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The Impact of a Low Energy Partially Hydrolysed Enteral Formula on Feeding Experiences in Children Tube Fed with Neuro-Disabilities: National Multicentre Retrospective Study

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Abstract

Background and Aims: To monitor the effectiveness of a low energy partially hydrolysed enteral formula on weight management and feed tolerance in tube fed children with a neuro-disability.

Methods: Retrospective, multicentre study to monitor anthropometric and health economics outcomes in children who had switched to Peptamen® Junior 0.6 (Nestlé Health Science).

Results: Dietitians collected data from 17 children, the median age of children who had switched to a low energy partially hydrolysed enteral formula was seven years old (IQR 3, 8). The most frequently recorded neuro-disability was cerebral palsy, 8 of 17 children (48%). The primary mode of nutrition delivery was via a gastrostomy (94%). After one month switching to a low energy partially hydrolysed formula both weight (kg) and BMI Z-scores stabilised. 80% of families reported an improvement in feeding intolerance symptoms and 81% reported children's feeding regimen simplified after switching formula.

Conclusion: Children with a neuro-disability who have feeding intolerances may benefit from a low energy hydrolysed enteral formula to maximise tolerance and minimise excess weight gain; eliminates the need for additional electrolytes, multivitamins, and fluid boluses. Healthcare professional should be knowledgeable of the effectiveness and availability of low energy, nutritionally complete formulas for tube fed children with neuro-disabilities.

Keywords: *Nutritional Support; Enteral Nutrition; Neuro-Disability; Low Energy Enteral Formula; Children*

Highlights:

- A low energy partially hydrolysed enteral formula may promote weight control and optimise feed tolerance in tube fed children with neuro-disabilities.

- Switching to a 'Ready to Feed' low energy partially hydrolysed enteral formula may simplify overly complicated feeding plans in tube fed children with neuro-disabilities.
- Healthcare professional should be knowledgeable of the effectiveness and availability of low energy, nutritionally complete formulas for tube fed children with neuro-disabilities.

Introduction

The prevalence of children with complex neuro-disability has increased due to advances in the medical management of preterm infants and improved care for children with severe neurological impairment [1]. Neuro-disability covers a wide range of clinical conditions, including acquired brain injury, epilepsy and learning disability. Neuro-disabilities present a significant disease burden for the child and family, with the focus for families to promote the best possible participation in life for all affected [2].

Children with neuro-disabilities can be significantly disadvantaged in their ability to nourish themselves due to poor hand to mouth motor coordination, along with disordered swallowing, resulting in aspiration of food in the lungs. The length of feeding time may be considerably increased and instead of mealtimes being an enjoyable experience, they are distressing for both child and carer. These impairments in feeding eventually lead to undernutrition and invariably children require a feeding tube to ensure nutritional requirements are met [3].

Although tube feeding improves overall nutritional status, it has also been associated with an excess deposition of body fat compared with typically developing children. Children with neuro-disability are at risk of becoming overweight because of their low activity and psychosocial constraints [4]. Additionally, children with a neuro-disability tend to grow slowly for non-nutritional reasons and have altered body composition due to underdeveloped skeletal muscle. Children are more likely to be overweight and tend to have low lean muscle mass - therefore a low BMI in this group does not necessarily imply low fat stores [5]. Efforts are needed to protect severely disabled children from overfeeding and to help families of children with neuro-disabilities to manage their child's weight [6].

Children with neuro-disabilities who are fed to 80% of their estimated average energy requirements have reported a positive energy balance resulting in high body fat mass [7]. Of note, any attempt to dilute the existing proprietary feeds to reduce the calorie intake to a level commensurate with the energy expenditure of a child with a disability is likely to have an adverse impact on micronutrient and protein intake [8].

The clinical nutrition industry has responded to this need and developed commercially available enteral formulas that are low in energy but nutritionally adequate for protein and micronutrients, essential for developing children who are reliant on enteral formula to supply a major proportion of their intake [8]. Additionally, feed tolerance is generally worse in children with neuro-disabilities, associated with comorbidities including epilepsy, posture and tone disorders, and medications used for the treatment of these conditions can further exacerbate gastrointestinal function [9].

Common feed related symptoms associated with neuro-disabilities include vomiting, retching, pain associated with feeding - feed-induced dystonia, constipation, and gastrointestinal dysmotility [10].

Aim of the Study

The aim of this national multicentre retrospective study was to monitor the effectiveness of a low energy hydrolysed enteral formula on weight management, feed tolerance and health economics in children with a neuro-disability.

Materials and Methods

Study design

This is a retrospective, multicentre study that monitored weight change and feed tolerance in children who have switched to Peptamen® Junior 0.6 (Nestlé Health Science), a nutritionally complete low energy (0.6 kcal per 1 ml), partially hydrolysed peptide-based whey

protein, containing, omega-3 fatty acids, fibre (0.8g per 100 ml) and 35% of the fat as medium chain triglycerides. Ethical approval was granted by the Health Research Authority and Health and Care Research Wales 21/HRA/1346-2296700.

The study was conducted from January 2021 to August 2022 across two National Health Service Trusts: one tertiary centre and one district general community hospital. Children were included in the study if they had switched to a low energy partially hydrolysed enteral formula because of previous feed tolerance issues related (retching, vomiting, flatulence, and/or abnormal stool consistency and frequency) or to simplify their current feeding regimen. Children had to have been receiving the low energy partially hydrolysed enteral formula for at least one month, and the enteral formula must have accounted for at least 80% of their total energy requirements. All eligible children were aged between 1 and 17 years old.

Data were collected by paediatric dietitians from dietetic and medical records and inputted to a Microsoft form to capture anthropometric and gastrointestinal outcomes over a month-long period when children were switched to a low energy partially hydrolysed enteral formula. Information was also collected on perceived risk factors associated with being overweight including pressure sores and physical activity level. A link to the Microsoft forms was sent to each site by the clinical research company, Ixia Clinical Ltd. Once the Microsoft forms were completed by the dietitian, forms were automatically sent to Ixia Clinical Ltd. Data were compiled to represent all sites and downloaded into an Excel sheet for analysis performed by an independent statistician.

Clinical dietetic documentation on feeding tolerance was measured as either improved, no change, or worsened and on key markers of tolerance (gastro-oesophageal reflux, retching/ gagging, vomiting, and stool consistency). Stool consistency is a central component in the description of normal or altered bowel habit. Physical examination of stool can be considered as a proxy measure for stool consistency and refers to the shape and apparent texture of the stool, which can be assessed visually. Stool form scales are a standardized and inexpensive method of classifying stool into a finite number of categories that can be used by families and healthcare professionals. The Bristol Stool Scale is a visual stool form scale; the ideal stool is generally type 3 or 4 and easy to pass without being too watery. Types 1 and 2 indicate constipation, whereas types 6 and 7 indicate loose stools [11].

Constipation was defined as Rome IV Criteria, less than three defecations a week, and painful and hard stools [12]. Diarrhoea was defined as more than one loose stool a day lasting longer than 7 days [13]. Reflux was defined as parental observation of the passage of gastric contents into the oesophagus causing regurgitation, posseting, or vomiting, which leads to troublesome symptoms that affect daily functioning [14]: The nutrition status (weight for age and height for age) was assessed using Z-scores [15]. Moderate overweight was identified if Z-scores were between +2 and +3 standard deviation (SD) and severe overweight was identified if the Z-scores were above +3 (SD) [16]. Conversely, moderate underweight was identified if z-scores were between -2 and -3. Measurement of height or length is essential in the assessment of nutritional status. However, in some conditions, for example cerebral palsy (CP), such measurements may be difficult and inaccurate and must be factored when interpreting [17]. Energy requirements were calculated on reduced activity at 80% of estimated average requirements [18].

Statistical analysis

Normally distributed continuous variables are expressed as means ± standard deviations, while medians and interquartile ranges (IQR) are used to describe non-normal distributions. Descriptive statistics of between-group differences in subject anthropometric characteristics were tested for significance using two-sided paired t tests. A P-value < 0.05 was deemed statistically significant. Statistical analysis was performed with SPSS software (version 23; IBM SPSS Statistics, Armonk, NY, USA).

Results

Data was collected on 17 children in this national multicentre, retrospective study. Demographic and baseline anthropometric data are provided in table 1. The median age of children who had switched to a low energy partially hydrolysed enteral formula was 7 years old

(IQR 3, 8). The most frequently recorded neuro-disability of children who had switched to the new enteral formula was cerebral palsy, 8 of 17 children (48%). The primary mode of nutrition delivery was via a gastrostomy feeding tube: 16 of 17 children (94%) with one child was feeding via a jejunostomy. Nearly half of the children (7 of 17) were on a whole protein formula prior to switch to low energy partially hydrolysed formula (Table 1).

Characteristic	
Gender, n (%)	
Female	7 (41%)
Male	10 (59%)
Age, years, median (IQR)	7.3 (3, 8)
Weight, kg, median (IQR)	24 (13, 34)
Height, cm, median (IQR)	112.5 (92, 120)
Ethnicity, n (%) Asian or Asian British White or White British Middle Eastern Black British African	 8 (47%) 6 (35%) 2 (12%) 1 (6%)
Neuro-disability Diagnosis, n (%)	
Cerebral palsy	8 (48%)
Mitochondrial disease	6 (35%)
Seizure related	3 (17%)
Feed Formula Prior to switch, n (%)	
Whole Protein (1kcal/ ml)	7 (41%)
Hydrolysed protein (1kcal/ ml)	7 (41%)
Amino Acid based	3 (18%)
Mean feed volume, ml, excluding water boluses (IQR)	833 (700,950)

Table 1: *Demographic, anthropometric, and diagnostic characteristics of study participants*
Abbreviation: IQR: Interquartile Range.

The baseline mean weight and BMI Z-scores were bordering the moderate overweight category at 1.79 (1.7 SD) and 1.93 (0.95 SD), respectively. After one month switching to a low energy partially hydrolysed formula both weight and BMI Z-scores decreased to 1.3 (0.6SD) and 1.82 (1.2SD), there was no statistically significant difference in weight, or BMI Z-scores post switch of formula (p-value 0.1 and 0.09, respectively) (Table 2).

Anthropometrics	Baseline Mean (SD)	One month after feed change Mean (SD)	P-value (95% Confidence Interval)
Weight, kg	24.81 (11.92)	24.29 (11.84)	0.07 (-0.04 - 1.09)
Weight Z-score	1.38 (0.76)	1.30 (0.6)	0.1
Height, cm	107.53 (21.28)	108.25 (20.85)	0.17 (-1.79 -0.33)
Height z score	-0.85 (1.0)	-0.80 (0.8)	0.4
Body Mass Index (BMI)	20.21 (4.51)	18.96 (4.49)	0.068 (-0.45 - 6.93)
BMI Z-score	1.93 (0.95)	1.82 (1.2)	0.09

Table 2: *Anthropometric characteristics before and after enteral formula was switched to a low energy partially hydrolysed formula (N = 17).*

Fifteen children were switch to a low energy partially hydrolysed formula due to feeding intolerance. Twelve out of 15 (80%) children reported an improvement in one feeding intolerance symptom after feed was switched (Table 3). The number of children who reported an improvement in constipation was 6 out of 8 children (75%). Improvements in feed tolerance after switch also reported in vomiting, reflux and abdominal distension/pain (Table 3).

Symptom	Reported number with symptoms before switch, n (%)	Reported number with symptoms after switching formula n (%)	Improvement rate (%)
Vomiting, n (%)	2 (11)	0	100
Reflux, n (%)	1 (6)	0	100
Retching/ gagging, n (%)	1 (6)	0	100
Constipation, n (%)	8 (47)	2 (12)	75
Abdominal distention/ pain on feeding, n (%)	3 (17)	1 (6)	66

Table 3: *Dietitians who reported benefits in feed intolerance symptoms when children switched to a low energy partially hydrolysed formula (N = 17).*

The number of children whose feeding regimens simplified after switching to a low energy partially hydrolysed formula was 14 of 17 (81%). Of which, six children's feeding regimen had been simplified by removing additional nutritional supplements (oral rehydration solution and/or multivitamins), with a further six children's hydration regimen simplified by reducing the need for additional water boluses (Table 4). The mean feed volume (excluding water boluses) before switch was 833 ml (IQR 700, 950) compared to post switch 1017ml (800, 1300), p-value 0.03.

Other perceived outcome benefits associated to the simplification of feeding plans along with weight reduction after switching to a low energy partially hydrolysed formula included: easier to physically transfer child, reduced risk of pressure sores and increased physical activity (Table 4).

A case study has been devised for one of the children who switched from an amino acid formula with added multivitamin and oral hydration solutions to a low energy hydrolysed formula to illustrate the health economic implications for reducing time to prepare feed recipe (Total savings per year = 212 hours) and cost savings (Total savings per year = £3931) (Table 5).

Clinical Outcome	
Simplified feeding regimen, n (%)	
Hydration regimen - Less water boluses	6 (35%)
Feed preparation - removed additional supplements (oral hydration solution and/ or multivitamin)	6 (35%)
Switch from powder to 'Ready to Hang' formula	2 (11%)
Easier to move/ transfer patient, n (%)	14 (82%)
Reduce risk of obesity, n (%)	
Weight gain slowed/ stabilise	11(64%)
Weight reduction	2 (12%)
Perceived reduced risk of pressure sores, n (%)	11 (64%)
Reduced feeding preparation increased time for physical activities/ play, n (%)	13 (76%)

Table 4: *Dietetic clinical assessment of reported impact of switching to a low energy partially hydrolysed formula simplified N = 17.*

Discussion

Children with complex neuro-disabilities are unable to meet all their nutritional requirements orally and may require a feeding tube. Children tube fed with neuro-disabilities can become overweight due to reduced energy requirements. In our study we assessed the association between a low energy partially hydrolysed formula on weight trajectory and feed tolerance. Children who switch formula slowed their weight gain trajectory. Furthermore, our study found that the low energy formula was well tolerated from a feeding perspective and families reported feeding regimens were more simply after switching formula, eliminating the need for additional fluid boluses and modular nutrients (electrolytes and multivitamin) to meet micronutrient and fluid requirements.

The children recruited to our study were overweight but reassuringly weight maintenance was achieved when children switched to a low energy partially hydrolysed formula. Our findings support those of Vernon-Roberts., *et al*. (2010) who investigated whether healthy weight gain could be achieved without an adverse effect on body composition by using a low energy (whole protein) formula in gastrostomy fed children with neuro-disabilities. The team concluded that children with severe neuro-disabilities who are fed a low-energy, micronutrient-complete formula continue to grow even with energy intakes below 75% of the estimated average requirements. This was not associated with a disproportionate rise in fat mass, and micronutrient levels remained within the reference range [8].

The importance of controlling weight gain in this cohort of children has been outlined by Pascoe., *et al.* (2016) who performed a retrospective study of 587 children with cerebral palsy. The team concluded that 19% of ambulant children with cerebral palsy were overweight or obese, which is of concern as BMI may impact on the outcomes of surgical intervention and rehabilitation [5]. Furthermore, a study by Barja., *et al*. (2020) delved deeper to explore the associated complications of obesity (dyslipidaemia and hyperinsulinemia) in children with neuro-disabilities. The team reported that the frequency of cardiometabolic risk factors was high in their sample of paediatric patients with cerebral palsy, associated with overweight and low mobility. The team propose a BMI > 75th percentile as a cut-off point for metabolic risk factors [19]. However, Duran., *et al*. (2018) assessed the diagnostic performance of BMI cut-off values to identify excess

Health Economic Category	Cost Breakdown		Cost Saving
Financial (As of January 2023 – pound sterling [£])	**Baseline Formula Recipe** 3 x 100g Amino Acid Formula Sachets = £28 per day 20g multivitamin powder = £2.30 per day 1 sachet of rehydration solution = £0.50 per day 3 x 200ml water boluses Total cost = £30.80 per day **Accessories**: 1500ml Feed reservoir container = £4 per day Total cost for feed and accessories = £34.80 per day	**Post Switch feed recipe** 3 x 500ml 'Ready to Hang' bottles Peptamen Junior 0.6 Total cost = £24 per day	Cost difference between before and after formula switch = £10.80 per day Total savings per week = £75.60 Total savings per year = £3931
Disease Burden on Family (Time minutes/ hours)	Reduce time to prepare recipe post formula change = 20 minutes/ day Reduce time for additional water boluses = 15 minutes/ day		Total savings per week = 4 hours Total savings per year =212 hours

Table 5: *Case study: Health economic implications of simplifying feeding plan by switching from an amino acid formula to a low energy partially hydrolysed formula in a 9yr old female with cerebral palsy who was exclusively tube fed.*

body fat in children with cerebral palsy and found BMI showed high specificity, but low sensitivity in children with cerebral palsy. Thus, 'normal-weight obese' children were overlooked, when assessing excess body fat only using BMI [20].

Our study reported that 76% of families felt they had more time to dedicate to physical activity/ play after switching to the low energy partially hydrolysed formula, which was largely attributed to simplifying children's feeding regimen. Physical activity level along with nutritional modification are essential components when considering weight management in this cohort of children with neuro-disabilities. Of note, the British Academy of Childhood Disability - James Lind Alliance research priority setting partnership, which brings together

patients, carers and clinicians as equal stakeholders to decide on future research, highlighted physical activity as one of their top 10 priorities [21]. However, Lauruschkus., *et al*. (2012) highlights the importance of careful consideration when planning interventions for increased physical activity in children with CP, as the individual prerequisites differ, even among children with the same gross motor function level [22].

An interesting and unexpected observation identified from our study were the unnecessarily complex feeding regimens, which consisted of additional nutritional supplementation in a bid to reduce total energy intake to avoid overfeeding; whilst meeting essential micronutrient requirements. This practice from well-meaning health professionals meant overly complicated feeding plans were incorporated to the already busy lives of parents caring for children with neuro-disabilities. Dietetic practices observed included significant reduction in total feed volumes or dilutions, which then require the addition of oral hydration solutions to meet electrolytes deficiencies. Similarly, additional multivitamins were added to feeding plans to account for the loses from the feed volume reduction/dilution. To further complicate matters, the reduction in feed volume meant additional fluid blouses were incorporate to meet hydration needs.

Meeting the micronutrient requirements of these child is of valid concern, especially when you consider the micronutrient status of children with neuro-disability in relation to bone health. Low bone mass in children with cerebral palsy means increased bone fragility and therefore maximising peak bone mass during childhood is vital [23], especially when you factor in lower levels of physical activity, which further contributes to the long-term negative health consequences of poor bone mineral density.

Although not specifically measured in this study, simplifying the feeding plan by switching to a 'ready to feed', nutritionally complete low energy enteral formula, thereby reducing time dedicated to feed preparation and administration, may have had an impact on the quality of life for families caring for children with neuro-disabilities; the presence of an individual with disability in a family affects the whole family [24]. Families of individuals with neuro-disabilities experience increased psychological anxiety and financial problems [25]; specifically, parents feel time pressured and struggle to maintain their social and cultural activities [26].

Limitations of the Study

The limitations of this study include its small sample size; therefore, results are ungeneralizable and rather than stating causation, we can only allude to a potential association of a low energy partially hydrolysed enteral formula with weight management and reduced associated risks of obesity. Other limitations include short trial period, and retrospective design. However, a strength of the study was its national, multi-centre design and that data gathering was from dietitians at different clinical settings.

Summary

In summary, children with neuro-disabilities who have low energy expenditure coupled with feed intolerances may benefit from a low energy hydrolysed enteral formula to minimise risk of excessive weight gain, further compromising mobility. Additionally, implementing a low energy hydrolysed 'ready to feed' formula may beneficially impact health economic outcomes by simplifying the feeding regimens - eliminating the need for additional fluid, electrolytes and multivitamins, thereby, reducing time and financial cost attributed to feeding. Healthcare professionals should be knowledgeable of the effectiveness and availability of low energy, nutritionally complete formulas for tube fed children with neuro-disabilities.

Statement of Authorship

Graeme O'Connor and Sharan Saduera contributed to the conception and design of the research and drafted the manuscript. Zoltan Hartfiel Capriles contributed to the statistical analysis of data. All authors agree to be fully accountable for ensuring the integrity and accuracy of the work and read and approved the final manuscript.

Conflict of Interest

Graeme O'Connor and Martha Van Der Linde received payment per participant recruited from Nestlé Health Science UK during the conduct of the study. The statistician Zoltan Hartfiel Capriles received payment from Nestlé Health Science UK for the sub analysis. S. Saduera is a Medical Affairs Dietitian and employed by Nestlé Health Science UK.

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