Cue-based versus scheduled feeding for preterm infants transitioning from tube to oral feeding: the Cubs mixed-methods feasibility study

Alison McFadden,^{1*} Bronagh Fitzpatrick,¹ Shona Shinwell,¹ Karen Tosh,¹ Peter Donnan,² Louise M Wallace,³ Emily Johnson,⁴ Steve MacGillivray,¹ Anna Gavine,¹ Albert Farre¹ and Helen Mactier⁵

¹School of Health Sciences, University of Dundee, Dundee, UK
²Tayside Clinical Trials Unit, University of Dundee, Dundee, UK
³School of Health, Wellbeing and Social Care, The Open University, Milton Keynes, UK
⁴Great Ormond Street Hospital, London, UK
⁵Princess Royal Maternity, NHS Greater Glasgow and Clyde, Glasgow, UK

*Corresponding author a.m.mcfadden@dundee.ac.uk

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Disclaimers: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

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Scientific summary

Background

The transition to oral feeding is a critical developmental stage for preterm infants. Although enteral feeds for preterm infants are usually given as prescribed volumes at scheduled intervals, some evidence exists that preterm infants can self-regulate their intake. While feeding cues may be more difficult to detect in preterm than in term infants, they may be sufficiently evident for a parent or caregiver to recognise and respond to, thereby supporting safer and more successful feeding experiences.

Cue-based feeding may also increase rest between feeds, promoting infant-led sleep and wake patterns. Potentially, infant-led feeding patterns will facilitate the development of organised behaviour states leading to earlier establishment of oral feeding, and thereby shorten hospital stays for preterm infants.

There is a lack of strong or consistent evidence of the effect of cue-based feeding compared with scheduled feeding on important outcomes for preterm infants or their families. A Cochrane review concluded that there was low-quality evidence that cue-based feeding compared with scheduled feeding leads to earlier transition to full oral feeding (Watson J, McGuire W. Responsive versus scheduled feeding for preterm infants. *Cochrane Database Syst Rev* 2016;8:CD005255).

Objectives

The overall aim of this study was to develop a manualised intervention and to assess whether or not it is feasible to conduct a clinical and cost-effectiveness study of cue-based compared with scheduled feeding for preterm infants in neonatal units (NNUs).

The objectives were to:

- 1. describe the characteristics, components, theoretical basis and outcomes of approaches to feeding preterm infants transitioning from tube to oral feeding, including by feeding type (i.e. breast milk, donor breast milk, formula and combined) and method (i.e. breastfeeding and bottle feeding)
- identify operational policies, barriers and facilitators and staff and parents' education needs in NNUs implementing cue-based feeding
- 3. co-produce an evidence-informed, adaptable, manualised intervention, including staff and parent educational support for feeding preterm infants at the transition from tube to oral feeding in response to feeding cues and signs of infant stability
- 4. appraise the willingness of parents and staff to implement and sustain the intervention
- 5. assess associated costs of implementing cue-based feeding in NNUs
- 6. determine the feasibility and acceptability of conducting a future randomised controlled trial (RCT), incorporating the views of parents, staff and service commissioners on important outcomes
- scope existing data-recording systems and potential short- and long-term outcome measures (e.g. feeding outcomes, length of time to transition to full oral feeding, length of stay in NNUs, adverse events, infant growth, parent-infant attachment and well-being, and parent and staff satisfaction)
- 8. determine key stakeholders' views based on the evidence from our study (objectives 1–7) of whether or not a RCT of this approach is feasible and what the components of a future study would look like.

Methods

Work package 1: building the evidence base

Work package (WP) 1 comprised a systematic review, an analysis of policies and guidelines, three case studies, a telephone survey, qualitative interviews and focus groups.

The systematic review synthesised evidence on the components, characteristics, theoretical basis and associated behaviour change techniques (BCTs), infant and parent outcomes, and economic evaluations of cue-based feeding interventions. Searches of the following databases were conducted in August 2018: Cochrane, Campbell, Centre for Reviews and Dissemination (CRD)/Database of Abstracts of Reviews of Effects (DARE), MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews (CDSR), Health Technology Assessment (HTA) database, Cochrane Central Register of Controlled Trials (CENTRAL), Social Science Citation Index, PsycInfo[®] (American Psychological Association, Washington, DC, USA), Health Management Information Consortium (HMIC), Applied Social Sciences Index and Abstracts (ASSIA), Social Policy and Practice, Bibliomap, Database of Promoting Health Effectiveness Reviews (DoPHER), Trials Register of Promoting Health Interventions (TRoPHI), Social Care Online, British Nursing Index, Research Councils UK, OAlster and OpenGrey. Studies were included if they reported empirical findings of cue-based feeding interventions for developmentally normal, clinically stable preterm infants transitioning from tube to oral feeding. Titles and abstracts were screened independently for inclusion by two reviewers and full texts were examined by two members of the research team to determine eligibility. Data were extracted regarding (1) study country, (2) design, (3) characteristics, (4) intervention components, (5) theoretical basis for the intervention and (6) outcomes. All included studies were assessed for methodological quality according to individual elements of quality. The findings were synthesised narratively.

We conducted searches using the Google (Google Inc., Mountain View, CA, USA) advanced interface to identify relevant policies and guidelines. Data were extracted and tabulated by one researcher regarding target population, components of feeding protocols and plans, education and training for parents and staff, criteria and parameters for cue-based feeding, safety, monitoring and evaluation strategies and any other details pertinent to the development of a cue-based feeding intervention.

Case studies of three NNUs (two in Sweden and one in the UK) with embedded cue-based feeding comprised observational visits, informal interviews with key informants and access to relevant documentation, policies, guidelines and training materials. Data collection was guided by a template of 46 questions. Field notes were analysed thematically based on the aims of the case studies.

Telephone interviews were conducted with a purposive sample of 18 NNUs across the UK to understand the range and variation in approaches to the transition from tube to oral feeding in preterm infants. Each unit nominated a knowledgeable participant(s). The interviews were conducted by a member of the research team using a semistructured interview schedule based on the aims of the survey. Interview transcripts were analysed thematically by two researchers.

Focus group discussions supplemented by individual interviews were conducted with a convenience sample of 15 parents (12 mothers and three fathers) and 32 health-care practitioners in three NNUs in the UK to understand their experiences, views and understanding of cue-based feeding. Interviews and focus group discussions were conducted by site research nurses guided by a semistructured interview topic guide. Audio-recordings were listened to by a member of the research team, who noted key points.

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Work package 2: co-production of the intervention

The intervention was co-produced with stakeholders, including parents. A matrix of interventions was developed by the research team and discussed at a workshop where consensus was reached on each component of the intervention. The final version of the intervention was then co-produced by the research team with parents.

Work package 3: feasibility study

The intervention was implemented in three NNUs. The mixed-methods feasibility study assessed recruitment and retention, weight, intervention duration and feeding outcomes for 50 infants who were followed up until 2 weeks after discharge from the NNU. An embedded qualitative study comprising interviews with 14 parents and 16 staff, and 21 hours of non-participant observation, used implementation outcomes and normalisation process theory to assess factors influencing the implementation and feasibility of a future evaluation.

Work package 4: next steps

Using a structured process, and working with stakeholders, solutions to overcome challenges and preferences for a future evaluation were assessed.

Results

Work package 1

The systematic review included 25 studies, of which 10 were RCTs, nine were quality improvement projects and six were observational studies. The quality of studies was low, with high risk of bias in all but one study. Our review does not change the findings of the Cochrane review, which indicated that evidence in favour of cue-based feeding is of low quality and should be treated cautiously.

The findings of the case studies, telephone interviews and qualitative research suggested that contextual factors, such as the facilities provided for parents to be with their infants in NNUs and the extent to which skin-to-skin contact is practised, are key facilitators of cue-based feeding. Barriers to implementing cue-based feeding included some staff's resistance to change from a volume-driven scheduled approach, safety concerns and lack of access to training. The qualitative data suggested that health-care practitioners' views that they are implementing cue-based feeding were not always consistent with parents' experiences. The telephone survey found that most NNUs either had started making changes or were considering changes to implement cue-based feeding.

Work package 2

The consensus-building and co-production processes resulted in the development of an evidenceinformed multicomponent intervention comprising a training package covering the approach to cue-based feeding and study procedures, a feeding protocol, feeding assessment tools, supplementary training materials in the form of posters, a film, a narrated PowerPoint (Microsoft Corporation, Redmond, WA, USA) presentation, and the 'Our Feeding Journey' document for recording each feed.

Work package 3

We recruited 50 infants, representing 83% of our target sample of 60 infants and 37% of eligible infants. Of the sample of 50 infants, 49 received the intervention, 48 were retained in the study until discharge from the NNU, but a small number, only 18, were followed up 2 weeks after discharge. It was feasible to collect data on important outcomes such as weight and duration of the intervention; however, there were a large number of missing data relating to feeding outcomes.

Recruitment to the embedded qualitative study was low, affected in part by closing the study before the intended date because of the COVID-19 pandemic. The qualitative findings suggested that the intervention was acceptable and the resources well received, although there was some dissatisfaction

with the amount of documentation. The cascade approach to training did not reach all staff. The intervention was perceived to fit well with current neonatal care practice. In general, there was good evidence that the intervention was implemented as intended, especially in relation to not applying a lower gestational age to the start of oral feeding and not having a set rate of transition. However, there was evidence that most infants were fed to a 3-hourly schedule. Infant growth and time to establish full oral feeding and discharge were the most important outcomes to parents and staff. Staff would also like to see assessment of mother–infant attachment and longer-term follow-up of infants. There were mixed views on randomisation suggesting that many parents and staff were not in equipoise for cue-based feeding, believing it to be the best approach.

Work package 4

Stakeholder views of the next steps were that the intervention should be digitalised [i.e. an app (application) developed that includes both the intervention and feeding outcome data collection]. A minimum data set should be agreed to avoid overburdening parents and staff. To further assess feasibility, a survey of all 220 UK NNUs could be conducted to provide a more complete and updated assessment of approaches to transitioning from tube to oral feeding and willingness to participate in a multicentre study. A pilot trial would be needed to assess sample size, feasibility of mother-infant attachment and longer-term outcomes. Prioritised solutions to the recruitment and training challenges were to screen infants earlier in their feeding journey so that consent can be taken before the infant progresses to start oral feeding, to embed a researcher within the NNU to support screening and recruitment, and to improve the approach to training.

Conclusions

Our work has demonstrated that it is feasible and acceptable to implement an evidence-informed cue-based feeding intervention for the transition from tube to oral feeding for preterm infants in NNUs. The intervention was well received, but the training element needs to be improved. Further work is needed to digitalise the intervention and feeding outcome data collection, and to assess the feasibility of a future evaluation, noting evidence of existing lack of equipoise.

Study registration

This study is registered as PROSPERO CRD42018097317 and ISRCTN13414304.

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This report

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