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The role of different diets in children who are gastrostomy fed

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
17/04/2019

Overall study status
Completed

Last Edited
15/01/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are growing numbers of children living in England who require to be fed through a tube directly into the stomach (gastrostomy). The current professional recommendations in England are that formula feeds should be used when children are fed by gastrostomy, but there are growing numbers of parents who are choosing to feed their own children a more conventional diet of home-blended foods. This study aims to address a research gap by assessing the symptom profile (reflux, constipation, pain) and quality of life of children who are gastrostomy fed, comparing those who are formula fed and those who are predominantly fed a home-blended diet. The study will also examine the impact on parents' quality of life and explore costs to the families and the NHS.

Who can participate?
Children aged between 6 months and 18 years old (inclusive) who have a gastrostomy for nutritional purposes

What does the study involve?
There are two phases in this study.
Phase 1 involves interviews with parents and young people, and group discussions with health professionals, to explore the different diets that children receive and the resources (e.g. time, cost) associated with gastrostomy feeding. The study also identifies which outcomes (e.g. quality of life, complications with feeding, healthcare use) are the most important to measure for children with a gastrostomy, and how to measure these. The findings are used to decide what information should be collected from children and their families in phase 2.
Phase 2 is a study of children who are gastrostomy fed, some of who receive the recommended formula feeds and some of who receive a diet of home-blended foods. Information is collected from this group of children and their parents at the beginning of the study, and then again at 9 and 18 months, to compare the outcomes for children who receive formula feeds with those who receive home-blended feeds.

What are the possible benefits and risks of participating?
There are no direct benefits associated with taking part in this study. However, this study will provide important evidence about the risks and benefits associated with these different diets,

which will be used to improve the advice and support that is available to families, and also healthcare staff who support them. There is no risk to children who take part in this study because they are not asked to change their diet or the way they are fed, or to keep things the same if their feeding needs to change. It is possible that some parents who take part in the study experience distress as a result of talking about their child's gastrostomy, and the study team will ensure appropriate support is available.

Where is the study run from?
The study is being run by Dr Lorna Fraser and a team of researchers based in the Department of Health Sciences at the University of York. Families will be recruited from NHS services throughout England who provide nutritional care for children and young people with a gastrostomy.

When is the study starting and how long is it expected to run for?
February 2019 to July 2023

Who is funding the study?
National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
Dr Julia Hackett, julia.hackett@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/public-health/projects/yourtube/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253510

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41067, HTA 17/76/06, IRAS 253510

Study information

Scientific Title
The role of different diets in children who are gastrostomy fed; an exploratory sequential mixed methods study

Study objectives
What are the risks, benefits and resource implications for using home-blended food for children with gastrostomy tubes compared to currently recommended formula feeds?

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 104 8086; Email: nrescommittee.yorkandhumber-leedswest@nhs.net), ref: 19/YH/0028

Study design
Exploratory sequential mixed methods design

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Children who are gastrostomy fed

Interventions
Stage 1: Interviews of parents (n=20) of children who are gastrostomy fed, young people (n=5-10) who are gastrostomy fed, and relevant healthcare professionals (n=24-32) including paediatrician, dietitians and community nurses. The researchers will ask participants to identify important outcomes for children with a gastrostomy (e.g. symptoms, quality of life, safety, complications) and also explore the best way to measure these outcomes in this study.

Stage 2: 300 children who are gastrostomy fed and their parents will be recruited from children's health services and followed up for 18 months during which time the outcomes identified from stage 1 will be measured. Detailed clinical information (e.g. diagnosis, medications) will also be collected from the child's paediatrician and dietitian. The safety and risk of complications will be examined by asking parents about visits to A&E and hospital and also by examining hospital records. At the end of the study the researchers will compare the different outcomes, symptoms, complications, and costs between children who are formula fed and those who are mainly fed blended food.

Intervention Type
Other

Primary outcome measure
Gastrointestinal symptoms measured using the PedsQL Gastrointestinal Symptoms module at baseline, 9 and 18 months

Secondary outcome measures
1. Child health-related quality of life measured using the PedsQL Generic module at baseline, 9 and 18 months
2. Parent health-related quality of life measured using the EQ5D-5L at baseline, 9 and 18 months
3. Dietary intake measured using parent-reported food diaries and using the MyFood24 dietary assessment tool at baseline, 9 and 18 months
4. Anthropometric measurements (weight, height/length, body mass index, mid upper arm circumference, multiple skin folds) measured at baseline, 9 and 18 months
5. Healthcare usage (appointments with paediatric and dietetic teams, emergency hospital admissions, GP attendance, A&E visits) measured at baseline, 9 and 18 months
6. Safety (parent-reported tube blockages, A&E or hospital visits to unblock or replace the gastrostomy device, gut or stoma site infections and antibiotics prescribed for these) measured at baseline, 9 and 18 months
7. Resource use (cost of feeds, including dietetic resources, cost of equipment to prepare feeds, time to prepare and administer feeds) measured at baseline, 9 and 18 months

Outcomes are subject to change based on the results of phase 1 of the study

Overall study start date
01/02/2019

Completion date
31/07/2023

Eligibility

Key inclusion criteria
Workstream 1:
1. Parents of children and young people (aged 6 months up to 18 years) who are fed via a gastrostomy
2. Young people aged 12-18 years currently using a gastrostomy and with no significant cognitive impairments
3. Health professionals, specifically paediatricians, dietitians, children's community nurses, and Speech and Language Therapists

Workstream 2:
Children (aged 6 months - 18 years inclusive) who receive all or part of their nutrition via gastrostomy tube, and their parent/guardian

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
6 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
Workstream 1: 20 parents, 5-10 young people, 24-32 health professionals; Workstream 2: 300 children and their parents (n=600 participants)

Total final enrolment
567

Key exclusion criteria
1. Children with a temporary gastrostomy
2. Infants up to 6 months and young people who are 19 years and older
3. Non-residents of England

Date of first enrolment
01/03/2019

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road

Sunderland Tyne and Wear
United Kingdom
SR4 7TP

Study participating centre
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Shropshire Community Health NHS Trust
William Farr House,
Mytton Oak Rd,
Shrewsbury
United Kingdom
SY3 8XL

Study participating centre
Cambridgeshire Community Services NHS Trust
Unit 3
Meadow Lane
St. Ives
United Kingdom
PE27 4LG

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3, Priestley Wharf
Holt Street
Birmingham Science Park
Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
Heart of England NHS Foundation Trust
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5ST

Study participating centre
Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
Wye Valley NHS Trust
County Hospital
Union Walk
Hereford
United Kingdom
HR1 2ER

Study participating centre
The Dudley Group NHS Foundation Trust
C Block
Russells Hall Hospital
Pensnett Road

Dudley
United Kingdom
DY1 2HQ

Study participating centre
Worcestershire Health and Care NHS Trust
Isaac Maddox House
Shrub Hill Industrial Estate
Worcester
United Kingdom
WR4 9RW

Study participating centre
Leeds Community Healthcare NHS Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Somerset Partnership NHS Foundation Trust
2nd Floor
Mallard Court
Express Park
Bristol Road
Bridgwater
United Kingdom
TA6 4RN

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre

Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle Upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Childrens Hospice South West
Charlton Farm
Bristol
United Kingdom
BS48 1PE

Study participating centre
University of York
Department of Health Sciences
York
United Kingdom
YO10 5DD

Study participating centre

Harrogate and District NHS Foundation Trust
Lancaster Park Road
Harrogate
North Yorkshire
United Kingdom
HG2 7SX

Study participating centre
Sussex Community NHS Foundation Trust
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Northern Lincolnshire and Goole NHS Foundation Trust
Scunthorpe General Hospital
Cliff Gardens
Scunthorpe
United Kingdom
DN15 7BH

Study participating centre
Airedale NHS Foundation Trust Airedale General Hospital
Skipton Road
Steeton
Keighley
West Yorkshire
United Kingdom
BD20 6TD

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
West Yorkshire
United Kingdom
BD9 6RJ

Study participating centre
Lincolnshire Community Health Services NHS Trust
Beech House
Witham Park
Waterside South
Lincoln
Lincolnshire
United Kingdom
LN5 7JH

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
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HU3 2JZ

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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer reviewed scientific journals
2. Conference presentation
3. Publication on website
4. NIHR funder report

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to being unable to share the linked healthcare data which is important in the analyses.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.1	05/03/2019	17/04/2019	No	No

Protocol article	protocol	09/10/2019	10/10/2019	Yes	No
Protocol file	version v1.3	21/04/2020	02/02/2021	No	No
Other publications	qualitative findings	10/04/2021	21/05/2021	Yes	No
Protocol file		20/04/2021	21/05/2021	No	No
Protocol file	version 1.4	20/04/2021	02/03/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		21/12/2023	27/12/2023	Yes	No
Interim results article		10/11/2023	15/01/2024	Yes	No
Plain English results		15/01/2024	15/01/2024	No	Yes