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Outcomes for gastrostomy-fed children and their parents: qualitative findings from the 'Your Tube' study

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ABBREVIATION
COS Core outcome set

AIM To identify child and parent outcomes relevant to having a gastrostomy, and to specify outcomes believed to be particularly salient to type of diet (formula vs blended food).
METHOD Twenty parents, two children (both 12y), 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 (2–18y) 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.
RESULTS Participants identified a range of children's outcomes relevant to a gastrostomy, including physical health, gastrointestinal 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 type of diet would most likely effect gastrointestinal symptoms, time spent feeding, sleep, and physical health.
INTERPRETATION 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. Further qualitative research with children and young people is needed.

The number of children with complex medical conditions dependent on one or more medical technologies is increasing.[1–3] This is because of improvements in the way such conditions are treated and managed, hence extending the lives of these children.[4,5] Gastrostomies are one such technology.

There are two feed options for gastrostomy-fed children: commercially produced complete liquid nutrition (formula) prescribed by a dietician, or blended food. The latter may be home-prepared or shop-bought, blended to a consistency suitable for a gastrostomy tube, or regular foods purchased in a pureed/blenderized form. A lack of existing evidence on the nutritional adequacy and the safety of a blended-food diet has meant individual clinicians and professional bodies may not support use of this type of diet.[6–8] Despite this, clinicians increasingly report parents using, or wishing to use, a blended-food diet.[6,9–11]

In the UK, this stimulated the National Institute for Health Research to commission a study to address these evidence gaps.[2] The National Institute for Health Research specified it have a first stage (Workstream 1) which identified the outcomes important to understanding the impact of gastrostomy feeding on children's and parents' lives, including those likely to be affected by type of diet. Findings from this workstream would then inform outcomes assessed by a prospective cohort study (Workstream 2).

This paper reports Workstream 1 findings. We consider our findings against the core outcome set (COS) for children with neurological impairment and tube feeding[12] published shortly after Workstream 1 was completed.

METHOD

The objective was to identify outcomes relevant to gastrostomy feeding and, within this, those believed to be particularly salient to understanding the effects of type of diet. The design and methods are summarized below; see the protocol[2] for full details.

Study design

The study was qualitative, grounded in the phenomenological approach. Data were collected from parents (child aged 6mo–18y), children (12–18y), and health professionals.

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Sampling and recruitment

See the protocol for eligibility criteria, sampling frameworks, participant identification, recruitment, and consenting procedures.[2] Community and specialist paediatric services in five NHS Trusts in England identified eligible study participants and shared study recruitment materials with them. Target sample sizes were: parents (*n*=20), children (*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).

Data collection

Parents and children were interviewed. They could choose a face-to-face or telephone interview. Focus groups were held with health professionals and took place on participating NHS trust premises. Topic guides, described in detail in the protocol,[2] ensured consistent coverage of topics across interviews and focus groups. To facilitate interviews, the children received a simple, illustrated booklet in advance which set out interview topics with space, should they wish, to note down responses. JM conducted all the interviews; focus groups were carried out by JM and BB. Researchers made field notes after each interview/focus group. 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 using thematic analysis techniques[13] (full details in protocol;[2] see Appendix S1, online supporting information, for initial coding frameworks). The data were specifically interrogated for views on the ways diet and other factors may affect outcomes and their relevance or importance to a specific child. After initial coding, data from the three participant groups were collated under a common outcomes framework. Differences in views within and between participant groups were investigated. Data analysis was carried out by JM (lead) and BB. Ongoing dialogue and sharing/commenting on analytical writings supported the process and included the wider team and the project's Parent Advisory Group.

Ethics

The study was approved by Leeds West NHS research ethics committee (research ethics committee reference: 19/YH/0028).

RESULTS

Sample characteristics

Eighteen of 59 parents were recruited and all sites represented; two pilot interviews were used to supplement this sample (research ethics committee approved). Seven children (from 3/5 sites) were invited to participate and two were recruited (2/3 sites). Both chose to have a parent with them during the interview; one interview lasted 19 minutes, the other 33 minutes. Forty-one health professionals were recruited. Table 1 provides an overview of the parent and professional samples. The average duration of parent interviews was 83 minutes (range: 36–172 min). The average duration of focus groups for health professionals was 75 minutes (range: 66–83 min). The two children were 12-year-old females with cerebral palsy and an unsafe swallow. All children represented had been gastrostomy-fed for at least 6 months, typically much longer, and parents described this aspect of their child's care as relatively settled.

What this paper adds

- Sleep is a key outcome for children and parents.
- Gastrointestinal symptoms and physical health were regarded as outcomes most likely to be affected by type of diet.
- Well-being and participation were identified as key distal outcomes.
- Gastrostomies are complex interventions.
- Further specification of the core outcome set is possible.

Gastrostomy as a complex intervention

A clear theme emerging from our data was a gastrostomy can be understood as a complex intervention[14] in the following ways.

Table 1: Sample characteristics

Children and young people represented in parent sample (*n*=20)	
Age range	2–18y (median=7y)
Duration of gastrostomy	6mo–14y (median=5y)
Sex	
Male	9
Female	11
Clinician-reported diagnosis	
Cerebral palsy	8
'Global developmental delay'	3
Developmental anomaly of brain or spine (e.g. spina bifida)	3
Metabolic and genetic conditions	3
No diagnosis	3
Parent-reported reason for gastrostomy	
Unsafe swallow	14
Food aversion	4
Other	2
Fundoplication or Bianchi procedure	
Yes	4
No	16
Mode of feed administration	
Pump	10
Syringe	6
Both	4
Continuous overnight feeds? (excludes syringe-fed only, *n*=6)	
Yes	3
No	11
Type of diet	
Formula	11
100% home-blended food	7
Mixed	2
Health professionals[a] (*n*=41)	
Dietitian	10
Speech and language therapist	7
Paediatrician (including neurology and gastroenterology specialists)	12
Nurse (community, hospice, and hospital based)	12

[a]All professions represented in all sites.

Multiple 'active ingredients'

Outcomes were typically attributed to one or more specific feature of the gastrostomy. These included its visibility, invasive nature, and that substances enter the gastrointestinal tract at the stomach. In addition, there were two direct consequences of a gastrostomy: changes in diet and the rate at which food enters the stomach. Singly or together, these features were regarded as either affecting outcomes directly or indirectly, via their effects on nutritional, fluid, and/or medication intake (Fig. S1, online supporting information).

An additional feature relevant to understanding outcomes was feeding equipment. For example, pump-administered feeds were reported as being less constraining compared to syringe feeds. Type of diet could affect feeding equipment used, with some children on blended-food diets precluded from having pump-administered feeds. Pump failure and tube blockages (typically caused by granular anti-reflux medication) were presented as transitory inconveniences (for parents) rather than substantively affecting child or parent outcomes. Whilst some professionals believed blended foods increased the risk of tube blockages, this was not the experience of other professionals nor parents.

Range of outcomes and outcome hierarchies

Intervention outcomes were conceived as falling along the proximal-distal continuum.[15] Outcomes identified as direct consequences, or directly relevant, to a gastrostomy were wide-ranging (Table 2). Hierarchies of outcomes were described (e.g. gastrointestinal symptoms affecting duration of feeding affecting energy levels affecting motor development), as was the interdependency of some outcomes (e.g. sleep, energy levels). Three distal outcome domains were identified: participation, well-being (physical and subjective), and achievement of developmental potential.

Multiple factors affect outcomes

A number of factors were identified as having the potential to influence gastrostomy outcomes. These included child's age, type of diet, condition-centred factors (e.g. disease process, gut motility), and, for children on a blended-food diet, quality of health care support and whether non-home settings (e.g. schools, short-breaks) allowed blended-food feeds.

Child outcomes

Parents and professionals identified the same outcome domains. Any differences in views and opinion between and within participant groups are reported.

Physical health

A number of physical health outcomes relevant to a gastrostomy were identified, primarily attributed to improved nutritional status (Table 2). Regarding infection resilience and recovery, some parents and professionals believed a blended-food diet offered additional beneficial effects because of its impacts on gut biome and immunity. Survival was discussed only in terms of how a gastrostomy may be necessary to sustain life.

Among professionals, views differed on whether height was a meaningful, and for some children feasible, outcome to assess. They also questioned whether stoma site infections were an appropriate outcome given susceptibility to this appeared to be idiosyncratic. A few expressed concerns that blended diets may increase the risk of gastrointestinal infections if food hygiene was poor. However, this was only observed among staff with no or very limited experience of this diet.

Gastrointestinal symptoms

The unpleasant physical sensations caused by gastrointestinal symptoms and their potential to significantly affect other outcomes meant they were consistently identified as a key outcome by all participants. However, their accounts suggest significant individual variation in the gastrointestinal symptom causing most distress. Type of diet emerged as relevant. Some children represented in the study were on blended-food diets primarily as a strategy to manage gastrointestinal symptoms, and it had proved successful.

Table 2: Child outcome areas affected by a gastrostomy and/or gastrostomy feeding

Outcome area	Outcome dimensions
Physical health	Survival; weight; body fat proportion/distribution; condition of skin, hair, nails; energy levels/ lethargy; infection resilience and recovery; height
Gastrointestinal symptoms	Retching; gagging; reflux; vomiting; trapped wind/bloating; abdominal pain/discomfort; flatulence; constipation; diarrhoea; dry mouth
Duration of daytime feeding	Time required to administer feed; duration of time when feeding precludes other activities; time required to remain still/upright after feed
Emotional well-being	Pain-/other gastrointestinal symptom-related distress; hunger-associated irritability; feeding-related anxiety; exclusion-related distress; fear/embarrassment associated with gastrointestinal symptoms
Sleep	Settling to night-time sleep; night wakings
Severity of condition-specific symptoms/comorbidities	Change in symptoms managed by medication (e.g. seizure frequency); change in medication dose
Sensory world	Taste experiences (pleasant vs unpleasant); range of taste experiences; texture experiences
Motor development	[More granular outcome dimensions not identified]
Cognitive functioning	Attention/concentration; cognitive development
Food averse children only: Increased, or a return to, oral feeding.	

However, professionals with extended experience of blended-food diets reported they were not always tolerated.

Duration of daytime feeding

This was another key outcome area. Gastrostomies were identified as having the potential to significantly reduce duration of daytime feeding due to faster feeding, reductions in gagging, retching, and vomiting, and/or the option of overnight feeds. It was also an outcome prioritized by the two children. Type of diet was identified as relevant because of potential effects on gastrointestinal symptoms and possible restrictions on use of pumps. Parents and children believed this outcome should capture the extent to which daytime feeding restricts or precludes other activities. The time a child needs to stay still and upright after feeding was identified as potentially relevant here.

Emotional health

Pain/other gastrointestinal symptom distress and hunger-associated irritability were regarded as important to all gastrostomy-fed children. Multiple sources of exclusion-related distress were described including: being unable to eat orally, (partial) exclusion from situations where food plays a significant role (e.g. festivals, family gatherings), gastrostomy feeding causing differences between child's and peers' daily routines, and the visible nature of the device. Our data suggest that cognitive ability may affect the degree to which this distress is experienced. This was also the case for fear of, or embarrassment associated with, gastrointestinal symptoms (e.g. leakage caused by constipation). Feeding-related anxiety was identified as relevant to children with an aversion to eating orally.

Sleep

Settling to sleep and night waking were consistently described as highly relevant and important outcomes, predominantly influenced by nutritional sufficiency and gastrointestinal symptoms. Overnight feeds had the potential to disturb sleep but some families traded this off against reduced daytime feed duration. This serves to alert to potential individual differences in how parents and children may prioritize outcomes.

Management of comorbidities

Professionals and parents believed gastrostomies may support retention or absorption of complete doses of medication. They believed this offered the potential for reduced severity/improved management of comorbidities (e.g. seizures) and/or lowering of dose. Gastrointestinal symptoms were regarded as moderating any impacts.

Sensory world

Gastrostomies were seen to potentially affect a child's sensory world in positive (e.g. unpleasant tasting medications no longer administered orally) and negative ways (e.g. loss of pleasurable taste experiences). For food-averse children with a safe swallow, tube-feeding could allow oral feeding to become, primarily, a (positive) sensory experience. This could, in turn, support a return to (greater) oral feeding. Type of diet was also implicated. Parents using a blended-food diet believed burps were likely to be a more pleasant sensory experience compared to formula.

Other outcomes and outcome measurement

Two further outcome domains were described, but not with the same degree of consistency or strength of opinion. They were cognitive functioning outcomes (attention, cognitive development) and motor development. Nutritional intake, sleep, duration of daytime feeding, and energy/lethargy were cited as affecting these outcomes. It was noted that the individualized nature of developmental trajectories of children with neurological impairments make discerning the effects of a gastrostomy on these outcomes challenging.

Finally, where a child had significant cognitive or communication impairment, the challenge of capturing some outcomes (e.g. gastrointestinal symptoms, emotional well-being), was frequently noted.

Parent outcomes

Emotional health

Difficulties establishing gastrostomy feeding and temporary or longer-lasting issues with gastrointestinal symptoms had negative effects on parents' emotional health (e.g. distress, worry). Some described a heightened vigilance 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 if feeding became easier. Contrary to some previous studies,[16,17] parents' accounts did not include themes of sadness or regret around the move to gastrostomy feeding. Professionals reflected these emotional responses may become less salient once the effects of improved nutritional intake are observed. That said, some parents described an enduring sadness that their child no longer ate orally and the losses and exclusion this caused.

Sleep

A gastrostomy was identified as being relevant to parents' sleep in three ways. First, gastrointestinal symptom-distress or hunger-associated irritability may interrupt their sleep. Second, overnight feeds could cause parents to sleep 'lightly' because of concerns about vomiting or equipment malfunction. Finally, where late evening/bedtime feeds were used, parents may delay their own bedtime. Type of diet was identified as relevant to understanding this outcome (e.g. blended diet precludes overnight feeds, impacts of diet on gastrointestinal symptoms).

Support networks

Some parents reported the gastrostomy had meant family members no longer felt able to manage feeding and/or respite care services refused to take a child. Loss of such support could be transitory or long term. Type of diet had

the potential to affect support available from clinical teams because of differences between services or staff on how or whether blended-food diets were supported.

Caregiver confidence

Confidence in their ability to manage stoma care and feeding was regarded as particularly salient in the period after gastrostomy insertion. When parents first moved to a blended-food diet, their ability to meet the child's nutritional needs emerged as a further component of caregiver confidence. Dietitians and parents were identified as key sources of support during this period.

Parenting satisfaction

Parents and professionals noted that using a home-blended diet could contribute to parenting satisfaction. Some blended-diet parents said they derived a sense of fulfilment from their child's diet being consistent with their wider life views, and that one aspect of their child's life was 'de-medicalized' and as similar as possible to the rest of the family. For other parents, satisfaction was not derived from this aspect of their child's life and care.

Physical health

A couple of parents using a blended-food diet reported it had prompted a wider rethink about the family's diet, resulting in a shift to cooking from scratch with varied ingredients. These parents reported they had lost weight, which was regarded as a positive outcome in all cases.

Parents' time

Parents regarded time as a value-laden concept and subject to individual differences in whether demands on time were unquestioned, regarded as 'worth it', or experienced as burdensome. Specifically, views about time appeared to be affected by the extent parents sought to normalize their child's needs, and priorities related to different aspects of the parenting role. Trade-offs between time invested and observed benefits on child outcomes were frequently described. Mode of administration (pump vs syringe) and gastrointestinal symptoms emerged as key factors affecting parent time. Components of parents' time identified as important to capture were: (1) feed administration; (2) administration of anti-reflux medication; (3) if not directly administering, monitoring feed and/or child during feed; (4) capacity to attend to other tasks; (5) for food-averse children, time taken to offer food orally; and (6) for children on blended-food diet, whether feed preparation is separate or incorporated into family meal preparation.

Some parents using blended-food diet described, early on, taking a more painstaking approach to feed preparation. However, this was not maintained as familiarity and confidence grew.

Financial costs

Here our focus was costs associated with a blended-food diet compared to prescription formula (provided free of charge in the UK). Parents using a blended-food diet varied in whether feeds were blended versions of family meals or prepared separately, sometimes using foods the family would not ordinarily consume. All had purchased blenders. Some parents using a blended-food diet argued that associated food costs were irrelevant given they would be incurred if their child did not have a feeding difficulty.

DISCUSSION

This study identified a wide range of outcomes which parents and professionals believed were relevant to having a gastrostomy. Among these, it identifies outcomes regarded as particularly salient to type of diet. It also offers some preliminary evidence on outcomes children regard as important. Finally, it articulates the gastrostomy as a complex intervention: a concept relevant to decision-making on many aspects of study design. Our findings have directly affected which outcomes we are assessing in our cohort study[2] (Workstream 2) (see Appendix S2, online supporting information).

While this study was underway, a COS for tube-fed children was published comprising 12 outcomes (see Table 3).[12] Its authors presented it as 'a first step'. They noted the systematic review used to identify 'candidate outcomes' found few studies which had investigated impacts on children's and parents' lives, and resource use.[18] In addition, professionals participating in COS consensus meetings were typically doctors and 'researchers', with just a few nurses. No dieticians or speech and language therapists took part. Furthermore, most parent/carer involvement took place in a validation exercise after the final COS consensus meeting. The authors therefore called for further studies to allow outcomes to be more closely defined, including specification of sub-outcomes within the broad outcomes domains set out in the COS. They also noted the need to redress imbalances in the populations represented. Others have cautioned against assuming the COS's suitability for studies addressing 'within population' issues (e.g. type of diet).[19]

Table 3 maps our findings onto the COS framework. We discuss below their contribution to its refinement, including outcomes which may be particularly salient to understanding how type of diet affects outcomes, and work on identifying measures.

Life impact domains

The COS systematic review[18] did not identify sleep as an outcome and it does not appear in the COS.[12] However, in our study, it emerged as highly relevant to children and parents and we would recommend its inclusion. Regarding the COS's physical health status outcome domain, energy levels and resilience to/recovery from infections were widely cited as relevant indicators. In addition, changes in condition symptoms/comorbidities (e.g. seizures) managed by medication administered via the gastrostomy may be a salient outcome.

Table 3: Findings mapped against the core outcome set for tube-fed children with neurological impairment

Core outcome set[9] Outcome domains (and definition)	Findings from current study	
	Proximal vs distal	Outcomes identified
Growth and development: 'elements of growth, death and nutritional status'		
Nutrition	Proximal	*Proxy indicators identified as relevant*: weight, body fat proportion/ distribution, condition of skin, hair and nails, energy levels/lethargy
Growth	Proximal	Weight
Developmental state	Distal	Motor development
		Cognitive functioning (see Table 2 for sub-domains)
	Distal	Achievement of developmental potential
Life impact: 'specific and general impact ... on lived experience of children and their families'		
Child pain	Proximal	Gastrointestinal-symptom related pain
Child physical health status	Proximal	Infection resilience and recovery
		Severity of condition-specific symptoms/co-morbidity
Child's quality of life, condition-specific	Proximal	Emotional well-being (see Table 2 for sub-domains)
		Sensory world (see Table 2 for sub-domains)
	Distal	Participation
		Subjective well-being
Duration and ease of food/medicine administration	Proximal	Duration of day-time feeding (see Table 2 for sub-domains)
Caregiver quality of life, condition specific	Proximal	Emotional health, support networks, technology-related confidence, parenting satisfaction, physical health
		Sleep: child, parent (see Table 2 for sub-domains)
Death: 'condition-specific death'		
Death (related to tube)	Proximal	Survival (due to improved nutritional status)
Pathophysiological manifestations: 'structural and surgical defects and upper-gastrointestinal and respiratory complications that can occur post-insertion'		
Tube malfunction/reoperation		[Tube blockages not identified as affecting child or parent outcomes]
Retching/vomiting	Proximal	Individual differences re which gastrointestinal symptom most salient/ troublesome. Wide range of additional gastrointestinal symptoms: gagging, reflux, bloating/flatulence, constipation, diarrhoea, dry mouth
Aspiration pneumonia		Identified as only relevant pre-gastrostomy
Resource use: 'impact ... on the economic health of an individual, the family, and broader healthcare system'		
Days/year spent admitted to hospital/intensive care		
Frequency of doctor/clinic/emergency	Proximal	Feed and equipment costs
room appts. per year	Proximal	Parents' time: feed preparation, feed administration/monitoring feeding; administration of anti-reflux medication

Emotional health and sensory world emerged as important proximal outcomes within the COS's child's quality of life domain. Emotional health was identified by the COS's systematic review,[18] but not retained as a specific outcome domain. Our study revealed a number of different threats to emotional health. We particularly note exclusion-related distress and fear/embarrassment of gastrointestinal symptoms, both key issues for the children in our study and parents of children with no or less significant cognitive impairment. Sensory world may be particularly relevant where studies are investigating the impact of types of diet. More globally, our findings suggest quality of life measures that capture perceived participation and physical and emotional well-being should be preferred. With respect to parent/caregiver quality of life, we identified a wide range of relevant proximal outcomes; some were more salient at particular time-points, suggesting this should be taken into account when selecting parent outcome measures.

Pathophysiological manifestations

Gastrointestinal symptoms were a key source of distress, with the potential to have significant negative impacts on children's and parents' lives. However, whilst the COS[12] specifies retching/vomiting, in our study no specific gastrointestinal symptom consistently emerged as the main symptom of concern or distress. We would therefore recommend using gastrointestinal symptom measures which capture the widest range of symptoms. Tube malfunction was not identified as impacting child or parent outcomes.

Relevance of diet to pathophysiological manifestations and life impact outcomes

Type of diet (formula vs blended-food) was regarded as relevant to most outcomes identified, particularly gastrointestinal symptoms and physical health status. Sleep and duration of daytime feeding were also frequently implicated, primarily because of their association with gastrointestinal symptoms. Previous studies of blended-food diets also report these outcomes.[6,10,20–22] We note that, in seeking explanations for reported benefits of blended-food diets, increasing attention is being paid to the role of gut biome.[23–25] Whilst clinician concerns about the safety of blended-food diets (e.g. infections caused by poor food hygiene, tube blockages) is reported in the existing

literature,[6,7,9] we found it was only questioned by professionals who had no direct experience of them. Studies which systematically investigate these potential risks or strategies to mitigate against them, are to be welcomed. It is essential these are conducted in home as well as inpatient settings.[2,26,27] Finally, in terms of life impact outcomes, improved parenting satisfaction (principally located around notions of demedicialization)[28] was consistently identified as a consequence of moving to a blended-food diet.

Resource use outcomes

The current COS[12] restricts this domain to health service use. Depending on country, this cost may fall to the family and/or the state/public purse. Although the 'extra costs' associated with caring for a disabled child are well documented,[29,30] few studies have included costs of feeds.[31,32] However, it may be pertinent where there are differences in who funds different diets. For example, in the UK the NHS pays for formula feeds, but not food costs associated with using a blended-food diet. In terms of costs borne by the family, our findings caution against only using objective measures of financial cost as they do not capture that the way the household purse is spent is, to some degree, values-driven.

Parents of disabled children spend more time caregiving than other parents and the introduction of a medical technology may have a positive or negative impact.[33] Whilst duration of feeding is included in the COS,[12] it is conceived only as a child outcome. However, it also emerged as highly relevant to parents along with other demands on their time directly associated with the gastrostomy. In terms of measurement, parents strongly advocated capturing whether demands on their time were perceived as burdensome as well as collecting objective data on duration.

Study limitations

The size and characteristics of parents' and professionals' samples were as intended. The target sample for children/young people was not achieved. Further work to understand children and young people' experiences of living with a gastrostomy should be prioritized. Whilst featuring in parents' and professionals' accounts, the focus of the study was not outcomes in the period immediately after gastrostomy insertion and we did not seek to identify outcomes specific to the postoperative period.

CONCLUSIONS

The study generated detailed data on parents' and professionals' views (and some initial data from children) on gastrostomy-related outcomes. It adds to the limited evidence base on which the current COS for tube-fed children was created and we make some recommendations to its refinement and how outcomes are defined and measured. Additionally, it has identified outcomes particularly salient to investigating types of diet. Finally, study participants presented gastrostomies as a complex intervention, something highly relevant to designing evaluative studies.

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DATA AVAILABILITY STATEMENT

Data available on request from the authors.

SUPPORTING INFORMATION

The following additional material may be found online:

Appendix S1: Qualitative data analysis coding framework.

Appendix S2: Changes to Your Tube cohort study (Workstream 2) protocol arising from Workstream 1 study findings.

Figure S1: Diagrammatic representation of a gastrostomy as a complex intervention

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