A multi-centre, single arm study designed to evaluate the gastro-intestinal tolerance and compliance of a standard adult enteral tube feed with food derived ingredients in the United Kingdom.

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BACKGROUND

Home- made blended diets is increasingly popular in children, however these children will need to transition to adult services[1]. A cross-sectional study carried out in adults showed that using blenderized feed via a feeding tube was mainly motivated by better tolerance, a wish to share the same food with all family members and a perception that it is more natural [2.] However, the administration of home-made blenderized foods through tube feeding cannot be conducted by patients, parents, or caregivers as it requires a lot of resources. There are also some documented studies describing the risk of nutritional inadequacy [2,3,4] others have reported that home- made blenderized foods may lead to a higher viscosity which can increase the risk of tube occlusion[3]. A growing body of evidence indicates tube feeds with food-derived ingredients are safe, well-tolerated and may improve symptoms of retching, nausea, vomiting loose stools and constipation [5,6].

OBJECTIVE

The primary objective of the study was to assess the tolerability, acceptability of a whole-protein 1.1 kcal/mL enteral tube feed containing 16% of food derived ingredients and assessing compliance with the new tube feed. Secondary objectives included assessing reported changes to feed tolerance, compliance and a patient satisfaction.

METHODS

Ethical approval granted by United Kingdom (UK) Research Ethics Committee (REC) and Health Regulation Authority (HRA) (IRAS ID 308680 Ref: 22/SC/0004. The study design was based on the United Kingdom (UK) Advisory Committee on Borderline Substances (ACBS) criteria to support submission for prescription usage within the National Health Service (NHS). The ACBS criteria assess gastrointestinal (GI) tolerance including symptoms of diarrhoea, constipation, bloating, distension, nausea, vomiting, burping, flatulence, regurgitation, abdominal discomfort, pain and product compliance as intake versus amount suggested by health care professional.

All participants were recruited from 5 UK NHS settings, 2 hospital inpatient centres and 3 community centres. All participants were enterally fed patients in the hospital and or community. 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. Participants were switched to Compleat® a 1.1 kcal/mL enteral tube feed with 16% of ingredients derived from food. Gastro-intestinal tolerance and tube feed intake was recorded by the parent, patient and or caregiver after switch.

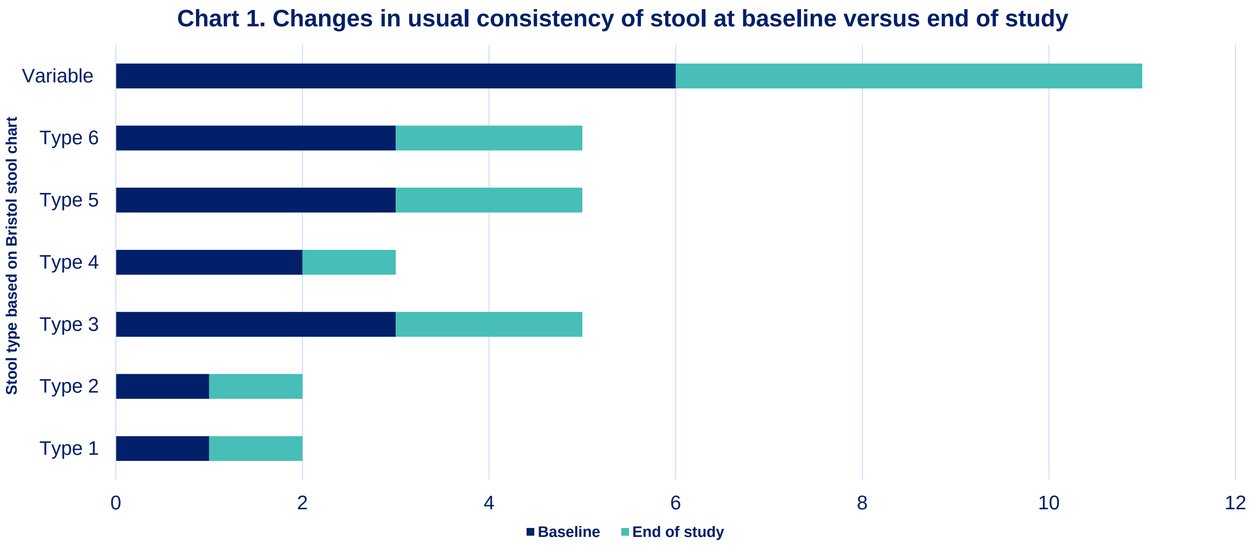
Demographic data such as age, gender, weight, height, medical history and baseline symptoms were collected by the dietitian. Over the 7-day period the following outcomes were measured; a change to gastrointestinal symptoms as “yes” or “no” and if the patient experienced “none”, “mild”, “moderate” or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

RESULTS

The tolerance study took place between January 2023 to January 2024 where 16/17 participants completed 7 days. No serious adverse events reported. Majority of the participant in the study have neurological conditions such as cerebral palsy, learning difficulties, stroke and brain injury.

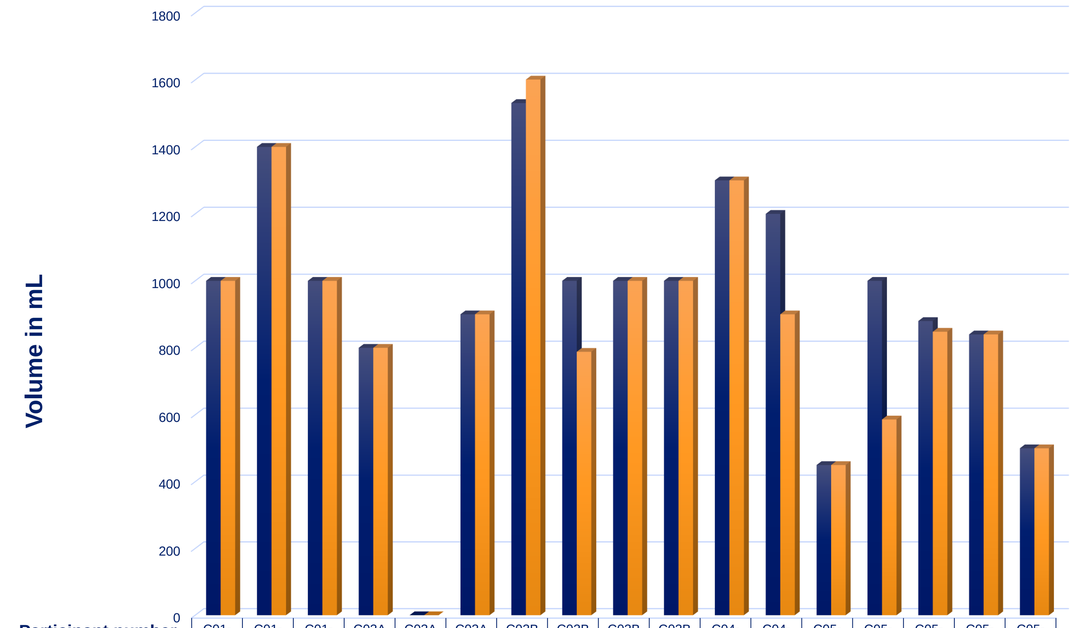
Male to female ratio was 11:6. Average age 28 years, the youngest being 8 years and 2 months and the eldest 71 years of age. Average weight 41 kg, height 1.39 meters and average BMI 21 kg.m^2. Average volume consumed was 877mLs versus 929mLs prescribed by the dietitians with a compliance rate of 94%.

Chart 1. Changes in usual consistency of stool at baseline versus end of study



- C01-001 saw a change in stool type from 5/6 to type 4, suggestive of a change towards more formed stool consistency.
- C01-002 reported bowels opening every 2 days prior to switch and after switch opening bowels some days to once a day. Parents satisfied as child no longer requires separate fibre doses via feeding tube, child is more settled on the new trial feed.
- C01-003 reported type 6 large stools pre and post switch with no change. Participant was satisfied with the new trial feed.
- C03A-001 saw a change in stool type from type 2 large to type 4 medium. Parents reported his stools are no longer watery when using the new trial feed.
- C03A-002 experienced vomiting during switch and stopped the new feed. Investigator concluded vomiting was not feed related as previously on a paediatric version of trial feed.
- C03A-003 reported pre-switch type 6 stools, after switch type 5 medium stools. Parent reported vomiting was improved to none on most days. His stools became more solid and does not experience flatulence. Significant improvements were observed, and parent was very satisfied.
- C03B-001 reported type 3 medium stools, after switch type 3 large, slightly improved and parents were satisfied with new trial feed.

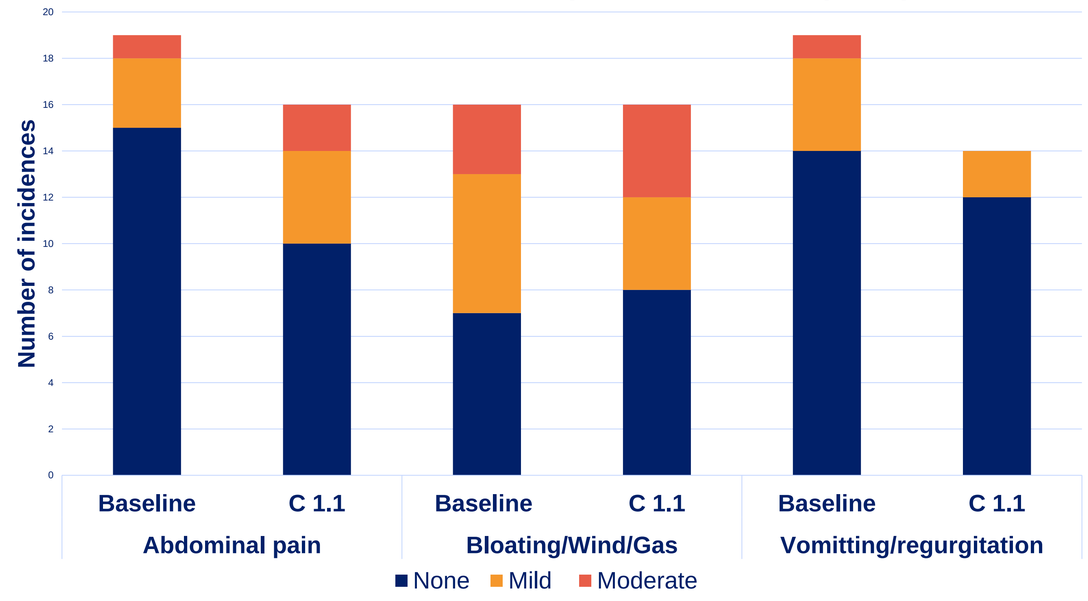
Chart 2. Total volume of tube feed prescribed versus total volume consumed in mL per participant



Participant number	C01-001	C01-002	C01-003	C03A-001	C03A-002	C03A-003	C03B-001	C03B-002	C03B-003	C03B-004	C04-001	C04-002	C05-001	C05-002	C05-003	C05-004	C05-005
Total volume prescribed (mL)	1000	1400	1000	800	0	900	1531	1000	1000	1000	1300	1200	450	1000	880	840	500
Total volume consumed (mL)	1000	1400	1000	800	0	900	1601	788	1000	1000	1300	900	450	586	848	840	500

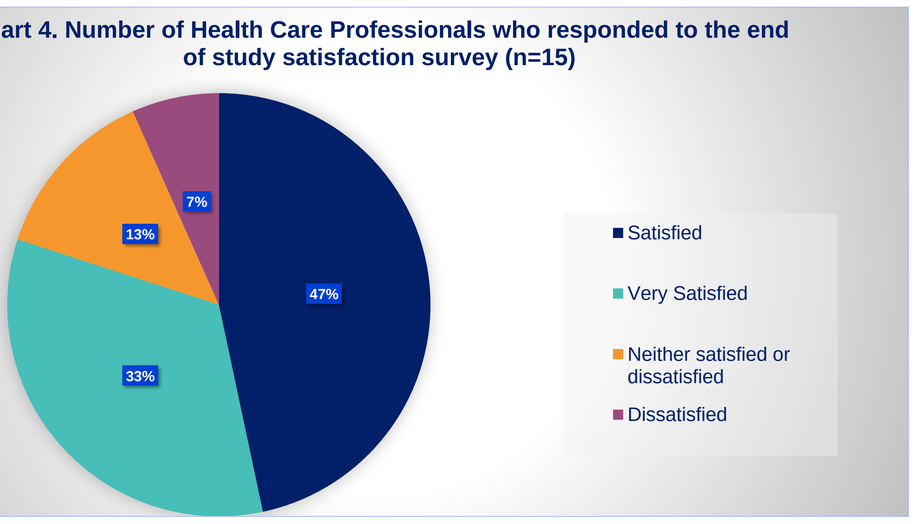
Total volume prescribed (mL) Total volume consumed (mL)

Chart 3. Gastrointestinal symptom changes at baseline versus after switch to Compleat 1.1 kcal/mL (C 1.1)



- C03B-002 reported formation of flatulence, medium variable to medium type 3 stools but was still satisfied with the new trial feed.
- C03B-003 pre-switch had type 5 small stools, post switch type 5 large stools. Parents saw slight improvements and were satisfied.
- C03B-004 reported constipation, however baseline reported constipation with variable stools between type 1-5, suggesting these are normal symptoms. Participant reported being dissatisfied with new trial feed.
- C04-001 pre-switch reported type 5 medium stools, post-switch medium variable stools. Constipation was resolved although some flatulence and abdominal pain was experienced on day 2,6 and 7 due to the fibre in the new trial feed. Reports of significant improvements and parent was very satisfied. The child was in a better mood.
- C04-002 reported on day 6 and 7 “more normal” stools compared to previous feed. Parents were very satisfied, and child more settled on feed. Reports of feeling more “fuller” and no long requires extra fibre doses via the feeding tube.
- C05-003 stopped trial feed due to previous history of constipation and on bowel cleansing medication. After adjustments to medication, parent restarted trial feed and achieved tolerance. Parents were very satisfied.
- C05-004 reported medium variable type 6/7 stools pre-switch, post switch type 4 medium stools with no straining and passing stools without extra laxatives. Parents noted significant improvements and were very satisfied.
- C05-005 pre-switch reported type 3 medium stools, post-switch medium type 4, caregiver reported slight improvement and were satisfised since flatulence was reduced post switch.

Chart 4. Number of Health Care Professionals who responded to the end of study satisfaction survey (n=15)



CONCLUSION

Compleat® 1.1 kcal/mL was well tolerated by majority of patients, with some experiencing improvements in stool type and consistency. Two participants did experience flatulence and one with additional abdominal pain due to the fibre content in the new trial feed. Suggest a slower infusion for those patients sensitive to fibre.

REFERENCES

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