Positive feeding of the preterm infant (PoP)

A feasibility study of a developmentally supportive feeding strategy in the NICU

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1. Introduction

Infants born prematurely leave the protective environment of their mother's womb and must therefore develop in an extrauterine environment while their nervous system is still immature (Als, 1986). One central aspect affected by this is the ability to eat independently, which is a milestone that most infants do not achieve before reaching closer to term age (Jadcherla, Wang, Vijayapal, & Leuthner, 2010). Achieving full oral feeding requires medical follow-up from specialized healthcare services and specialized knowledge in neonatal care. Despite this, feeding development in premature infants is a field that relies largely on experiential knowledge and needs further research. This study aims to evaluate the feasibility of implementing a developmentally supportive feeding strategy for premature infants in a Neonatal Intensive Care Unit (NICU).

1.1 Background

Preterm infants (born before gestational week 37) constitute around 10% of all newborns worldwide and approximately 6% in Norway, according to the Norwegian Gynecological Association (2020) and the World Health Organization (2019). In Norway, it is a common practice to admit premature newborns to one of the 19 Neonatal Intensive Care Units (NICUs) if they are born before 35 gestational weeks. In the NICU they receive necessary medical care during the first days, weeks, or even months of their lives.

Developmentally supportive care

Developmentally supportive and neuroprotective care has evolved over 50 years and are now an integrated part of the treatment provided to preterm infants. This involves a range of interventions aimed at minimizing stress and promoting normal development for the immature infant (Symington & Pinelli, 2006; Westrup, 2007). In recent decades, there has also been an increased emphasis on including parents in the care and treatment of their infants, with NICUs practicing the principles of family-centered care (Gooding et al., 2011). According to The World Health Organization (WHO), small and sick infants have the right to receive family-centered developmentally supportive treatment and care (World Health Organization, 2020).

Growth and development

Preterm infants are low birth weight infants and in addition, many of them are born small for gestational age (SGA). These babies also face the risk of suboptimal weight gain during their stay in the NICU (Griffin, 2020; Horbar et al., 2015). Inadequate growth in premature infants is associated with reduced cognitive development (Guellec et al., 2016). However, a study has shown that breast milk can counteract these negative effects (Rozé et al., 2012). Generally, preterm infants have an increased risk of severe illness and early death due to cardiovascular disease, chronic lung disease, and diabetes in adulthood. There is though, a lack of knowledge about causal relationships (Risnes et al., 2021). Feeding challenges in children born prematurely are common and can persist into childhood, which may have negative effects on growth and development later in life (Britt Frisk Pados, Hill, Yamasaki, Litt, & Lee, 2021; Park, Thoyre, Pados, & Gregas, 2019).

Breastfeeding and development of feeding skills

It is well-documented that breastfeeding has health benefits for both mother and infant and that breast milk has positive effects for the infant (Victora et al., 2016). However, preterm infants are breastfed to a lesser extent than full-term infants, which can be attributed to factors both in the mother and the infant. (Ericson, Flacking, Hellström-Westas, & Eriksson, 2016; Jonsdottir, Jonsdottir, Orlygsdottir, & Flacking, 2021; Lau, 2018; Maastrup et al., 2014).). Most mothers of premature infants want to breastfeed, but they require closer follow-up and support to achieve this (Ericson & Palmér, 2019).

The infants' feeding challenges, in addition to any medical conditions, are associated with immaturity due to being born prematurely. Hence, almost all infants born before 34 weeks of gestation require a feeding tube to ensure adequate nutrition, as medically prescribed in each department's nutrition protocol (Embleton et al., 2022). Most preterm infants reach full oral feeding by around 36 weeks of postmenstrual age (PMA). However, most of them still face challenges at term age, related to sleep-wake regulation, ability to maintain body tone, coordination of sucking and swallowing, regulation of breathing, and discomfort during mealtimes (Pineda, Prince, Reynolds, Grabill, & Smith, 2020). Consequently, preterm infants

require closer monitoring and follow-up regarding feeding compared to full-term infants, even after discharge from the NICU.

Cue-based feeding of the preterm infant

While it is widely agreed that developmentally supportive care is best for premature infants, most NICUs still rely on scheduled feedings and volume-based approaches concerning nutrition and feeding practices in preterm infants. For the tiniest or sickest infants, careful control may be necessary to ensure adequate nutrition. However, for medically stable preterm infants who have reached around 32-34 weeks PMA and show greater behavioral maturity, there has been a trend in recent years to adapt to the infant's cues during the transition from tube feeding to full oral feeding (Lubbe, 2018). This approach, which goes by various names with slightly different content, involves assessing the infant's cues and behavior to determine readiness for oral feeding. Moreover, the definition of successful feeding is based on the quality of the meal rather than the quantity.

Evidensen for å tilpasse seg barnets signaler vurderes til å være noe svak, med lav kvalitet og med sterk bias Enkeltstudier og kvalitetsforbedringsprosjekter tyder dog på at intervensjonen kan føre til at barnet bruker kortere tid i overgangen fra sonde til å spise selv og reduserer antall liggedøgn i sykehus, samt er medisinsk trygt. Det er ikke funnet studier som ser på langtidsutkomme for denne tilnærmingen, for bruk hos barn under 32 uker PMA eller at den er benyttet direkte opp mot sondemåltider.

According to recent systematic reviews, the evidence supporting cue-based feeding is considered to have low quality and a strong bias. (McFadden et al., 2021; Watson & McGuire, 2016). However, single studies and quality improvement projects have shown positive results as shortened transition time from tube feeding to oral feeding, reduced length of hospital stay, and that it is medically safe (Fry, Marfurt, & Wengier, 2018; Osman, 2019; Puckett, Grover, Holt, & Sankaran, 2008; Thomas, Goodman, Jacob, & Grabher, 2021; Ziadi, Héon, & Aita, 2016). No studies have been found that examine long-term outcomes for this approach, its use in infants under 32 weeks PMA, or that it has been used related to tube feedings.

På tross av svak evidens for selve intervensjonen, er det konsensus i fagmiljøene om at barn fra 32-34 uker PMA skal vurderes i forhold til sine signaler når det skal lære seg å spise selv.

Despite the lack of evidence for the intervention cue-based feeding, it is generally agreed that infants from 32-34 weeks PMA should be assessed based on their cues when they are breast or bottle feeding. However, there are variations in the systematic use of this approach in clinical work. Healthcare professionals describe a wide use of a "trial and error" approach, where health personnel's individual experience plays a role in the assessment of premature infants during the transition from tube feeding to full oral feeding (McFadden et al., 2021). Several units employ a "semi-demand-feeding" approach, which combines cue-based and schedule-based feeding with quantitative evaluations of meals Infants are allowed to feed from the breast or bottle, and then receive supplementation at the feeding tube to reach the medically prescribed amount (Davanzo, Strajn, Kennedy, Crocetta, & De Cunto, 2014)Infants are often awakened if they do not wake up on their own three to four hours after the previous meal. For example, for a premature infant at 35 weeks PMA, this could mean being awakened eight times during a day to attempt feeding, in addition to potential test weighing before and after breastfeeding to measure intake. This contradicts recommendations to protect sleep and avoid unnecessary stress, which are fundamental elements of developmentally appropriate care for premature infants (Altimier & Phillips, 2013).

Both healthcare professionals and parents have described positive experiences with testing an intervention that considers the infant's signals (McFadden et al., 2021). However, this approach is not commonly used in clinical practice in Norway, particularly not in infants younger than 34 weeks PMA and during tube feedings for these children.

There is a need for a better understanding of feeding progression and challenges the preterm infants face. Therefore, it is important for neonatal care, to develop strategies that promote developmentally supportive care related to feeding and nutrition, which is an important part of the infants' treatment in the NICU.

This project's objective is to develop an intervention that supports infants to reach full oral feeding with strategies based on the infant's cues and family-centered developmental care. The intervention will from now be referred to as PoP (Positive feeding of the preterm infant). Before implementing the intervention, it is necessary to test its feasibility.

Testing of the intervention will be conducted as a feasibility study. A feasibility study aims to explore the potential for success of an intervention for subsequent implementation in a neonatal intensive care unit. The results will provide us with the opportunity to evaluate the potential for success with future implementation. Therefore, the primary outcome of this study is not the effect of the intervention itself but rather to assess and clarify any uncertainties. These uncertainties may include the organization's potential to implement the intervention, acceptability of the intervention, recruitment strategies, or methods of data collection (Orsmond & Cohn, 2015; Skivington et al., 2021).

2. The aim of the study

This study aims to develop a developmentally supportive feeding strategy and test the feasibility of implementing it in the NICU.

Hypothesis:

- A developmentally supportive feeding strategy for preterm infants (PoP) is feasible to implement in a modern NICU with today's available resources.
- This strategy (PoP) ensures satisfactory growth in the infant through cue-based feeding.
- Guidance in a developmentally supportive positive nutrition strategy for premature infants (PoP) will be perceived as useful by parents as they experience increased competence and confidence in feeding their infant.

3. Design and method

The PoP-intervention is a complex intervention and the new framework for developing and evaluating complex interventions from the UK Medical Research Council and the National Institute for Health Research will be used (Skivington et al., 2021).
The framework describes core elements and four phases: *develop or identify intervention, feasibility, implementation, and evaluation.* This study will focus on the two first phases of the framework. Figure 1 provides an overview of the study and its sub-studies.

Figure 1. Overview of the study and its sub-studies

STUDY PURPOSE		
To develop the PoP-intervention and test the feasibility of implementing it in the NICU		
FRAMEWORK		
Framework for developing and evaluating complex interventions from Medical Research Council guidance and National Institute for Health Research (Skivington, 2021)		
SUB-STUDY 1	SUB-STUDY 2	SUB-STUDY 3
Develop the PoP-intervention	Feasibility study of the PoP-intervention	Exploring the parents' experiences with the PoP-intervention

3.1 Sub-study 1 – Develop the PoP-intervention

This sub-study falls under the phase *Identify or develop intervention (Skivington et al., 2021)* and will be carried out systematically following the process described by O'Cathain and colleagues (O'Cathain et al., 2019). This study is not part of the clinical trial, and will therefore not be elaborated further here.

3.2 Sub-study 2 – Feasibility study of the PoP-intervention

Sub-study 2 involves the feasibility phase, where there will be systematic testing of the PoP intervention with a perspective that goes beyond the direct effect of the intervention (Skivington et al., 2021). The study will be conducted in the Neonatal Intensive Care Unit, Vestre Viken, which is a category 3c single family-room neonatal unit.

The study is set to begin in August 2024 and will involve premature infants born between the gestational age of 28 and 34 weeks, as well as infants who have been transferred from a regional hospital at 28 weeks postmenstrual age (PMA). To participate, parents must be able to speak either Norwegian or English. The inclusion period will last for one year.

Description of the draft of the intervention that will be finalized in sub-study 1:

The intervention protocol will be divided into three components: parent guidance, a guideline for monitoring the child's eating development, and a guideline for nutrition.

1. ***Parent counseling***: Structured counseling sessions will be conducted throughout the stay to provide parents with knowledge about developmentally supportive care, nutrition, and feeding progression in preterm infants. The program will also include a practical component on how parents can support their child's feeding progression and provide positive experiences during mealtimes. This includes when the child receives milk in their mouth during tube feeding, as well as when the infant is breast or bottle fed.

2***. Guideline for monitoring feeding progression:*** The progress of the infant's feeding will be recorded according to specific milestones. A tool called "The Milk Way" which is based on evidence, will be utilized to describe the path to breastfeeding (Sundhetsstyrelsen i Danmark, 2021). In addition, the milestones related to tube feeding and progression will be documented and described. The parents will receive guidance on how to encourage the infant's positive development at each stage. The different milestones will be described in detail and the last one will be the ability to eat all food independently.

3. Nutrition guideline: Nutrition guidelines specific to the study will be developed. This guide will be based on the current guidelines in the unit, as well as updated European guidelines (Embleton et al., 2022).

The study guidelines will not deviate significantly from the unit's current guidelines but will allow for individual adjustments within safe boundaries. The guide will describe the minimum nutritional needs, vitamin supplementation, enrichment, and any limitations/possibilities for adjusting to the infant's cues and sleep/wake cycle. The guide will gradually provide the infant with increased opportunities for individual adjustment as the infant matures. The infant's weight will be monitored as usual according to current procedures, and the responsible pediatrician will prescribe the nutrition in the infant's treatment plan as is currently standard.

The intervention is scheduled to be finalized in spring 2024.

Data collection

Quantitative and qualitative data will be collected from parents, healthcare personnel, electronic patient records, and electronic patient charts. In addition, an assessment of infant feeding will be collected at four weeks after term age with a validated questionnaire called NeoEAT assessment tool (Britt F Pados, Estrem, Thoyre, Park, & McComish, 2017).

Analysis

The results that will be evaluated and analyzed include criteria related to the study design, such as recruitment, attrition, data collection, and resource utilization, An evaluation of the intervention will also be conducted by examining its acceptability, adherence, and implementation (Skivington et al., 2021). The actual effect of the intervention will not be an outcome in the study, but it will instead serve as a pilot study of the intervention.

3.3 Sub-study 3 - Exploring the parents' experiences with the PoP-intervention

As part of the phase *feasibility* (Skivington et al., 2021), in-depth interviews with parents participating in sub-study 2 will be conducted.

The interviews aim to explore the parents' experiences with the PoP intervention and assess acceptability. A semi-structured interview guide will be used to ensure relevant questions are answered in the evaluation. The interviews will be conducted when the child is approximately four weeks past their due date. Informed consent for the study will be obtained as part of the consent for sub-study 2. The interviews will be conducted by the PhD candidate using audio recording.

4. Project timeline

This is a Ph.D. project being conducted by a candidate in the Health Sciences program at Oslo Metropolitan University. The results will be published in scientific articles and a thesis. The project is expected to be completed by the end of 2026.

5. Approvals and ethical considerations

Children are considered a vulnerable group and are specifically mentioned in the Helsinki Declaration, and in this study, parents will provide written consent on behalf of their children (World Medical Association, 2013). Therefore, the written and verbal information will clearly state the advantages and disadvantages of participation, as well as the voluntary nature of it.

The project underwent an evaluation by the ethical council and was approved. The project is also approved by the privacy contacts at the university and health trust.

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