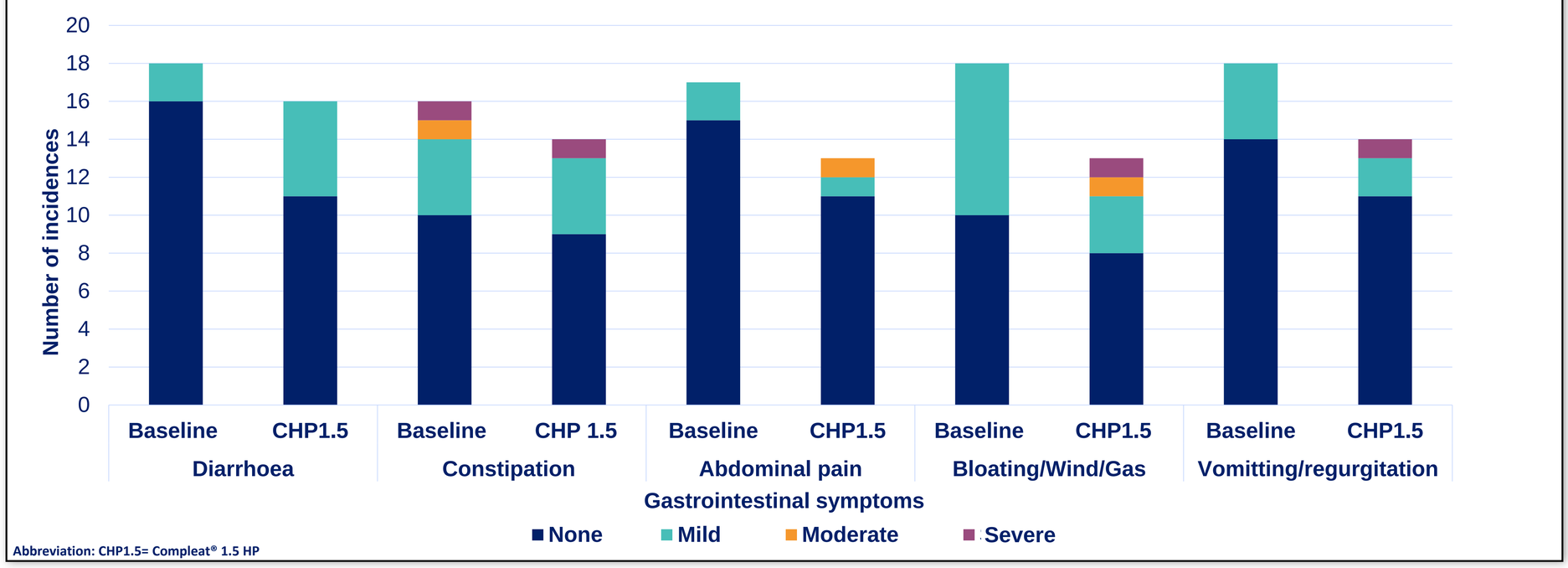
A multi-centre, single arm study to evaluate the gastro-intestinal tolerance and compliance of a high energy adult enteral tube feed with food derived ingredients.

S. Ogundere, [1], A Carter [2] A. Gilson [3] H. Meanwell [4], M. Van der Linde [5], S. Saduera [6]

1. Dietetics, Lewisham and Greenwich NHS trust United Kingdom 2. Dietetics The Walton Centre NHS Foundation Trust Liverpool United Kingdom 3. Dietetics Newham University Hospital, London United Kingdom 4. Dietetics Nottinghamshire Home Enteral Feeding Team United Kingdom 5. Dietetics Herefordshire and Worcestershire Health and Care NHS Trust United Kingdom. 6. Medical Affairs, Nestlé Health Science, Gatwick, United Kingdom

Chart 1. Changes in gastrointestinal symptoms before and after switch to Compleat® 1.5 HP tube feed.



Abbreviation: CHP1.5= Compleat® 1.5 HP

BACKGROUND

There is now a body of evidence to show tube feeds with a proportion of food-derived ingredients are safe and well-tolerated. Five studies in paediatric, adolescents and adults [1,2,3,4,5] have shown improvements in stool frequency[1,2] and consistency[1,2] retching[2], flatulence[2], constipation[2,4,5] loose stools[2,4] diarrhoea [3,4,5] nausea[5] and vomiting [5].

OBJECTIVE

The primary objective of the study was to assess the tolerability, acceptability of a 1.5 kcal/mL high protein enteral tube feed containing 19% of food derived ingredients and assessing compliance with the new tube feed. Secondary objectives included assessing reported changes to feed tolerance, compliance, patient satisfaction and any weight changes.

METHODS

Ethical approval granted by United Kingdom (UK) Research Ethics Committee and Health Regulation Authority (IRAS ID 324749, Ref: 23/YH/0036). The study measured gastrointestinal (GI) symptoms including diarrhoea, constipation, bloating, distension, nausea, vomiting, burping, flatulence, regurgitation, abdominal discomfort, pain pre and post switch of the new trial feed. Tube feed compliance was measured looking at the volume consumed by the participant versus amount suggested by the health care professional (HCP).

All participants were recruited from 5 UK NHS settings, 1 hospital inpatient site and 4 community centres across the UK. Participants were under the care of a dietitian and or a multidisciplinary team who determined the appropriate feed volume and rate of delivery for each patient. Informed consent from patients as well as those who lack capacity to consent a consultee, parent or caregiver consent was obtained prior to the start of the study.

Baseline data and a post satisfaction questionnaire was completed using Microsoft forms. Gastro-intestinal tolerance and tube feed intake diaries were recorded by the parent and or patient. Participants were switched to Compleat®1.5 HP (1.5 kcal/mL with 19% of ingredients derived from food) by the dietitian.

Demographic data such as age, gender, weight, height, medical history and baseline symptoms was collected by the dietitian. Over the 14-day period the following outcomes were measured, a change to gastrointestinal symptoms as “yes” or “no” and if the patient experienced “none”, “mild”, “moderate” or “severe” symptom changes. Volume of tube was recorded using an intake diary on suggested volume by HCP and the actual amount consumed by the patient over 7 days.

Table 1. Gender ratio, average age, weight, height and BMI for all participants.

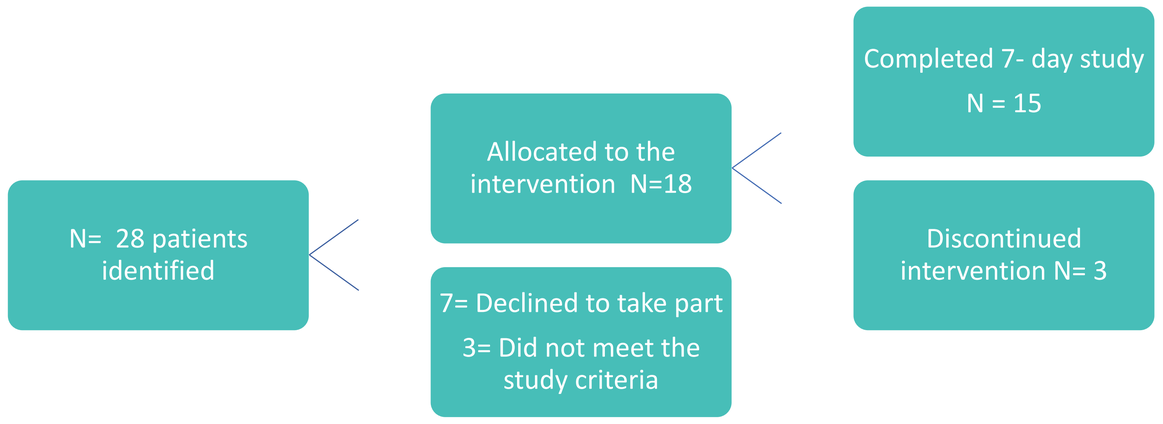
Male: Female ratio	Age Average, Years (Min - Max)	Weight Average, Kg (Min - Max)	Height Average, meters (Min - Max)	BMI Average, Kg/m²	Volume consumed vs prescribed Average, mL
13:5	46.35 (15 - 84)	59.57 (29.9 – 95.3)	1.53 (1.30 – 1.80)	25.1 (15.3-31.8)	975 vs 989 (98% compliance rate)

Abbreviations: Kg=kilograms; Kg/m²=kilograms per square meters; mL=milliliter; Max=maximum; Min=minimum;

RESULTS

- Chart 1. shows improvements in mild symptoms for constipation, abdominal pain, bloating, wind, gas, vomiting and regurgitation. CHP1.5 refers to the switch to Compleat® 1.5 HP.
- Majority of the participants had neurological condition such as cerebral palsy and stroke.
- C21-001 reported to have less bloating and stable bowel management since switching to the new trial feed. Participant was very satisfied.
- C21-002 experienced moderate symptoms of constipation at baseline and then a complete resolution of constipation post switch. There was also a reduction in bloating, wind and gas. The family were very satisfied with the outcome.

Diagram 1. Number of participants enrolled, allocated and completed Compleat® 1.5 HP acceptability and tolerance study.



- C22-002’s mother observed a positive impact on the colour of her son’s stool which were green prior to switch and changed to brown in colour post switch. There was also a reduction in gas, bloating and wind. The patient has a medical history of inflammatory bowel disease. The mother was very satisfied with the new trial feed.
- C23-002’s stopped feed at day 8 due to vomiting that was an ongoing clinical presentation and not related to the new trial feed.
- C23-003 at pre-switch family reported mild symptoms of diarrhoea x 7 per week, post-switch a reduction in diarrhoea x 2 per week (mild), suggesting a movement towards more “formed” stools. This participant was neither satisfied nor dissatisfied towards the new trial feed.
- C24-001 stopped his laxatives 2 days towards the end of the study. The dietitian reported if the participate stops his laxatives he would become constipated within a day or two. He managed to go much longer without laxatives on the new trial feed. Participant was very satisfied with the feed.
- C24-004 pre-switch reported mild diarrhoea symptoms 3-4 times per week, with moderate vomiting, bloating and wind. Post switch noticed mild symptoms of vomiting, bloating and wind and stools. Participant also reported slight improvement with no loose stools, burning or stinging when opening his bowels which was experienced with his previous feed. The participant was neither satisfied or dissatisfied with the trial feed.
- C25-001 and C25-005 both observed an increase in symptoms of abdominal pain, bloating, gas and wind reported; none to mild (pre switch) and post switch moderate to severe. C25-001 reported no constipation at baseline and after switch became more constipated. Baseline feeds did not contain fibre and it was a clinical decision to include a fibre feed. Both were dissatisfied with the trial feed.
- C25-002’s mother stopped the trial feed as she felt her son looked moody, tired, gloomy and not laughing. The participant was already consuming a fibre- containing feed at baseline, therefore the symptoms not likely to be feed related.
- C25-003’s wife noticed on day 2 an itchy rash on legs and arms and the feed was stopped. A further examination of the ingredients within the tube feed was ruled out for any cross contamination and concluded the rash was not feed related.
- C25-004’s father reported although no changes to GI symptoms using the new trial feed, he observed his son sleeping much deeper. Normally his son would wake up from a 2-hour afternoon nap but with Compleat® 1.5 HP his son slept straight through. Parent was satisfied with new trial feed.

CONCLUSION

Fifteen patients completed the study, with the new feed being tolerated by majority of patients. For those who are enterally fed using a non-fibre containing feed, we recommend a slow introduction for the bowels to adjust. Good quality of life such as a reduction in using laxatives and better sleep has also been observed in previous studies [2].

REFERENCES 1. Samela et al. Transition to a tube feeding formula with real food ingredients in pediatric patients with intestinal failure. Nutr Clin Pract. 2017; 32(2):277-281 2.Thornton-Wood C and Saduera S. Tolerance and Acceptability of a New Paediatric Enteral Tube Feeding Formula Containing Ingredients Derived From Food: A Multicentre Trial In The United Kingdom. J Neonatol Clin Pediatr 2020, 7: 050 DOI: 10.24966/NCP-878X/100050 3. O’Connor G, Watson M, Van Der Linde M, Bonner RS, Hopkins J, Saduera S. Monitor gastrointestinal tolerance in children who have switched to an “enteral formula with food-derived ingredients”: A national, multicenter retrospective chart review (RICIMIX study).Nutr Clin Pract. 2021;1-6.https://doi.org/10.1002/ncp.108129342022;37:929–934. 4.Schmidt et al. The effect of a natural food-based tube feeding in minimizing diarrhoea in critically ill neurological patients. Clinical Nutrition. 2019; 38(1): 332-340 5. Steel et al. Understanding the use and tolerance of a pediatric and an adult commercial blenderized enteral formula through real-world data. Nutr. Clin. Pract. 2023;38:449–457.

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