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FEEDS: Focus on Early Eating, Drinking and Swallowing

Submission date
08/02/2018

Recruitment status
No longer recruiting

Registration date
15/02/2018

Overall study status
Completed

Last Edited
29/03/2021

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Long-term conditions in children affecting the brain, nerves and muscles are often grouped under the term 'neurodisability'. Difficulties with eating and drinking are common in young children with neurodisability. Eating and drinking difficulties may lead to a restricted diet, poor growth, and impact on development, in addition to general physical health risks such as choking or chest infections. The difficulties may also create stress at mealtimes that can affect wider aspects of family life. Some young children have mostly physical difficulties; for example, those with cerebral palsy may find chewing and swallowing problematic. Other young children have mostly sensory difficulties, such as extreme sensitivity to lumpy food, or difficulties associated with not wanting to eat or making faddy choices, such as in children with autism. Some children have combinations of difficulties. A team of health professionals usually works with parents and carers of young children with eating and drinking difficulties. The professionals identify the cause of the child's difficulties and suggest to parents how eating and drinking might be improved. This could include adjusting posture, reducing the child's sensitivity to certain textures, using medication, or special equipment. The treatments suggested depend on the cause of the child's difficulty. As there is no strong evidence on whether the treatments suggested by professionals actually work, more research is needed to understand whether they are effective. However, before doing these studies the researchers need to know which treatments are regularly recommended, which types of improvement in eating and drinking are considered most important by parents and professionals, and how best to measure a child's progress. This will help to decide which treatments should be tested in a future study and how to assess whether they work.

Who can participate?
Young people aged 12-18 with neurodisability and eating, drinking and swallowing difficulties, their parents, and the healthcare and education professionals who support them

What does the study involve?
Discussion groups and surveys are carried out with parents and professionals to find out about the different treatments recommended for young children with eating and drinking difficulties and how acceptable they are to parents. They are also asked how improvements in a child's eating and drinking should be measured, and when they should be assessed. Published research

is examined to see what is currently known about the effectiveness of treatments people think could be important. All the information is combined to identify whether there are treatments that would be worth investigating further, and how best to measure children's progress with eating and drinking. The researchers meet again with parents and professionals, and meet young people who have experienced eating and drinking difficulties, to see whether they can agree how to test treatments in further research. Finally recommendations are made about how future studies should be designed and conducted.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants. Participants of the focus groups receive a £50 voucher to thank them for their time and cover travel expenses. Participants who complete the surveys can enter a prize draw to win one of five £100 vouchers for each survey. Some participants may be upset or distressed when recounting their own or their child’s difficulties and the amount of intervention received or not received. The researchers are skilled at discussing these matters with young people and parents briefly in focus groups, and then having a more detailed discussion after the group, if that is desirable for the young person and parent. The guidance for the focus groups gives clear instruction on supporting young people and parents. Documentation gives the contact details of members of the research team so that people completing a group or survey can contact them if they wish to.

Where is the study run from?
1. Newcastle University (UK)
2. Exeter University (UK)
3. Sussex Community NHS Foundation Trust (UK)
4. Guy's and St Thomas' NHS Foundation Trust (UK)
5. Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2017 to December 2019

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Helen Taylor

Contact information

Type(s)
Scientific

Contact name
Dr Helen Taylor

Contact details
Institute of Neuroscience
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United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 15/156/02

Study information

Scientific Title
What interventions, which could be delivered at home by parents, are available to improve eating in young children with neurodisability and are suitable for investigation in pragmatic trials?

Acronym
FEEDS

Study objectives
What interventions, which could be delivered at home by parents, are available to improve eating in young children with neurodisability and are suitable for investigation in pragmatic trials?

Study aims:
1. To determine which parent-delivered interventions are currently offered by NHS professionals and how parents and professionals evaluate whether an intervention is successful or not.
2. To review the clinical practice and research evidence for interventions, outcomes measured and the tools used to measure these outcomes.
3. To construct one or more trial frameworks acceptable to children, young people, parents and professionals; or to specify the additional evidence about interventions, outcomes and tools that would be needed to support a future trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethics Committee, 03/01/2018, REC ref: 17/WM/0439, IRAS Project ID: 215629

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

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
Neurodevelopmental conditions

Interventions
Sequential mixed methods design:
1. 1st round of focus groups: Professionals (health and education staff) and parents to gain a preliminary understanding of interventions offered to families of children with eating, drinking and swallowing difficulties.
2. Survey 1: Professionals (health and education staff) and parents to identify current use of interventions that parents of young children with eating, drinking and swallowing difficulties can use at home.
3. Updating systematic reviews: Update three recent systematic reviews about interventions.
4. Evidence mapping: To identify potential interventions, outcomes and measurement tools and examine properties of the identified tools most frequently used and most valued to measure outcomes.
5. Evidence synthesis 1: Synthesis of evidence gathered through steps 1-4.
6. Second round of focus groups: Professionals (health and education staff), parents and young people to review evidence from synthesis 1.
7. Delphi survey: To gain consensus on trial components.
8. Evidence synthesis 2: Synthesis of evidence from steps 6-7 consensus workshops.
9. Consensus workshops: To draw together all the available evidence to suggest a framework and outcomes for one or more trial(s) of interventions for children with eating, drinking and swallowing difficulties.

Intervention Type
Other

Primary outcome measure
This is a scoping study and therefore the outcomes are to identify treatments, key outcomes and measurement tools that could be used in future trials, so there are no outcome measures at this stage
1. Identification of treatments available in the NHS for children with physical and non-physical eating, drinking and swallowing difficulties
2. Identification of the most promising interventions and specification of the patient groups in whom the intervention(s) should be tested, including whether exemplar conditions should be used in a trial; what 'treatment as usual' comprises, and its acceptability
3. Selection of the key outcomes and recommendation of the measurement tools that could be

used
4. A suggested framework and outcomes for one or more substantive pragmatic trials

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/07/2017

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Young people aged 12-18 years with neurodisability and eating, drinking and swallowing difficulties
2. Parents of young children with neurodisability who experience eating, drinking and swallowing difficulties up to and including 12 years of age. Parents who have been discharged home from neonatal units will be included
3. Healthcare professionals who support children with neurodisability who experience eating, drinking and swallowing difficulties
4. Education professionals who support children with neurodisability who experience eating, drinking and swallowing difficulties

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Focus groups: 84 (parents, professionals and young people); survey: 500 (parents and professionals); Delphi survey: 100-200 (parents and professionals); consensus workshops: 20 (parents and professionals)

Total final enrolment
951

Key exclusion criteria
1. Young children with progressive neurodisability and their parents
2. Young children without neurodisability and their parents
3. Parents of children with neurodisability who are inpatients postnatally at time of study

Date of first enrolment
01/12/2017

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Development and Disability Group
Sir James Spence Institute
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Exeter University
Medical School
St Luke's Campus
Heavitree Road
Exeter
United Kingdom
EX1 2LU

Study participating centre
Chailey Clinical Services - Sussex Community NHS Foundation Trust
Beggars Wood Road
North Chailey
Nr Lewes
United Kingdom
BN8 4JN

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Evelina London Children's Hospital
St Thomas's Hospital
Westminster Bridge Road
London

United Kingdom
SE1 7EH

Study participating centre
Great North Children's Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

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
The study protocol has been reviewed and approved by NIHR and is awaiting upload to the NIHR Journals Library website (https://www.journalslibrary.nihr.ac.uk/programmes/hta/1515602/#/).

The trialists will start dissemination following Stage 1 by sending newsletters to participants and through organisations. They will create a project website.

In addition to a report to the HTA and possible publication in the HTA journal, the trialists will prepare one article for submission to a major journal in child health or child disability. They will present the findings at the British Academy of Childhood Disability annual meeting, and at the European Academy of Childhood Disability annual meeting - this focuses on conditions such as cerebral palsy, autism spectrum disorder and others. If possible, they will also present data at the International Meeting for Autism Research.

The trialists will offer to present their findings at regional neurodisability meetings - parents and professionals often attend these. They will share information with clinical networks through speciality groups and Royal Colleges, and others through whom they link during the project, for example voluntary sector organisations and parent carer forums. Written summaries of the findings will be sent to parent and professional participants from the project, and national charities. The findings will be presented at parent/carer meetings.

Different groups within the community prefer different formats and dissemination routes (for example, many adults on the autism spectrum disorder prefer social media, many older parents prefer paper, younger people make more use of web based approaches). The trialists will aim to accommodate the preferences of all audiences and tailor dissemination formats, methods and content for the people to whom it is directed. They will provide feedback findings to end-users following each research stage to build and maintain engagement.

The trialists will use printed materials, email and social media for dissemination, as well as webinars and YouTube videos that can be distributed online or through Facebook or Twitter.

Finally, the trialists will share their findings with research partners in other countries, to ensure best use of the results (for example, colleagues in Australia).

Intention to publish date
30/05/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2021	29/03/2021	Yes	No
HRA research summary			28/06/2023	No	No