervention:** 2 groups. A total of 255 children were recruited. The intervention group (n=127) received DC at baseline and each post-baseline visit plus instructions for ONS, PediaSure™, to be consumed daily over a 90-day period. The control group (n=128) received DC at baseline and each post-baseline visit.

**Outcomes measured:** Anthropometrics, duration and incidence/recurrence of URTI, child’s appetite and palatability and 24-h dietary recalls and product compliance were assessed.

**RESULTS**
Compared to the control group, the PediaSure group had significant increases in weight-for-age Z-scores from 10 days onwards (p<0.0001) and body mass index-for-age Z-scores from 10 days onwards (p=0.0002). There was a lower risk for URTI recurrence in the intervention group, after controlling for confounding factors (P<0.05). Total energy consumption in this intervention group was also significantly increased from 30 days onwards.

**CONCLUSIONS**
ONS plus DC is effective for improving weight and reducing the incidence of URTI in nutritionally at-risk, picky eating children with an acute URTI episode.
Continuation of Oral Nutritional Supplementation Supports Continued Growth in Nutritionally At-Risk Children With Picky Eating Behavior: A Post-Intervention Observational Follow-Up Study


OBJECTIVE
To evaluate the growth trajectory of picky-eating children with upper respiratory tract infection (URTI) who previously completed a 90-day, randomized, controlled trial of oral nutritional supplementation (ONS) plus dietary counselling (DC) compared with DC alone.

STUDY DESIGN

**Study type:** Prospective, observational, follow-up study (follow-up study from the clinical trial described in Ghosh AK, et al. J Int Med Res 2018; 0:1-16).

**Study population:** Subjects who had successfully completed the ONS (PediaSure) study without significant adverse safety events and without major deviation to the protocol.

**Intervention:** 2 groups. Children were free to consume ONS, PediaSure*. They were followed up for 120 days. A total of 203 children were included (ONS + DC, n = 98; DC, n = 105).

**Outcomes measured:** Anthropometrics, child’s appetite and palatability, 24-h dietary recalls and product compliance were evaluated.

RESULTS
In this follow-up period, there were significant declines in weight-for-age percentiles in both groups, but the children who voluntarily consumed PediaSure during this period had significantly less declines than those not consuming the supplement (p=0.001). Moreover, children in the DC group showed a larger decline in height-for-age in those who did not take the ONS during the follow-up compared with those who did. This difference was not found in the ONS group.

CONCLUSION
Continued parental self-administration of ONS to their children slows down the loss of growth percentiles, supporting continued weight gain in picky-eating children at nutritional risk.

*Reconstituted PediaSure powder

PediaSure Compendium of Abbott Studies
OUTPATIENT/COMMUNITY SETTING

Growth and Mealtime Stress Levels in Spanish Children Receiving Oral Nutritional Supplementation (ONS)

OBJECTIVE
To assess the effects of oral nutritional supplement (ONS) usage on growth and meal-related stress in picky eater children.

STUDY DESIGN
Study type: Post-marketing, observational study.
Study population: Children aged 2-5 years, who were below the 10th percentile for weight-for-age and exhibiting picky eater behaviors.
Intervention: 1 group. 118 children received orally an average of 1.5 servings per day of PediaSure* during 12 weeks.
Outcomes measured: Anthropometrics, family stress level related to mealtimes via questionnaire, ONS acceptance by subjects and caregivers were assessed.

RESULTS
Weight and height increased, with mean gains for weight, height and weight-for-age (all p< 0.0001). Family stress levels related to mealtime occasions decreased over the 12 weeks (p<0.0001). 73% of children rated the ONS as “good” or “very good” and 89% of caregivers felt the ONS reached or exceeded expectations for their child at the end of the trial.

CONCLUSION
Reducing family stress levels and increasing growth in small picky eater children, as shown in this study, may have beneficial long-term results on eating behaviors and the family dynamic.
OBJECTIVE
To assess the effects of dietary counseling (DC) with long-term oral nutritional supplementation (ONS) on promoting longitudinal growth and health in children at nutritional risk.

STUDY DESIGN

Study type: Prospective, single-arm, multicenter trial.

Study population: Children aged 3–4 years with weight-for-height percentiles from 5th to 25th (WHO Child Growth Standards).

Intervention: One group. Parents of children received dietary counseling at baseline, and at weeks 4 and 8. Two servings of ONS, PediaSure®, were consumed daily during the 48 weeks. 200 children were enrolled.

Outcomes measured: Dietary intakes, anthropometrics, number of sick days, physical activity and appetite and palatability data were collected. Nutrient adequacy and dietary diversity score (DDS) were calculated.

RESULTS

Weight-for-height percentiles showed the greatest increase in the first 4 weeks (P < 0.0001) and remained significantly higher than baseline (P < 0.0001). Height-for-age percentiles increased steadily over time and became significantly higher than baseline from week 24 onwards (P < 0.0001). Parent reported appetite and physical activity scores significantly improved (P < 0.0001), and a reduction in the number of sick days from week 16 onwards was also observed (P < 0.0001). The percentages of children with adequate intake of energy, protein, iron, calcium and some vitamins at each post-baseline visit were improved. DDS was also increased reaching significance from week 16 onwards.

CONCLUSIONS

Intervention consisting of initial dietary counselling and continued ONS helped sustain normal growth after catch-up growth in nutritionally at-risk children.

*Reconstituted PediaSure TripleSure 1 kcal/ml powder
OBJECTIVE
To compare the energy intake of children receiving a standard oral nutritional supplement (ONS) with or without synbiotics with a fruit-flavored drink in conjunction with their antibiotic medications.

STUDY DESIGN

Study type: Prospective, parallel, multicenter, randomized, study.

Study population: Acutely ill children aged 1–6 years receiving antibiotic therapy.

Intervention: Three groups. Subjects enrolled included 140 children who consumed orally 1 of 3 study products: 2 groups were fed PediaSure* products (with or without synbiotics) and another group received a fruit-flavored drink. This feeding was maintained up to 14 days following antibiotic regimen.

Outcomes measured: 24-h dietary recall, diary product and medications intake were reported. Stool frequency, consistency, and bacteria profile (Lactobacillus, Bifidobacterium) was determined. Gastrointestinal symptoms, subject’s appetite and activity and body weight and temperature were also evaluated.

RESULTS

For all groups, activity and appetite returned to normal by days 3 and 5 respectively. Total energy intake and weight gain were significantly greater in the group that consumed the PediaSure with synbiotics; this group had the highest increases in Lactobacillus (P<0.05). PediaSure with synbiotics also resulted in the lowest rate of relapse or new bacterial infections, though these differences were not statistically significant compared to the other 2 groups.

CONCLUSIONS

ONS increase energy intake and promote weight gain in acutely ill children receiving antibiotics; synbiotics may confer additional benefits by increasing bifidobacteria levels.

*Reconstituted PediaSure 1kcal/ml powder

OBJECTIVE
To determine and compare the safety and gastrointestinal tolerance of two energy-dense enteral formulas with a standard enteral formula in children who require tube feeding.

STUDY DESIGN
Study type: Prospective, randomized, open, controlled, multicenter trial.
Study population: Children aged 1-6 years who required at least 75% of their daily tube feed from the study formula.
Intervention: Three groups. 113 children were enrolled to take different PediaSure products during 21 days: a control formula,* a high caloric density formula,** or a high caloric density formula with fiber.*** Subjects were required to receive at least 75% of their nutritional support from the formula treatment.
Outcomes measured: Gastrointestinal symptoms, energy intake, body weight, frequency/consistency of stools and adverse events were evaluated.

RESULTS
Gastrointestinal and stool parameters or adverse events were the same for all 3 groups. Mean weight gain for the PediaSure with high caloric density (with and without fiber) was significantly higher than the control group. Energy intake was similar among the 3 groups, but volume intake was lower in the two groups receiving PediaSure Plus (p<0.05) compared with the PediaSure group.

CONCLUSIONS
Energy dense formulae are an option for children with fluid restriction or increased energy of fiber needs without compromising safety or tolerance.
Effect of Oral Supplementation on Catch-Up Growth in Picky Eaters

OBJECTIVE
To investigate the efficacy of physician-directed nutritional counseling with and without oral nutritional supplementation (ONS) in improving the growth of children who had picky-eater behaviors and who had evidence of growth faltering.

STUDY DESIGN
Study type: Prospective, randomized, controlled, parallel, multicenter trial.

Study population: Children aged 36-60 months with picky-eating behavior who were below the 25th percentile for weight-for-height.

Intervention: Two groups. 92 children were randomized to receive either nutrition counseling alone, or nutrition counseling plus an oral nutritional supplement, PediaSure*, for 90 days. Parents were given nutrition counseling by a physician.

Outcomes measured: 3-day diet history and product diary intake, appetite and activity levels, height and weight, medical history, physical examination clinical, gastrointestinal symptoms were all evaluated. Laboratory measurements such as serum albumin, iron, ferritin, zinc were also collected.

RESULTS
The group receiving PediaSure had significantly greater increases in weight and height. There were no significant differences between groups in changes in appetite or activity levels, or in gastrointestinal symptom scores. Based on adverse event reporting, the percent of subjects who developed upper respiratory tract infections was significantly lower in the PediaSure group.

CONCLUSIONS
ONS in addition to nutrition counseling promotes catch-up growth and may contribute to lower rates of infectious disease in children with picky eater behaviors.

*Reconstituted PediaSure powder
OUTPATIENT/COMMUNITY SETTING

Effect of Oral Nutritional Supplementation With or Without Synbiotics on Sickness and Catch-Up Growth in Preschool Children

OBJECTIVE
To evaluate incidence, duration of illness and anthropometrics in children receiving an oral nutritional supplement (ONS) with or without synbiotics.

STUDY DESIGN
Study type: Prospective, randomized, parallel trial.

Study population: Children 1-6 year of age that were between -1 SD and -3 SD from the median of in weight-for-height.

Intervention: Two groups. 626 children received an oral nutritional supplement with PediaSure* with synbiotics (n=310) or without synbiotics (n=316) for 16 weeks.

Outcomes measured: Stool frequency and consistency, study product intake, adverse events and incidence and duration of sick episodes.

RESULTS
The number of sick days per month decreased significantly in both feeding groups (p<0.001). There was a significant increase in anthropometric measures for both groups (p<0.001). The mean number of sick days and constipation for children 3-5 years of age was significantly lower in the PediaSure with synbiotics than in the group without synbiotics (p=0.047).

CONCLUSIONS
Oral supplementation with a nutritionally complete product, at an average intake of 40ml/kg/day, can improve the nutritional status of underweight preschool children.

*Reconstituted PediaSure 1kcal/ml powder

PediaSure Compendium of Abbott Studies
OBJECTIVE
To evaluate the effects of oral nutritional supplementation and dietary counseling on the growth and nutritional status of an outpatient pediatric population at risk of malnutrition.

STUDY DESIGN
Study type: Prospective trial.

Study population: Children aged 12 months to 10 years at risk of malnutrition with weight for height below 25th percentile, decreased energy and nutrient intake correlated with poor appetite, or weakness lasting for at least 3 months, and/or <5% decrease in habitual body weight, or pulmonary (bacterial or viral pneumonia) or urinary tract infections (UTI), with possible unfavorable effects of ongoing infectious episodes on the subject’s appetite.

Intervention: One group. 174 subjects received a daily ONS, PediaSure,* during 4 months and nutritional counselling was provided to their parents. PediaSure was supplemented to provide at least 16% (maximum of 22%) of energy intake for LARN – Italian Recommended Dietary Allowances.

Outcomes measured: Anthropometrics, 24 h diet recall, compliance with oral nutritional supplement intake and nutritional habits were evaluated.

RESULTS
The percentage of subjects at <25th percentile in weight-for-height significantly decreased from 56% to 42% at the end of the study (p=0.007). The mean weight-for-height percentile for all subjects increased from 27.6 to 33.9 (p<0.001) after 4 months. Adequate dietary intake was observed in 72% of patients after 4 months of nutritional intervention. 78% of children found the formula agreeable to the taste and complied with the intake prescriptions.

CONCLUSIONS
Oral nutritional supplementation, together with nutritional counseling, can improve food intake and growth in children at risk of malnutrition.

*Reconstituted PediaSure 1kcal/ml powder
OBJECTIVE
To study the tolerance of a pediatric adapted enteral formula with added soy fiber.

STUDY DESIGN

Study type: Prospective, randomized, crossover study.

Study population: Children and adolescents aged 1 to 17 years with developmental disabilities (mild, moderate or severe mental retardation) that were receiving enteral nutrition supplements to provide more than 80% of estimated energy requirements orally or via tube feeding.

Intervention: Two groups. 20 children participated in the study. Intervention started with a crossover study with 4 weeks on each of two products, PediaSure* or PediaSure Fiber** (10g total dietary fiber/l). Thereafter, subjects were fed PediaSure Fiber for an additional 2 months.

Outcomes measured: Anthropometrics, daily formula intake, gastrointestinal tolerance and stool characteristics were evaluated in the crossover study and in the follow-up period. As additional measurements, biochemical assessment at baseline, at the end of crossover study and exit and bowel scintigraphy was performed for gastric emptying and bowel transit time.

RESULTS
There were no differences between the two formulas for tolerance, stooling, growth or biochemical measurements in the children that completed the study. There was a slight trend towards less use of elimination aids during the last phase of the crossover study.

CONCLUSION
PediaSure Fiber is well tolerated in children with developmental disabilities.

Gastrointestinal Tolerance of a Pediatric Fiber Formula in Developmentally Disabled Children


*PediaSure 1kcal/ml, **PediaSure Fiber 1kcal/ml liquid products
A Randomized Trial of Nutritional Intervention in Children With Failure to Thrive

BACKGROUND
To compare a commonly used nutritional intervention for failure to thrive infants with a more caloric dense formula.

STUDY DESIGN
Study type: Prospective, randomized parallel trial.
Study population: Children with failure to thrive 6-24 months old.
Intervention: 2 groups. 80 infants completed the study. 44 infants received PediaSure* with 30kcal/oz as a caloric dense formula and 36 received Similac with iron with 24kcal/oz during 4 months. For children under the age of 1 year, randomized formula was to be fed as sole source nutrition. For children older than 1 year, formula was to be fed as 150 kcal/kg/day in the first feeding of each day.
Outcomes measured: Anthropometrics, dietary intake, biochemical measurements, formula tolerance and patient satisfaction.

RESULTS
Change in Z scores for weight for age and weight for length from baseline to 4 months improved significantly (p<0.01) for both groups; the two groups did not differ from each other. The PediaSure group was rated better on both the parent satisfaction and formula tolerance questionnaires at 1 month (p<0.05). Both formula groups showed normal improvement in anthropometrics over 4-month period.

CONCLUSION
PediaSure was better accepted and resulted in caloric intake and biochemical analyses as beneficial as Similac formulation.

*Reconstituted PediaSure 1 kcal/ml powder
PediaSure is not indicated in children under 1 year.
OBJECTIVE

To examine whether oral nutritional supplementation can improve growth parameters in children with nonorganic failure to thrive.

STUDY DESIGN

Study type: Prospective trial.

Study population: Infants aged 13 to 30 months who failed to consume adequate calories and had delayed growth. All were below the 5th percentile for weight and all but 1 child was below the 5th percentile for height.

Intervention: One group. Initially an increase in caloric intake with normal diet was tried in 7 subjects; afterwards, oral nutritional supplementation with PediaSure* in addition to meals (meals provided 20-60% of caloric needs) was given to 5 subjects orally, plus via nasogastric or gastrostomy tube. 2 subjects received other nutritional supplements (Osmolite, Ensure). The study ran from 21 to 60 months.

Outcomes measured: Anthropometrics, bone age and 3-day diet records were assessed. Laboratory assessment with complete blood count, erythrocyte sedimentation rate, biochemical profile, T4, TSH, zinc, total protein, albumin IgG and IgA was carried out. Radiographic barium contrast studies were performed.

RESULTS

A significant increase in caloric intake caused improvement in growth percentile. Height and weight percentiles improved in all and entered the normal curve in 4 and 5 patients, respectively. Weight loss was associated with tapering of the nutritional supplementation in all subjects.

CONCLUSIONS

These data suggest that there is a critical need for early aggressive nutritional intervention in infants with nonorganic failure to thrive.

*Reconstituted PediaSure 1kcal/ml powder

PediaSure Compendium of Abbott Studies
Use of a Pediatric Enteral Product As Supplemental Nutrition in Malnourished Children

OBJECTIVE
To examine how supplementation of malnourished children’s diets with a powdered formulation affects growth, biochemical parameters and gastrointestinal tolerance.

STUDY DESIGN

Study type: Prospective trial.

Study population: Children aged 1 to 6 years that were undernourished as defined by Waterlow criteria of weight-for-height values or if they exhibited increased nutrients requirements or decreased food intake.

Intervention: One group. Children were supplemented for 12 weeks with PediaSure* to achieve at least 30% of estimated caloric needs per Taiwanese RDA. 36 children were enrolled and 30 subjects completed the study.

Outcomes measured: Anthropometrics, 3-day diet record, product intake records, blood parameter and tolerance were assessed.

RESULTS
Children’s Z scores for weight and length measures increased significantly (p<0.001 and p<0.01, respectively). Supplementation with PediaSure increased intake of calories, protein and iron in the children. As for blood analytes, mean hemoglobin and hematocrit levels rose significantly and cholesterol was decreased. PediaSure was well-tolerated.

CONCLUSION
As a supplement, PediaSure is well tolerated and can improve growth in malnourished children.

*Reconstituted PediaSure 1 kcal/ml powder
The Effect of PediaSure on the Growth of Developmentally Disabled Children

OBJECTIVE
To compare the effects of enteral feeding on weight gain and macro- and micro-nutrient intakes of children with failure to thrive.

STUDY DESIGN
Study type: Prospective trial.

Study population: Children aged 1 to 3 years with developmental disabilities, including failure to thrive.

Intervention: 1 group. 6 children were fed PediaSure* for 13-28 weeks at caloric levels nearly equivalent to prestudy intakes (prestudy intake: 92kcal/kg, study intake: 89kcal/kg). During the prestudy period, subjects were fed infant formulas.

Outcomes measured: Body weight, weight gain and macro- and micro-nutrient intakes were collected.

RESULTS
Subjects consuming PediaSure gained significantly more weight than pre-study consumption of formula (p<0.01). Moreover, Z scores for body weight had a greater positive change with PediaSure. No macronutrient differences were seen between both periods, but some of the micronutrient levels were higher in the group supplemented PediaSure.

CONCLUSION
PediaSure is a suitable form of enteral feeding in the growing child.

*PediaSure Fiber 1kcal/ml liquid
OBJECTIVE
To evaluate the suitability of a pediatric enteral product in young children requiring specialized nutrition support.

STUDY DESIGN
**Study type:** Prospective trial.

**Study population:** Children 1-6 years old with at least one of the following conditions: 1) the convalescent stage following acute malnutrition, 2) an inability to maintain adequate nutrient intake, 3) undernutrition or increased nutrient requirements. Total or partial nasogastric feeding.

**Intervention:** Subjects were fed PediaSure® providing at least 90% of their estimated energy requirements for 12 weeks. 14 subjects completed the study.

**Outcomes measured:** Anthropometrics, formula consumption, intake of other supplements/foods, stool number and consistency, and incidents of vomiting were recorded. Blood parameters were evaluated.

RESULTS
Anthropometric indices all increased during the study of subjects. Gastrointestinal tolerance and acceptance of the study formula were excellent; there were not clinically significant changes in biochemical parameters.

CONCLUSION
PediaSure is both safe and efficacious in the maintenance of the nutritional status and the promotion of growth in chronically disabled children who require specialized nutritional support.

*PediaSure 1kcal/ml liquid*
**OBJECTIVE**
To measure the effect of oral nutritional supplementation on serum prealbumin in pediatric burn patients.

**STUDY DESIGN**

**Study type:** Prospective, randomized, controlled, multicenter study.

**Study population:** Children aged 1-10 years with a total body surface area (TBSA) burned of at least 15% were enrolled into this study. Patients had baseline serum prealbumin levels <10 mg/dL and were capable of exclusive oral feeding within 72 hours of hospitalization.

**Intervention:** Two groups. 54 subjects were randomized to a control group (28 subjects) with a typical hospital diet for mild to moderate burn patients or to the intervention group (26 subjects) with the same diet plus PediaSure® as additional oral nutritional supplementation (ONS) during 14 days.

**Outcomes measured:** Blood parameters as serum prealbumin and C-reactive protein, body weight and number of wound infections during the study.

**RESULTS**
There were no significant differences in baseline serum prealbumin concentration. Nutritional supplementation significantly increased serum prealbumin levels of the subjects from baseline to day 7; after 1 week, children consuming the supplementation had a major increase in prealbumin concentration than children on hospital diet only (p=0.0265).

**CONCLUSIONS**
The increase in prealbumin related to enteral supplementation with PediaSure may provide future guidance for the nutritional management of pediatric burn patients or patients with increased energy and protein needs.
PediaSure in the Treatment of Severe Malnutrition in Pakistani Children

OBJECTIVE
To evaluate a high-density supplemental high caloric feed for the purpose of nutrition therapy in malnourished children during the initial 2 weeks of rehabilitation.

STUDY DESIGN
Study type: Prospective, single-arm study.
Study population: Children aged 1-5 years and severely malnourished.
Intervention: One group. 31 children received PediaSure as their source of calories for 2 weeks.
Outcomes measured: Weight gain, clinical tolerance, and stool output were monitored, as were hematological and biochemical parameters.

RESULTS
Significant increase in caloric intake (p<0.01) over the 2-week period. The biochemical parameters registered an increase in serum potassium levels, but no untoward chemical imbalance was noted. Tolerance for PediaSure was very high, only one child was excluded from the study due to limited intake. None of the children developed diarrhea.

CONCLUSION
PediaSure can be used effectively in the initial stage of nutrition rehabilitation of severely malnourished children.

*Reconstituted PediaSure 1kcal/ml powder

**OBJECTIVE**

To evaluate the feasibility and safety of early enteral feeding of critically ill pediatric patients.

**STUDY DESIGN**

**Study type:** Prospective study.

**Study population:** Critically ill children aged 5 days to 18 years. All were mechanically ventilated and transpyloric nasoenteric tubes were placed in subjects for the study.

**Intervention:** One group. Tube feeding with an isotonic lactose-free pediatric formula, PediaSure,* was started in 42 children at a rate of 5-10 ml/h and increased as tolerated to meet caloric goals in 24 h during 12 months.

**Outcomes measured:** Time to achieve estimated caloric requirement, stool patterns, gastrointestinal symptoms and signs of nasal or gastrointestinal mucosal injury were evaluated. Cost savings.

**RESULTS**

There were no complications from early enteral feeding, including aspiration. 31 patients achieved estimated caloric requirements within 24 hours, and the remaining 11 patients achieved this within 48 hours. Estimated patient charge savings averaged $425 for each day of enteral feedings.

**CONCLUSION**

Early enteral feeding is feasible, well tolerated, and cost effective in critically ill pediatrics patients.

*Reconstituted PediaSure 1kcal/ml powder
PediaSure is not indicated in children under 1 year.
**OBJECTIVE**
To assess the suitability of a new enteral nutrition product for total nutrition support during the rapid growth phase of recovery from protein-energy malnutrition.

**STUDY DESIGN**

**Study type:** Prospective trial.

**Study population:** In a first phase, children 6-26 months old recovering from protein-energy malnutrition (weight for length deficit of at least 2 standard deviations). In the second phase, children 30-40 months old acutely ill with marasmus and kwashiorkor.

**Intervention:** In the first phase, 9 subjects were tube fed PediaSure* as sole source of nutrition for minimum of 60 days. In the second phase, 13 subjects were tube fed PediaSure* as sole enteral nutrition support for 8 to 35 days of hospitalization.

**Outcomes measured:** First phase: Anthropometrics, serum biochemistry values, apparent nitrogen absorption and retention, fat absorption and fecal losses were evaluated. Second phase: assessment on ability to consume sufficient quantities of the product, changes in weight and length and changes in serum biochemistries were evaluated.

**RESULTS**
Prompt weight gain and increases in serum proteins were observed.

**CONCLUSION**
PediaSure offers a notable advantage over products designed for infants or adults in the enteral alimentation of young children.

---

*PediaSure 1 kcal/ml liquid*
BIBLIOGRAPHY

ALPHABETICAL BY AUTHOR ...........................................30
ALPHABETICAL BY AUTHOR

A


B

C


F


G


H


K


# Appendix: Timeline of Clinical Studies

## 1988
- **Pediasure is introduced in the United States**

## 1991
- **Ramstack M, et al.**
  - Population: Children ages 1-6 years old
  - Description: Use of Pediasure significantly increased weight gain and increased weight percentiles in children with nutritional deficiencies.

## 1994
- **Lai HU, et al.**
  - Population: Malnourished Thai children ages 1-5 years old
  - Description: PDS supplementation significantly increased weight gain, weight percentiles, and iron levels in first week of recovery.

## 1997
- **Tolia VK, et al.**
  - Population: Children aged 1-10 years old
  - Description: PDS significantly increased growth and weight gain in developmentally disabled children.

## 1999
- **Finch HE, et al.**
  - Population: Children ages 13-30 months
  - Description: Use of PDS and dietetic consumption with antibiotic therapy significantly improved growth measures, gastrointestinal symptoms, and stool characteristics.

## 2002
- **Fisberg M, et al.**
  - Population: Children aged 1-15 years
  - Description: PDS supplementation in children with acute infections showed significant weight gain.

## 2003
- **Alarcón JP, et al.**
  - Population: Children ages 36-60 months
  - Description: PDS plus nutritional counseling promoted catch-up growth for children at risk for growth problems.

## 2004
- **Fiore AL, et al.**
  - Population: Children aged 12-30 months
  - Description: PDS was positively associated with catch-up growth.

## 2005
- **Aram E, et al.**
  - Population: Pediatric subjects aged 3-15 years
  - Description: Both PDS formulas had a positive effect on on days and growth parameters.

## 2006
- **Huyhn DT, et al.**
  - Population: Children ages 2-32 months
  - Description: Use of Pediasure significantly improved physical growth, reduced stunting and micronutrient deficiency.

## 2008
- **Vanhoefer AL, et al.**
  - Population: Children ages 1-15 years
  - Description: Oral nutritional supplements significantly improved growth and micronutrient deficiencies in stunted children.

## 2009
- **Ninh N, et al.**
  - Population: Children ages 24-48 months
  - Description: Use of Pediasure significantly improved growth measures, gastrointestinal symptoms, and symptoms of chronic disease.

## 2010
- **Schrezenmeir J, et al.**
  - Population: Children aged 1-6 years
  - Description: Use of PDS and dietetic consumption improved food intake and growth in children at risk for malnutrition.

## 2011
- **Lai HU, et al.**
  - Population: Children aged 1-5 years
  - Description: PDS significantly increased iron levels in first week of recovery.

## 2013
- **Williams RJ, et al.**
  - Population: Pediatric burn patients age 1/2 years with a TBSA burn of at least 15% (range of 15-25%)
  - Description: Both PDS formulas had a positive effect on on days and growth parameters.

## 2015
- **Van Aerdemans W, et al.**
  - Population: Pediatric subjects aged 3-5 years with weight-for-height percentile below 5th percentile for height
  - Description: PDS supplementation in children showed significant improvements in growth and weight percentiles.

## 2016
- **Ghosh AK, et al.**
  - Population: Picky eaters with weight-for-age percentile below 5th percentile for height and no more than 5% at 4th degree or higher, with baseline serum albumin levels below 10 g/L and exclusive oral feeding within 72 hours of hospitalization
  - Description: PDS supplementation in children with acute infections showed significant weight gain.

## 2017
- **Bodas SA, et al.**
  - Population: Children aged 24-72 months
  - Description: Use of PDS and dietetic consumption with antibiotic therapy defined as weight and height below 2.5 standard deviations for age.

## 2018
- **Ninh N, et al.**
  - Population: Children aged 1-10 years diagnosed with growth failure, defined as weight and height below 2.5 standard deviations for age
  - Description: Use of Pediasure and fiber formulas significantly improved growth measures, gastrointestinal symptoms, and symptoms of chronic disease.

## References
STUDIED IN MORE THAN 2,000 INDIVIDUALS
IN MORE THAN 20 CLINICAL STUDIES

Use of PediaSure significantly improved physical growth, and reduced stunting and micronutrient deficiency.7

PDS supplementation in children showed significant improvements in growth in children, even in the first 4 weeks of supplementation.6

PDS plus nutritional counseling promoted catch-up growth for children at risk for growth problems.5

PDS significantly increased caloric intake and weight gain in severely malnourished children.4

PDS with fiber increased weight gain in developmentally disabled children.2

For children recovering from malnutrition, PDS resulted in weight gain and increase in serum proteins. For initial management of acutely ill malnourished children, PDS was positively associated with catch-up growth.1

Use of PDS in the ICU with critically ill children using bedside transpyloric tube placement, allowed children to achieve caloric requirements quickly and without complications.3

INDIVIDUALS IN THE NEW STUDY
CUMULATIVE INDIVIDUALS FROM PAST STUDIES

0 500 1000 1500 2000 2500
NUMBER OF PARTICIPANTS

RAMSTACK  MORALES  FINCH  SHARRET  LAI  TOLIA  CHELLIS  LAI  CASEY  AKRAM  POIRE  FISBERG  ALARCON  VAN AERDE  SCHRZLENMEIR  WILLIAMS  KANSU  GHOSH  FIORE

References:

*Based on published papers and abstracts.