TO EVALUATE THE ACCEPTABILITY (INCLUDING GASTROINTESTINAL TOLERANCE AND COMPLIANCE) OF A PAEDIATRIC ENTERAL FORMULA WITH INGREDIENTS DERIVED FROM REAL FOOD FOR CHILDREN OVER 12 MONTHS OF AGE.

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Background

Giving blenderised foods via a feeding tube is becoming popular amongst caregivers and parents of children requiring long term tube feeding [(1)]. A cross sectional study carried out in adults showed that using blenderised feed via a feeding tube was mainly motivated by a better tolerance, a wish to share the same food with all family members and a perception that it is more natural [(2).] However, current policies and position statements do not recommend the administration of home-made blenderised foods through tube feeding due to risk of nutritional inadequacy [(1,2,3)] ; others have reported that blenderised feeds may lead to a higher viscosity which can increase the risk of tube occlusion[(1, 2)].

Two recent studies tested a commercially available product with ingredients from real food[(4, 5)]; Samela et al. 2017 noted improvements in stool consistency and frequency. Ninety percent of the intestinal failure children tolerated the feed at the prescribed volume when moving from an elemental formula to a commercial tube feed with ingredients from real food [(4)]. Schmidt et al 2018 also found significant reduction in the number of watery stools ($p<0.001$) amongst critically ill neurological patients[(5).]

The objective of the present study is to evaluate tolerance of an enteral formula derived with real food ingredients administered to children via tube feeding.

Methods

The study was designed to fulfil the UK Advisory Committee on Borderline Substances (ACBS) criteria to support submission for prescription usage within the National Health Service (NHS). The ACBS criteria assess tolerance including diarrhoea, constipation, bloating, distension, nausea, vomiting, burping, flatulence, regurgitation, abdominal discomfort, pain and product compliance (intake vs. prescribed amount) in a minimum of 15 children requiring tube feeding over a period of 7 days. The formula tested is a new paediatric enteral formula with ingredients derived from real food (Nestlé Health Science Isosource Junior Mix 1.2 Kcal/mL).

Participants (aged 1-14 years) were recruited from NHS settings, mainly via community dietetic services. All children were under the care of a dietitian and a multidisciplinary team. Participants were changed to the new enteral formula and monitored for 7 days. Demographic and medical data were obtained; gastrointestinal tolerance (diarrhoea, constipation, bloating, distension, nausea, vomiting, flatulence, abdominal pain and prescribed formula versus taken were all recorded). Stool type was measured using the Bristol Stool Chart.

Results

Participants had a range of medical conditions at enrolment including global developmental delay, epilepsy, cerebral palsy and Down's syndrome (table 1).

Gastrointestinal symptoms reported by caregivers in those completing the study were positive, except 1 case of constipation with flatulence:

- Participant 4 experienced improvements in stool consistency; this helped with initiation of potty training.
- Similar observation was reported for participant 6, with improved stool consistency and frequency; decreased bowel movements from two to one per day and stools more formed.
- Participant 8 usually experienced reflux after every feed; once the new formula was started the reflux resolved. There was also a change in stool frequency and consistency; with number of stools decreased from 3 times a day to once a day and a change in consistency towards firmer stools (from type 6/7 to type 4).
- Participant 9 usually retched throughout the day; when the new formula was started there was a gradual decrease in retching through days 1 to 5.
- Participant 2 experienced flatulence and constipation; the child received 20% of intake via food which is a confounding factor that may have caused symptoms

All remaining participants completed the 7 day trial and had no undesirable affects.

The main reasons for withdrawal were:

- Participant 1 - Feed was not stored in the correct conditions, caused user error and stopped the trial
- Participant 3 - Stools began to move towards constipation
- Participant 7 - Became unwell with vomiting whilst travelling

The 16 participants who completed the 7 day trial consumed an average of 730 mL per day (480-1400 mL) equivalent to the expected prescribed volume (figure 1). There were no changes in weight in any participants during the study.

Table 1. Participants Medical conditions

Participant	Medical condition
1	Cerebral Palsy
2	Dravet Syndrome
3	Cerebral Palsy
4	Nemaline Rod Myopathy
5	Born prematurity
6	Craniofacial cutaneous syndrome
7	Polymicrogyria and heterotopia
8	Born prematurely
9	Early developmental impairment
10	Born prematurely
11	Born prematurely
12	Downs Syndrome
13	Cerebral palsy with quadriplegia and epilepsy
14	Born prematurely
15	Global developmental delay
16	Severe cerebral palsy
17	Cerebral palsy
18	Cerebral palsy and epilepsy
19	Bilateral Striatal necrosis

Figure 2 Participant completion summary

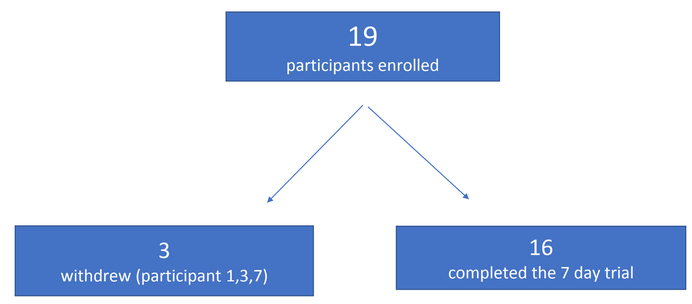
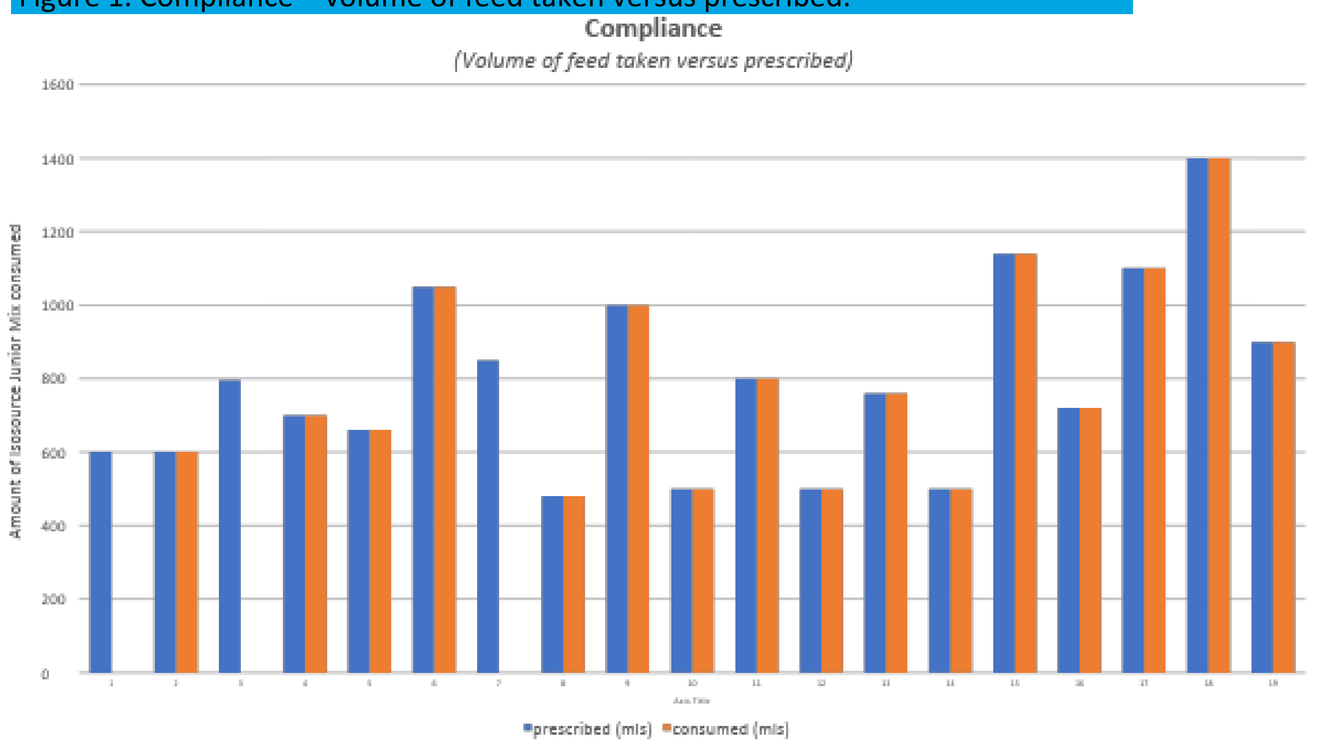


Figure 1. Compliance – volume of feed taken versus prescribed.



Conclusion

The new tube feed formula made with real food ingredients was well tolerated by the majority of participants, with a decrease in gastrointestinal symptoms in some and beneficial changes in stool type in others.

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