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Exploring Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge(HUMMINGBIRD Study): a protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction Mother's own breast milk (MOM) is the optimal nutrition for preterm infants as it reduces the incidence of key neonatal morbidities and improves long-term outcomes. However, MOM shortfall is common and either preterm formula or pasteurised donor human milk (DHM) may be used, although practice varies widely. Limited data suggest that the use of DHM may impact maternal beliefs and behaviours and therefore breastfeeding rates. The aim of this pilot study is to determine if longer duration of DHM exposure increases breastfeeding rates, and if a randomised controlled trial (RCT) design is feasible.

Methods and analysis The Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge (HUMMINGBIRD) Study is a feasibility and pilot, non-blinded RCT with a contemporaneous qualitative evaluation. Babies born less than 33 weeks' gestation or with birth weight <1500 g whose mothers intend to provide MOM are randomly assigned to either control (DHM used to make up shortfall until full feeds and preterm formula thereafter) or intervention (DHM used for shortfall until 36 weeks' corrected age or discharge if sooner). The primary outcome is breast feeding at discharge. Secondary outcomes include growth, neonatal morbidities, length of stay, breastfeeding self-efficacy and postnatal depression using validated questionnaires. Qualitative interviews using a topic guide will explore perceptions around use of DHM and analysed using thematic analysis.

Ethics approval and dissemination Nottingham 2 Research Ethics Committee granted approval (IRAS Project ID 281071) and recruitment commenced on 7 June 2021. Results will be disseminated in peer-reviewed journals.

Trial registration number ISRCTN57339063.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Mother's own milk (MOM) benefits for preterm infants are well recognised but uncertainties remain around the optimal strategy for donor human milk (DHM) use, especially whether it impacts breast feeding. DHM is a complex intervention which has effects on infant health and maternal and healthcare staff behaviours and beliefs.

WHAT THIS STUDY ADDS

⇒ This pilot randomised controlled trial (RCT) strives to determine if DHM provision affects breastfeeding rate at discharge and if RCT is a suitable design to answer this research question.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ A single RCT of a complex intervention is unlikely to resolve all uncertainties. Studies incorporating quantitative and qualitative methods may better elucidate the role of DHM in neonatal intensive care units. HUMMINGBIRD may help optimise the design of future studies in larger scale.

INTRODUCTION

Approximately 60 000 babies are born prematurely (<37 weeks) in the UK each year and around 10 000 babies are born very preterm (<32 weeks' gestation).[1] While survival rates of extremely preterm (<28 weeks) infants have improved recently, serious adverse outcomes including late-onset sepsis (LOS) and necrotising enterocolitis (NEC) remain common.[2 3] Preterm infants are at significant risk of long-term complications including retinopathy of prematurity (ROP), bronchopulmonary dysplasia (BPD) and cognitive impairment.[4] Nutritional management impacts short-term and long-term outcomes[5] but remains challenging as macronutrient intake can be hard to meet.[6]

Mother's own milk

Mother's own milk (MOM) provides the basis of the optimal diet for preterm babies due to its composition including key proteins and lipids, as well as enzymes, growth factors and other unique dyad-specific bioactive

nutrients such as human milk oligosaccharides.[7] Use of MOM is associated with a dose–response decreased risk of neonatal morbidities such as NEC, LOS and BPD.[8–11] While an exclusive MOM diet has been associated with slower growth compared with preterm formula (PF),[12 13] cognitive, cardiac and metabolic outcomes are better.[14–16]

Challenges of expressing MOM and breast feeding in neonatal intensive care unit

Despite well-recognised benefits of MOM, low breastfeeding rates remain a major health concern. Over 90% of mothers delivering prematurely now provide some breastmilk, but breastfeeding rates at discharge vary considerably across the UK (25%–91%).[17] Mothers of preterm babies must cope with the stress of having a preterm, sick infant and maintain breastmilk expression for several weeks. Furthermore, the initiation of lactogenesis is often impaired after preterm birth,[18] and despite targeted support, infants require additional milk at some stage.[17]

Donor human milk

The WHO, American Association for Pediatrics and European Society of Paediatric Gastroenterology, Hepatology and Nutrition recommend the use of donor human milk (DHM) for feeding premature infants as a first alternative when there is a MOM shortfall,[7 19] despite few high-quality randomised controlled trials (RCTs) and heterogeneity of studies. A recent Cochrane review suggested that DHM may reduce the risk of NEC compared with PF, with at least 33 infants needing to receive DHM to prevent one NEC case. The data do not support a reduction in mortality or longer-term neurodevelopmental benefits.[20] Differences in DHM use exist among UK neonatal intensive care units (NICUs),[21] with some only providing DHM for the first 10 days, whereas other units use DHM for closer until discharge. Variation between NICU may be linked to uncertainties around DHM use including whether DHM affects duration of breastmilk expression or breast feeding.[22] A systematic review showed that DHM may have a positive effect on *any* breast feeding, but rates of *exclusive* breast feeding on discharge are unchanged.[23] A large observational study in 56 NICUs in the USA showed increased rates of breast feeding in NICUs where a DHM programme was implemented, along with a decrease in NEC rate.[24] In contrast, another single-centre retrospective study showed that MOM provision *decreased* following the implementation of a donor milk programme, and preterm infants consumed less MOM in the first 14 days in the post-DHM cohort.[25] Esquerra-Zwiers *et al* showed similarly reduced MOM use in the first 14 days of life with DHM availability. However, in this study, enteral feeds were commenced earlier, and infants were exposed to formula later in life after DHM introduction.[26] More recently, DHM used in addition to optimising breastfeeding support and kangaroo care led to improved exclusive human milk feeding.[27] To date, no RCT has studied the relationship between donor milk availability and breast feeding at hospital discharge.

Preterm formula

The composition of PF is designed to meet the high nutrient demands of the preterm infant and results in improved weight gain, linear and head growth.[20] However, no RCTs have shown improved long-term growth or neurodevelopmental outcomes compared with the use of MOM or DHM.[20 28] PF may provide a more consistent delivery of macronutrients and micronutrients but generally lacks bioactive component, which might be key in reducing disease and improving long-term outcomes.[29 30] The cost of PF (around £5 per litre) is almost 30-fold lower than the cost of DHM (between £125 and £150 per litre). However, a systematic review of economic evaluations of DHM determines it is a cost-effective intervention because it reduced occurrence of NEC by two-thirds compared with formula.[31]

Summary of key issues: DHM as a 'complex intervention'

While MOM is the optimal source of nutrition for preterm infants, rates of breastmilk feeding could be improved. Around 90%–95% of mothers in the North East start breastmilk expression, but only 35% still provide breastmilk at discharge compared with the national average of 60%.[32] Improving availability of MOM is crucial to reducing key neonatal morbidities. DHM use is increasing in most UK neonatal units and is recommended by European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) when there is a MOM shortfall.[7] However, because DHM may affect growth, the optimal strategy for improving lifelong health remains uncertain. Observational data show that DHM availability is associated with breastmilk expression and breastfeeding duration suggesting that DHM affects beliefs and behaviours of mothers and perhaps healthcare staff, and DHM is therefore a 'complex intervention'. Complex interventions in healthcare influence biology (ie, health and disease) as well as behaviour and belief (eg, breastfeeding rates). Complex interventions may have multiple relevant outcomes and mechanistic causal pathways, and may be affected by context, for example, NICUs with differing background rates of NEC or breast feeding. Like many other complex interventions, there is a long lag time between dietary interventions such as DHM and outcomes, for example, metabolism and cognition in adulthood.[33]

Provision of DHM may be the best example of a complex intervention in neonatal medicine, and uncertainties around the optimal strategy are unlikely to be resolved with a single RCT. We designed this pilot trial to determine the foundation for further trials that can

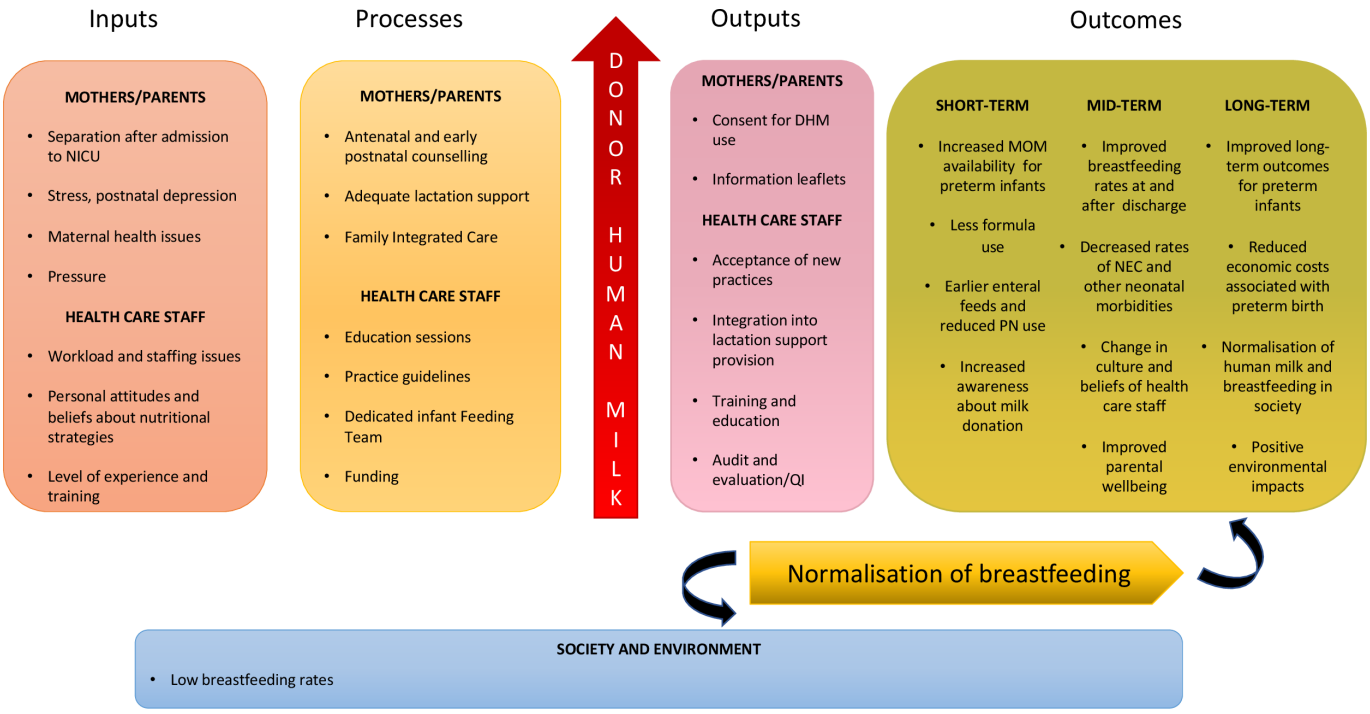

Figure 1 Logic model to illustrate role of DHM as complex intervention. DHM, donor human milk; MOM, mother's own milk; NEC, necrotising enterocolitis; NICU, neonatal intensive care unit; PN, parenteral nutrition; QI, quality improvement.

investigate the optimal implementation and use of DHM (figure 1).

METHODS AND ANALYSIS

The HUMMINGBIRD (Human Milk, Nutrition, Growth, and Breastfeeding Rates at Discharge) Study is a randomised open-label controlled trial in two tertiary neonatal units in the North East of England, the second site being added in May 2022. It is designed to compare two different nutritional strategies, both of which use DHM to make up any shortfall in MOM for preterm infants, but provided until two points of time—full feeds versus 36 weeks' corrected age (ca) (table 1).

Table 1 Summary of study methods

Setting	Tertiary-level NICUs in North East England
Population	Preterm infants <33 weeks or with a birth weight <1500 g admitted in the first 7 days of life
Intervention	Use of DHM to make up any shortfall in MOM until 36 weeks' corrected age (or discharge if this comes earlier)
Control	Use of DHM to make up any shortfall in MOM until full feeds are achieved (tolerating 150 mL/kg/day for 48 hours)
Design	Pilot randomised open-label controlled trial
Time frame	Until 36 weeks' corrected gestation or hospital discharge if earlier

DHM, donor human milk; MOM, mother's own milk; NICUs, neonatal intensive care units.

Population

Infants born before 33 completed weeks of gestation or with a birth weight of less than 1500 g whose mothers intend to express breastmilk after delivery and are willing to accept DHM are eligible. Only infants with written informed consent from parents and randomised within 7 days of birth can be included. Infants who were born with major congenital or life-threatening abnormalities or who were exposed to formula milk prior to randomisation are excluded.

Intervention: DHM to 36 weeks

DHM is used to make up any shortfall in MOM until 36 weeks' ca. If infants do not experience any shortfall, they will continue to receive MOM. This study aims to assess the effect of DHM on breast feeding at discharge; therefore, infants in the intervention group will only continue to receive DHM if their mother is still expressing breastmilk. Where the infant has not received any MOM for 1 week, or where the mother has told clinical staff she stopped expressing, the use of DHM will be discontinued and the baby will receive PF.

Control: DHM until full feeds only

DHM is used to make up any shortfall in MOM until full feeds are achieved (tolerating 150 mL/kg/day for 48 hours). If a shortfall of MOM occurs beyond this point, infants in the control group will receive PF.

Infants in both arms follow standard routine care. Human milk feeds (both MOM and DHM) are fortified with human milk fortifier once full feeds are achieved.

Randomisation

Infants are randomised with a secured, password-protected web-based randomisation tool (www.sealedenvelope.com) using random permutated blocks and stratification incorporating the following strata: gestation (<28 weeks yes/no) and twin/triplet status (yes/no). Twins, triplets and higher multiples are co-randomised to the same trial arm.

Data collection and management

Feeding data are collected prospectively on a daily basis by the research team. Trained research team members perform measurements weekly on each infant at care times. Length is measured using Leicester Incubator Measure. Head, mid-arm and thigh circumference are measured using single-use tape measure. Combined UK-WHO growth charts for preterm infants are used as a reference to calculate centiles and Z-scores. Trial completion is defined as reaching 36 weeks' ca or earlier if the infant is discharged home or to a postnatal ward. Data about neonatal morbidities are collected at this stage. Families are contacted via telephone by research team members at around 6 and 12 weeks' time from discharge. Data about type of feeding, milk, recent weight and head measurements are obtained. All data are recorded electronically, and confidential data are password secured.

Study outcomes

Primary outcome

Any breast feeding, or mother still actively expressing milk, at 36 weeks' ca or discharge if this is earlier.

Secondary outcomes: growth, feeding and neonatal outcomes

1. Growth—weekly weight, length, head, mid-arm and thigh circumference, absolute changes (g/kg/day and mm/week) and change in SD score.
2. Neonatal morbidities:
   - Episodes of confirmed NEC Bell stage 2 or greater.
   - LOS confirmed and clinically suspected according to existing case definitions.[34]
   - Severe BPD (oxygen requirement or respiratory support at 36 weeks' ca).
   - ROP—worst stage and zone.
   - Intraventricular haemorrhage—worst grade recorded and/or cystic periventricular leucomalacia.
3. Days of intensive, high and low dependency care[35]; ca at discharge, total length of stay (days).
4. Total volume (litres) of milk (MOM, DHM and formula) received from birth to 36 weeks' ca.
5. Age at starting breastmilk fortifier and number of days when fortifier is provided.
6. Type of feeding at discharge (direct breast feeding, tube feeding, etc).
7. Type of milk and feeding, weight and head circumference at 6 and 12 weeks post-discharge.

Secondary outcomes: feasibility data

DHM is a complex intervention and its effect on breast feeding has not been studied in RCTs. Therefore, the following feasibility elements will be assessed.

1. Number of patients who declined DHM.
2. Number of patients who did not wish to enrol.
3. Number of patients unable to continue the intervention.
4. Number of patients who were lost to follow-up.
5. Protocol deviation frequency.

Secondary outcomes: maternal questionnaires and qualitative data

A validated questionnaire, Breastfeeding Self-Efficacy Scale–Short Form (BSES-SF) adapted for preterm infants,[36] is given to mothers at two time points—around 10 days' postnatal age and again at 36 weeks' ca or prior to discharge if sooner. The Edinburgh Postnatal Depression Scale (EPDS) questionnaire is also administered to mothers around day 10 post partum.[37] BSES-SF and EPDS scores will serve as a guide to ensure that mothers' both spectrums (with scores in the bottom and top quartile) will be represented in the subset chosen for interviews.

Qualitative interviews with mothers will be conducted to explore perceptions around DHM use and barriers and facilitators to expressing MOM. These one-to-one, in-person semistructured interviews will be audio-recorded and transcribed. We estimate that 15–20 interviews will be recorded although the final number of interviews will be determined by thematic saturation generated through interpretation of data.[38] Qualitative data will also inform whether an 'RCT' design was problematic or unacceptable for mothers.

Hypothesis, sample size and power

We hypothesise that longer access to DHM (intervention) will improve the rate of breast feeding at discharge from 35% (the rate in our NICU in 2019) to 60% (the average rate in UK NICUs using NNAP UK-wide data). Fifty-eight infants per trial group will be required to detect an improvement in breastfeeding rates at discharge from 35% to 60%. Assuming 10% of infants do not survive, at least 130 infants need to be recruited to complete the trial. We estimate that up to 20% of infants may be discharged before 36 weeks' ca to other neonatal units that do not have access to DHM. We will therefore need to recruit between 130 and 156 infants for the study to be powered at 80%, and we estimate this will take 18–24 months of recruitment.

Analysis

Data will be analysed using an intention-to-treat approach. Additional analysis will be performed using breastfeeding outcome data for those completing the study (ie, excluding transfers) and the first baby from a multiple pregnancy enrolled. Categorical data will be presented as counts and frequencies and will be compared using X^2 or Fisher's exact test as appropriate. Morbidities will use logistic regression. Continuous data will be presented

as mean (SD) or median (IQR), and the Shapiro-Wilk test will be used to test the normality of the data. Group differences in continuous data will be compared using Student's t-test or Mann-Whitney U test for normally and non-normally distributed data, respectively, or quantile regression as appropriate. Feeding data will be compared using multinomial statistics. All tests will be performed two tailed and $p<0.05$ will be deemed statistically significant. Qualitative data will be analysed using reflexive thematic analysis.[39]

Patient and public involvement

The study involved discussion with parents and is aligned with the James Lind alliance priority setting that identified feeding and nutrition as key areas for research in preterm infants. A trial steering committee including parents oversees trial conduct and progress. The trial is compliant with the UNICEF Baby Friendly Initiative.

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Contributors NE had original idea for HUMMINGBIRD Study after discussions with NS and played a key role in developing the protocol. JB contributed to study design and protocol development. All authors contributed to the writing and review of this paper and gave final approval for its submission.

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Competing interests NS is the co-founder of the Human Milk Foundation, a UK charity that provides donor human milk. NE and JB report research grants paid to their institution from the National Institutes for Health Research, Action Medical Research, Prolacta Biosciences US, Danone Early Life Nutrition and NeoKare but received no personal fee, and have no other financial conflicts related to industry funding. NE reports lecture honoraria from Nestle Nutrition Institute donated to charity, and Astarte Medical.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval Nottingham 2 Research Ethics Committee granted approval for HUMMINGBIRD Study on 6 April 2021 (IRAS Project ID 281071, study protocol available in online supplemental file 1). Recruitment commenced on 7 June 2021. Results will be disseminated in peer-reviewed journals and discussed with Tiny Lives Charity and Bliss UK to consider the implications of findings.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study. Not applicable.

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