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Health Technology Assessment

Synopsis

The risks, benefits, and resource implications of different diets in gastrostomy-fed children: The YourTube mixed method study

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Abstract

Background: Many children receive some or all their nutritional intake via a gastrostomy. More parents are using home-blended meals to feed their children, reporting beneficial effects, such as improved gastro-oesophageal reflux and less distress.
Aim: To compare safety, outcomes and resource use of those on home-blended diets compared to formula diets.
Methods: A mixed-methods study of gastrostomy-fed children.
Workstream 1: Qualitative study involving semistructured interviews with parents ($n \approx 20$) and young people ($n \approx 2$) and focus groups with health professionals ($n \approx 41$).
Workstream 2: Cohort study; data were collected on 180 children at months 0, 12 and 18 from parents and clinicians using standardised measures. Data included gastrointestinal symptoms, quality of life, sleep (child and parent), dietary intake, anthropometry, healthcare usage, safety outcomes and resource use. Outcomes were compared using propensity scored weighted multiple regression analyses.
Results: Workstream 1: Participants believed the type of diet would most likely affect gastrointestinal symptoms, time spent on feeding, sleep and physical health.
Workstream 2: Baseline: Children receiving a home-blended diet and those receiving a formula diet were similar in terms of diagnoses and age, but those receiving a home-blended diet were more likely to live in areas of lower deprivation and their parents had higher levels of education. They also had a higher dietary fibre intake and demonstrated significantly better gastrointestinal symptom scores compared to those receiving a formula diet (beta 13.8, $p < 0.001$). The number of gut infections and tube blockages were similar between the two groups, but stoma site infections were lower in those receiving a home-blended diet.
Follow-up: There were 134 (74%) and 105 (58%) children who provided follow-up data at 12 and 18 months. Gastrointestinal symptoms were lower at all time points in the home-blended diet group, but there was no difference in change over time within or between the groups. The nutritional intake of those on a home-blended diet had higher calories/kg and fibre, and both home-blended and formula-fed children have values above the Dietary Reference Values for most micronutrients.

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Safety outcomes were similar between groups and over time. Total costs to the statutory sector were higher among children who were formula fed, but costs of purchasing special equipment for home-blended food and the total time spent on child care were higher for families with home-blended diet.

Conclusion: Findings show that home-blended diets for children who are gastrostomy fed should be seen as a safe alternative to formula feeding for children unless there is a clinical contraindication.

Limitations: The target sample for children in workstream 1 was not achieved. The observational study design means unmeasured confounding may still be an issue. Children in this cohort had been on their home-blended diets for different periods of time. A lack of good reference data for nutritional and anthropometric data for disabled children does hinder further interpretation of nutritional adequacy.

Future work: Future research on: impact of a home-blended diet on the gut microbiome in children who are gastrostomy fed and equality of access. Children's experiences of living with a gastrostomy, nutritional requirements and quality of life should also be prioritised.

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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/RRREF7741.

Synopsis

This report details a mixed-methods sequential study with the aim to assess the safety, benefits and risks of gastrostomy feeding by comparing children who have formula feeds with children who have blended food in their diet. The study was funded via a call commissioned by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme.

Rationale and background

There are increasing numbers of children with complex healthcare needs that require having all, or part, of their nutritional intake via gastrostomy feeds. The recommended feed for children via gastrostomy is commercially produced formula.[3] However, there is a growing body of parents who are interested in and/or choosing to feed their children with home-blended meals.[4,5] These parents report benefits such as improved gastro-oesophageal reflux symptoms, less constipation and less distress in their child.[6] The need for further research in this area came from a research prioritisation exercise,[7] review of the literature[8] and professional organisations, for example, the British Dietetic Association (BDA).[3]

Aim

The overall research question for this two-stage study was: What are the risks, benefits and resource implications for using home-blended food for children with gastrostomy tubes compared to currently recommended formula feeds?

Study objectives

1. To identify the important outcomes of gastrostomy feeding for parents, young people and health professionals.
2. To assess the safety of home-blended diets for children who are gastrostomy fed compared to liquid formula diets.
3. To identify and quantify the benefits of home-blended diets compared to liquid formula diets for children who are gastrostomy fed and their parents.
4. To identify and quantify the resources (family and statutory services) required to support home-blended diets compared to liquid formula diets.
5. To assess whether long-term follow-up of children who are gastrostomy fed is feasible using routine data sources.

Protocol

Full details of the study were published as a protocol in *BMJ Open*[1] and are registered (ISCTRN13977361).

The study design devised by the HTA was a programme containing two workstreams. A primary qualitative study, involving semistructured interviews with parents of gastrostomy-fed child and focus groups of healthcare professionals (HCPs) that care for these children, which was followed by a secondary prospective cohort study (*Figure 1*).

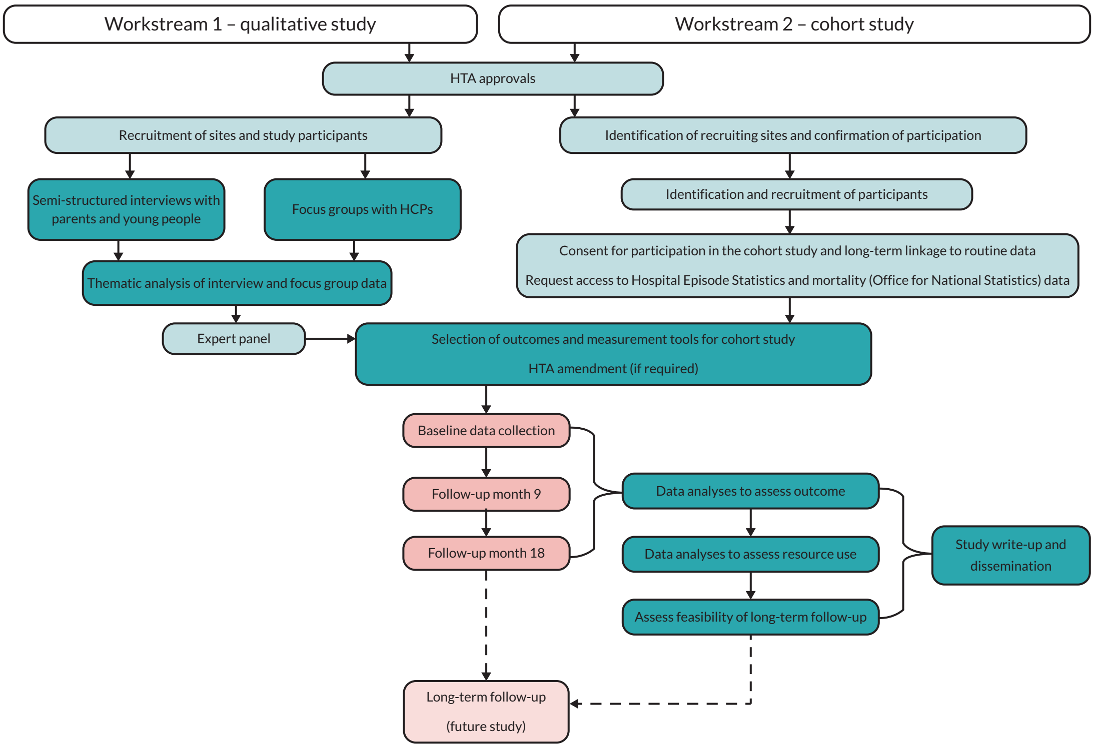

FIGURE 1 Study flow chart demonstrating mixed-methods sequential design. Reproduced with permission from British Dietetic Association.[3] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

Workstream 1

The findings from workstream 1 (WS1) have been published in this linked paper, Maddison *et al*.[9]

Aim

To identify child and parent outcomes relevant to having a gastrostomy and to specify outcomes believed to be particularly salient to a type of diet (formula vs. blended food).

Methods

Study design

Qualitative research methods were used to ascertain and explore the views and experiences of parents, young people and health professionals. We used interviews to collect data from parents and young people (12–18 years) and focus groups with professionals.

Sampling

Target sample sizes were: parents (*n* = 20), young people (*n* = 5–10), paediatricians (*n* = 6–8), dietitians (*n* = 6–8), children's community nurses (*n* = 6–8) and speech and language therapists (*n* = 6–8).

Study participants were recruited via community or specialist paediatric services in five NHS Trusts located in different English regions. For the professionals' sample, these services also recruited staff from community nursing and dietetic teams attached to, or working into, their services. Services differed in support offered to parents using blended diets. For the parent and young people samples, purposeful sampling ensured representation of factors hypothesised to affect participants' views and experiences (e.g. primary diagnosis, age, duration of gastrostomy-feeding and type of diet). See protocol for participant identification, recruitment and consenting procedures.[1]

Data collection

Topic guides ensured consistent coverage of topic areas across interviews and focus groups. Topics covered are detailed in the protocol.[1] Data reported in this paper concern parents', young peoples' and health professionals' views regarding key outcomes of gastrostomies and gastrostomy feeding. Sections from the parent and professional topic guides regarding the effects of gastrostomies and gastrostomy feeding explored are:

- gastrointestinal (GI) symptoms
- other observed health outcomes and quality of life impacts
- risk/safety issues
- financial and time costs to families.

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Given the focus of the overall study and concerned type of diet, throughout interviews/focus groups, the perceived effects of diet type on outcomes and impacts were probed.

Interviews with young people focused on perceived benefits and disadvantages of being gastrostomy fed and experiences of GI symptoms and other outcomes/impacts. To facilitate these interviews, young people were sent a simple, illustrated booklet in advance, which set out interview topics with space, if they wished to use it, to note down responses (see *Report Supplementary Material 1*).

One researcher (Jane Maddison) conducted all the interviews; focus groups were carried out by two researchers (Jane Maddison and Bryony Beresford). Parents and young people were offered a telephone or face-to-face interview at home. Professionals' focus groups were held on each site's premises. Data collection took place between May and October 2019.

Data analysis

Interviews and focus groups were audio-recorded and transcribed verbatim. We adopted an inductive approach to data analysis using thematic analysis techniques[10] (full details given in protocol;[1] see *Report Supplementary Material 2* for coding frameworks). Data analysis was carried out by Jane Maddison (lead) and Bryony Beresford. Ongoing dialogue via face-to-face discussions and sharing/commenting on analytical writings supported the process.

Results summary

Sample

Twenty parents, two children (both 12 years) and 41 professionals [dietitians (*n* = 10); nurses (*n* = 12); paediatricians (*n* = 12); speech and language therapists (*n* = 7)] were recruited. Parents and children were interviewed; professionals participated in focus groups. Children (2–18 years) represented included those on formula (*n* = 11), blended-food (*n* = 7) and mixed (*n* = 2) diets. All had been tube-fed for at least 6 months. Neurological, genetic and metabolic conditions were represented.

Overview

Participants identified a range of children's outcomes relevant to a gastrostomy, including physical health, GI symptoms, sleep and time spent feeding. The children described experiences of exclusion caused by being tube-fed. Time, sleep and emotional health were regarded as most salient to understanding parents' gastrostomy outcomes. Participants believed that the type of diet would most likely effect GI symptoms, time spent feeding, sleep and physical health.

Understanding how gastrostomies affect children's lives

One of the aims of our analysis was to develop an initial theory to describe the way in which gastrostomies and gastrostomy feeding affect children's lives, see *Figure 2*.

Features of a gastrostomy which emerged as fundamental to understanding its effects were its *visibility* and *invasive* nature and that, through the use of feeding equipment (e.g. pumps), *substances enter the* GI *tract at the stomach* rather than orally. It may also result in *changes in diet* and *the rate at which food enters the stomach*. Singly or together, features of the gastrostomy affected outcomes either directly or indirectly, via their effect on the child's *nutritional, fluid and/or medication intake*.

The terms outcomes and impacts are often used interchangeably,[11] and we deliberately assign them with different meanings. We define outcomes as *specific aspects* of children's lives, which study participants regarded as *direct consequences*, *or directly relevant*, to a gastrostomy or gastrostomy feeding (see *Figure 2*). These were wide-ranging, including physical health, GI symptoms, duration of day-time feeding, emotional health, sleep, other condition-related symptoms, sensory world, motor development and cognitive functioning. A single outcome was often implicated in a number of different 'chains of response' or outcome hierarchies (e.g. GI symptoms causing pain-related distress; GI symptoms prolonging duration of feeding, thereby reducing opportunities for movement with consequences for motor development). Cycles of reinforcement were also described (e.g. attention and cognitive development).

Impacts, by contrast, are *broad domains of children's lives*, which study participants identified as being potentially affected by not only one or more of the identified outcomes but also affected and influenced by a number of other factors not identified as relevant to gastrostomy outcomes. Impacts identified by study participants can be conceived as falling into three broad domains: participation, well-being (physical and emotional) and achievement of developmental potential.

A number of contextual factors (ovals in *Figure 2*) were also identified, which study participants believed moderated or mediated outcomes and/or impacts. These included the child's age, condition-centred factors (e.g. gut motility), quality of healthcare support (particularly from dietitians) and how feeding was managed in other settings.

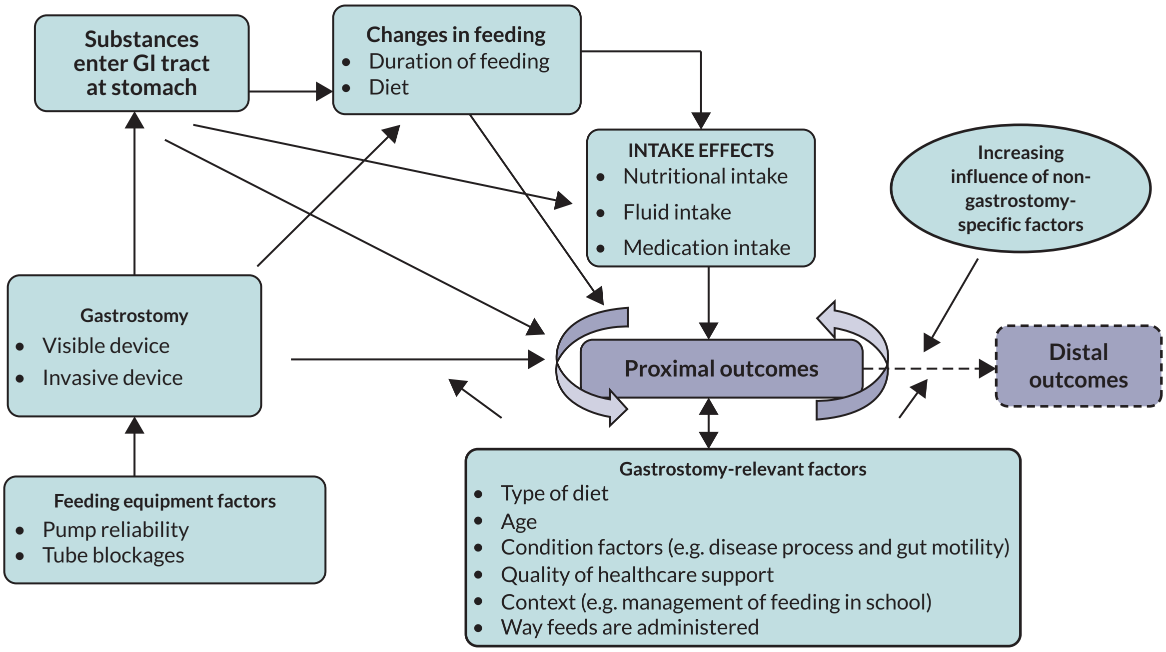

FIGURE 2 Gastrostomy-associated factors and processes impacting outcomes.

Type of diet (i.e. prescribed formula vs. blended food) was also identified as having the potential to affect outcomes and impacts. *Gut biome* was one mechanism through which the diet type affected outcomes.

Finally, there were equipment-related factors. Issues with feeding equipment (e.g. pump failure and tube blockage) emerged as a cause of transitory inconvenience for parents. However, they were not identified as substantively affecting child, or parent, outcomes. Granular antireflux medication was consistently identified as the predominant cause of tube blockages. While some HCPs had concerns that blended foods may cause tube blockages, this was not the experience of other HCPs or parents using this type of diet.

Adjusting to a gastrostomy

Two broad phases of having gastrostomy emerged from participants' accounts and were relevant to our understanding of gastrostomy outcomes. First was a period of adjustment for both child and parent. The first weeks, and sometimes months, post gastrostomy could be difficult and challenging, particularly when feed intolerance increased GI symptoms or when the process of identifying optimal feed rates and routines was protracted. Overall, however, both positive and negative outcomes were described during this period. A generally settled time was arrived at where, relative to other aspects of the child's health, feeding and feeding-related outcomes caused fewer concerns. All the parents/children in our sample had reached this period. Changes from a formula to home-blended diet occurred in both phases, largely determined by whether change of diet was due to the management of GI symptoms or parents wishing to assume control of their child's diet. While not represented in our parent sample, HCPs noted that not all children tolerated a home-blended diet and returned to formula.

Child outcomes

Key *physical health outcomes* included weight (and including body fat proportion and distribution), the condition of their skin/hair/nails and presence/absence of lethargy. Resilience to and recovery from illness and infection (indicated by hospital admissions and school absence) were also regarded as relevant outcomes. Here, some participants (parents and HCPs) noted potential beneficial effects of a home-blended diet on the gut biome and immune system. At the same time, some HCPs expressed the concern (not necessarily based on clinical experience) that home-blending increased the risk of GI infections due to poor food hygiene practices. HCPs typically questioned the meaningfulness of stoma site infections as a gastrostomy outcome, given the idiosyncratic way children were, or were not, susceptible.

The GI *symptoms* were another key outcome area. Being (potentially significant) unpleasant and uncomfortable physical experiences, these symptoms caused emotional distress. Their potential to affect achievements or improvements in other outcome areas was consistently noted. Participants' accounts suggest significant individual variation in GI symptoms for causing most distress and

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the potential effects of other factors (e.g. gut motility medication side effects and fundoplication) on GI symptoms. Individual, and idiosyncratic, differences in feeding rate tolerance further contributed to the complexity of assessing GI symptom outcomes. The type of diet emerged as relevant. Some parents and HCPs had found that changing from a formula to a home-blended food diet improved GI symptoms and, indeed, could be the primary reason for changing diet. However, HCPs with extended experience of home-blended diets reported that they were not always tolerated and returning to formula feeds eased GI symptoms. Finally, the difficulty and resultant uncertainty of ascertaining GI symptom experiences of children unable to communicate were a consistent theme in the data, particularly parents' interviews.

Duration of day-time feeding was consistently regarded as a further key outcome area and one prioritised by the two young people taking part in the study. For some children, a gastrostomy had the potential to significantly reduce the duration of day-time feeding due to increases in the rate at which feeds could be administered compared with oral intake, reductions in gagging, retching and vomiting (symptoms which prolonged feeding sessions) and/or the option of overnight feeds. Parents' accounts, in particular, further specified this outcome area. First, and also raised by the young people, was the importance of discerning when, and for how long, daytime feeding restricted or precluded other activities. Second, the period of time a child needed to stay still and upright post feed (and therefore unable to engage in other activities) may be relevant.

The type of diet emerged as potentially relevant to the duration of daytime feeding. As reported earlier, formula intolerance could exacerbate GI symptoms (e.g. vomiting) and consequently prolong the duration of feeds. By contrast, some parents and HCPs reported experiences of blended food being tolerated better than formula, reducing the time taken to give feeds. At the same time, a blended food diet could prohibit using a pump which, if the portable type contained in a back-pack, had the potential to allow children to be less restricted during feeding times compared to syringe feeding.

A number of specific outcomes falling within the concept of *emotional health* were articulated. Pain/other GI symptom distress (e.g. caused by persistent vomiting) and hunger-associated irritability (the term 'settled' was often used in this respect) were regarded as relevant to all gastrostomy-fed children. We note again the issue of capturing these experiences from those with significant cognitive impairments. Other emotional health outcomes emerged as being specific to particular groups of children. Feeding-related anxiety was specifically mentioned in situations where children were food/oral-feeding averse. Exclusion-related distress was relevant to children with no or mild/moderate cognitive impairment and had the potential for significant impact on emotional health. Sources of distress included being unable to eat orally, (partial) exclusion from situations where food plays a significant role (e.g. celebrations), differences in daily routines imposed by gastrostomy feeding and the visible nature of the device generating a sense of difference.

Sleep was an outcome area which parents and HCPs believed to be highly relevant to gastrostomy-fed children, and it was affected by nutritional sufficiency, GI symptoms (including those caused by overnight feeds), need for/duration of overnight feeds and feeding equipment-related issues (e.g. alarms). This was an outcome area where trade-offs between outcomes were observed, for example, choosing overnight feeds as the main intake so as to reduce day-time feed duration. Some participants noted that attributing sleep disturbance to gastrostomy feeding was not always straightforward, given other factors related to a child's condition could affect sleep (e.g. seizures and other causes of pain) or where behavioural insomnia was a pre-existing issue.

That a gastrostomy allows medications to be introduced directly into the stomach and potential reductions/improvements in vomiting or diarrhoea, meant that complete doses were being retained. This could result in reduced severity/improved *management of comorbidities* (e.g. seizures and colitis) and/or a reduction in dosage.

Gastrostomy feeding was also regarded as having the potential to affect – in a positive or negative way – a *child's sensory world*, specifically taste and texture experiences. This could happen in a number of ways, some of which were dependent on the reason for the gastrostomy. For any child, unpleasant tasting medications were no longer administered orally. For previously non-formula, orally fed children with unsafe swallow, there was the loss of a source of sensory pleasure. For food-averse children with a safe swallow, the purpose of taking food orally could shift to primarily being for (positive) sensory stimulation. It was believed such positive experiences could support a return to (greater) oral feeding. The type of diet was also implicated; parents using home-blended diets believed burps more likely to offer a pleasant sensory experience compared to formula.

Outcomes in two further aspects of children's lives were identified. Compared to other outcome areas, they were not mentioned with the same degree of consistency or strength of opinion. They were *cognitive functioning outcomes* (attention and cognitive development) and *motor development*, and both were affected by the changes in nutritional intake. Other gastrostomy-relevant outcomes (e.g. sleep, duration of daytime feeding and energy/lethargy) were cited as further supporting improvements in these outcomes. It was noted that the individualised nature of developmental trajectories of many tube-fed children may render discerning the effects of a gastrostomy feeding on these outcome areas challenging.

Parent outcomes

Parent outcomes which were identified as related to their child's gastrostomy and feeding are summarised in *Table 1*.

Emotional health

Difficulties in establishing gastrostomy feeding, and temporary or longer-lasting issues with GI symptoms, had negative effects on parents' emotional health (e.g. distress and worry). Some described a heightened vigilance, or sense of threat, when their child was being fed, which did not necessarily ease over time. At the same time, positive effects – predominantly, a sense of relief – were described when improvements in the child's health were observed and feeding became easier. Contrary to some previous studies, parents did not focus on sadness or regret over the erosion of their nurturing (i.e. food provider) role. HCPs reflected that such feelings are often present during the decision-making process but become less salient once the gastrostomy is in place and the effects of improved nutritional intake are observed. However, some parents described an enduring sadness that their child no longer ate orally (and this was highly unlikely to change) and the losses and exclusion this caused.

TABLE 1 Parent outcome domains

Emotional health
Caregiving demands
Confidence managing gastrostomy and g-feeding
Support network
Parenting satisfaction
Sleep
Physical health
Time
Financial costs

Caregiving demands and caregiver confidence

Gastrostomy insertion and feeding regime had the potential to affect existing *caregiving demands* (e.g. feeding, settling and administering medication), either positively or negatively. There were also new demands such as stoma care, managing supplies of formula and cleaning feeding equipment.

Confidence in their ability to manage stoma care and feeding was a particularly salient outcome in the period following gastrostomy insertion. Where parents had moved to a home-blended diet, confidence in their ability to meet the child's nutritional needs was an additional component of caregiver confidence. Dietitians/the clinical team and parents (the latter often via social media) emerged as key sources of support during this period.

Support network

Gastrostomy feeding also had the potential to impact parents' support networks. Participants reported family members who were previously involved in child care feeling unable to manage the feeding and the respite care services refusing to take a child. Loss of such support could be transitory or long term, with knock-on effects on the caregiver burden. The requirement for informal/paid carers to be observed administering feeds before this was permitted by the clinical team could also reduce the availability of support.

The type of diet had the potential to further influence parents' support networks. Some parents using a home-blended diet reported poor levels of support from the clinical team. Service-level differences in policy regarding support for this diet type, and individual differences between professionals, were reported. In terms of informal support, there were instances where 'de-medicalisation' of feeding (e.g. creating a feed using regular kitchen equipment and food rather than making up prescription formula; use of a syringe rather than a pump) led to family members feeling more able to administer a child's feeds.

Parenting satisfaction

Parents and HCPs alike noted that, for some parents, the decision to use a home-blended diet contributed to parenting satisfaction. Pleasure and a sense of fulfilment were gained from their child having a diet consistent with their wider priorities and ethos and/or that one aspect of their child's life was 'de-medicalised' and as similar as possible to the rest of the family. For other parents, however, this was not among their priorities for their child.

Sleep

Three ways in which gastrostomy feeding may have affected the duration or quality of parents' sleep emerged. First, overnight feeds could cause parents to sleep 'lightly' due to concerns about vomiting, equipment malfunction or the child getting tangled in the feeding tube. Second, GI symptom – distress or hunger-associated irritability (the latter identified as typically reducing following gastrostomy insertion) – interrupted sleep. Finally, where late evening/bedtime feeds were being used, parents reported delaying their own bedtime. Type of diet emerged as having the potential to affect parents' sleep. For example, switching to a blended food diet meant overnight feeds were no longer used, or resulted in improved GI symptoms.

Physical health

Some of the parents who had changed to a home-blended diet reported this had prompted a wider re-think about the quality of the family's diet. This resulted in a shift to cooking from scratch with fresh and varied ingredients. These parents reported weight loss and improved energy levels.

Time

Parents believed their time was a value-laden concept and subject to individual differences in whether demands on time were unquestioned (or even unnoticed), regarded as 'worth it', or were experienced as burdensome. Parents' views about the impacts of gastrostomy feeding on their time were variously affected by:

- a desire to normalise parenting and child's needs
- personal beliefs and priorities related to the parenting role (e.g. family's diet and shared mealtimes)
- observed benefits of time investment on child outcomes.

Key components of parents' time identified as important to capture were:

- feed preparation separate or incorporated into family meal preparation (i.e. blended food diet)
- feed administration
- administration of antireflux medication
- if not directly administering feed, monitoring feed and/or child during feed
- capacity to attend to other tasks at same time as above
- time taken to offer food orally for food-averse children.

Mode of administration (pump vs. syringe) and GI symptoms were key factors affecting parent's time. Some parents using a home-blended diet reported a more painstaking approach to feed preparation in the early days of using the diet. In some instances, this was required of them by the clinical team.

Finances

The 'extra costs' associated with caring for a disabled child and impacts on parent employment are well documented.[12–14] In this study, the particular focus regarding impacts on family finances concerned the use of a home-blended diet compared to prescription formula which, in the UK, is provided free of charge by the NHS. Parents using a home-blended diet varied in whether feeds were blenderised versions of regular family meals or prepared separately, sometimes using foods that the family would not ordinarily consume. Some parents using a home-blended diet did not believe that the associated food costs should be attributable to the gastrostomy, since this would be incurred if their child did not have a feeding difficulty.

Conclusion

Findings indicate a number of refinements to, and allow further specification of, the current 'initial' core outcome set for tube-fed children. Findings also have implications for choice of outcomes' measures. The number of children recruited to this study was lower than target; therefore, further qualitative research with children and young people is needed.

Integration of workstream 1 findings into design of workstream 2

Reference to the following were made when weighing up the implications from WS1 for workstream 2 (WS2) design and data collection:

- the study objectives for WS2, which was focused on the outcomes associated with diet rather than gastrostomy feeding
- the study objectives for WS2, which was focused on the immediate/direct outcomes associated with diet rather than the distal outcomes that may occur as a result of these
- potential risks for WS2 in relation to participant burden and distress, reporting bias, data quality and completeness
- ability to measure proposed variables and outcomes
- ability to analyse collected data.

For a detailed account of the decision-making around WS1 integration, see *Report Supplementary Material 1*.

Summary

The WS1 findings confirmed that GI symptoms should be the primary outcome for the cohort study (WS2).

There was a list of additional outcomes identified in WS1, some of which were able to be included in WS2:

- food aversion
- changing feed administration technologies
- child's condition/diagnosis and feeding history
- physical thriving
- illness/infection episodes
- general health – time off school as an indicator
- school participation
- sleep
- GI treatments/medications
- parental anxiety
- physical comfort
- parental ease of feeding; includes data on time spent preparing feeds, administering feeds and medications and duration of feeds
- retching and gagging
- health service resource use
- survival.

Other relevant outcomes that were not able to be included in WS2:

- Gut microbiome – outside scope of study.
- Service support – outside of scope of study.
- Formula intolerances – challenging to collect meaningful data.
- Judgements regarding physical presentation – inappropriate as highly subjective.
- Use planned collection health service use data as indicator of physical health outcomes – not feasible.
- Cognitive thriving – unfeasible and outside scope of study.
- Sensory world – outside scope of study.
- Child time of daily duration of day-time feeds collected from sleep data – significant data collection needs. Non-feeding awake time is also more related to feeding schedule rather than diet.
- Participation in life – inappropriate to make this assumption; would involve significant additional data collection and is highly dependent on child's cognitive impairment/disability and parenting.
- Safety outcome: recording reason for blockages – too burdensome for participants and not possible to include in planned analyses.

Workstream 2

The baseline data have been published[15] and the longitudinal data analyses.[2]

Aim

To assess the risks, benefits and resource implications of home-blended food for children with gastrostomy tubes compared with formula diet.

Methods

This was a prospective cohort study which aimed to recruit 300 families via 32 sites across England [28 NHS trusts and 4 children's hospices) (see *Table 2*)]. This target was reduced to 200 after the implications of COVID-19 on research in the NHS in the UK. The original sample size of 300 was based on a 1 : 2 ratio of formula to home–blended food-fed children.[1] With the new sample size, with similar-sized groups of around 100 (total $n = 200$), there would still be under 10% margin of error. Participating families were followed up for 18 months with data collected at baseline (August 2019–November 2021), 12 months and 18 months via online or on paper-based questionnaires. Clinical, feeding, demographic and outcome data were collected from *parents and clinicians*. Parents were asked to report on the prescribed formula and amount given per day. Children who received home-blended diets also provided dietary information via the online myfood24 (Dietary Assessement Ltd, Leeds, UK) food diary tool.[16]

Primary outcome

Pediatric Quality of Life Inventory (PedsQL) gastro symptoms scale.[17]

Secondary outcomes

Child quality of life (DISABKIDS),[18] parental quality of life (EuroQol-5 Dimensions),[19] sleep disturbance (PROstate MRI Imaging Study),[20] anthropometric information [body mass index, standard deviation score and mid-upper arm circumference (MUAC)], nutritional intake and safety outcomes (tube blockages, stoma site infections and gut infections).

Analysis

All statistical analyses were undertaken using R (The R Foundation for Statistical Computing, Vienna, Austria) and alpha of 5%. Descriptive statistics for all clinical, demographic and outcome information used means and standard deviations for continuous data and counts and percentages for categorical data. When appropriate, group comparisons used *t*-tests and Pearson's Chi-squared tests. Box plots were used to represent data on the secondary outcomes. Summaries were provided overall and by the

TABLE 2 Workstream 2 – inclusion/exclusion criteria

	Eligible	Ineligible
A	Child is at least 6 months old and < 19 years	Infants up to 6 months and young people who are ≥ 19 years
B	Child is gastrostomy feed-dependent	Child has another type of feeding tube (e.g. nasogastric and jejunostomy)
C	Child receives most or all of their nutrition via the gastrostomy	
D	Child is living with parent(s): biological or adoptive	Child is not living with a parent (e.g. in residential setting or foster care)
E	Family resident in England	Family not resident in England

Note

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two groups of interest: those who are 100% formula fed and those with any amount of home-blended feeds.

Propensity scores were used to balance the sample for demographic data using the index of multiple deprivation score and were calculated using package WeightIt v0.13.1 (https://cran.r-project.org/web/packages/WeightIt/index.html). The propensity score weights were applied in a generalised linear mixed model (GLMM) using PedsQL total score as the outcome; group, age, sex and diagnosis as fixed effects; and recruitment site as a random effect. Assumptions were checked using graphical and GLMM inspection of Akaike information criterion values. Inferential analyses were not performed on secondary outcomes due to the large amount of outcomes' data collected and concerns over multiple testing.

Results summary

Baseline data were obtained for 180 children (2019–21, *Figure 3*). Children receiving a home–blended diet (n = 104) had similar diagnoses and ages, but many lived in areas of lower deprivation and parental education was higher compared to children receiving a formula diet (n = 76). At baseline data collection, children receiving home-blended diets had significantly better GI scores than those receiving formula diets (β 13.8, $p < 0.001$). The number of gut infections and tube blockages were similar between groups but with lower stoma site infections in the home-blended group. Children having a home-blended diet had more fibre in their diet compared to children having a formula diet.

Follow-up

One hundred and thirty-four (74%) and 105 (58%) children provided follow-up data at 12 and 18 months. GI symptoms were lower at all time points in the home-blended diet group, but there was no difference in change over time within or between the groups. The nutritional intake of those on a home-blended diet had higher calories/kg and fibre; both the home-blended and formula-fed children have values above the Dietary Reference Value (DRV) for B12, folate, vitamin D, calcium, iron, manganese and zinc. Only vitamin D intake was insufficient in the home-blended group.

The mean number of safety outcomes was similar between the groups and over time, that is, number of gastrostomy tube replacements: home-blended versus formula-fed 3.0 versus 3.4, 3.2 versus 3.2 and 1.8 versus 1.5 at 0, 12 and 18 months. The total costs to the statutory sector higher among children with formula-fed than those with home-blended diet, that is, £16,386 versus £12,028 per annum at baseline, but the cost of purchasing special equipment for home-blended food and the total time spending on child care were higher for family feeding their child with home-blended diet.

Conclusion

Children with a gastrostomy who received home-blended diets had lower burden of GI symptoms and higher fibre intake than children receiving a formula diet. The risk of infection was similar in both groups.

Feasibility of long-term follow-up using routine data sources

The final objective was to assess the feasibility of long-term follow-up of this cohort. The primary outcome of GI symptoms is not routinely collected or collated in a format that would enable any assessment of this primary outcome in longer term using routine data sources.

Information on the healthcare use of this cohort was obtained both from parent report and also via Hospital

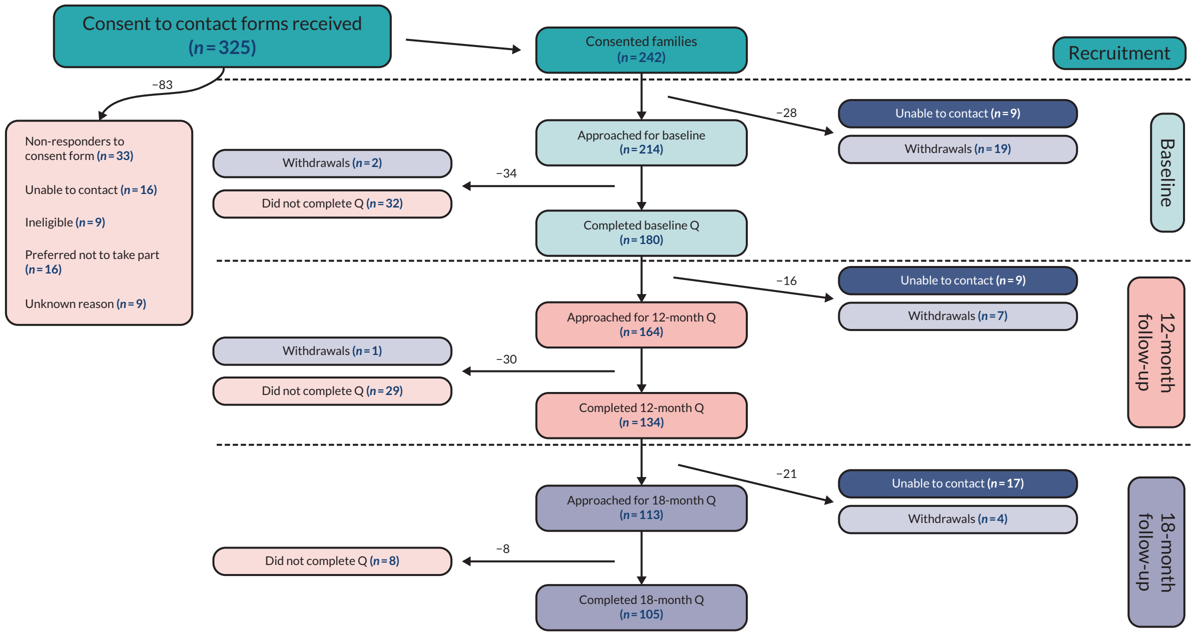

FIGURE 3 Participant flow chart.

Episode Statistics (HES) data from NHS England from 2018–9 to 2021–2. We used data available from the Admitted Patient Care (APC) and Emergency Care Data Set (ECDS). For APC, we initially create the continuous inpatient spells (CIPS) to account for the whole period of care, and we used the Centre for Health Economics Algorithms for Spells and CIPS Construction (www.york.ac.uk/media/che/documents/papers/researchpapers/CHERP182_NHS_update2018_2019_supplementary.pdf).[21]

All analyses considered the respective time period to derive the data for each participant. For baseline and 12-month follow-up, we only considered episodes and reports during the previous 12 months. For the 18-month follow-up, we considered the last 6 months from the date parents completed the questionnaire. This ensured that both HES and parent data referred to the similar time period.

Outcomes

On HES, the number of hospital admissions (emergency and planned) was calculated by summing any episodes in the APC or ECDS data. On parents' report, we used the number of occasions the child stayed in hospital overnight in the last 12 months.

The length of stay was obtained by the number of nights stayed in hospital reported by parents and the duration of the hospital stay in days (HES). The duration of hospital stay in HES was the difference between the episode end and episode start corresponding to the CIPS.

Emergency visits were obtained from parents' reports on the number of times the child attended an accident and emergency (A&E) department during the last 12 months (last 6 months for the 18-month follow-up). On the HES data, the number of A&E visits was calculated using the sum of reported episodes for the corresponding time period.

For all outcomes' calculations, we considered the date of parent report when calculating the episodes. We used the date of questionnaire completion or the last date available on the questionnaire completion. (For baseline and some of 12 months' parents' reports, we did not have date of completion available, and the end date of the questionnaire completion was used. For paper-based received questionnaires, the end date of the questionnaire is a later date than the date the parent completed the questionnaire.)

Statistical analysis

Results are presented for the total sample and separately by the home-blended and formula-fed group. We used Cohen's kappa to assess the concordance between parents' reports and data from the NHS Digital. The strength of agreement using kappa values was considered (Landis and Koch 1977)[22] (Poor: < 0.00; Slight: 0.00–0.20; Fair: 0.21–0.40; Moderate: 0.41–0.60; Substantial: 0.61–0.80; Almost Perfect: 0.81–1.00).

This synopsis should be referenced as follows:
Fraser L, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge K, *et al.* The risks, benefits, and resource implications of different diets in gastrostomy-fed children: The YourTube mixed method study. *Health Technol Assess* 2025;**29**(25). https://doi.org/10.3310/RRREF7741

Findings

Table 3 shows the concordance between the parent report and HES data. Only 12-month data showed a level of agreement that was acceptable, if be it low.

Interpretation

The primary outcome is not routinely available for the long-term follow-up of this cohort. In terms of healthcare use, there is a lack of agreement between parents' report and national hospital statistics. While this may be due to issues with the date recording in this cohort, there is also a question over the recording of admissions in this cohort.

Health Economic Evaluation

The objective of Health Economic Evaluation was to assess the costs and resource use of providing a home-blended diet compared to a formula-fed-only diet to children with gastrostomy tubes and to compare some of the health consequences of providing two types of diet. We compared the costs of providing formula and health care under an NHS and Personal Social Services (PSS) perspective, associated with the health-related quality of life (HRQoL) outcomes of children and carers. Resource use data were collected at three different time points: at recruitment (baseline), 12 and 18 months. Data on utilisation were gathered from parents/children/young people and clinicians at each time point. The primary method of data collection was through parent questionnaires. The cost of equipment purchased exclusively for home-blended diet and time associated with child care, which were categorised into time spent on preparing and administering food, time spent on preparing and administering medications and time spent on caring for gastrostomy, were also collected. To calculate the cost for each child, a microcosting framework was used. All available covariates were included in a multiple imputation model in which the number of chains were considered using a two-step approach.[23] Considering that the quantity of resource usage is non-normally distributed, a predictive mean matching method was used. The complete case analyses of HRQoL outcomes of parents and children are presented in the main *Workstream 2* section, while multiple imputation model was attempted in this section. Details of the methods are provided in the *Report Supplementary Material 2*.

The total costs to the NHS and PSS comprising of the cost for formula food and cost for health and social care services were higher among children who were formula fed than those with the home-blended diet: £16,386 versus £12,028 per annum at baseline, £18,049 versus £14,357 per annum at 12 months, £8345 versus £5887 per half-year at 18 months, respectively. The cost of formula food mainly contributed to such differences. As a trade-off, families in the home-blended group spent an estimated £294 in the previous 12 months (at baseline), £176 in the previous 12 months (at 12 months) and £97 in the previous 6 months (at 18 months) on kitchen equipment for blending and storing blended food. They also spent on average of 88 minutes (at baseline), 85 minutes (at 12 months) and 103 minutes (at 18 months) per day higher than those in formula-fed group on caring children. As seen in the main *Workstream 2* section, the HRQoL of parents and children showed consistent similarity across all metrics. Given the missingness in outcomes such as EuroQol-5 Dimensions, five-level version, DISABKIDS, visual analogue scale was small, the multiple imputation model had a minimal impact on the results. Parents in both groups reported more health issues relating to pain/discomfort and anxiety/depression.

TABLE 3 Agreement between parent-reported data and HES data for hospital stays, length of stay and number of A&E attendances

	Kappa	Statistic	*p*-value
[Baseline] number of hospital stays	−0.005	−0.115	0.909
[12 months] number of hospital stays	0.232	4.845	0.000
[18 months] number of hospital stays	0.065	0.935	0.350
[Baseline] length of stay (days)	−0.029	−0.521	0.603
[12 months] length of stay (days)	0.211	3.438	0.001
[18 months] length of stay (days)	−0.044	−0.511	0.609
[Baseline] number of A&E attendances	0.029	0.408	0.683
[12 months] number of A&E attendances	0.268	3.606	0.000
[18 months] number A&E attendances	0.218	1.911	0.056

This economic analysis illustrates the implications of choosing a home-blended diet over a formula-fed diet for children with gastrostomy tubes. The findings suggest that, while the home-blended diet was associated with a reduction in costs for the NHS and PSS, it was also associated with increased expenses for equipment and child-care time, along with a small home-made food cost. The HRQoL outcomes for parents and children were similar between the two groups.

Discussion

Principal findings and achievements

In this large, prospective, national cohort study, children who were fed a home-blended diet maintained an adequate nutritional intake and had no increase in safety events when compared to children who were formula fed in this 18-month study. There may also have been a benefit in terms of parental HRQoL, but there was an increase in financial costs to families of feeding a home-blended diet. There was evidence that families who used a home-blended diet had higher levels of education and lived in areas of lower deprivation, so future policies should address the inequalities in access. Home-blended diets should be seen as safe and able to provide an adequate nutritional intake as commercial formula in children who require gastrostomy feeding, unless there is a specific clinical contraindication. High-quality studies are required to address any differences in the long-term outcomes for children who are fed with home-blended diets.

Contribution to existing knowledge

The lower burden of GI symptoms in the home-blended diet group was maintained across the time period of this study, and these findings are consistent with the small number of published studies which have reported GI symptoms.[24]

Children who required gastrostomy feeds are often fragile and at risk of recurrent infections, and concerns over the additional risk of using a home-blended diet have been discussed.[25] In this study, there was no evidence of an increase in the number of stoma site, gut infections or pneumonia in the home-blended diet group compared to the formula-fed group.

One of the main concerns raised by professionals about the nutritional adequacy of the home-blended diets relates to the viscosity of the feeds required to get through the tubes and therefore the large volumes that may be required to maintain an adequate calorific intake.[25,26] In this study, the calorific intake was higher in the home-blended group across the time period while maintaining adequate anthropometric measures. Previous research has shown that gastrostomy-fed children may be able to tolerate higher volumes of home-blended diet than formula.[26] The micronutrient content in this current study was also relatively stable and above DRV for all apart from vitamin D, which is similar to what cross-sectional studies have shown.[25,27]

The economic analyses showed that while there was a reduction to the statuary budget when using a home-blended diet, there was an associated increase in costs to families. This may in part explain why families in this study who used a home-blended diet tended to be from areas of lower deprivation. There is no financial cost to the family of formula feeds in the UK, but the distribution of costs may be different in other healthcare systems. Children with complex disabilities are already at risk of inequalities in access to health and social care, so future services and policies relating to enteral feeding must address the potential financial impact of a home-blended diet.

Strengths and weaknesses

This was the largest cohort study of children who are gastrostomy fed worldwide. This is despite having to reduce our recruitment target due to the impact of the COVID-19 pandemic. The primary outcome was chosen after the involvement of parents, children and professionals in a qualitative study. This was an observational cohort study; the groups were different in measured variables, for example, deprivation and parental education, which we used in our propensity score weighting, but there was still likely to be an issue with unmeasured confounders. There was also more loss to follow-up in the children and families from areas of higher deprivation.

Take-home messages

- Home-blended diets can be a safe alternative to formula feeds in children who require gastrostomy feeding and they can provide an adequate nutritional intake.
- Similar to public health advice for all children in the UK, vitamin D supplementation is recommended for those on a home-blended diet.
- There are resource implications for families feeding a child with a home-blended diet which has to be taken into account when considering and discussing with families about being able to feed their child a home-blended diet.
- Meaningful long-term follow-up of this cohort will require further primary data collection.

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Fraser L, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge K, *et al.* The risks, benefits, and resource implications of different diets in gastrostomy-fed children: The YourTube mixed method study. *Health Technol Assess* 2025;**29**(25). https://doi.org/10.3310/RRREF7741

Project reflections

This study required a large amount of data collection from parents. Supported by our patient and public involvement (PPI) partners, we have shown that this is possible. Including parents in measuring MUAC is also possible, if given appropriate support and training information.

Challenges faced and limitations

The COVID-19 pandemic started just as we had most of our 30+ research sites open to recruitment. All recruitments were paused for several months in 2020. The implications of the pandemic included:

- A reduction in target sample size from 300 to 180.
- A change in data collection schedule from 0, 9 and 18 months to 0, 12 and 18 months.
- Large amount of additional work to pause and reopen a large number of research sites.
- The change to more virtual consultations with HCPs meant that we relied more upon parent reporting and were being more flexible about the timing of measurements such as height, weight, etc.

Engagement with partners and stakeholders

All of the research sites were very enthusiastic about participating in this study. This was evidenced in the successful recruitment to this study despite the COVID-19 pandemic and a period of repeated strike action and staff absences in the NHS.

Institutional capacity strengthening

We recruited from 28 NHS sites and 4 children's hospices. For the hospices, this was an opportunity to recruit to a national portfolio study for the first time.

Linked papers:

Protocol paper

- Taylor J, O'Neill M, Maddison J, Richardson G, Hewitt C, Horridge K, *et al.* 'Your Tube': the role of different diets in children who are gastrostomy fed: protocol for a mixed methods exploratory sequential study. *BMJ Open* 2019.[1]

Workstream 1 outcomes paper:

- Maddison J, Taylor J, O'Neil M, Cade J, Hewitt C, Horridge K, *et al.* Outcomes for gastrostomy-fed children and their parents: qualitative findings from the 'Your Tube' study. *Dev Med Child Neurol* 2021.[9]

Workstream 2 baseline findings:

- Fraser LK, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge K, *et al.* YourTube' the role of different diets in children who are gastrostomy fed; baseline findings from a prospective cohort study. *Dev Med Child Neurol* 2024.[15]

Workstream 2 longitudinal findings:

- Fraser LK, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge KA, *et al.* Safety, resource use and nutritional content of home-blended diets in children who are gastrostomy fed – findings from 'YourTube' a prospective cohort study. *Arch Dis Child* 2024.[2]

Patient and public involvement

Aim

The aim was to ensure the views and experiences of parents of gastrostomy-fed children were central to this study, resulting in findings having a greater impact on parents' lives and the lives of their children.

Methods

Our PPI plans were designed with reference to the NIHR INVOLVE National Standards for Public Involvement, which are referred to throughout this section to demonstrate our commitment to these standards. We worked in partnership with PPI representatives from grant application stage through to dissemination. Involvement extended across considerations around research design, development, iteration of participant facing documents, study management, interpretation of the data and writing and dissemination of study findings.

During the development of this proposal, we worked with PPI representatives who inputted into the plain English-language summary, advised us on recruitment of professionals, tested initial acceptability of the study outcomes and helped us understand the importance of GI symptoms, which were subsequently included in the study. We then established a Parent Advisory Panel (PAP) (standard 2) comprising six parents with experience of feeding a child with a gastrostomy. Virtual meetings were held twice a year and additional consultation work was undertaken where required. If members had withdrawn their involvement, we planned to recruit new members (standard 1), however, this did not occur.

A PPI log, guided by the Public Involvement Impact Assessment Framework,[28] recorded planned and unplanned involvement, including details about who was involved, and how, and how these activities impacted on the study (standard 5).

Results of patient and public involvement input

Patient and public involvement shaped the study through a number of ways, for example: changes to study processes and recruitment materials based on feedback. Parents believed that too much information on blended diets on the Participant Information Sheet may have influenced parents' decisions to switch to a blended diet, therefore the amount of information on blended diets was reduced. They also suggested that the focus should be on gastrostomy feeding rather than blended diets due to differing professional views on blended diets. They advised that this would increase support for the study from HCPs with mixed views on blended diets. They also advised on recruitment strategies, not just limiting sites to NHS sites and not only sites which supported blended diets. This was to ensure a less biased sample.

As a result of their advice, a study-specific PAP was created (standard 2). The PAP came up with a memorable short study title, the 'Your Tube' study. They piloted study materials, processes and data collection tools (standard 4). For example, pilot interviews and online food diaries. They advised on blended diet recipes, enabling the study team to visualise typical recipes for food diaries for WS2. They ensured the appropriateness and accessibility of a MUAC training video for collecting WS2 anthropometric data.

Parent advisory panel members also advised on important outcomes to measure in WS2 based on the WS1 findings. Throughout the study, they provided input on strategies for improving participant engagement and retention, from how best to approach new families to the most appropriate way to send reminders to complete study questionnaires. Two parents were also members of the Study Steering Committee (standard 6).

Discussion of patient and public involvement input

The research centre, in which this study is embedded, is a multidisciplinary centre for research on the care and support of children and young people with life-limiting conditions or medical complexity. PPI is embedded into every study that is conducted, and in YourTube, it has been woven throughout all stages of the research cycle. PPI input has been particularly pivotal with this population, particularly around strategies for improving participant engagement and retention. It has been a positive and essential guiding influence.

Reflections and critical perspective

The active involvement of PPI has been vital at all stages. Through this, those with lived experience (as parents of children with a gastrostomy) have made this research more impactful. Dissemination will have a broader reach than originally planned. We have also shown that PPI can be conducted in a meaningful and reflective way with this population, while remaining sensitive and flexible to the family's ever changing and unpredictable lives.

Equality, diversity and inclusion

We recruited from organisations purposively across England to ensure inclusion of services where home-blended diets are, or are not, promoted and included areas diverse in terms of their geography, ethnicity and socioeconomic status.

This study obtained data for a cohort of 180 children at baseline; 13.9% of children were from non-white ethnic minority groups and 84.9% of children were from white ethnic groups, with data missing for the others. At 12- and 18-month follow-up, 14.2% and 15.2% of children were from non-white ethnic groups. In Census 2021 data, 74% of children were from a white ethnic group, suggesting that the children recruited may not be representative of the wider population. Data collection was only possible using instruments validated in English; therefore we may be missing some groups of children.

There is evidence from this study that more children from areas of lower deprivation and where parents had higher levels of education were fed a home-blended diet. This may be in part due to the additional cost to families, but we have highlighted the need for any guidelines and policies regarding gastrostomy feeding to address these potential inequalities.

Impact and learning

This study is an important addition to the body of literature and has considerable potential for impact through providing the evidence on the risks, benefits and resource implications for using a home-blended diet compared to currently recommended formula feeds for children with a gastrostomy. It is the largest cohort study, to date, of children with a gastrostomy worldwide.[24]

During the period of conducting this study, many of the organisations who had previously raised concerns over the risks associated with feeding a child, with a gastrostomy, a diet of home-blended foods, including the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) and BDA, have released new guidelines or position statements which are more supportive of the use of home-blended diets. However, even the most recent ESPGHAN position statement states,

> *"There is little evidence published to formally inform about the potential health benefits or risks of this practice and how to use it in the best way. This leaves health professionals caring for such patients in a relative vacuum regarding what to consider when providing a duty of care to patients and carers who wish to pursue this method of feeding. This article provides guidelines*

> *for safe and appropriate use of a home-blended diet, but more research is needed."*[29]

This study has addressed this gap in evidence and will be available for the next iteration of these and similar evidence based clinical guidelines.

To ensure the study outcomes are taken forward for implementation by key stakeholders, partners and target audiences, our PAP has assisted with the content and format of all outputs, in particular those which are parent-/child-facing. For professionals, a text-based research briefing, setting out key findings and implications for practice and a summary for commissioners, have been created. For parents, a summary of findings presented in a meaningful way for both parents and children has also been created. A multimedia presentation for use by professionals in multidisciplinary team meetings, as an individual learning resource, and also for parent- and child-facing charities and organisations, will be created. This output, in particular, will ensure that the study findings have a broad reach and can be disseminated more widely. This will be launched and then highlighted to key stakeholders and organisations once all academic outputs have been published.

We have worked with professional (British Academy of Childhood Disability, British Association of Community Child Health and the Royal College of Paediatrics and Child Health), third-sector (Together for Short Lives, Council for Disabled Children) and parent organisations (e.g. the National Network of Parent Carer Forums, Contact) to disseminate study outputs. E-mail alerts to highlight the key outputs from the study have been co-ordinated through these professional networks and third-sector organisations. The Project Advisory Panel have also assisted with dissemination through their parent and family networks.

We have directly contacted the chairpersons of the key professional organisations, which currently produce clinical guidelines on this topic (BDA and the ESPGHAN) with the results of our study and worked with them to ensure effective dissemination to their members.

The wider clinical and academic audiences have been reached via presentations at the European Association of Palliative Care (Lorna Fraser presented baseline)[30] and the Royal College of Paediatrics and Child Health Conferences (Lorna Fraser presented baseline and 12-month findings).[31] Additionally, the team presented at an academic meeting for clinicians at Sussex Community NHS Foundation Trust.

Implications for practice/decision-makers

This study adds considerably to the body of literature, as it is the largest study of children who are gastrostomy fed worldwide. The results show that home-blended diets can be a safe alternative to formula feeds in children who require gastrostomy feeding. In addition, they can also provide adequate nutritional intake.

There are implications for a range of stakeholders, including children with complex health conditions and their families, professionals, commissioners and parents.

This research has benefited children with complex health conditions and their families through providing high-quality evidence on the risks and benefits of using home-blended diets in an accessible format. The results of this study have helped to address the gaps in evidence and therefore should enable families to make informed choices about their child's diet. However, there are resource implications for families wanting to feed their child a home-blended diet, which needs to be taken into account.

The professionals who care for these children (dietitians, paediatricians, specialist nurses and other members of the multidisciplinary teams) have benefited by the study addressing current questions raised about the risks, benefits and resource implications of using a blended diet in this population of children with high-quality evidence. The findings are also important and useful to commissioners of paediatric dietetic services.

The results of this study have a wider policy impact by feeding into the current professional guidelines and policy statements about the types of feeds used for children with gastrostomies and clinical support needed. It will enable these guidelines and statements to be based on higher-level evidence rather than the low-quality evidence and expert opinion.

Findings will also be useful to NIHR and other research funders in terms of informing decisions about the need for, and type of, further research in this area.

Research recommendations

We identified the following recommendations for future research:

1. Home-blended diets:
    - Nutritional content of home-blended diets, especially those commercially produced.
    - Assessment of the impact of a home-blended diet on the gut microbiome in children who are gastrostomy fed.
    - Interventions to ensure equality of access to home-blended diets for children with gastrostomy if clinically appropriate.

  - Long-term follow-up (> 5–10 years) of children who are gastrostomy fed and the relationship with type of diet and gut failure.
  - Equality of access to home-blended diets for children with gastrostomy should be assessed by local clinical teams.

2. Children with complex health needs/neurodisability:
   - Measurement of quality of life for children with complex health needs.
   - Nutritional requirements of children with complex health needs.

Conclusion

Children with a gastrostomy who received a home-blended diet have a lower burden of GI symptoms and high fibre and calorie intake compared to children receiving a formula diet. They also had no more complications than children receiving a formula diet. These findings show that home-blended diets for children who are gastrostomy fed should be seen as a safe alternative to formula feeding for children unless there is a clear clinical contraindication. Professionals who care for these children can now advise parents on the risks, benefits and resource implications of using a blended diet. Parents can therefore make more informed choices over their child's diet.

Additional information

CRediT contribution statement

Lorna Fraser (https://orcid.org/0000-0002-1360-4191): Conceptualisation (lead), Data collection (equal), Data analyses (equal), Writing – original draft, Writing – reviewing and editing (lead).

Andre Bedendo (https://orcid.org/0000-0001-9554-6564): Data analyses (equal), Writing – reviewing and editing (supporting).

Mark O'Neill (https://orcid.org/0000-0002-9915-1823): Data collection (equal), Writing – reviewing and editing (supporting).

Johanna Taylor (https://orcid.org/0000-0001-5898-0900): Conceptualisation (equal), Data collection (equal), Writing – reviewing and editing (supporting).

Julia Hackett (https://orcid.org/0000-0003-1720-6665): Data collection (equal).

Karen Horridge (https://orcid.org/0000-0003-1834-5296): Conceptualisation (equal), Data collection (supporting), Writing – reviewing and editing (supporting).

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Gerry Richardson (https://orcid.org/0000-0002-2360-4566): Conceptualisation (equal), Writing – reviewing and editing (supporting).

Thai Han Phung (https://orcid.org/0000-0001-6193-4673): Data analyses (equal), Writing – reviewing and editing (supporting).

Bryony Beresford (https://orcid.org/0000-0003-0716-2902): Conceptualisation (WS1-lead), Data collection (equal), Writing – reviewing and editing (supporting).

Alison McCarter: Data collection (supporting), Writing – reviewing and editing (supporting).

Catherine Hewitt (https://orcid.org/0000-0002-0415-3536): Conceptualisation (equal), Data analysis (lead), Writing – reviewing and editing (supporting).

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Research Ethics Committee (Leeds West REC) and Health Research Authority approvals were obtained for this study (REF 19/YH/0028) on 19 March 2019.

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Information governance statement

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/RRREF7741.

Primary conflicts of interest: Lorna Fraser is NIHR Academy and NIHR Health service and delivery panel member. Janet Cade is Director of Dietary Assessment Ltd, which supports myfood24. Gerry Richardson is associated with NIHR RSS, NIHR PGFAR, NIHR RFPB, NIHR ARC: Evaluation of the Mental Health Navigator scheme, NIHR ARC: Health Economics and Outcome Measurement (HEOM), NIHR RfPB: A Feasibility, Randomised Controlled Trial Of A Complex Breathlessness Intervention In Idiopathic Pulmonary Fibrosis and NIHR HTA: Strategies for reducing sitting time in office workers: a three arm cluster randomised controlled trial. Catherine Hewitt is associated with HTA CET Funding Committee, HTA General Committee, HTA Post Funding (CET and GB) Programme Oversight Committee, HTA Post-Funding Committee (Commissioning), HTA Programme Oversight Committee and NRCP. The other authors have no conflicts of interest to declare.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Study registration

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Award publications

This synopsis provided an overview of the research award *The role of different diets in children who are gastrostomy fed*. Other articles published as part of this thread are:

Taylor J, O'Neill M, Maddison J, Richardson G, Hewitt C, Horridge K, *et al*. 'Your Tube': the role of different diets in children who are gastrostomy fed: protocol for a mixed methods exploratory sequential study. *BMJ Open* 2019;**9**:e033831. https://doi.org/10.1136/bmjopen-2019-033831

Maddison J, Taylor J, O'Neill M, Cade J, Hewitt C, Horridge K, *et al*. Outcomes for gastrostomy-fed children and their parents: qualitative findings from the 'Your Tube' study. *Dev Med Child Neurol* 2021;**63**:1099–106. https://doi.org/10.1111/dmcn.14868

Fraser LK, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge K, *et al* ' 'YourTube' the role of different diets in gastrostomy-fed children: Baseline findings from a prospective cohort study. *Dev Med Child Neurol* 2024;**66**:755–64. https://doi.org/10.1111/dmcn.15799

Fraser LK, Bedendo A, O'Neill M, Taylor J, Hackett J, Horridge KA. *et al*. Safety, resource use and nutritional content of home-blended diets in children who are gastrostomy fed: findings from 'YourTube' – a prospective cohort study. *Arch Dis Child* 2024;**109**:628–35. https://doi.org/10.1136/archdischild-2023-326393

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/17/76/06).

Additional outputs

EAPC Conference 2023. URL: https://journals.sagepub.com/doi/full/10.1177/02692163231172891 (accessed 9 June 2025).

RCPCH Conference 2023. URL: https://adc.bmj.com/content/108/Suppl_2/A30.2 (accessed 9 June 2025).

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List of supplementary material

Report Supplementary Material 1
Synthesis of implications from WS1 and documentation of WS2 decisions: summary reference document

Report Supplementary Material 2
Methods of economic evaluation

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/RRREF7741).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

Glossary

Enteral feeding Food/nutrition that is given directly into the stomach or small bowel (either orally or via a tube).

Formula feeds Formula is a type of liquid nutrition, which contains all the nutrients a child needs for growth and maintenance.

Gastrostomy An opening through the abdominal wall into the stomach.

Gastrostomy feeding tube A gastrostomy is an opening through the skin to the stomach. A feeding tube is put into this opening and feed is delivered directly into the stomach.

Gut failure The inability of the gut to absorb necessary water, macronutrients (carbohydrate, protein and fat), micronutrients and electrolytes sufficient to sustain life.

Gut infection An infection of the colon, caused by pathogenic bacteria.

Gut microbiome The microorganisms, including bacteria, archaea, fungi and viruses, that live in the digestive tracts of humans and animals.

Health-related quality of life This is an individual's or a group's perceived physical and mental health over time.

Home-blended feeds/diets Food that has been prepared and cooked at home and then blended to a smooth, thin puree-like consistency.

Jejunostomy An opening through the abdominal wall into the jejunum.

Nasogastric tube A narrow tube that is passed into the nose and down the oesophagus into the stomach, which allows liquid feed/medication to be delivered directly into the stomach.

Prospective cohort study This is a longitudinal cohort study that follows over time a group of similar individuals, who differ with respect to certain factors under study, to determine how these factors affect rates of a certain outcome.

Stoma An opening in the body. In the context of gastrostomy feeding, the gastrostomy is a type of stoma.

Stoma site infection An infection of the opening in the abdomen through which the feeding tube is placed.

Tube blockage Blockage of feeding tube caused by lumps of food or partially dissolved medication.

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List of abbreviations

A&E	accident and emergency
APC	Admitted Patient Care
BDA	British Dietetic Association
CIPS	continuous inpatient spells
DRV	Dietary Reference Values
ECDS	Emergency Care Data Set
ESPGHAN	European Society for Paediatric Gastroenterology Hepatology and Nutrition
GI	gastrointestinal
GLMM	generalised linear mixed model
HCP	healthcare professional
HES	Hospital Episode Statistics
HRQoL	health-related quality of life
HTA	Health Technology Assessment
MUAC	mid-upper arm circumference
NIHR	National Institute for Health and Care Research
PAP	Parent Advisory Panel
PedsQL	Pediatric Quality of Life Inventory
PPI	patient and public involvement
PSS	Personal Social Services
WS1	workstream 1
WS2	workstream 2

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