

NUTRITIONAL RESEARCH IN COLLABORATION WITH THE NHS

A SELECTION OF RECENT ABSTRACTS

Generating new evidence to demonstrate
the role of nutrition support in optimising
patient and health economic outcomes

**Intended for Healthcare
Professional use only**



This is a small selection of recent abstracts from research which the Nutricia UK Clinical Research Team has conducted in collaboration with NHS healthcare professionals, external experts, and academics.

Nutricia award a research grant annually to those who wish to investigate the role of nutrition in the management of various diseases and conditions, including disease related malnutrition, allergy, inherited metabolic disorders, faltering growth and more.

We also run numerous clinical trials each year, in collaboration with NHS healthcare professionals, to support the launch of new medical nutrition products. If you are interested in collaborating with Nutricia in conducting research, please contact a member of the UK Clinical Research Team at: ukclinicalresearch@nutricia.com.



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CONTENTS

Disease Related Malnutrition	
A multi-center prospective study of plant-based nutritional support in adult community-based patients at risk of disease-related malnutrition	7
A systematic review and meta-analysis of the effects of community use of oral nutritional supplements on clinical outcomes	8
Adults with impaired gastrointestinal function show improvements in gastrointestinal symptoms and protein intake with a high-protein, peptide-based oral nutritional supplement	9
Economic Impact of Implementing Malnutrition Screening and Nutritional Management in older adults in General Practice	10
Low volume energy dense oral nutritional supplements improve micronutrient intakes in free living malnourished older people – A randomised trial	11
GP patient databases show that malnutrition is under-reported and undertreated in patients with chronic disease	12
Enteral Tube Feeding	
Effects of a plant-based high energy and protein enteral tube feed in home enterally tube fed patients: results from a 6-month single-arm intervention trial	13
A plant-based high energy and protein enteral tube feed is highly tolerated, complied with and accepted, and decreases feeding time per day in home enterally tube fed patients	14
Appropriate handling and storage reduce the risk of bacterial growth in enteral feeding systems reused within 24 hours	15
Compliance and tolerance of a ready-to-use, low calorie, low volume, high protein modular feed in patients with increased protein needs	16
Critically ill patients with and without SARS-CoV-2 better achieve energy and protein targets with a high-energy, high-protein peptide-based enteral tube feed; insights from a multicentre clinical audit performed during the COVID-19 pandemic	17
Evaluation of a new enteral feeding tube nurse clinic at the Weston Park Hospital Radiotherapy department	18
Increased protein intake is associated with improved hand grip strength and quality of life in home enterally tube fed adults using a high-energy, high-protein feed	19

CONTENTS

Enteral Tube Feeding	
Complex Enterally Tube-Fed Community Patients Display Stable Tolerance, Improved Compliance and better Achieve Energy and Protein Targets with a High-Energy, High-Protein Peptide-Based Enteral Tube Feed: Results from a Multi-Centre Pilot Study	20
A survey of bolus tube feeding prevalence and practice in adult patients requiring home enteral tube feeding	21
Cow's Milk Allergy	
Synbiotic containing extensively hydrolyzed formula improves gastro-intestinal and atopic symptom severity, growth, caregiver quality of life, and hospital-related healthcare use in infants with cow's milk allergy	22
Improved clinical outcomes with an amino acid formula containing synbiotics in infants with cow's milk allergy	23
The clinical burden of cow's milk allergy in early childhood: A retrospective cohort study	24
Amino acid formula containing synbiotics in infants with cow's milk allergy: A systematic review and meta-analysis	25
The Use of an Amino Acid Formula Containing Synbiotics in Infants with Cow's Milk Protein Allergy—Effect on Clinical Outcomes	26
The use of amino acid-based nutritional feeds is effective in the dietary management of pediatric eosinophilic oesophagitis	27
The use of amino-acid formulas in the dietary management of infants with food protein enterocolitis syndrome: a literature review	28
Faltering Growth	
Effect of oral nutritional supplements on clinical outcomes in children with faltering growth: A systematic review and meta-analysis	29
A survey of the use of bolus tube feeding in paediatric patients receiving home enteral tube feeding in the UK	30
A third of paediatric home enterally tube fed patients receive low energy feeding regimens: results of a UK survey	31

CONTENTS

Inherited Metabolic Diseases	
Evaluation of a new 'Mix-In' style Glycomacropeptide-based protein substitute for food and drinks in patients with Phenylketonuria and Tyrosinemia	32
Evaluation of a new Glycomacropeptide-based protein substitute in powdered and liquid format in patients with PKU	33
New condition-specific protein substitutes demonstrate good acceptability with improved compliance, stable tolerance and metabolic control in children and adults with HCU, MSUD and TYR	34
Nutritional and metabolic characteristics of UK adult phenylketonuria patients with varying dietary adherence	35
Improved eating behaviour and nutrient intake in noncompliant patients with phenylketonuria after reintroducing a protein substitute: observations from a multicentre study	36
A Glycomacropeptide based protein substitute helps promote stable blood phenylalanine and branched chain amino acids in patients with phenylketonuria	37
Other	
A cross-sectional survey of patients prescribed elemental feed in the UK	38
A survey of dietetic opinions and views on the use of an elemental feed in clinical practice in the UK setting	39
Benefits of use of human milk fortifier in preterm infants in the community practical experience from a case study series	40
Minor reformulations of infant FSMPs due to EU regulations 2016/127 & 2016/128 are well tolerated, accepted, complied with and continue to support growth in infants & children requiring nutrition support	41
A ready to use, nutritionally complete, medium chain triglyceride (MCT)-rich, 2.5:1 ratio liquid feed increased MCT intake, allowing for a high protein intake, and improves seizure outcomes in patients with refractory epilepsy	42
Notes	43

ABSTRACTS

A MULTI-CENTER PROSPECTIVE STUDY OF PLANT-BASED NUTRITIONAL SUPPORT IN ADULT COMMUNITY-BASED PATIENTS AT RISK OF DISEASE-RELATED MALNUTRITION

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Published in *Frontiers in Nutrition*, (2023) Vol 10

Introduction:

There is an emerging need for plant-based, vegan options for patients requiring nutritional support.

Method:

Twenty-four adults at risk of malnutrition (age: 59 years (SD 18); Sex: 18 female, 6 male; BMI: 19.0kg/m² (SD 3.3); multiple diagnoses) requiring plant-based nutritional support participated in a multi-center, prospective study of a (vegan suitable) multi-nutrient, ready-to-drink, oral nutritional supplement (ONS) [1.5kcal/mL; 300kcal, 12g protein/200mL bottle, mean prescription 275mL/day (SD 115)] alongside dietary advice for 28 days. Compliance, anthropometry, malnutrition risk, dietary intake, appetite, acceptability, gastrointestinal (GI) tolerance, nutritional goal(s), and safety were assessed.

Results:

Patients required a plant-based ONS due to personal preference/variety (33%), religious/cultural reasons (28%), veganism/reduce animal-derived consumption (17%), environmental/sustainability reasons (17%), and health reasons (5%). Compliance was 94% (SD 16). High risk of malnutrition ('MUST' score $\geq$ 2) reduced from 20 to 16 patients ($p=0.046$). Body weight (+0.6 kg (SD 1.2), $p=0.02$), BMI (+0.2 kg/m² (SD 0.5), $p=0.03$), total mean energy (+387 kcal/day (SD 416), $p<0.0001$) and protein intake (+14 g/day (SD 39), $p=0.03$), and the number of micronutrients meeting the UK reference nutrient intake (RNI) (7 vs. 14, $p=0.008$) significantly increased. Appetite (Simplified Nutritional Appetite Questionnaire (SNAQ) score; $p=0.13$) was maintained. Most GI symptoms were stable throughout the study ($p>0.06$) with no serious adverse events related.

Conclusion:

This study highlights that plant-based nutrition support using a vegan-suitable plant-based ONS is highly complied with, improving the nutritional outcomes of patients at risk of malnutrition.

A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE EFFECTS OF COMMUNITY USE OF ORAL NUTRITIONAL SUPPLEMENTS ON CLINICAL OUTCOMES

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Published in *Ageing Research Reviews*, (2023) Vol. 88, 101953

Introduction:

The impact of oral nutritional supplements (ONS) on patients with complications (disease related morbidity) requires further exploration.

Method:

This systematic review included 44 randomised controlled trials (RCT) (29 RCT surgical, 15 RCT medical patients) examining the effect of ONS in community settings on the incidence of complications (n = 716, mean age 67 years, range 35–87).

Results:

ONS (mean intake 588kcal/day, range 125–1750; protein 22g/day, range 0–54; mean energy from protein 22%, range 0–54) were prescribed for a mean 74 days, range 5–365. Most RCT (77%) reported fewer complications in the ONS group versus control. Meta-analysis (39 RCT) showed ONS consumption reduced complications including infections, pressure ulcers, wound and fracture healing (OR 0.68, 95% CI 0.59,0.79; p<0.001). Results showed reductions when ONS were used in hospital and community settings (OR 0.72, 95% CI 0.59,0.87; p = 0.001) or just in the community (OR 0.65, 95% CI 0.52, 0.80; p<0.001). Reductions in complications were only seen with high ONS adherence ≥ 80% (OR 0.63, 95% CI 0.48,0.83; p = 0.001) and ready-to-drink ONS (OR 0.69, 95% CI 0.60,0.81; p<0.001).

Conclusion:

This systematic review and meta-analysis show community-based use of ONS in addition to the diet substantially reduces the incidence of complications. The diversity of ONS, patient populations and complication outcomes within the trials included in this review mean further research is warranted.

ADULTS WITH IMPAIRED GASTROINTESTINAL FUNCTION SHOW IMPROVEMENTS IN GASTROINTESTINAL SYMPTOMS AND PROTEIN INTAKE WITH A HIGH-PROTEIN, PEPTIDE-BASED ORAL NUTRITIONAL SUPPLEMENT

B Green, M Phillips, L Green, R Watson, A McCallum, S Brook, S Oldham, L Tomlinson, A Williams, C Wills, R Talbot, R Thomas, J Barker, A Lumsdon, S Morris, C McMurray, C Day, S Price, S Duff, R Smith, A Julian, J Thomas, C-A Fleming, L Nash, N Bergin, K Jones, V Deprez, R Capener, GP Hubbard, RJ Stratton

Published in *Clinical Nutrition Open Science* (2023), Vol. 50: p1-6

Introduction:

Provision of feeds containing hydrolysed, peptide-based proteins and medium-chain triglycerides (MCT), can help mitigate gastrointestinal (GI) intolerance in adults with impaired GI function, maldigestion and/or malabsorption. This study evaluated a high-protein, peptide-based, MCT-containing oral nutritional supplement (PEHP; 1.5kcal/ml and 7.5g protein/100ml).

Method:

Adults with impaired GI function were recruited by their managing dietitian and took PEHP orally for 28-days, with GI tolerance, compliance, weight, energy and protein intake assessed via non-validated questionnaires and a 24-hour dietary recall at baseline and at intervention end.

Results:

Fifteen, adults (56 years (16), 67kg (26.0), 24kg/m² (7.6)) took part in this study. Intensity of nausea (Z= -2.070, p=0.038, n=15) and abdominal pain (Z= -2.236, p=0.025, n=15) improved significantly compared to baseline. Reductions in the intensity of diarrhoea, constipation, vomiting, flatulence, and burping were observed but were not statistically significant (p>0.05 for all). Compliance was higher with PEHP (81% (24)) than baseline feeds (63% (42)) but not significantly. Weight remained stable between baseline (67kg (26)) and at intervention end (67kg (27), p=0.414, n=15). Compared to baseline, total energy intake increased with PEHP albeit not significantly (1661kcal/day (572) vs 1981kcal/day (592), p=0.137, n=15). Increases in total protein intake were also observed, this time significantly (61g/day (23) vs 78g/day (29), p=0.042, n=15).

Conclusion:

This study in adults with impaired GI function found that PEHP improved GI tolerance and protein intake compared to feeds taken at baseline (including both polymeric and peptide-based feeds).

ECONOMIC IMPACT OF IMPLEMENTING MALNUTRITION SCREENING AND NUTRITIONAL MANAGEMENT IN OLDER ADULTS IN GENERAL PRACTICE

F Brown, G Fry, AL Cawood, RJ Stratton

Published in *The Journal of Nutrition, Health & Aging* (2020), Vol. 24 (3): p305-31 (Abridged)

Introduction:

Malnutrition is a common and significant public health problem, especially for older adults, as the consequences are costly. National guidelines (NICE CG32/QS24) highlight the need to identify and manage malnutrition, the implementation of which was deemed “high impact to produce cost savings”. The ‘Malnutrition Pathway’, endorsed by NICE and other professional bodies, is a practical evidence-based guide to help community healthcare professionals (HCP) to implement guidance on malnutrition management. Published evaluations of its use are needed.

Method:

This service evaluation in older adults assessed the impact of implementing the ‘Malnutrition Pathway’ on health care use and costs, as well as the acceptability of the management strategies and effect on malnutrition risk. 5 GP surgeries were recruited in Gloucestershire. 163 older adults (80±9 years) with a range of primary diagnoses, living in their own home, were screened using the Malnutrition Universal Screening Tool (‘MUST’) (n50 low risk (LR); n41 medium risk (MR); n72 high risk (HR)). All patients were managed according to risk (LR: no further management; MR: dietary advice (DA); and HR: DA plus two oral nutritional supplements (ONS) (1 serve 300kcal, 18g protein; 125ml). At each review (6weeks, 3 and 6 months), ‘MUST’ score, compliance and satisfaction to their management plan were recorded. Healthcare use was collected from GP records 6 months before and after implementation of the pathway. A simple cost analysis was completed.

Results:

Implementing appropriate management of malnutrition led to significant reductions in hospital admissions ($p=0.028$), length of hospital stay ($p=0.05$), GP visits ($p=0.007$) and antibiotic prescriptions ($p=0.05$). Over 6 months, the costs to manage malnutrition (HCP time, ONS) were more than offset by the savings associated with these reductions in health care use (per patient savings of -£395.64 MR+HR; -£997.02 HR). The proportion of individuals at risk of malnutrition reduced over time, and patients reported being satisfied with the DA (97%) and ONS (96%), consuming 90% of their ONS prescription.

Conclusion:

Managing malnutrition significantly reduces healthcare use, with a positive budget impact, in older malnourished patients in primary care. This represents an opportunity to improve patient care with benefit on health care spend.

LOW VOLUME ENERGY DENSE ORAL NUTRITIONAL SUPPLEMENTS IMPROVE MICRONUTRIENT INTAKES IN FREE LIVING MALNOURISHED OLDER PEOPLE – A RANDOMISED TRIAL

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Presented at ESPEN 2017. Published in *Clinical Nutrition* (2017), Vol. 36: S175-176

Introduction:

We have previously shown that low volume energy dense oral nutritional supplements (ONS) significantly increase intakes of energy and protein with little suppression of food intake¹, but the effect on micronutrients requires further investigation.

Method:

308 older people (>50y) recruited through GPs (age 71.5±10.7y; BMI 19.4±2.5kg/m², Charleston Comorbidity Index (CCI) 1.02±0.93, 67% female) at risk of malnutrition (‘MUST’) were randomised to low volume ONS (Fortisip Compact range, Nutricia; 2.4kcal/ml) plus dietary advice (DA) (as a diet sheet) (n154; ONS group) or DA alone (n154; DA group) for 12 wks. At baseline, 4, 8, 12 wks, food and total intake were measured, micronutrient intakes analysed and compared to EFSA reference values where available. Percentage difference between groups over 12wks for 25 micronutrients was calculated (trace elements (n7), minerals (n5), vitamins (n13)), along with the extent to which ONS intake was additive to the diet (2). Intention to treat analysis was undertaken (controlled for baseline, age, sex, ‘MUST’, CCI), results presented as mean±SE.

Results:

Total micronutrient intake was significantly higher in the ONS group compared to the DA group (for all except sodium, chloride, vitamin B12). Overall 92±4% of the ingested ONS was additive to food intake with no difference in intakes of micronutrients from food between groups ($-1 \pm 1\%$; NS). Total intake in the ONS group exceeded that of DA group by 40±5% overall (46±7% vitamins, 43±8% trace elements, 19±7% minerals). Over 12wks, 86% of micronutrients (18/21) met EFSA values in the ONS group compared to 43% in the DA group (9/21) ($p=0.004$).

Conclusion:

This large randomised trial shows that malnourished free living older people are unable to achieve adequate micronutrient intakes from food alone, and the addition of low volume energy dense ONS is effective at significantly improving intakes, helping them to meet recommended reference intakes.

References:

(1) Smith TR et al, Clin Nutr Supp 2017, Vol 36: S7-8; (2) Stratton & Elia 1999. Clin Nutr 18, 29-84.

GP PATIENT DATABASES SHOW THAT MALNUTRITION IS UNDER-REPORTED AND UNDERTREATED IN PATIENTS WITH CHRONIC DISEASE

Fry C, Ramet S, Hubbard GP, Stratton RJ

Presented at BAPEN 2016. Published in *Clinical Nutrition ESPEN* (2017) Vol. 22: p120-121. (Abridged)

Introduction:

Disease-related malnutrition is a significant, common and costly problem^{1,2}, with most of those affected living in the community (93%)¹ and under the care of a GP. Patients with chronic disease are particularly vulnerable and it is recommended that they are routinely screened and appropriately managed (including the use of nutrition support³). This study investigated the recorded prevalence of malnutrition and use of nutrition support products in UK community-based malnourished adults with chronic diseases.

Method:

Electronic longitudinal GP patient data (IMS Information Solutions UK Ltd) was collected from April 2014 - March 2015, from 1,150,744 adults (76% 19-65 years, 24% 65+ years) registered with UK GP practices. Patients with a read code for stroke, COPD, dementia/Alzheimer's or cancer, were identified as malnourished if they had a BMI of <18.5kg/m² and/or a read code for malnutrition recorded in the GP database. Prescriptions of nutrition support were also assessed.

Results:

Overall, 43.5% (501,098) of patients had a BMI recorded, 2.9% (33,877) were identified as malnourished and 0.9% (10,507) were receiving nutrition support. The documented prevalence of malnutrition in patients with chronic disease ranged from 7%-15%, and of these, 18%-34% were prescribed nutrition support (see Table 1).

Table 1 – Malnutrition prevalence and use of medical nutrition

Chronic Disease (n)	Number (%) of malnourished patients	Number of malnourished patients who had a prescription for nutrition support
Cancer (11,262)	904 (8%)	270 (30%)
COPD (29,047)	3001 (10%)	537 (18%)
Dementia (14,339)	2161 (15%)	741 (34%)
Stroke (41,540)	3108 (7%)	627 (20%)

Conclusion:

This is the largest survey of GP records to assess recording of malnutrition and prescription of nutrition support in adults with chronic diseases in the UK. Malnutrition was common, but overall prevalence was lower than previously reported in GP practices⁴, possibly due to under-reporting, lack of screening, or the malnutrition criteria used (i.e. lower BMI cut off). The data also suggests under-treatment of malnutrition as more than two thirds did not receive a prescription for nutrition support, although the use of other dietary strategies/dietetic intervention could not be assessed.

References:

1. Elia M, Russell C. BAPEN, 2009. 2. Elia M. BAPEN, 2015. 3. NICE. CG32, 2006. 4. McGurk P, et al. Proc Nutr Soc 2011; 70 (OCE5).

EFFECTS OF A PLANT-BASED HIGH ENERGY AND PROTEIN ENTERAL TUBE FEED IN HOME ENTERALLY TUBE FED PATIENTS: RESULTS FROM A 6-MONTH SINGLE-ARM INTERVENTION TRIAL

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Presented at BAPEN 2023

Introduction:

Many home enterally tube fed (HETF) patients require a high energy and protein enteral feed due to increased nutritional requirements or to reduce daily feed volume, due to fluid restrictions and poor volume tolerance, or to reduce time spent tube feeding, which has adverse effects on quality of life (QoL). Recent data highlights a multifaceted need for plant-based medical feeds in clinical practice¹; however, evidence of long-term (≥6-months (6M)) use in HETF patients is limited. This single-arm multi-centre intervention study evaluated the effects of a plant-based (vegan suitable) multi-nutrient, high energy, high protein enteral tube feed (PBTF) for 6M in HETF patients.

Method:

Following a 1-day baseline (BL), 17 adult HETF patients (age: 49±22years; BMI: 22.1±3.5kg/m²) received ≥500ml/day of the PBTF (2.0kcal/ml; 10g protein/100ml; +/- 1.5g fibre/100ml; Nutrison PlantBased 2.0kcal HP/HP Multi Fibre, Nutricia Ltd, UK) for 6M. Gastrointestinal (GI) tolerance (%patients reporting no symptoms), compliance, daily feed volume, estimated time feeding/day, nutrient intake and body weight were assessed at BL, 4-weeks (4W) and 6M. Data were analysed by one-way repeated-measures ANOVA with Bonferroni adjustment for pairwise comparisons.

Results:

Compared to BL, at 4W and 6M, %patients reporting no GI symptoms increased (BL: 59±19%; 4W: 74±12%; 6M: 66±17%, p<0.04) with no difference between feed variants (p=0.55); compliance was similar (BL: 96±13%; 4W: 99±3%; 6M: 99±3%, p=0.72); and daily feed volume (BL: 999±514mL/d; 4W: 774±284mL/d; 6M: 774±284mL/d, p<0.03) and estimated time feeding/day (BL: 9.9±4.4hrs/d; 4W: 8.4±4.2hrs/d; 6M: 8.4±4.2hrs/d, p<0.05) decreased. Protein intake increased (BL: 1.2±0.3g/kg/d; 4W: 1.4±0.4g/kg/d; 6M: 1.4±0.5g/kg/d, p<0.03), whereas energy intake (BL: 1724±500kcal/d; 4W: 1814±512kcal/d; 6M: 1798±538kcal/d, p=0.55) and body weight (BL: 59.0±11.1kg; 4W: 59.8±11.2kg; 6M: 59.3±12.1kg, p=0.55) were maintained. All mean micronutrient intakes (excluding electrolytes) met the UK Reference Nutrient Intake (RNI) at all timepoints.

Conclusion:

This study provides novel longer-term data that a PBTF is highly tolerated and complied with, increases protein intake, maintains body weight, and decreases daily feed volume and estimated time feeding/day, which might have important implications for QoL in HETF patients.

References:

1. Griffen C, Delsoglio M, Syed R, et al. A ready to drink, plant-based oral nutritional supplement is highly complied with, palatable and tolerated in community-based patients at risk of disease-related malnutrition. *Clinical Nutrition ESPEN*. 2023;54:706.

A PLANT-BASED HIGH ENERGY AND PROTEIN ENTERAL TUBE FEED IS HIGHLY TOLERATED, COMPLIED WITH AND ACCEPTED, AND DECREASES FEEDING TIME PER DAY IN HOME ENTERALLY TUBE FED PATIENTS

C Griffen, N Wyer, R Martin, E Michaels, Y Dube, J Bates, D Griffith, H Meanwell, E Diamond, C Lennon, L Szymanski, J Ward, K Nosworthy, S Morris, N Hatchett, N Glanville, R McNaughton, C Banks, S Owen, N Blackburn, A Bidgood, R Raif, E Tripp, L Allan, C Brici, L Green, L Lewis, L Chandler, C Robinson, A Lumsdon, H Hitchings, A Campbell, J Baxter, S Cooper, S Richardson, M Hardy, A McCloskey, R Capener, GP Hubbard, RJ Stratton

Presented at ESPEN 2023

Introduction:

Plant-based (vegan suitable) high energy and protein enteral tube feeds (PBTF) available to home enterally tube fed (HETF) patients are limited. This one-arm multi-centre intervention study evaluated the effects of a PBTF.

Method:

Following a 1-day baseline, adult HETF patients ($n=41$; age: 51 ± 23 years; BMI: 21.5 ± 5.0 kg/m²) received ≥ 500 ml/day of a PBTF (2.0 kcal/ml; 10g protein/100ml) either with or without added fibre (1.5g/100ml) (Nutrison PlantBased 2.0kcal HP +/- Fibre, Nutricia Ltd., UK) for a 28-day intervention period. Gastrointestinal (GI) tolerance (%patients reporting no symptoms), daily compliance, prescribed daily feed volume, estimated time feeding/day, acceptability, nutrient intake and body weight were assessed at baseline and end of intervention.

Results:

Compared to baseline, with the PBTF, the proportion of patients with no GI symptoms increased (63 ± 11 vs. $70\pm 10\%$, $p=0.006$) with no difference between feed variants ($p=0.87$); compliance was greater (91 ± 17 vs. $97\pm 16\%$, $p=0.04$); and prescribed daily feed volume (1126 ± 503 vs. 861 ± 354 ml/d, $p<0.001$) and estimated time feeding/day (10.0 ± 4.6 vs. 8.2 ± 3.9 hrs/d, $p<0.001$) reduced. Patients scored the PBTF highly (mean score $\geq 8.4/10$) for all acceptability outcomes. Protein intake increased from baseline to end of intervention (1.3 ± 0.5 vs. 1.6 ± 0.6 g/kg/d, $p<0.001$), and energy intake (1864 ± 512 vs. 1950 ± 559 kcal/d) and body weight (60.2 ± 15.3 vs. 60.6 ± 15.5 kg) were maintained ($p>0.08$). All mean micronutrient intakes (excluding electrolytes) met the UK reference nutrient intake (RNI) at baseline and end of intervention.

Conclusion:

In adult HETF patients, a PBTF is highly tolerated, complied with and accepted, increases protein intake, and decreases prescribed daily feed volume and estimated time feeding/day.

APPROPRIATE HANDLING AND STORAGE REDUCE THE RISK OF BACTERIAL GROWTH IN ENTERAL FEEDING SYSTEMS REUSED WITHIN 24 HOURS

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Published in *Nutrition in Clinical Practice* (2023); p1-13

Introduction:

Enteral tube feeding can require considerable amounts of plastic equipment including delivery sets and containers, often disposed of after a single feeding session because of bacterial contamination concerns. The aim of this research was to assess whether reuse of delivery sets and containers for up to 24h is safe from a microbiological perspective.

Method:

Four enteral tube feeding systems (FS) were tested under hygienic controlled or repeated inoculation challenge conditions using key foodborne pathogens, to assess bacterial growth over time (FS1: ready-to-hang, closed 1-L system with delivery set reused, stored at room temperature [RT]; FS2: a prepared, powdered, open 1-L system with delivery set and container reused, stored at RT; FS3 and FS4: prepared, powdered, open 200-ml bolus systems with delivery set and container reused, stored at RT [FS3] and refrigeration [FS4]). Feed samples were cultured at 0.5, 6.5, 12.5, 18.5, and 24.5 h with $>2\Delta\log$ considered significant bacterial growth.

Results:

Under hygienic control, FS1, FS3, and FS4 were below the level of enumeration (<5 CFU/g) for all bacteria tested, at all time points. In FS2, significant bacterial growth was observed from 18.5h. Under repeated bacterial inoculation challenge, no significant growth was observed in FS1 and FS4 over 24.5h; however, significant growth was observed in FS2 after 6.5h and in FS3 after 10–12h.

Conclusion:

With hygienic handling technique, there is limited bacterial growth with reuse of delivery sets and containers over 24h. Refrigeration between feeding sessions and using boluses of reconstituted powdered feed reduce bacterial growth risk.

COMPLIANCE AND TOLERANCE OF A READY-TO-USE, LOW CALORIE, LOW VOLUME, HIGH PROTEIN MODULAR FEED IN PATIENTS WITH INCREASED PROTEIN NEEDS

B Green, K-H Jones, C Brookes, S McKinnon, R Mapson, S Richardson, S Oldham, L-M Baldwin, L Tomlinson, A Williams, E Warsop, E Caygill, A Martin, A Hutchinson, F Short, A Smith, E Partridge, E Coombes, C Goodger, H James, K Alderton, L Albrich, L Pippard, S Harries, M Collins, E Craig, T Flood, E Dorkel, E Barrett, J Barker, L Gregory, C Taylor, V Gallivan, K Angel, C Widdows, P Kaye, K Howells, L Rounds, GP Hubbard, RJ Stratton

Presented at BAPEN 2022. Published in *Clinical Nutrition ESPEN* (2023), Vol. 57: p836 (Abridged)

Introduction:

Many clinical conditions warrant high protein intakes with recommendations ranging from 1.0-1.5g/kg BW-1. It can be challenging to provide adequate protein, especially where caloric overfeeding and/or fluid restriction are a concern¹ and additional protein from modular feeds may be beneficial². Protein modular feeds are mostly composed of hydrolysed collagen and require preparation, increasing the risk of contamination, incorrect preparation and inadequate provision of volume that could impact nutritional status, clinical and functional outcomes.

Method:

After a 1-day baseline, 15 patients (61±13 years; 87.5±26.9kg, 60% male) with increased protein needs (93.3g/day) recruited across UK healthcare centres received a whey- and collagen-based, low calorie, low volume, high protein liquid modular feed (Nutrison Protein Shot: 45kcal and 11g/40ml; Nutricia Ltd, UK) provided in a novel, ready-to-use 40ml pot alongside routine care for up to 28 days. Compliance, tolerance, nutrient intake (energy and protein), and body weight were observed before and after the study product and ease of use was also assessed.

Results:

At baseline, 10 patients were receiving a liquid protein modular feed. All patients had complex conditions and 93% (n=14) presented with multiple diagnoses. The mean prescription of the study product was 64ml/day (SD: 25ml/day; range 40 – 120ml/day). Compliance was excellent versus prescription (93%), providing 18.7% of estimated protein requirements. For patients receiving a liquid protein modular feed at baseline, contribution of the study product to protein intake remained unchanged (24%). Tolerance was good and remained stable or improved, though not significantly. Body weight (-0.4kg, p=0.695), energy (1429kcal/day (SD 366) vs. 1508kcal/day (SD 352), p=0.344) and protein intake (79g/day (SD 14) vs. 83g/day (SD 18), p=0.386) remained stable. Patients and healthcare professionals (HCPs) reported the study product was easy, quick and highly convenient to use and posed low contamination risk.

Conclusion:

This study shows that a new, convenient, whey- and collagen-based, ready-to-use, modular protein top-up feed can be introduced with excellent compliance and tolerance without impacting body weight or energy intakes, giving HCPs flexibility to tailor tube feeding regimens without overfeeding in patients with increased protein needs.

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CRITICALLY ILL PATIENTS WITH AND WITHOUT SARS-COV-2 BETTER ACHIEVE ENERGY AND PROTEIN TARGETS WITH A HIGH-ENERGY, HIGH-PROTEIN PEPTIDE-BASED ENTERAL TUBE FEED; INSIGHTS FROM A MULTICENTRE CLINICAL AUDIT PERFORMED DURING THE COVID-19 PANDEMIC

BP Green, M Phillips, L Morgan, K Hughes, E Terblanche, S King, A Fiddes, K Atwal, GP Hubbard, RJ Stratton

Published in *Clinical Nutrition ESPEN* (2022), Vol. 4: p506-507 (Abridged)

Introduction:

Meeting energy and protein requirements in critically ill patients is important for prognosis, yet difficult to achieve as a consequence of disease, management and/or altered nutritional intake¹. Improvements in achieving energy and protein requirements with a high-energy, high-protein peptide-based tube feed were observed in community patients². To establish whether this remained true in the critical care setting, where feeding intolerance is observed frequently⁴, a retrospective multicentre audit was performed.

Method:

Adults (>18years), admitted to critical care across 6 UK hospitals between May 2020 and December 2020, were retrospectively included if they received a peptide-based enteral tube feed (Nutrison Peptisorb Plus HEHP®, Nutricia Ltd), containing 1.5kcal/ml and 7.5g protein/100ml (herein referred to as HEHP). Data were collected from 15 critically ill patients (52±12y; 87% male), with mean length of hospital stay being 26days (range: 7-49days). Of these, 10 were SARS-CoV-2 positive, with the remainder having pancreatitis (n=3), delayed gastric emptying (n=1) or unconfirmed diagnosis (n=1). HEHP was used second line (after whole protein) and indications for use included tolerance issues (n=10), elevated energy and protein requirements (n=5) or primary diagnosis (n=2). Estimated energy and protein intakes (% of requirements achieved) were recorded before and during use of HEHP. In addition, Dietitians were asked whether HEHP allowed patients to better meet their nutrient target.

Results:

Mean intake of HEHP was 2008±461kcal/day and 100±23g protein/day provided over a mean of 12days (range: 3-29days). The percentage of estimated energy and protein targets achieved increased albeit non significantly with the use of HEHP (from 76% before vs 87% during use of HEHP for both) and the direction of effect remained true regardless of SARS-CoV-2 status. Two thirds (67%, n=10 of 15) of Dietitians reported HEHP helped patients better meet their nutrient targets and 87% (n=13 of 15) perceived the high protein content of HEHP as beneficial.

Conclusion:

Enteral tube feeding in critically ill patients poses numerous difficulties, especially in SARS-CoV-2. This audit in critically ill patients demonstrates that a high-energy, high-protein, peptide-based enteral tube feed can help complex patients better achieve energy and protein targets.

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EVALUATION OF A NEW ENTERAL FEEDING TUBE NURSE CLINIC AT THE WESTON PARK HOSPITAL RADIOTHERAPY DEPARTMENT

L Cowell, N Wayne, J Solomon, V Gallivan, L Gregory, GP Hubbard

Presented at BAPEN 2021. Published in *Clinical Nutrition ESPEN* (2022), Vol. 48: p521-522 (Abridged)

Introduction:

Approximately 300 patients each year receive radiotherapy for head and neck cancer at Weston Park Hospital, approximately 50% of these patients have enteral feeding tubes placed. Historically, Dietitians provided support for all patients with enteral feeding tubes receiving radiotherapy treatment and the local nursing service provided by the enteral tube feeding contract provider provided community clinical support. Due to increasing patient numbers and increased Dietetic workload, a new "enteral feeding tube nurse clinic" was introduced, run by the local enteral tube feeding homecare nurse. This clinic has been running since 2019 and is a "drop-in clinic" which both staff and patients' can access for support, including troubleshooting advice. This is a unique service built in conjunction with the Dietetic team, designed to meet local patient's needs.

Method:

In 2020 a review took place to evaluate the level of patient satisfaction with the enteral feeding tube nurse clinic, to establish the confidence of patients in caring for their feeding tubes and to explore feedback to develop the service. A questionnaire was given to patients during the last week of their radiotherapy treatment over a 6-week period assessing: the patient's satisfaction with the support and service, how confident they felt after receiving the support (both assessed using a 5-point scale: where 5 was 'very satisfied'), and their experience overall.

Results:

The questionnaire was completed by 12 patients. For satisfaction with the support and service 10/12 (83%) patients scored 5: very satisfied, with the remaining 2 patients scoring 3: neutral. Comments from patients included: "excellent nurses, great, quick, professional job-no fuss", "help available whenever it is needed", "every time I have requested their help, I have had a prompt reply and always each problem has been addressed". For confidence with enteral tube feeding procedures, 100% of patients scored 5: very confident. Comments from patients included: "I feel much happier with the tube", "very confident in cleaning and rotation, and excellent instructions from nurses". When asked about their experience overall, patient comments included "Thank you for all your support", "expert care, friendly, informative", "fantastic prompt treatment", "grateful that I have had the support", "friendly, professional staff are always willing to help and always have said 'if you need me, just ask, at any time'". Due to Covid-19 the clinics were stopped, however Dietitians and Consultants missed the instant, direct access to enteral feeding tube support, suggesting that the clinic was also highly valued by the healthcare professionals. In August 2021 the clinics started again and there are plans to expand the service later this year.

Conclusion:

In summary, the enteral feeding tube nurse clinic was positively evaluated by the patients attending the radiotherapy clinic. The overwhelming feedback was that the service provides patients with rapid access to support, advice, reassurance, and training if their feeding requirements changed. Due to the success of this clinic, development of similar clinics in other areas should be considered.

INCREASED PROTEIN INTAKE IS ASSOCIATED WITH IMPROVED HAND GRIP STRENGTH AND QUALITY OF LIFE IN HOME ENTERALLY TUBE FED ADULTS USING A HIGH-ENERGY, HIGH-PROTEIN FEED

BP Green, E Wong, S Andrews, K Hampshire-Jones, S McKinnon, C Brooks, R McAdam, S Gray, C Vickers, Y Blake, G Sekhon, S Merrick, J Faerber, P Mather, E Gilbert, R McBride, A Coombes, M Walker, A Owen, J Davies, S Richardson, S Carr, R Mapson, J Spivey, S Draper, F Kendall, GP Hubbard, RJ Stratton

Presented at BAPEN 2019. Published in *Clinical Nutrition ESPEN* (2020), Vol. 35: p208 (Abridged)

Introduction:

Increased energy and protein requirements are frequently observed in disease and can be difficult for patients to achieve with standard tube feeds. This is especially true for patients who present with tolerance issues and impaired quality of life with larger volume tube feeds. A lower volume, nutrient- and energy-dense feed may therefore offer compositional, clinical and functional advantages.

Method:

After a 3-day baseline period, 22 home enterally tube fed patients (63±12y; 68% male, BMI 23.8±3.8kg/m²) recruited across the UK healthcare centres received a mean of 764±308mL/d of a high-energy (1.5kcal/ml), high-protein (7.5g/100ml) tube feed (Nutrison Protein Plus Energy, Nutricia Ltd, in addition to other feeds and oral intake) for 28 days. Energy and protein intake, anthropometry, hand-grip strength and quality of life (EQ5D visual analogue scale) were recorded at baseline (day 0) and at the intervention endpoint (day 31).

All patients had complex clinical conditions and most presented with multiple diagnoses. Twenty patients completed the study and were subsequently included in the final analysis. Tolerance with the experimental feed was good and compliance was excellent (98.5%).

Results:

Weight and BMI remained stable ($p>0.05$) from day 0 to day 31, as did total energy intake (day 0: 1851±703kcal/d vs. day 31: 1874±688kcal/d, $p=0.738$), yet total protein intake increased significantly (day 0: 72±19g/d [1.0±0.3g/kg-BW-1] vs. day 31: 81.1±21g/d [1.2±0.4g/kg-BW-1], $p=0.013$ [$p=0.011$]). Total protein intake as a percentage of requirements also increased significantly from 88% at day 0, to 106% at day 31 ($p=0.004$). The change in total protein intake was positively associated with change in hand-grip strength ($r=0.433$, $n=16$, $p=0.047$). Protein intake at day 31 from the high-energy, high-protein tube feed, and when expressed as percentage of protein requirement, were both positively associated with change in quality of life (EQ5D: $r=0.478$, $n=20$, $p=0.033$ and $r=0.532$, $n=20$, $p=0.016$, respectively).

Conclusion:

This study demonstrates that a high-energy, high-protein tube feed effectively increases protein intake to better meet requirements without impacting on energy intake or anthropometric measures. Furthermore, increased protein intakes were positively associated with improved hand grip strength and quality of life, and corroborates previous meta-analysis findings, which together present important clinical implications. Whether long-term intake translates to improvements in quality of life and muscle strength remains to be determined.

COMPLEX ENTERALLY TUBE-FED COMMUNITY PATIENTS DISPLAY STABLE TOLERANCE, IMPROVED COMPLIANCE AND BETTER ACHIEVE ENERGY AND PROTEIN TARGETS WITH A HIGH-ENERGY, HIGH-PROTEIN PEPTIDE-BASED ENTERAL TUBE FEED: RESULTS FROM A MULTI-CENTRE PILOT STUDY

BP Green, K Sorensen, M Phillips, L Green, R Watson, A McCallum, S Brook, S Oldham, M Barry, L Tomlinson, A Williams, S Crease, C Wills, R Talbot, R Thomas, J Barker, A Owen, J Davies, C Robinson, A Lumsdon, S Morris, C McMurray, N Cunningham, L Miller, C Day, K Stanley, S Price, S Duff, A Julian, J Thomas, C-A Fleming, GP Hubbard, RJ Stratton

Published in *Nutrients* (2020), Vol. 12 (11): p3538

Introduction:

This pilot study evaluated a high-energy, high-protein, peptide-based, (medium-chain triglycerides) MCT-containing enteral tube feed (Nutrison Peptisorb Plus HEHP®, Nutricia Ltd, Trowbridge, BA14 OXQ, UK) containing 1.5kcal/mL and 7.5g protein/100mL.

Method:

Fifteen community-based, enterally tube-fed adults (42 (SD 16.3) years) received the intervention feed daily for 28 days, with gastrointestinal tolerance, compliance and nutrient intake assessed at baseline and after the intervention period.

Results:

Incidence and intensity of constipation ($p = 0.496$), nausea ($p = 1.000$), abdominal pain ($p = 0.366$) and bloating ($p = 0.250$) remained statistically unchanged, yet the incidence and intensity of diarrhoea improved significantly after receiving the intervention feed ($Z = -2.271$, $p = 0.023$). Compliance with the intervention feed was significantly greater compared to the patient's baseline regimens (99% vs. 87%, $p = 0.038$). Compared to baseline, use of the intervention feed enabled patients to significantly increase total energy (1676kcal/day (SD 449) to 1884kcal/day (SD 537), $p = 0.039$) and protein intake (73 g/day (SD 17) to 89 g/day (SD 23), $p = 0.001$), allowing patients to better achieve energy (from 88% to 99%, $p = 0.038$) and protein (from 101% to 121%, $p < 0.001$) requirements.

Conclusion:

This pilot study demonstrates that a high-energy, high-protein, peptide-based, MCT-containing enteral tube feed maintains gastrointestinal tolerance and improves compliance, energy and protein intake in complex, enterally tube-fed, community-based adult patients, though more work is recommended to confirm this.

A SURVEY OF BOLUS TUBE FEEDING PREVALENCE AND PRACTICE IN ADULT PATIENTS REQUIRING HOME ENTERAL TUBE FEEDING

GP Hubbard, S Andrews, S White, G Simpson, S Topen, L Carnie, C Murphy, R Collins, J Davies, A Owen, J Barker, L Green, I Patel, J Ridgway, J Lenchner, J Faerber, L Pearce, H Meanwell, N Kominek, L Stark, H Best, R Simons, T Cross, RJ Stratton

Published in *British Journal of Nutrition* (2019), Vol. 122, p1271–1278

Introduction:

Anecdotal evidence suggests the use of bolus tube feeding is increasing in the long-term home enteral tube feed (HETF) patients.

Method:

A cross sectional survey to assess the prevalence of bolus tube feeding and to characterise these patients was undertaken. Dietitians from ten centres across the UK collected data on all adult HETF patients on the dietetic caseload receiving bolus tube feeding (n 604, 60% male, age 58 years). Demographic data, reasons for tube and bolus feeding, tube and equipment types, feeding method and patients' complete tube feeding regimens were recorded.

Results:

Over a third of patients receiving HETF used bolus feeding (37%). Patients were long-term tube fed (4.1 years tube feeding, 3.5 years bolus tube feeding), living at home (71%) and sedentary (70%). The majority were head and neck cancer patients (22%) who were significantly more active (79%) and lived at home (97%), while those with cerebral palsy (12%) were typically younger (age 31 years) but sedentary (94%). Most patients used bolus feeding as their sole feeding method (46%), because it was quick and easy to use, as a top-up to oral diet or to mimic mealtimes. Importantly, oral nutritional supplements (ONS) were used for bolus feeding in 85% of patients, with 51% of these being compact-style ONS (2.4kcal (10.0kJ)/mL, 125mL).

Conclusion:

This survey shows that bolus tube feeding is common among UK HETF patients, is used by a wide variety of patient groups and can be adapted to meet the needs of a variety of patients, clinical conditions, nutritional requirements and lifestyles.

SYNBIOTIC CONTAINING EXTENSIVELY HYDROLYZED FORMULA IMPROVES GASTRO-INTESTINAL AND A TOPIC SYMPTOM SEVERITY, GROWTH, CAREGIVER QUALITY OF LIFE, AND HOSPITAL-RELATED HEALTHCARE USE IN INFANTS WITH COW'S MILK ALLERGY

GP Hubbard, K Atwal, L Graham, S Narayanan, L Cooke, C Casewell, S Denton, J Gavin, RM Browne, FJ Kinnear, AJ McHardy, D Evans, R Vallis, D Venkataraman, AL Cawood, S Donohoe, V Steele, S Armstrong, RJ Stratton

Published in *Immunity, Inflammation and Disease* (2022), Vol. 10 (6): e636

Background:

Healthy gut microbiota is important for prognosis in cow's milk allergy (CMA). The application of synbiotics (specific pre- and probiotics) in extensively hydrolyzed formulae (eHF) is a relatively new concept.

Aims:

To evaluate a synbiotic-containing, whey-based eHF (SeHF) with galacto-oligosaccharides, fructo-oligosaccharides, and bifidobacterium breve M-16V in infants with CMA.

Method:

A 31-day one-arm pilot study in 29 infants with CMA (mean age 30.8 weeks [SD 11]) was undertaken, with outcomes including gastrointestinal tolerance, atopic dermatitis symptoms, dietary intake, growth, SeHF acceptability, caregiver quality of life, and hospital-related healthcare use.

Results:

Significant improvements ($p < .05$) in the severity of abdominal pain (in 57%), burping (in 46%), flatulence (in 79%), constipation (in 14%), rhinitis (41%), and itchy eyes (73%), as well as atopic dermatitis in those with severe baseline symptoms (PO-SCORAD[®] reduction: 34.7–18.2 ($p = .003$), $n = 6$) were observed over time. Growth and caregiver quality of life scores significantly increased (+26.7%, $p < .05$) over time. Hospital visits and medications significantly reduced (–1.61 and –2.23, respectively, $p < .005$) in the 6 months after SeHF initiation.

Conclusion:

In this small, single-arm, pilot study, the use of SeHF enhanced the management of infants with non-IgE mediated CMA who were already established on eHF. Conclusion: Whilst this study adds to the evidence base for the use of SeHF in CMA, further robust research to explore the longer-term benefits of synbiotics, specifically the blend used in this study, for the clinical management of infants with CMA is warranted.

IMPROVED CLINICAL OUTCOMES WITH AN AMINO ACID FORMULA CONTAINING SYNBIOTICS IN INFANTS WITH COW'S MILK ALLERGY

K Sorensen, AL Cawood, LH Cooke, D Acosta-Mena, RJ Stratton

Presented at Nutrition and Growth 2022

Introduction:

Cow's milk allergy (CMA) is common and costly. Clinical trials of infants with CMA have shown that use of an amino acid formula containing pre- and probiotics (synbiotics) (AAF-S) may lead to significant reductions in infections, medication prescriptions and hospital admissions, compared to AAF without synbiotics¹. These effects are yet to be confirmed in real-world settings.

Method:

This retrospective matched cohort study examined clinical and healthcare data from The Health Improvement Network (A Cegedim Proprietary Database) from 148 infants with CMA (54% male, mean age at diagnosis 4.69m) prescribed either AAF-S (probiotic Bifidobacterium breve M16-V; prebiotics including chicory-derived oligo-fructose and long chain inulin) or AAF. Outcomes including symptoms, infections, healthcare usage (medication prescriptions, healthcare contacts) and time to asymptomatic management without hypoallergenic formula (clinical course of symptoms) were measured from diagnosis (mean observation period 1.19 years for both cohorts). Statistical tests included Fisher's exact or chi squared, where appropriate, for proportional data; Poisson for rates; and Cox proportional hazards regression for clinical course of symptoms. A simple cost analysis, based on published UK healthcare unit cost tariffs and accounting for the cost of the AAF powders, compared healthcare costs between groups, using healthcare usage rates extrapolated over the respective median clinical course of symptoms for each group.

Results:

AAF-S was associated with lower rates of symptoms (–37%, $p < .0001$), infections (–35%, $p < .0001$), medication prescriptions (–19%, $p < .0001$) and healthcare contacts (–18%, $p = .015$) vs AAF. Infants prescribed AAF-S had a significantly higher probability of achieving asymptomatic management without hypoallergenic formula (HAF) (adjusted HR 3.70, 95% CI 1.97x–6.95, $p < .0001$) with a shorter median time to asymptomatic management without HAF (1.35y vs 1.95y). AAF-S was associated with potential cost-savings of £452.18 per infant over the clinical course of symptoms. This may be attributable to the effect of the specific synbiotic on the gut microbiome. Further research is warranted to explore this.

Conclusion:

This real-world study provides evidence consistent with clinical trials that AAF-S may produce clinical and healthcare benefits with potential economic impact.

References:

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THE CLINICAL BURDEN OF COW'S MILK ALLERGY IN EARLY CHILDHOOD: A RETROSPECTIVE COHORT STUDY

K Sorensen, R Meyer, KE Grimshaw, AL Cawood, D Acosta-Mena, & RJ Stratton

Published in *Immunity, Inflammation and Disease* (2022), Vol. 10 (3): e572

Introduction:

Cow's milk allergy (CMA) is common in infants and children. Clinical presentations may vary, with a range of symptoms affecting the gastrointestinal (GI), skin and respiratory systems. Whilst the primary focus of research to date has been on the management of these symptoms, studies investigating the broader clinical burden of CMA are limited.

Method:

We performed a retrospective matched cohort study examining clinical data, including allergic symptoms and infections, extracted from case records within The Health Improvement Network database. A total of 6998 children (54% male) were included in the study, including 3499 with CMA (mean age at diagnosis 4.04 months) and 3499 matched controls without CMA, observed for a mean period of 4.2 years.

Results:

GI, skin and respiratory symptoms affected significantly more children with CMA ($p < .001$), which recurred more often ($p < .001$), compared with children without CMA. More children with CMA had symptoms affecting multiple systems ($p < .001$). CMA was associated with a greater probability of these symptoms requiring hypoallergenic formula (HAF) prescription persisting over time (log-rank test $p < .0001$, unadjusted hazard ratio [HR]: 0.81, 95% confidence interval [CI]: 0.76–0.85, $p < .001$), with a longer median duration of symptoms and HAF prescription compared with the duration of symptoms in those without CMA (3.48 vs. 2.96 years). GI, skin, respiratory and ear infections affected significantly more children with CMA than those without, increasing by 74% ($p < .001$), 20% ($p < .001$), 9% ($p < .001$), and 30% ($p < .001$) respectively. These infections also recurred more often among children with CMA, increasing by 62% for GI infections, 37% for skin and respiratory infections, and 44% for ear infections ($p < .001$).

Conclusion:

This real-world study provides evidence to suggest that CMA presents a significant clinical burden to children, which has implications for the healthcare system. Further research is warranted to understand the health economic impact of this, and the phenotypes, factors and management approaches which may affect clinical outcomes.

AMINO ACID FORMULA CONTAINING SYNBIOTICS IN INFANTS WITH COW'S MILK ALLERGY: A SYSTEMATIC REVIEW AND META-ANALYSIS

K Sorensen, AL Cawood, GR Gibson, LH Cooke, RJ Stratton

Published in *Nutrients* (2021), Vol. 13 (3): p935

Introduction:

Cow's milk protein allergy (CMPA) is associated with dysbiosis of the infant gut microbiome, with allergic and immune development implications. Studies show benefits of combining synbiotics with hypoallergenic formulae, although evidence has never been systematically examined.

Method:

This review identified seven publications of four randomised controlled trials comparing an amino acid formula (AAF) with an AAF containing synbiotics (AAF-Syn) in infants with CMPA (mean age 8.6 months; 68% male, mean intervention 27.3 weeks, $n = 410$).

Results:

AAF and AAF-Syn were equally effective in managing allergic symptoms and promoting normal growth. Compared to AAF, significantly fewer infants fed AAF-Syn had infections (OR 0.35 (95% CI 0.19–0.67), $p = 0.001$). Overall medication use, including antibacterials and antifectives, was lower among infants fed AAF-Syn. Significantly fewer infants had hospital admissions with AAF-Syn compared to AAF (8.8% vs. 20.2%, $p = 0.036$; 56% reduction), leading to potential cost savings per infant of £164.05–£338.77. AAF-Syn was associated with increased bifidobacteria (difference in means 31.75, 95% CI 26.04–37.45, $p < 0.0001$); reduced *Eubacterium rectale* and *Clostridium coccoideis* (difference in means –19.06, 95% CI –23.15 to –14.97, $p < 0.0001$); and reduced microbial diversity ($p < 0.05$), similar to that described in healthy breastfed infants, and may be associated with the improved clinical outcomes described.

Conclusion:

This review provides evidence that suggests combining synbiotics with AAF produces clinical benefits with potential economic implications.

THE USE OF AN AMINO ACID FORMULA CONTAINING SYNBIOTICS IN INFANTS WITH COW'S MILK PROTEIN ALLERGY—EFFECT ON CLINICAL OUTCOMES

K. Sorensen, AL Cawood, L Cooke, D Acosta-Mena, RJ Stratton

Published in *Nutrients* (2021), Vol. 13 (7): p2205

Introduction:

Cow's milk protein allergy (CMPA) is common and costly. Clinical trials of infants with CMPA have shown that the use of an amino acid formula containing pre- and probiotics (synbiotics) (AAF-Syn) may lead to significant reductions in infections, medication prescriptions and hospital admissions, compared to AAF without synbiotics. These effects have not yet been confirmed in real-world practice.

Method:

This retrospective matched cohort study examined clinical and healthcare data from The Health Improvement Network database, from 148 infants with CMPA (54% male, mean age at diagnosis 4.69 months), prescribed either AAF-Syn (probiotic *Bifidobacterium breve* M16-V and prebiotics, including chicory-derived oligo-fructose and long-chain inulin) or AAF.

Results:

AAF-Syn was associated with fewer symptoms (−37%, $p < 0.001$), infections (−35%, $p < 0.001$), medication prescriptions (−19%, $p < 0.001$) and healthcare contacts (−18%, $p = 0.15$) vs. AAF. Infants prescribed AAF-Syn had a significantly higher probability of achieving asymptomatic management without hypoallergenic formula (HAF) (adjusted HR 3.70, 95% CI 1.97–6.95, $p < 0.001$), with a shorter clinical course of symptoms (median time to asymptomatic management without HAF 1.35 years vs. 1.95 years). AAF-Syn was associated with potential cost-savings of £452.18 per infant over the clinical course of symptoms.

Conclusion:

These findings may be attributable to the effect of the specific synbiotic on the gut microbiome. Further research is warranted to explore this. This real-world study provides evidence consistent with clinical trials that AAF-Syn may produce clinical and healthcare benefits with potential economic impact.

THE USE OF AMINO ACID-BASED NUTRITIONAL FEEDS IS EFFECTIVE IN THE DIETARY MANAGEMENT OF PEDIATRIC EOSINOPHILIC OESOPHAGITIS

K Atwal, GP Hubbard, C Venter, RJ Stratton

Published in *Immunity, Inflammation and Disease* (2019), Vol. 7: 292-3013

Introduction:

Eosinophilic oesophagitis (EoE) is an immune-mediated, chronic disease characterized by eosinophilic inflammation and esophageal dysfunction. Specific food allergens including cow's milk protein, are partially causative to disease progression, and dietary management forms three main options; the elemental diet (ED), the empirical elimination diet (EED), and the targeted elimination diet (TED). The dietary choice should be individualized, however, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition guidelines recommend an ED for pediatric EoE with multiple food allergies, failure to thrive, unresponsive disease or unable to follow a highly restricted diet. The aim of this narrative review was to explore the effectiveness of the ED (using amino acid formula [AAF]), in the management of pediatric EoE.

Method:

Literature searches were performed to identify eligible studies that described outcomes including eosinophil count, clinical symptoms, growth, and medications.

Results:

Overall, 10 eligible studies were found, with $n = 462$ patients assigned to receive AAF from a total of $n = 748$ (average age 6.7 years), for a duration of 4 to 8 weeks. The use of AAF reduced eosinophil levels and demonstrated remission (defined as ≤ 10 eosinophils per high power field) in 75%-100% of children with improvements, if not resolution, in clinical symptoms. AAF was more clinically effective than the use of the EED or TED, where remission rates were 75%-81% and 40%-69%, respectively. Few studies collected growth outcomes, however where documented these were positive for those on AAF. The long-term impacts of each diet were not thoroughly explored.

Conclusion:

The use of AAF is a clinically effective management option for pediatric EoE, and further research is required to guide long-term management.

THE USE OF AMINO-ACID FORMULAS IN THE DIETARY MANAGEMENT OF INFANTS WITH FOOD PROTEIN ENTEROCOLITIS SYNDROME: A LITERATURE REVIEW

K Atwal, GP Hubbard, RJ Stratton

Presented at BSACI 2018. Published in *Clinical and Experimental Allergy* (2018), Vol. 48 (11): p1550

Introduction:

Recommendations in formula choice for the dietary management of food protein enterocolitis syndrome (FPIES) are not synonymous, although international FPIES guidelines recommend use of amino-acid formula (AAF) in those not responding to extensively hydrolysed formula (EHF) and faltering growth. This literature review was undertaken to summarise existing evidence for use of AAF in the dietary management of infants with FPIES.

Method:

Literature searches were performed (up to Mar 2018) on electronic databases (e.g. PubMed) to identify articles using relevant search terms including: 'elemental', 'amino-acid', all brand names of AAF. Studies describing outcomes (e.g. symptom resolution, growth) with AAF in infants with confirmed FPIES were included.

Results:

Whilst a number of studies described use of AAF in FPIES, no suitable trials with relevant outcomes were found. Five case studies were identified (mean age 42 days; all had poor weight gain at presentation) by four authors (Kelso et al 1993, Anand et al 2006, Mane et al. 2014, Joshi et al. 2018). Intervention with AAF led to symptom resolution (including vomiting, methemoglobinemia and bloody diarrhoea) in all cases, after failure with other formulas (including soya and EHF). Symptom resolution with AAF was reported rapidly (48-72 hours) by Kelso et al 1993 and Anand et al 2006. Improvements in mean weight gain by 51-97g/day were observed in two infants over 6-9 days (Anand et al. 2006) and after 5 months continuation with AAF, growth increased in one infant by 2 centiles (who had initially declined 4 centiles at presentation) (Joshi et al 2018).

Conclusion:

This limited number of case studies show symptom resolution and growth in infants with FPIES on AAF who failed to respond to other formulas. However, stronger research is required to assess the role of AAF in aiding symptom management, nutrient provision and growth in FPIES so clearer evidence-based guidelines can be developed.

EFFECT OF ORAL NUTRITIONAL SUPPLEMENTS ON CLINICAL OUTCOMES IN CHILDREN WITH FALTERING GROWTH: A SYSTEMATIC REVIEW AND META-ANALYSIS

F Kinnear, C Smith, AL Cawood, L. Upton, S Trace, G O'Connor, RJ Stratton

Presented at Nutrition and Growth 2022

Introduction:

Oral nutritional supplements (ONS) are used in the management of paediatric faltering growth (FG). The systematic review and meta-analysis aims to summarise the available evidence regarding ONS use in children with, or at risk of, FG.

Method:

A systematic search (up to Nov 2021) identified 10 randomised controlled trials (RCT) comparing changes in a range of nutritional and clinical outcomes amongst children with, or at risk of, FG (n=1116; weighted mean age 5y (range 2.7-10.4y); 59% male) receiving ONS (with or without nutritional counselling) compared to control (nutritional counselling, usual care, placebo).

Results:

ONS use (contribution to intake 412kcal/d, 16.3g/d protein; duration 116 days (weighted means)) was associated with significantly greater gains in weight (mean difference (MD) 0.396kg, 95% CI 0.357 – 0.435, $p < 0.0001$; 4 RCT), height (MD 0.297cm, 95% CI 0.025 – 0.570, $p < 0.0001$; 3 RCT) and total nutritional intake (MD 52.831kcal/d, 95% CI 28.887-76.776, $p < 0.0000$; 3 RCT) with no reduction in food intake. Mean compliance to prescribed dose was 98% (94-100%; 3 RCT). Heterogeneous reporting of clinical outcomes limited the ability to draw further conclusions, although the available data suggests ONS use may be associated with a reduced incidence of infections (3 RCT).

Conclusion:

This systematic review provides evidence to support the use of ONS in the clinical management of children with, or at risk, of FG from various aetiologies including acute and chronic health conditions. Further research to explore effects of ONS on a wider range of clinical outcomes is warranted.

A SURVEY OF THE USE OF BOLUS TUBE FEEDING IN PAEDIATRIC PATIENTS RECEIVING HOME ENTERAL TUBE FEEDING IN THE UK

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Presented at ESPGHAN 2018. Published in *Journal of Pediatric Gastroenterology and Nutrition* (2018), Vol. 66, Suppl 2: p1045 (Abridged)

Introduction:

Anecdotal evidence suggests bolus feeding is common in paediatric patients receiving home enteral tube feeding (HETF), yet there is limited information on practice. A preliminary survey in UK paediatric HETF patients was conducted to: i) estimate the number of paediatric HETF patients on bolus tube feeding regimens and; ii) characterise these patients and their regimens.

Method:

A cross-sectional survey of paediatric HETF patients receiving bolus tube feeding was undertaken across 9 UK HETF services (Apr-Aug 2017). Dietitians estimated the number of paediatric bolus fed patients from their total caseload, and for a subset of these completed a standardized questionnaire, including demographics (age, gender, medical diagnoses) and tube feeding regimen details (duration, tube type, seasons, daily feed regimen), using dietetic notes (n=155).

Results:

Bolus fed patients represented 60% (n=382/635) of paediatric HETF patients, which may equate to ~9,600 paediatric bolus tube fed patients in the UK. The survey cohort (n=155/635) had a mean age of 8y (SD 5y, range 1-16y), 57% were male and all lived at home. The patient group was diverse, with diagnoses of cerebral palsy (27%) and developmental delay (22%), and half (50%) required full assistance. Most patients were long term tube fed (mean 5y) via gastrostomy (92%) mainly due to dysphagia (62%). The decision to bolus tube feed was typically led by healthcare professionals (65%) to mimic family mealtimes (32%), top up oral diet (19%) or fit a care schedule (9%). The majority (96%) started on a bolus regimen at initiation of tube feeding, and 81% were expected to continue a lifelong bolus regimen. Many patients were tube fed exclusively via bolus (64%) and for the remainder (36%), bolus feeding met 56% of their energy requirements. Commercial tube feeds were most used to bolus (60%). Most patients (70%) were fully or partially bolus fed via pump (mean volume 198ml (SD 71); duration 56min (SD 33)), with 25% via plunger (mean volume 172ml (SD 115); duration 20min (SD 18)) and 15% via gravity (mean volume 163ml (SD 75); duration 16min (SD 5)).

Conclusion:

This is the first survey characterising bolus tube fed paediatric HETF patients in the UK, showing that bolus tube feeding is commonly used primarily to mimic mealtimes or top up oral diet, as also seen in adult HETF patients¹. Patients typically received tube feed boluses via pump. Further exploration of the effect of different bolus tube feeding practices on paediatric patient outcomes is needed to enable recommendations for clinical practice to be made.

References:

1. Simons, et al. *Clinical Nutrition ESPEN*. 2017;22:122

A THIRD OF PAEDIATRIC HOME ENTERALLY TUBE FED PATIENTS RECEIVE LOW ENERGY FEEDING REGIMENS: RESULTS OF A UK SURVEY

RH Evill, J Berry, H Marjoram, E Colyer, L Stark, E Silbernagl, C Bigwood, S Chidlow, E Brackley, A Widdows, V Fisher, S Armstrong, A Robinson, GP Hubbard, RJ Stratton

Presented at ESPGHAN 2018. Published in *Journal of Pediatric Gastroenterology and Nutrition* (2018), Vol. 66, Suppl 2: p923. (Abridged)

Introduction:

Around 16,000 paediatric patients receive home enteral tube feeding (HETF) in the UK. The use of low energy tube feeding regimens (LETFR), in these patients is common; however there is currently limited guidance¹ and little published literature. A survey of paediatric HETF patients was undertaken to: i) estimate the percentage of paediatric HETF patients receiving a LETFR and; ii) characterise these patients and their tube feeding regimens.

Method:

In a cross-sectional survey, Dietitians from 9 UK HETF services (n=700) provided: i) an estimate of the percentage of paediatric patients on a LETFR as a sole source of nutrition and; ii) for a subset of patients on a LETFR (n=103, 55% male, age 8y (SD4.6, range 1-17y) a standardised questionnaire on patient demographics and feeding regimen details was completed. Estimated energy requirements (EAR) were calculated using SACN EAR² for the less active.

Results:

Dietitians estimated 28% (n=196/700) of their paediatric HETF population were receiving a LETFR. The most common primary diagnosis was neurological impairment (n=103). Patients were predominantly PEG fed (71%) due to an unsafe swallow (75%). Mean weight was 25.4kg (SD12.1, range 7-57kg), mean height 109.0cm (SD22.6, range 64-167cm); 53% of the group had a weight <25th centile and 76% a height <25th centile. Overall the group were receiving 54% of the EAR/day(2); 1-3y 319-900kcal, 4-6y 360-1050kcal, 7-10y 434-1500kcal, 11-14y 467-1365kcal, 15-17y 500-1740kcal. Most (85%) were on a LETFR due to low energy needs, either due to being small for their age (26%), or another reason (74%), such as inactivity or mechanical ventilation. A small proportion (15%) were on a LETFR due to poor feed tolerance. Of those with low energy needs, 32% were on bespoke regimens using multiple feeds. For most patients (56%) the Dietitian reported difficulty in meeting the patient's complete nutritional needs with the LETFR.

Conclusion:

This is the first survey to characterise the paediatric LETFR patients in the UK, demonstrating the high prevalence of use of LETFR (up to 30%) and complexity of managing this patient population with currently available feeds. Further research is required to assess the energy requirements of such patients in order to make recommendations for their optimal dietetic management.

References:

1. ESPGHAN Guidelines for the Evaluation and Treatment of Gastrointestinal and Nutritional Complications in Children With Neurological Impairment. 2017
2. Dietary Reference Values for Energy. Scientific Advisory Committee on Nutrition. 2011

EVALUATION OF A NEW 'MIX-IN' STYLE GLYCOMACROPEPTIDE-BASED PROTEIN SUBSTITUTE FOR FOOD AND DRINKS IN PATIENTS WITH PHENYL-KETONURIA AND TYROSINEMIA

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Published in *Nutrients* (2023), Vol 15 (16), p3598

Introduction:

Poor palatability, large volume and lack of variety of some liquid and powdered protein substitutes (PS) for patients with phenylketonuria (PKU) and tyrosinemia (TYR) can result in poor adherence. This study aimed to evaluate a new unflavoured, powdered GMP-based PS designed to be mixed into drinks, foods or with other PS, in patients with PKU and TYR.

Method:

Paediatric and adult community-based patients were recruited from 8 metabolic centres and prescribed ≥ 1 sachet/day (10g protein equivalent (PE)) of the Mix-In style PS over 28 days. Adherence, palatability, GI tolerance, and metabolic control were recorded at baseline and follow-up. Patients who completed at least 7 days intervention were included in the final analysis.

Results:

Eighteen patients (3-45 years, 9 males) with PKU (n=12), and TYR (n=6) used the Mix-In style PS for ≥ 7 days (mean 26.4days (SD 4.6), range 11-28days) alongside their previous PS, with a mean intake of 16.7g (SD 7.7) PE/day. Adherence was 86% (SD 25) and GI tolerance was stable, with n=14 experiencing no/no new symptoms and n=3 showing improved symptoms compared to baseline. Overall palatability was rated satisfactory by 78% of patients, who successfully used the Mix-In style PS in various foods and drinks, including smoothies, squash, and milk-alternatives, as a top-up to meet their protein needs. There was no concern regarding safe-ty/metabolic control during the intervention.

Conclusion:

The 'Mix-In' style PS was well adhered to, accepted, and tolerated. Collectively, these data show that providing a flexible, convenient, and novel format of PS can help with adherence and meet patients' protein needs.

EVALUATION OF A NEW GLYCOMACROPEPTIDE-BASED PROTEIN SUBSTITUTE IN POWDERED AND LIQUID FORMAT IN PATIENTS WITH PKU

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Published in *Nutrients* (2023), Vol 15 (16), p3580

Introduction:

Good adherence to a Phe-restricted diet supplemented with an adequate amount of a protein substitute (PS) is important for good clinical outcomes in PKU. Glycomacropeptide (cGMP)-PS are innovative, palatable alternatives to amino acid-based PS (AA-PS). This study aimed to evaluate a new cGMP-PS in a liquid and powder format in PKU.

Method:

Children and adults with PKU recruited from 8 centres were prescribed at least one serving/day of cGMP-PS for 28 days. Adherence, acceptability and gastrointestinal tolerance were recorded at baseline and end of intervention. Blood Phe levels reported as part of routine care during the intervention were recorded.

Results:

23 patients (powder group, n = 13; liquid group, n=10) completed the study. The majority assessed the products to be palatable (77% of powder group; 100% of liquid group) and well tolerated; adherence to the product prescription was good. Fourteen patients provided blood Phe results during the intervention, which were within the target therapeutic range for most patients (n = 11) at baseline and during the intervention.

Conclusion:

These cGMP-PS were well accepted and tolerated, and their use did not adversely affect blood Phe control.

NEW CONDITION-SPECIFIC PROTEIN SUBSTITUTES DEMONSTRATE GOOD ACCEPTABILITY WITH IMPROVED COMPLIANCE, STABLE TOLERANCE AND METABOLIC CONTROL IN CHILDREN AND ADULTS WITH HCU, MSUD AND TYR

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Presented at International Congress of Inborn Errors of Metabolism 2021. Published in *Journal of Inherited Metabolic Disease* (2021), Vol. 44: p1-161

Introduction:

Dietary protein restriction and intake of condition-specific protein substitutes (CSPS) is necessary to protect against the consequences of Homocystinuria (HCU), Maple Syrup Urine Disease (MSUD) and Tyrosinemia (TYR). Though successful, dietary management is challenging, with little variety, and compliance largely impacted by poor acceptability to CSPS. A new range of powder-based CSPS has been made available for patients with HCU, MSUD and TYR, therefore the acceptability, compliance, tolerance and metabolic control to these was explored.

Method:

New powder-based, low volume, DHA- and amino acid-containing CSPS providing 20g PE/29g serving were assessed at five specialist UK metabolic centres in patients with HCU (n=5; mean age 27yrs (range 19-33)), MSUD (n=8; mean age 25yrs (range 5-42)) and TYR (n=5; mean age 18yrs (range 3-27); n=1 tube-fed). Data on acceptability (organoleptic properties, usability), compliance, tolerance and metabolic-control were collected retrospectively whilst on existing CSPS (n=11 liquid; n=4 powder; n=3 both) and after 28-days of using the new CSPS.

Results:

Acceptability to new CSPS was positively rated by 88% (n=16) of patients and 78% (n=14) of managing Dietitians. Compliance to the new CSPS improved in 60% of HCU, 20% of TYR and 75% of MSUD patients. New CSPS were well tolerated and no metabolic control issues were reported across all patients including in enteral tube feeding.

Conclusion:

The new CSPS demonstrate good acceptability, improved compliance in children and adults with HCU, MSUD and TYR which may better support restricted dietary regimens. Furthermore, the new CSPS supports stable tolerance and metabolic control.

NUTRITIONAL AND METABOLIC CHARACTERISTICS OF UK ADULT PHENYLKETONURIA PATIENTS WITH VARYING DIETARY ADHERENCE

BP Green, RM Browne, S Firman, M Hill, Y Rahman, K Kaalund Hansen, S Adam, R Skeath, P Hallam, I Herlihy, F Jenkinson, C Nicol, S Adams, L Gaff, S Donald, C Dawson, L Robertson, C Fitzachary, H Chan, A Slabbert, C Dunlop, A Cozens, C Newby, V Bittle, GP Hubbard, RJ Stratton

Published in *Nutrients* (2019), Vol. 11 (10): p2459

Introduction:

The nutritional and metabolic characteristics of adult phenylketonuria (PKU) patients in the UK with varying dietary adherence is unknown. In other countries, nutritional and metabolic abnormalities have been reported in nonadherent patients compared to adherent counterparts.

Method:

A pooled analysis of primary baseline data from two UK multi-centre studies was therefore performed to establish whether this is true from a UK perspective. Adult PKU patients who had provided 3-day food records and amino acid blood samples were included and grouped according to dietary adherence (adherent; n = 16 vs. nonadherent; n = 14).

Results:

Nonadherent patients consumed greater amounts of natural protein compared to adherent patients (61.6 ± 30.7 vs. 18.3 ± 7.7 g/day; $q < 0.001$). In contrast, the contribution of protein substitutes to total protein intake was lower in nonadherent compared to adherent patients (3.9 ± 9.2 g/day vs. 58.6 ± 10.2 g/day; $q < 0.001$). Intakes of iron, zinc, vitamin D3, magnesium, calcium, selenium, iodine, vitamin C, vitamin A and copper were significantly lower in nonadherent compared to adherent patients and were below UK Reference Nutrient Intakes. Similarly, intakes of thiamin, riboflavin, niacin, vitamin B6 and phosphorus were significantly lower in nonadherent compared to adherent patients but met the UK Reference Nutrient Intakes. Phenylalanine concentrations in nonadherent patients were significantly higher than adherent patients (861 ± 348 vs. 464 ± 196 μ mol/L; $q = 0.040$) and fell outside of European treatment target ranges.

Conclusion:

This study shows the nutritional and metabolic consequences of deviation from phenylalanine restriction and intake of PKU protein substitutes in nonadherent adult PKU patients. Collectively, these data further underlie the importance of life-long adherence to the PKU diet.

IMPROVED EATING BEHAVIOUR AND NUTRIENT INTAKE IN NONCOMPLIANT PATIENTS WITH PHENYLKETONURIA AFTER REINTRODUCING A PROTEIN SUBSTITUTE: OBSERVATIONS FROM A MULTICENTRE STUDY

BP Green, Y Rahman, S Firman, S Adam, F Jenkinson, C Nicol, S Adams, C Dawson, L Robertson, C Dunlop, A Cozens, GP Hubbard, RJ Stratton

Published in *Nutrients* 2019, 11(9): p2035

Introduction:

Noncompliance is widespread in adults with PKU and is associated with adverse metabolic, nutritional and cognitive abnormalities. Returning to the PKU diet is important for this at-risk population, yet for many this is challenging to achieve. Strategies that ease the return to the PKU diet, while offering nutritional and cognitive advantages, are needed.

Method:

Twelve PKU adults (33.7 ± 2.6 years), who had been noncompliant for 4.5 years (range: 1 to 11 years), took 33g of a low-volume, nutrient-enriched, protein substitute daily for 28 days. Outcomes of eating behaviour, nutrient intake and mood were assessed at entry (baseline, days 1–3) and after the intervention period (days 29–31).

Results:

At baseline, intakes of natural protein and estimated phenylalanine were high (66.4g and 3318.5mg, respectively) and intakes of calcium, magnesium, iron, zinc, iodine and vitamin D were below country-specific recommendations. With use of the experimental protein substitute, natural protein and estimated phenylalanine intake declined ($p = 0.043$ for both). Fat and saturated fat intakes also decreased ($p = 0.019$ and $p = 0.041$, respectively), while energy and carbohydrate intake remained unchanged. Micronutrient intake increased ($p \leq 0.05$ for all aforementioned) to levels well within reference nutrient intake recommendations. Blood vitamin B12 and vitamin D increased by 19.8% and 10.4%, respectively. Reductions in anxiety and confusion were also observed during the course of the study yet should be handled as preliminary data.

Conclusion:

This study demonstrates that reintroducing a low-volume, nutrient-enriched protein substitute delivers favourable nutritional and possible mood benefits in noncompliant PKU patients, yet longer-term studies are needed to further confirm this. This preliminary knowledge should be used in the design of new strategies to better facilitate patients' return to the PKU diet, with the approach described here as a foundation.

A GLYCOMACROPEPTIDE BASED PROTEIN SUBSTITUTE HELPS PROMOTE STABLE BLOOD PHENYLALANINE AND BRANCHED CHAIN AMINO ACIDS IN PATIENTS WITH PHENYLKETONURIA

RM Browne, R Skeath, P Hallam, M Hill, C Fitzachary, H Chan, J Gribben, A Slabbert, C Ellerton, F Freedman, K Kaalund Hansen, I Herlihy, K van Wyk, V Bittle, E Cameron, GP Hubbard, RJ Stratton

Presented at SIMD 2018. Published in *Molecular Genetics and Metabolism* (2018), Vol 123 (3): p220. (Abridged)

Introduction:

Glycomacropeptide (GMP) based protein substitutes (PS) offer a promising alternative to 100% amino acid (AA) based PS for the dietary management of Phenylketonuria (PKU), due largely to the improved palatability of GMP. However to date there is relatively limited data regarding how currently available GMP-based protein substitutes may influence blood AA profiles of patients with PKU. Therefore the aim of this study was to evaluate the blood AA profile of patients introducing PKU GMP[®] (Nutricia) into their diet for 28 days.

Method:

Twelve patients with PKU (mean age: 28yrs; range 5–50yrs) were recruited across 6 specialist hospitals in the UK. Patients undertook a 3 day baseline period, before introducing the study product (PKU GMP[®], 33.3g sachets, 10g Protein Equivalent), as advised by their Dietitian for a 28 day intervention period. The study product could either wholly or partially replace their current AA-based PS and patients were advised to reduce the amount of Phe they consumed from food by an amount approximate to the residual Phe in the study product (15.3mg Phe/10g PE), to the nearest 25mg. Fasting dried blood spots were collected on the morning after the baseline period, and days 7 and 28 of the intervention period, and blood AAs were analysed via HPLC.

Results:

The mean prescription of the study product in grams of protein equivalent was 21.6g PE/d (range 10–60; SD 13.4), which was estimated to provide a mean of 34% of calculated total protein requirements (range 18–81; SD 17). Compliance to the study product was excellent (96%; SD 1.6). Blood Phe remained stable between the baseline and intervention periods ($p=0.51$), whilst there was a small but significant improvement in Tyr ($p=0.02$), although this did not result in a significant change in Phe:Tyr ratio ($p=0.24$). All BCAAs remained stable over the study period ($p>0.05$) and the ratios of Ile:Leu:Val did not significantly change ($p>0.05$), remaining at approximately 1 : 2 : 3.8. Overall, during the intervention period, 95% of results for all 20 amino acids analysed (excluding Phe) were found to be within 95% population reference ranges.

Conclusion:

PKU GMP[®] resulted in no significant changes in blood AAs over the 28 day intervention period, with the exception of a significant improvement in Tyr levels. BCAA ratios remained within recommended ranges. These results demonstrate that PKU GMP[®] powder is safe and effective for the dietary management of PKU in adults and children.

*Original abstract refers to PhenylAde[®] GMP Drink Mix as study product. For clarity the UK brand name 'PKU GMP[®]' has been used in this booklet.

A CROSS-SECTIONAL SURVEY OF PATIENTS PRESCRIBED ELEMENTAL FEED IN THE UK

I Russo, M Delsoglia, R Wood, K Kite, G O'Connor, L Mcveigh, S Trace, L Green, G Parker, C Smith, M Burke, C Ellis, L Cummins, R Capener, GP Hubbard

Presented at BAPEN 2023

Introduction:

Elemental feeds are indicated in patients with intolerance to polymeric feeds and in other disorders such as severe impairment of intestinal absorption¹. Despite limited indications, these feeds appear to be prescribed in a wide variety of medically complex conditions². There is little published evidence on use of elemental feeds in UK, therefore, a cross-sectional survey of the patient population currently prescribed Elemental O28 Extra (E028) (Nutricia Ltd.) was undertaken.

Method:

A cross-sectional survey was undertaken across 8 services in the UK between November 2022 and March 2023. A standardised questionnaire, including patient characteristics, reason(s) for E028 prescription, historic, current and planned use of E028 and other feeding regimens, was completed by dietitians. Ten dietitians completed the survey for 19 (12 male, 7 female) patients (mean age 22.8 years (SD17.5, range 8.5-74.0 years), weight 51.1kg (SD20.6), height 1.60m (SD0.2), BMI 19.8kg/m² (SD4.3)).

Results:

Primary diagnoses included Crohn's disease (CD) (n=8/19), ulcerative colitis (n=1/19), other gastrointestinal/liver disease (n=3/19), neurodegenerative disorder (n=1/19), cerebral palsy (n=1/19), stroke (n=1/19), short bowel (n=1/19), cancer (n=1/19) or others (n=2/19). The main reason(s) for prescribing E028 were CD (n=8/19), intolerance of unknown cause (n=5/19), multiple food protein allergies (n=2/19), cerebral palsy (n=2/19), eosinophilic gastrointestinal diseases (n=2/19) and short bowel (n=1/19). Most patients received E028 liquid (n=12/19) vs. powder (n=7/19), all powder use was in tube fed patients. Eleven patients had previously trialled another feed, 8 of whom had trialled another elemental or semi-elemental feed, specifically. Ten patients were prescribed E028 as a sole source of nutrition (mean: 2053ml (SD847), 2006kcal (SD799), 57.3g protein (SD22.6)), the remainder (n=9/19) as a supplement (mean: 676ml (SD494), 619kcal (SD405), 18.3g protein (SD13.7)). Most patients reported good/very good tolerance (n=13/19) and acceptance (n=14/19) of E028. Reported duration of prescription was long (years, n=6/19), medium (months, n=5/19), and short term (weeks, n=5/19), and was unclear for 3 patients. Five patients were expected to transition from E028 to an alternative feed, 3 of whom required a higher energy and/or protein feed.

Conclusion:

We understand this to be the first cross-sectional survey of adult and paediatric populations currently prescribed an elemental feed. These findings describe the vast heterogeneity of the population prescribed E028, including complex medical conditions, duration of prescription and nutritional requirements. Further research is required to better understand this diverse patient population and inform clinical guidelines.

References:

1. Braegger C, Decsi T, Dias JA, et al. ESPGHAN Committee on Nutrition: Practical approach to paediatric enteral nutrition: a comment by the ESPGHAN committee on nutrition. *J Pediatr Gastroenterol Nutr.* 2010 Jul;51(1):110-22.
2. Meyer R, Smith C, Sealy L, et al. The use of extensively hydrolysed and amino acid feeds beyond cow's milk allergy: a national survey. *J Hum Nutr Diet.* 2021 Feb;34(1):13-23.

A SURVEY OF DIETETIC OPINIONS AND VIEWS ON THE USE OF AN ELEMENTAL FEED IN CLINICAL PRACTICE IN THE UK SETTING

M Delsoglia, I Russo, R Wood, K Kite, G O'Connor, L Mcveigh, S Trace, L Green, G Parker, C Smith, M Burke, C Ellis, L Cummins, R Capener, GP Hubbard

Presented at BAPEN 2023

Introduction:

Semi-elemental/elemental feeds are indicated in patients with intolerance to polymeric feeds, and those with a severe impairment of gastrointestinal (GI) function¹. They are used in a broad variety of conditions to achieve better tolerance², however very little evidence is published.

Method:

A preliminary survey to assess dietetic opinions and views on the use of an elemental feed (Elemental O28 Extra (E028), Nutricia Ltd.) in clinical practice was conducted with dietitians across services in the UK between November 2022 and March 2023. Dietitians completed a standardised questionnaire which recorded their role and patient caseload, circumstances and conditions when E028 is prescribed, mode and details of use of E028.

Results:

Ten dietitians (7 paediatric, 3 adult) across 8 centres completed the questionnaire. Patients on E028 represented 2.4% of caseloads. E028 use was reported for patients with GI diseases (8/10), intolerance of unknown cause (7/10), allergic disease (6/10), and neurodisability (1/10). Dietitians reported first line use of E028 in several clinical circumstances including inflammatory bowel disease (IBD) (n=5 of which Crohn's Disease +/- milk allergy (4/10), and ulcerative colitis (1/10)), eosinophilic oesophagitis (1/10) and poor feed tolerance alongside low-calorie requirements (1/10). E028 was used as both a supplement (8/10) and sole source of nutrition (10/10), and administered via enteral tube (5/10), orally (3/10) or in combination (2/10). E028 liquid was selected for ease of use (6/10) and patient's preference (4/10), and E028 powder for flexibility in concentration (7/10). The decision to use E028 was reported to be dietitian led (7/10) or mutually led (dietitian/consultant (2/10) or dietitian/patient (1/10)). Seven dietitians perceived their use of E028 had stayed the same in the last 3 years, 2 perceived it had increased (due to lack of similar products available and higher number of patients with unexplained GI diseases, allergies and intolerance), and 1 perceived that it had decreased.

Conclusion:

This survey shows that E028 was used in a select group of patients, mainly presenting with GI diseases, intolerance, allergies and neurodisability. E028 was used both as a supplement and sole source of nutrition and was administered via feeding tube, orally or in combination, depending on patient needs. Usage of liquid is primarily for convenience and powder for flexibility in concentration. Use of E028 was perceived to be stable in recent years by most dietitians.

References:

1. Braegger C, Decsi T, Dias JA, et al. ESPGHAN Committee on Nutrition: Practical approach to paediatric enteral nutrition: a comment by the ESPGHAN committee on nutrition. *J Pediatr Gastroenterol Nutr.* 2010 Jul;51(1):110-22. doi: 10.1097/MPG.0b013e3181d336d2.
2. Meyer R, Smith C, Sealy L, Mancell S, Marino LV. The use of extensively hydrolysed and amino acid feeds beyond cow's milk allergy: a national survey. *J Hum Nutr Diet.* 2021 Feb;34(1):13-23. doi: 10.1111/jhn.12794. Epub 2020 Aug 21.

BENEFITS OF USE OF HUMAN MILK FORTIFIER IN PRETERM INFANTS IN THE COMMUNITY PRACTICAL EXPERIENCE FROM A CASE STUDY SERIES

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Presented at ESPEN 2023

Introduction:

Breast milk supplementation with a multicomponent human milk fortifier (HMF) has been shown to be safe and effective in preterm infants during hospitalization, while there is little clinical evidence exploring its use in the community. This series of case-studies aimed to evaluate HMF use in preterm infants in the community.

Method:

Preterm infants experiencing faltering growth were recruited from two UK neonatal units and supplemented with a new HMF containing long-chain polyunsaturated fatty acids, medium-chain fatty acids, and beta-palmitate (Nutriprem HMF, Nutricia Ltd). Compliance with prescription, anthropometrics, gastrointestinal (GI) tolerance, acceptability and safety were recorded at baseline, and end of intervention.

Results:

Fourteen infants (8 males), aged 35weeks+4days (SD 2w+5d), were supplemented with HMF in the community (mean intake 6.2g/d (SD2.6), 26.8kcal/d (SD11.4)) for a mean of 29days (SD2, range 15-55days), with 2 infants being initiated at home and 12 continuing after hospital discharge. Mean compliance was 96% (SD13), with 13 infants consuming 100% of HMF prescribed by their healthcare professional (HCP). Infants showed an increase in mean weight (+1.14kg SD0.58), length (+6.66cm SD3.91) and head circumference (+4.35cm SD2.86), and 93% (n=13) met their growth goal at the end of intervention. HMF was well tolerated, with 4 infants experiencing no GI symptoms and 10 infants experiencing a few symptoms with no significant concerns. HCPs reported satisfaction with GI tolerance in 11/14 (79%) infants. Most parents (11/14; 79%) found HMF easy to use and were satisfied overall.

Conclusion:

The HMF was well complied with, tolerated and accepted by most parents for supporting ongoing growth of preterm infants in the community.

MINOR REFORMULATIONS OF INFANT FSMPS DUE TO EU REGULATIONS 2016/127 & 2016/128 ARE WELL TOLERATED, ACCEPTED, COMPLIED WITH AND CONTINUE TO SUPPORT GROWTH IN INFANTS & CHILDREN REQUIRING NUTRITION SUPPORT

K Atwal, GP Hubbard, S Trace, J Bartleman, L Upton, J Pena, J Rayner, S Aubrey, V Steel, J Wildgoose, K Ross, B Cochrane, S Kitchen, H Norris, K Jeffreys, C Tong, R Newbury, L Sealy, A Robotham, L Francey, L McVeigh, I Clarke, E Wong, BP Green, E Hockley, S McGlinchey, RJ Stratton

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Introduction:

The nutritional compositions of infant foods for special medical purposes (iFSMPs) are governed by the EU, and new regulations (2016/127; 2016/128) were implemented to take effect by February 2020. Nutrient minimum and maximum levels were redefined, as well as mandatory supplementation of docosahexaenoic acid (DHA). A case-study series was conducted to evaluate iFSMPs reformulated by Nutricia Ltd to understand any possible impact on tolerance and acceptability prior to commercial launch.

Method:

A multi-centre case-study series was conducted in infants and children who took iFSMPs manufactured by Nutricia Ltd for a range of clinical conditions. Gastro-intestinal tolerance (GI), acceptance and compliance were evaluated over 28 days in each case-study. From 17 paediatric centres across the UK, 44 infants and children were recruited [mean age 16.5m; range 1.5–87], receiving one of 10 iFSMPs prescribed for nutrition support relevant to their clinical condition. Mean intake of baseline iFSMP was 683±275 ml (which met 97% of prescribed daily volume), of which n=16 administered iFSMPs via enteral feeding tubes. The managing Dietitian determined the prescribed daily volume. Medical history was recorded at baseline, and growth, GI tolerance, compliance and acceptance was measured at baseline and intervention end.

Results:

Forty patients completed the 28-day evaluation. GI tolerance remained stable in the majority of case studies (n=41 including n=1 drop out), and any deviations were not attributed to the reformulated iFSMPs. For the patients that completed the 28-day evaluation, compliance remained stable (n=33), and any reduction was related to increased complementary feeding or medical reasons. Mean intake of reformulated iFSMP was 579±254 ml (which met 91% of prescribed daily volume), where most patients directly transitioned onto the reformulation (n=41). No deterioration in medical conditions or growth were reported during any of the case studies. Furthermore, caregiver and HCP satisfaction was positively recorded in 89% of case studies.

Conclusion:

This case-study series demonstrates that the minor reformulation of iFSMPs manufactured by Nutricia Ltd in line with the new Regulations are well tolerated, accepted and complied with in infants and children with various medical backgrounds. Furthermore, the reformulated iFSMPs continued to support growth and achieved positive caregiver and HCP satisfaction. The reformulated iFSMPs used in this case study series have since been implemented into clinical practice in the UK, with support from Nutricia Ltd, and are now widely accepted.

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Introduction:

Method:

Results:

Conclusion:

These findings provide an evidence-base to support the effective management of children and adults with drug-resistant epilepsy following a KD with the use of a ready-to-use, nutritionally complete, 2.5:1 ratio feed including MCTs.



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