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Meeting Nutritional Needs of the Enterally-Fed Child with Neurological Impairment

Abstract

Introduction: Children with developmental delay and neurological impairment (NI) frequently have gastrointestinal disorders that interfere with oral food intake. For children, enteral tube feedings (EN) are sometimes used. Some parents of tube-fed children seek to provide foods, via feeding tube, they believe are more healthful.

Objective: Primary objective assessed meeting daily calorie goals; secondary objectives assessed meeting protein-intake, formula intolerance, and quantifying adverse events.

Design: A prospective, observational study enrolled children requiring EN. Participants (N=21, 1-13 years) had enteral access via gastrostomy tube; were tolerant of their pre-study EN; and received $\geq 90\%$ of nutritional needs via EN. Study formula (SF), 1.0 kcal/mL, provided 15%, 51% and 34% of calories from protein, carbohydrate and fat, respectively, and contained ingredients from foods such as tomatoes, peas, green beans, peaches, chicken, and cranberry juice. Children received SF for 7 days.

Results: On average, 60% (n=12) of children met at least 90% of calorie goals, and 90% (n=18) met at least 70% of calorie goals, and 90% (n=18) met daily protein goals. All continued EN during entire study interval. Of 160 total feeding days, only 5 days reported adverse events, which were determined by a physician as unrelated or unlikely-related to SF.

Conclusion: The commercially-made, food-based formula tested was a safe, convenient, and nutritionally-balanced enteral feeding for children with NI and associated feeding disorders. Calorie and protein goals were achieved without notable intolerance and no reports of serious adverse events. The SF is a practical, nutritionally-complete, real-food option for enteral feedings in children with NI.

Keywords: Enteral Nutrition, Home care services, Neurologic Disorders, Nutrition, Pediatrics.

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Introduction

Up to 90% of children with developmental delays have some degree of feeding disorder as a result of neurological or neuromuscular impairment, physical anomalies, or sensory and behavioral food aversions [1] Children with neurological impairment (NI) frequently have a gastrointestinal (GI) disorders such as gastro esophageal reflux disease (GERD), dysphagia, or dysmotility, conditions that can interfere with adequate oral food intake [2-4] For children who cannot eat sufficient food safely and

in a reasonable amount of time, enteral tube feedings are usually used [5].

Children with neurodevelopmental disorders differ in their physical capabilities, activity levels, and caloric needs. Individual enteral diets must reflect these differences, providing adequate amounts of protein without excess calories in order to prevent muscle wasting or becoming overweight [6,7] Other health conditions such as constipation and micronutrient deficiencies are also common in these children [8-10] and may require added nutrients or modification of the enteral formula.

Some parents of tube-fed children with NI and associated feeding problems have expressed dissatisfaction with standard commercial formulas (SCF), reporting symptoms of GI intolerance in their child, and a desire to provide foods they believe are more healthful [11-13]. Some parents choose to blenderize food at home for tube feeding (H-BTF). While this allows parents to individualize HEN to meet a child's needs and the parents' preferences, H-BTFs may be time-consuming to prepare and without menu and recipe planning assistance with a registered dietitian nutritionist, H-BTFs may contain inconsistent or incomplete nutritional content [14].

In a growing trend, more commercially-blenderized food mixes and food-based commercial formulas have become available (Figure 1). Made in facilities registered by the Food and Drug Administration (FDA) and in compliance with good manufacturing processes, these food blends are designed as a safe, convenient, and nutritionally balanced alternatives to H-BTFs [15]. Indeed, survey results showed that a quarter to a third of parents interested in food-based enteral feeding are using these formulas some or all of the time [11,14].

Based on these observations, we hypothesized that a commercial enteral formula containing ingredients from real foods can meet estimated nutritional needs of children with neurological impairment without a significant increase in GI intolerance. This paper reports the results of a prospective, observational study of children requiring enteral tube feeding who received enteral formula containing real food ingredients. The primary objective

of the study was to assess the proportion of these children who met daily calorie goals, and the secondary objectives were to evaluate the proportion of these children who met daily protein goals, formula tolerance, irritability and the incidence and nature of adverse events (i.e., safety).

Research Methodology

Study design

This was a single-center, prospective, observational study of tube-fed children. The study was designed to assess how effectively an enteral formula containing real food ingredients met nutritional goals, as well as assessing its safety and tolerance.

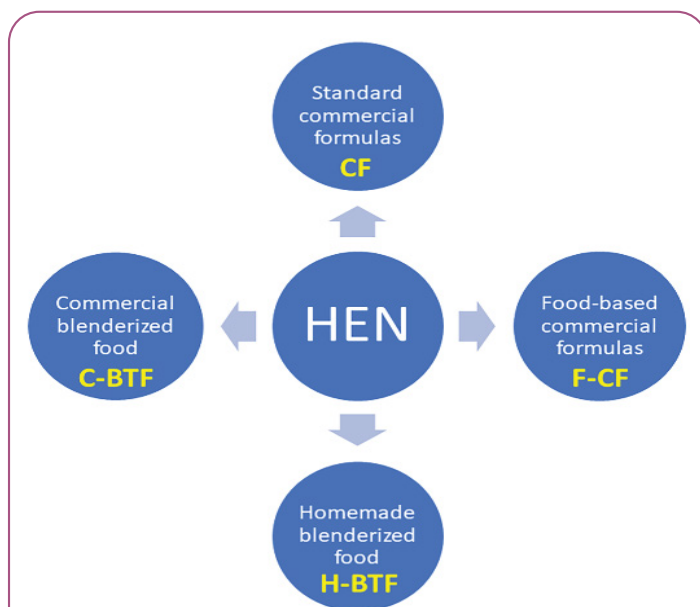
Study participants

To achieve the desired trial size, our goal was to enroll 20 children; 21 were enrolled between April and November 2016. To be eligible for inclusion in the study, children had to be between the ages of 1 and 13 years; have established enteral access via gastrostomy tube (G-tube); be tolerant of their pre-study enteral feeding; and regularly receive 90% or more of their nutritional needs (without the use of modular protein supplements) via enteral tube for at least 9 days. Children were excluded from the study if they had any medical conditions that would prevent enteral feeding into the gut and/or if investigator determined enteral feeding was not appropriate, any condition that would contraindicate use of the study product, such as, food allergies to study formula ingredients, if they were considered at risk for poor compliance to the study protocol, or were participating in another conflicting clinical trial at the time of this trial. We received informed consent from the legal representative for each child enrolled in the trial. Participants were recruited from the outpatient Pediatric GI clinic by the investigator. Since only one formula was offered in this study, the participants were not randomized. Formula was masked with the use of a non-commercial study formula label.

Study procedures

Upon enrollment, the study center's registered dietitian nutritionist (RDN) completed a nutrition assessment to establish calorie and protein needs for each child. The RDN determined pre-study (PSF) and SF prescriptions based on established nutritional goals. The SF was a 1.0 kcal/ml pediatric formula containing ingredients from foods (tomatoes, peas, green beans, peaches, chicken and cranberry juice). It provided 15%, 51% and 34% of calories from protein, carbohydrate and fat, respectively, and 2 g fiber per 250mL of formula (COMPLEAT® PEDIATRIC, Nestlé HealthCare Nutrition, Bridgewater, New Jersey, USA).

Following consent and enrollment, caregivers were given a diary to record daily formula intake of their current enteral formula. Caregivers recorded one day of the child's PSF intake (day -1). Starting on day 0, the children switched to the SF, as prescribed by medical providers, and continued for 7 full days (days 0 to 7). On day 8, the children returned to the clinic for the final study visit. During days 0 to 7, the children were fed exclusively the SF via a feeding tube, according to RDNs prescription. In a daily diary, caregivers logged the quantity of formula consumed;



A range of home enteral nutrition (HEN) feeding options are now possible

- SCF – Standard Commercial Formulas (SCF)
- F-CF – Commercially prepared tube feeds containing more food based ingredients than in CF
- H-BTF – Home-made food, blenderized for tube feeding
- C-BTF – Commercially-prepared food, blenderized for tube feeding (C-BTF)

Figure 1 Enteral tube feeding options for home enteral nutrition (HEN).

tolerance (stool frequency and consistency, incidence of vomiting, flatulence) and incidence of adverse and including serious adverse events. An RDN reviewed non-study enteral and oral intake to ensure compliance with inclusion criteria. Each day, caregivers also rated their child’s level of irritability/mood based on a 5-point scale. A physician determined whether any reported adverse events were related to the feeding of the SF.

Statistical analyses

The study used a convenience sample of children [16]. The analysis is based on 21 children, of whom twenty completed the study and one withdrew early. The children who completed the study were those who consumed an average of at least 90% of calories from the SF over 7 days and received no more than 10% of caloric needs from non-study formula or other foods. Data captured on paper-based case report forms and in each participant’s diary were entered into an electronic database. All data entries were checked for accuracy by a second team member.

Descriptive statistics were used to summarize all study measures. Means, standard deviations, minimum, and maximum values are presented for continuous data, and counts and percentages are presented for categorical data. The summary of demographics, diagnoses, and daily calorie and protein needs at enrollment were based on 21 children, while end-of-study measures (caregivers’ tolerance assessments, percentages of daily calorie and protein intake needs that were met) are reported for the 20 children who completed the study. When a range was provided for nutritional prescriptions or intake measures, the lower end of the range was used for analyses. Some data cleaning was performed on the GI tolerance measures; for example, when a diary entry recorded “No” to experiencing a tolerance measure but also reported a frequency for that measure, a query was issued to the clinic study coordinator to resolve the discrepancy, and the data were updated accordingly. Analyses were conducted using Stata Statistical software, version 15.0, and figures were created using R version 3.3.2 [17].

Ethical approval and informed consent

This study was approved by an Institutional Review Board IRB, (tracking number: NES1-16-164) of an independent group

(Copernicus Group IRB, Durham, NC, USA). The study fulfilled all requirements for human research, including written informed consent and the Declaration of Helsinki and Good Clinical Practice. This trial was registered at ClinicalTrials.gov (identifier: NCT02779335).

Results

Patient characteristics

Twenty-one children fed via G-tube were enrolled; one child was withdrawn early due to a single episode of emesis. Baseline demographics for participants (N=21) show that the mean age of study children was 6.4 ± 3.3 years (range: 2.1, 13.1) at enrollment; other characteristics are reported (**Table 1**). All children had a primary diagnosis of feeding disorder secondary to developmental delay or other neurological disorders.

At the time of enrollment, the reported mean caloric need was 1288 kcal/day (range: 750, 2585) and the mean protein need was 38 g/day (range: 21, 84). Mean fluid intake need was 1,383 mL/day (range: 950, 1840 mLs).

Percent of daily calorie intake met using the study formula

We analyzed the percentages of daily calorie intake met for days 1 through 7 for 20 children (**Figure 2**). On average, 60.0% (n=12) of children met at least 90.0% of calorie goals, and 90.0% (n=18) met at least 70.0% of the calorie goals. Three children exceeded their calorie goal (intake > 110.0%). The overall mean percentage of daily calories met was 94.8% per participant per day (26.0% to 156.0%). Calorie intake was similar with either formula, 1245.5 ± 473.2 (PSF) and 1205.4 ± 451.9 kcal/day (SF).

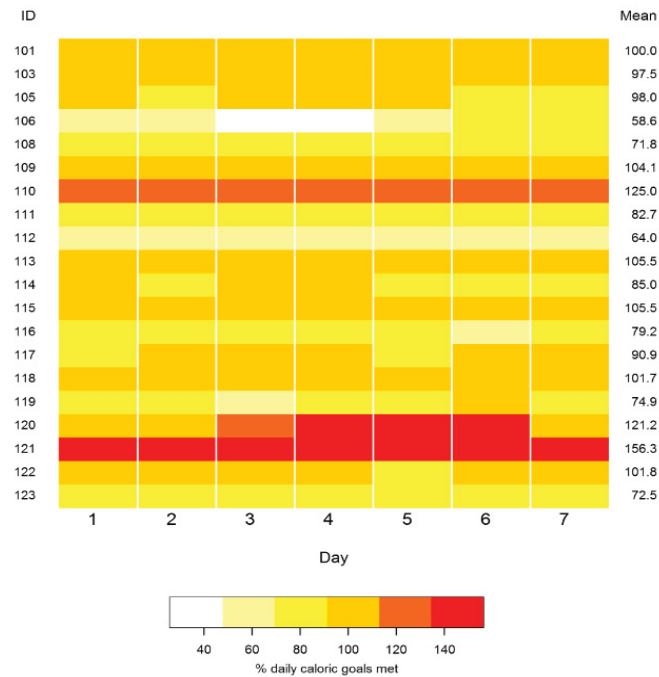
Percent of daily protein intake met using the study formula

We calculated the percentages of daily protein goal met over the course of the study for 20 children (**Figure 3**). On average, 90.0% (n=18) of children met their daily protein goals. The percentage of daily protein goals met ranged from 36.0% to 222.0%, and the overall mean was 130.9% ± 35.8% per child per day. The mean protein intake per day was 39.4 ± 17.3 (PSF) and 48.2 ± 18.1 g/day

Table 1 Characteristics of study children (n=21).

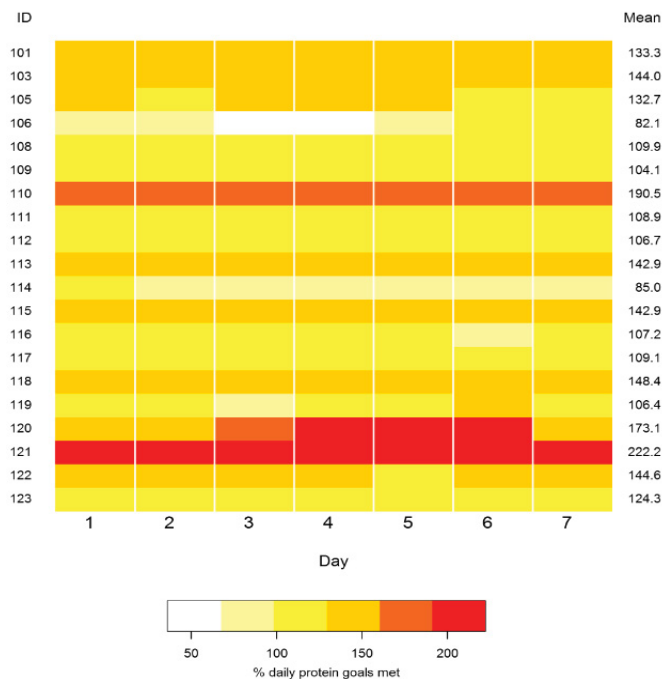
Sex	n (%)	Age and Anthropometrics	Mean ± SD [Min, Max]
Male	12 (57.1)	Age at enrollment (years)	6.4 ± 3.3 [2.1, 13.1]
Female	9 (42.9)	Height (cm)	110.2 ± 21.0 [80, 150]
Diagnoses ^a	n (%)	Weight (kg)	20.6 ± 8.6 [9.5, 36.9]
Developmental delay	19 (90.5)	BMI (kg/m ²)	16.2 ± 2.8 [11.8, 22.6]
Seizure disorder	6 (28.6)	BMI percentile (%) ^b	46.2 ± 39.1 [1, 99]
Trisomy 21	1 (4.8)	Weight for age percentile (%) ^c	35.2 ± 33.2 [0, 89]
Failure to Thrive	4 (19.0)	Height for age percentile (%) ^c	33.1 ± 35.9 [0, 99]
GERD	13 (61.9)	Weight for height percentile (%) ^{c,d}	37.4 ± 38.8 [0, 98]
Constipation	10 (47.6)		

^a Multiple diagnoses may be given to a participant
^b Missing BMI percentile data on one participant
^c Among participants age 10 and under
^d Missing weight for height percentile data on five participants



Note: The percentages of daily calorie goals met by twenty participants are shown in the heatmap over seven days. The participants are shown in rows, and study days are shown in columns. The higher and lower percentages are shown in red and white, respectively, as shown by the color key at the bottom. The mean percentages over seven days for each participant are shown at the right side of the heatmap.

Figure 2 Percentage of daily calorie intake met (N=20).



Note: The percentages of daily protein goals met by twenty participants are shown in the heatmap over seven days. The participants are shown in rows, and study days are shown in columns. The higher and lower percentages are shown in red and white, respectively, as shown by the color key at the bottom. The mean percentage over seven days for each participant is shown at the right side of the heatmap.

Figure 3 Percentage of daily protein intake met (N=20).

Table 2 Caregiver tolerance assessment (n=20).

Caregiver tolerance assessment	Pre-study formula (Based on day -1)	Study formula (Mean of days 1 – 7)
GI Tolerance		
• Number of stools per child per day		
Mean value ± SD	1.3 ± 1.1	1.2 ± 1.0
[Min, Max]	[0,4]	[0,4]
• Stool consistency, percent of stools (%)		
Hard to pass	20.00%	8.00%
Smooth and soft	28.00%	44.40%
Watery	4.00%	2.50%
• Vomiting		
Number of children (%)	19 (95.0)	18.1 (90.7)
• Gas		
Number of children (%)	13 (65.0)	10.6 (52.9)
• Mood		
Number of children (%)		
Happy	11 (55.0)	13.1 (65.7)
Content	8 (40.0)	3.6 (17.9)

GI: Gastrointestinal; SD: Standard Deviation

Table 3 State of the art for pediatric home enteral nutrition.

Which children use enteral nutrition?
• There are nearly 200,000 pediatric patients on home enteral nutrition in the US [30].
• Most are children with developmental delays and feeding disorders due to neurological impairment (NI) or neuromuscular conditions [1].
• Children with NI frequently have feeding and swallowing problems and GI dysfunction that interferes with normal nutrition [1,5].
There is a growing trend towards feeding real foods and their components.
• There is growing evidence that real food in enteral feeds can help improve GI tolerance [11, 19-25]
• Improved tolerance likely results from increased viscosity and from development of a more diverse microbiome, which follows intake of varied nutrients and fiber in a diet based on real foods [22].
Home-made FB-HENs are not convenient to prepare, and nutrition quality can vary.
• Preparation is time-consuming [13,27].
• Only 50% of parents report receiving recipe guidance from an HCP [11,31].
• Nutrition can be inconsistent day to day; with lower nutrient reserves, children are more sensitive to calorie and macronutrient shortfalls than adults [32].
• To ensure optimal intake of macro- and micronutrients, nutrition guidance and monitoring is advised [4,5,32].
• Many RDNs report feeling unprepared to offer recipes for home-made BTF [11,28].
Abbreviations: US, United States; GI, gastrointestinal; RDN, registered dietitian nutritionist.

(SF). Fifteen (75.0%) children received at least 90.0% of protein goals without exceeding 110.0% of their calorie goals.

Gastrointestinal and adverse events

The results of gastrointestinal tolerance assessments based on the twenty caregivers' reports are summarized (**Table 2**). The mean number of stools per child per day for PSF and SF was unchanged, with a 20.0% decrease in mean number of hard-to-pass stools and reports of flatulence. Watery stools and reports of vomiting remained unchanged. Out of 20 children, five experienced at least one gastrointestinal adverse event on one day of the study (5 days of 160 total study feeding days). These adverse events, however, were either unrelated or unlikely to be related to the SF based on medical provider assessments. For all children, tube feedings were continued through the entire study interval. As noted previously, one child was withdrawn early due to a single episode of emesis.

Discussion

For children who have feeding disorders and require enteral nutrition, our study results demonstrate that a commercial enteral formula that includes ingredients from foods, including fruit and vegetables, can meet calorie and protein goals without increasing adverse events. In fact, a majority of these children (60%) met their estimated daily protein goals without exceeding calorie needs, meaning the SF met their needs efficiently and effectively.

SCFs, widely used since the 1970's, have improved the nutritional status and quality of life of many children, including those with NI [12,13,18]. However, SCFs have limitations. They are associated with GI intolerance in some children, may lack fiber and certain nutrients derived from fruits and vegetables, and do not accommodate parents' growing interest in providing "normal" food to their tube-fed children [11-13]. Furthermore, children

with NI who are fed SCF may not obtain sufficient amounts of certain micronutrients because they are unable to consume quantities of standard enteral formulas to deliver appropriate levels of micronutrients as they are designed for the caloric requirements for healthy children [4,5]. Furthermore, because SCF is formulated for healthy children, a child with NI and lower activity may not be able to consume enough SCF to receive adequate levels of certain micronutrients.

There is a small but growing body of evidence that enteral formulas with real food ingredients are safe and can help improve GI tolerance compared to SCF [11,19-25]. Some parents of children who have transitioned to H-BTF report fewer symptoms of tube feeding intolerance (reflux, gagging, diarrhea, and constipation) [26]. Such H-BTF-fed children also met nutrient or growth goals, though to do so typically required feeding greater volumes of BTF compared to SCF [11,21,22] (**Table 3**).

Nutrition experts suggest several possible mechanisms for improved GI tolerance. These include increased viscosity of the feed that, like thickened commercial formula, [5] helps reduce regurgitation and aspiration pneumonia; and improved dietary diversity which contributes to microbial diversity [22]. Indeed, a recent prospective study of GI health in medically-complex children found stool-bacteria diversity was improved when the children transitioned from SCF to H-BTF [21]. In another study of 70 children requiring tube feeding, those who consumed home-made or commercially-prepared BTF received identical caloric and micronutrient profiles to children who were fed SCF, with the exception of vitamin D [22]. Followed for a year, the BTF-fed children had less abdominal pain and fewer GI symptoms compared to the SCF-fed children, and significantly fewer visits to the emergency room (43%), fewer hospital admissions (53%), and fewer admissions for respiratory issues (67%) [22].

For families, however, use of H-BTF presents challenges

Preparation can be labor-intensive, blends must be served within 2 hours of preparation, and enteral feeding tubes can become clogged by small food pieces [11,14]. Caregivers must take into

account any special food needs, food allergies, and the day-to-day variability of the blend's nutritional content and/or the child's physical activity while making sure their child receives adequate—but not excess—fluid and macro- and micronutrients as they grow [27]. Despite the complexity of preparation, only half of parents undertaking this task had help with recipes from a healthcare provider (HCP) [11]. Furthermore, a survey found parents and HCPs had a hard time finding a local pediatric RDN to provide recommendations in H-BTF preparation, and nearly 30% of RDNs reported feeling the need for more training [28]. Results of a recent study showed that with guidance, H-BTF could be prepared safely in home environments [29].

Our study had some limitations. Due to its relatively short duration (7 study-feeding days), we were unable to evaluate the long-term effects of the SF on growth and development. While a majority of children (60%) met 90% of their calorie goal, not all of them did. Nevertheless, this and a previous study [24] suggest that a commercial formula made with real food can be an option to address malnutrition caused by feeding disorders in children. Also limiting our study was that all children were recruited from a single center, and the possibility of increased variability in the measures studied (i.e., formula intake, tolerance, mood, adverse events) since it was reported by caregivers rather than by centralized, trained study personnel [30-32].

Conclusion

In conclusion, the commercially-made, enteral nutrition formula with food ingredients tested is a safe, convenient, and nutritionally-balanced solution for children with feeding disorders secondary to developmental delay and NI. The formula met calorie and protein goals without notable intolerance in children and with no reports of serious adverse events. It is a practical, nutritionally-complete, real-food option for parents who are unable to prepare home-made BTF. It is also appropriate option for quick meals or as a portable out-of-home option in settings away from refrigeration, or where there are limitations to providing home-made blenderized tube feedings, such as when a child is at school.

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