ISRCTN13414304 https://doi.org/10.1186/ISRCTN13414304

Cue-based versus scheduled feeding for premature babies in neonatal units

Submission date
05/06/2018

Recruitment status
No longer recruiting

Registration date
22/06/2018

Overall study status
Completed

Last Edited
09/12/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
When babies are born early they might not have developed the coordination needed to suck, swallow and breathe as they feed. Before babies are ready to feed using their mouths (oral feeding), feeds can be given by a tube running from their mouth or nose into their stomach. When the baby is ready this can be changed to feeding through their mouth, by breast, bottle or a cup or spoon. Many babies at this stage are fed at set (scheduled) times while others are fed when they show signs that they are hungry (cue-based). Some research has shown that feeding babies when they show they are hungry might be beneficial for them and their parents. For example, babies may be discharged from hospital earlier. Cue-based feeding may also allow parents to better understand the needs of their baby and become more involved in providing care. We aim to develop a written plan for cue-based feeding that includes training for healthcare professionals and education materials for parents, and to test this plan to see if it works in neonatal units and is acceptable to parents and staff. We will also find out if the plan could be tested in a future study comparing cue-based with scheduled feeding for premature babies in neonatal units.

Who can participate?
In phase 1 of the study: parents of babies in neonatal units who have experienced or are currently experiencing their baby changing from being fed by tube to being fed by mouth. Health care staff in neonatal units.
In phase 3 of the study: premature babies, including twins, who do not have any medical complications and who are being fed by a tube and are ready to move to being fed by mouth, and their parents. Staff working in neonatal units

What does the study involve?
In phase 1 of the study: parents and staff will take part in a group discussion or a one-to-one interview.
In phase 3 of the study: parents will be taught about cue-based feeding and asked to feed their babies this way with support and help from the neonatal care team. The babies will monitored closely to make sure they are progressing well and gaining weight. Researchers will collect some information by reviewing the baby's medical record and by observing care provided for babies in the study. Some (about half) of the parents will be invited to talk to researchers about their

experiences of feeding their babies according to their cues, and asked for their opinion about the best way to conduct a larger study in the future that would compare cue-based feeding to feeding babies according to a set schedule. Two weeks after the baby goes home, a researcher will telephone the parents to ask how the feeding is going at home. The staff will be invited to participate in an interview with researchers who will ask about their experiences of cue-based feeding and their opinions about a future study.

What are the possible benefits and risks of participating?
It is thought that there are benefits to cue-based feeding such as babies changing to full oral feeding and being discharged home sooner. Cue-based feeding may mean that parents are more involved in their baby's care and learning how to interpret feeding cues may help parents to understand their baby's needs better. Taking in part in the research may help babies and parents in neonatal units in the future. Some parents find it helpful to talk about their experiences in the neonatal unit, which can be very stressful. Some parents and staff might worry that their baby is not getting enough milk. The babies in the study will be monitored very closely as are all babies in neonatal units and if they show signs that they are not feeding enough, such as not gaining weight, not being settled or having low blood sugar, the feeding plan will be changed.

Where is the study run from?
The study is being led from the University of Dundee in Scotland. The research team also includes researchers from the Open University and the University of York, clinicians from Glasgow and Great Ormond Street Hospital in London and a member from the baby charity BLISS. The study will be carried out in 3 hospitals – Ninewells Hospital in Dundee, Coventry Hospital and Exeter Hospital.

When is the study starting and how long is it expected to run for? (what is the anticipated start date and the approximate duration of the trial?)
Phase 1 of the study will start in August 2018 and finish in November 2018 (4 months).
Phase 3 will start in March 2019 and finish at the end of November 2021

Who is funding the study?
The National Institute of Health Research (UK)

Who is the main contact?
Bronagh Raftery, Project Manager, School of Nursing and Health Sciences, University of Dundee.
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20170B03, HTA 16/144/05

Study information

Scientific Title
Development and feasibility study of an evidence-informed manualised intervention to compare CUe-Based versus Scheduled feeding for preterm infants transitioning from tube to oral feeding in neonatal units (CuBS)

Acronym
CUBS

Study objectives
The aim of the research is to develop a manualised intervention and to assess whether it is feasible to conduct a clinical and cost-effectiveness study of cue-based versus scheduled feeding for preterm infants in neonatal units (NNUs)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Current ethics approval as of 30/06/2021:
1. Work packages 1 and 2 approved 29/05/2018, East of Scotland Research Ethics Service (EoSRES), ref: LR/18/ES/0059
2. Work packages 3 and 4 approved 26/04/2019, North of Scotland Research Ethics Service, ref: 19/NS/0055

Previous ethics approval:
East of Scotland Research Ethics Service (EoSRES), 29/05/2018, LR/18/ES/0059

Study design
The study design is intervention development using evidence synthesis and primary qualitative research and the feasibility study and process evaluation.

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Feeding of preterm babies in neonatal units

Interventions
1. Work Package 1: Participants (parents and staff) recruited to this phase of the study will participate in either one focus group or one interview lasting about 1 hour. There will be no follow-up. This will form part of a telephone survey of 20 neonatal units to map and understand: i) the range of approaches to the transition from tube to oral feeding, ii) the scope of data collection systems, iii) staff training needs; and conduct qualitative research to explore parents' and staff's understanding and attitudes to cue-based feeding.
2. Work Package 3: Participants (babies and their parents) will be recruited when the baby is ready to transition to oral feeding. Parents will be given information about cue-based feeding and supported by staff to recognise their baby's cues and to feed accordingly. About half of the parents will be invited to take part in one face-to-face qualitative interview about their experiences of cue-based feeding. The transition to feeding will follow a protocol for cue-based feeding i.e. the babies will be fed according to their feeding cues rather than by a schedule. Babies will be monitored according to the usual practice in the neonatal unit and followed up until 2 weeks after they are discharged home to collect data about how feeding is progressing. Some information will be collected from the baby's medical records and there will be observations of care on specific times in the neonatal unit.

Intervention Type
Behavioural

Primary outcome measure
Feasibility to undertake an RCT. This will be assessed using the secondary outcome measures combined into a narrative/qualitative assessment of issues such as fidelity, dose, reach of the intervention, participants response, unexpected consequences etc (as described in the model by Moore et al 2015). The data to inform this will be collected throughout the intervention implementation (Work package 3) rather than at specific time-points. At the end of the study we will present the qualitative/narrative findings to Stakeholders who will make the decision using the ADePT framework (Bugge et al 2013).

Secondary outcome measures
1. Frequency and length of feeds (and volume for bottle fed babies) assessed by reviewing patient notes on a daily basis until 2 weeks after discharge from the neonatal unit
2. Daily weight change: assessed by reviewing patient notes on a daily basis until 2 weeks after discharge from the neonatal unit
3. Length of stay in hospital assessed by reviewing patient notes after discharge
4. Number of days to establish full oral feeding assessed by reviewing patient notes or 2-week follow-up if baby is discharged to home while still tube feeding
5. Adherence to cue-based feeding protocol assessed by reviewing patient notes/interviews /patient care observation on a daily basis
6. Feeding outcomes (method and type of milk) at discharge and 2-week follow-up
7. Important trial outcomes for a future trial assessed interviews during hospital stay
8. Feasibility of longer term follow-up assessed using interviews during hospital stay
9. Experiences and acceptability of cue-based feeding assessed using interviews during hospital stay
10. Number of infants meeting eligibility criteria and number of infants recruited assessed using research nurse recruitment logs throughout study
11. Willingness of parents to be randomised assessed using interviews during hospital stay

Overall study start date
01/05/2018

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Neonates:
1. Developmentally normal
2. Born before 37 weeks gestation
3. Clinically stable
4. At least partially enterally fed, with an intragastric tube in place at the start of the study
5. Parent(s) consent to inclusion in the study

Parents of infants meeting the above criteria

Healthcare staff:
1. Multi-disciplinary healthcare staff working in neonatal units, including medical consultants, registrars and junior doctors, neonatal nurses, advanced neonatal nurse practitioners, nurse managers and nursery nurses, speech and language therapists, and dieticians.

2. For the telephone interviews in WP1c, the target population includes senior nurses or infant feeding co-ordinators in neonatal units across the UK
3. The consensus-building and stakeholder workshops will include representatives from Neonatal Networks, professional associations (Neonatal Nurses Association, British Association of Perinatal Medicine) and third sector organisations (e.g. Bliss, TAMBA, La Leche League).

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
60 babies and at least one parent per baby, plus 45 health care practitioners. WP1 telephone interviews with an appropriate member of staff of 20 neonatal units across the UK . Focus group discussions with 6-8 parents and 8 health care practitioners.

Total final enrolment
149

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Tayside Ninewells Hopsital Neonatal Unit
United Kingdom
DD1 9SAY

Study participating centre

Neonatal Unit University Hospital Coventry & Warwickshire
United Kingdom
CV2 2DX

Study participating centre
Neonatal Unit, Royal Devon and Exeter Hospital
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Sponsor information

Organisation
NHS Tayside

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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

Organisation
University Of Dundee

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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. We plan to publish the finding of the feasibility study in a high impact, open access peer-reviewed journal by 30/12/2021
2. We will present the findings at relevant conference such as British Association of Perinatal Medicine by 30/11/2020
3. We will write summaries of the research for parents and post these on the Bliss website by 30 /11/2020

Intention to publish date
30/12/2021

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?
Participant information sheet	version V2	24/05/2018	22/06/2018	No	Yes
Participant information sheet	version V2	24/05/2018	22/06/2018	No	Yes
Results article		01/12/2021	09/12/2021	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No