STUDY PROTOCOLS

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# Evaluation of a complex couplet care intervention in a neonatal intensive care unit: A mixed methods study protocol

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## ABSTRACT

**Background:** Families with an infant in need of intensive care most often experience a harmful separation after birth. This is due to a division of medical specialties into neonatal care and maternal care. Therefore, a couplet care intervention is implemented for mother-infant dyads in a neonatal intensive care unit. This study protocol provides a comprehensive evaluation of the intervention. The aim is to evaluate the effect and implementation of a complex couplet care intervention to promote zero separation between mother and infant.

**Methods:** The couplet care intervention is a family-centered model of care, where treatment-requiring mother-infant dyads will be admitted together and receive couplet care by neonatal nurses. The study adheres to the framework of the Medical Research Council and will use a mixed methods embedded design

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comprising a quasi-experimental trial and a qualitative process evaluation. Finally, a health economic evaluation will be conducted to assess the cost-effectiveness of this complex couplet care intervention.
**Discussion:** Separation of mother-infant dyads after birth has an adverse impact on family health and well-being. This study protocol evaluates a complex couplet care intervention. With this study, a first step is taken to help bridge the gap between current practices and a new care model to prevent the separation of mothers and their infants

**KEYWORDS**
Complex interventions, Couplet care, Family-centered care, Neonatology, Zero separation

# INTRODUCTION

Commonly, families are united at a maternity unit (MU) after birth to strengthen recovery, underpin entry into parenthood, and initiate bonding and breastfeeding. However, worldwide approximately 10% of all newborn infants are admitted to a neonatal intensive care unit (NICU).[1] The implication of this practice is a harmful separation of mother and infant as mothers often need postpartum treatment and care at the MU after birth. Because of this current and historical division of medical specialties, families are separated after birth. In a study published in 2022 by van Veenendaal et al.[2] examining current neonatal settings, parent-infant separation was common practice in 42 out of 45 NICUs located in Europe and Canada. The currently accepted model of care imposes the separation of mother and infant. Thus, it is decisive to implement and examine couplet care interventions as an initial step towards keeping mother-infant dyads together during specialized neonatal and maternal care provided as standard practice.

To the infant, the first hours when the transition from intrauterine to extrauterine life occurs, are of particular importance as instability in this period may trigger a cascade of negative effects.[3] Even so, the first period of infant and maternal hospitalization is often characterized by infant-parent separation which limits skin-to-skin contact (SSC) and emotional closeness.[4] Separation of mother and infant interferes with establishing an early bond and limits the development of a secure relationship and attachment behaviors.[5] An article by Bergmann presented solid arguments for a 'zero separation paradigm' as separation is a source of toxic stress in the infant, defined as the absence of the buffering protection of adult support which affects the neuroendocrine system.[6] In another study by Bergmann et al. introducing 'nuturescience' a converging message was that mother-infant dyads should not be separated as closeness and emotional connection have a profound potential for preventing and minimizing developmental problems in infants.[7] Several studies have also examined parents' experiences of separation after birth.[4,8,9] Mothers reported separation from their infant as one of the primal sources of stress; and the association between early separation and the risk of developing maternal stress, depression, and anxiety is well described.[9,10] Fathers who experience mother-infant separation after birth find themselves in a vulnerable position characterized by stressful and torn feelings.[11,12] Inversely, zero separation promotes early SSC with parents, which is associated with various positive health outcomes.[13,14] Early SSC underpins the natural bonding process with parents, reduces stress, and improves breastfeeding.[15] The initiation of early breastfeeding and SSC promotes microbial exposure between mother and infant which contributes to the development of a healthy microbiome in the infant. The healthy microbiome is positively associated with intestinal function and immune stamina.[16] Furthermore, SSC promotes thermal control and is positively associated with cardiorespiratory stability and improved growth in infants.[17]

Couplet care is a practical approach to maintaining zero separation. Couplet care is defined as nurses delivering both neonatal and maternal care within a single unit.[18] The implementation of couplet care has been examined in Sweden and Canada, and its use has generated positive feedback from families and healthcare professionals (HCPs) alike.[19,20] However, a substantial need exists for research about the effect and implementation process of couplet care of treatment-requiring mother-infant dyads.

The aim of this study is to evaluate the effect and implementation of a complex couplet care intervention to promote zero separation between mother and infant in a NICU.

# METHODS

## Ethical approval

Participating families and nurses will be informed about the purpose of the project and will receive oral and written information about the project before participating. According to the Declaration of Helsinki, data will be handled confidentially; and when data are published the

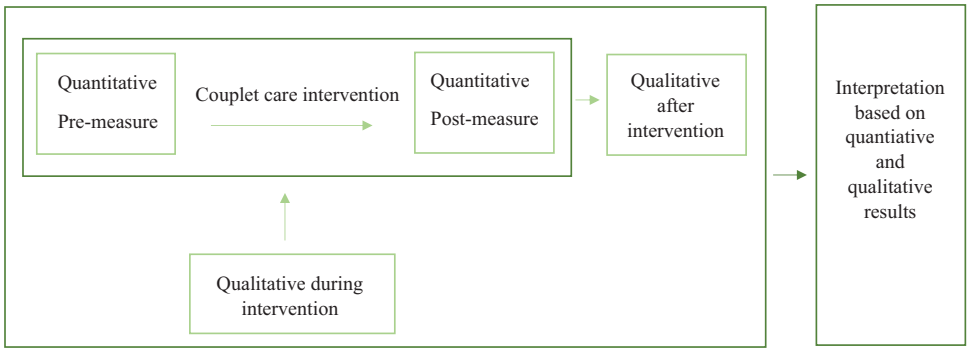


**FIGURE 1** Embedded mixed methods design.

participants will be anonymized.[21] Furthermore, written informed consent will be obtained from all participants. All personally identifiable data will be stored in the hospital servers' logged drive. The project is approved by the Danish Data Protection Agency through the Capital Regions server Pactius (No. P-2021-872). By Danish law ethical approval from the Capital Region Committee on Health Research Ethics is not required (No. 21056981).[22] The study was registered with Clinicaltrials.org: Family Centered Healthcare–Zero Separation and Couplet Care. Trial number: NCT05236023. Approved February 10, 2022.

## Patient, public, and professional involvement

Patient, public, and professional involvement (PPPI) in health research is a topic of increasing national and international interest.[23] PPPI is defined as 'Research being carried out "with" or "by" members of the public rather than "to", "about" or "for" them'.[24] In accordance with this definition six previously admitted families from the NICU and five neonatal nurses are involved in various stages of the research process and assessment of outcomes. The families are involved to ensure the adoption of a patient and family perspective; hence their knowledge and previous experiences will help further qualify the research process. The five neonatal nurses are involved in the research process and implementation of the intervention. They will enhance the implementation and ensure clinical relevance. The research group meets with the PPPI representative separately approximately four times a year for the duration of the project.

## Design

The study adheres to the framework of the Medical Research Council (MRC).[25] A mixed methods embedded design will be used consisting of a quantitative phase alongside a qualitative phase as illustrated in Figure 1.[26] We will comprehensively evaluate the intervention by combining a quasi-experimental trial for the effect evaluation and a qualitative process evaluation consisting of a field study and two interview studies. Finally, we will conduct a health economic evaluation.

The quasi-experimental trial investigates the effect of the intervention by comparing it with usual care with respect to:

a. Infant and maternal length of stay (LOS)
b. Infant first SSC with parents
c. Mother's first breast stimulation
d. Family health and wellbeing

The qualitative process evaluation examines the context, implementation, and mechanism of impact guided by MRC, specifically[27]:

a. Contextual factors and causal mechanisms
b. Fidelity, adoption, and reach
c. Acceptability and appropriateness

Finally, the health economic evaluation will assess:

The cost-effectiveness of implementing the intervention.

## Setting

The intervention will be implemented at the NICU of Copenhagen University Hospital Amager Hvidovre, Denmark. The hospital is the largest national delivery hospital in Denmark with approximately 7000 annual deliveries corresponding to 12% of all Danish births.[28] The study site does not practice golden hour or SSC in the delivery room or operating room as standard practice if an infant needs NICU admission. The NICU (neither a clear level II nor III) has approximately 1000 annual admissions and receives premature infants from a gestational age (GA) of 28 weeks. The mean LOS is 7 days ranging from 24 hours to three months. The NICU can take care of 20 infants and has 15 rooms whereof ten are considered single-family rooms. Data will be gathered from the setting in which the

intervention is implemented, except for the quasi-experimental trial in which data will be obtained from a control group consisting of both families admitted to the implementation site and families admitted to the NICU at the Copenhagen University Hospital Herlev Gentofte, Denmark. The NICU at Herlev Hospital has approximately 800 annual admissions and receives premature infants from GA of 28 weeks. It is standardized to 20 infants in single-family rooms The model of care practiced at the implementation site is based on family-centered care (FCC). A core element of FCC is a partnership, which is characterized by the formation of a mutual relationship and interactions between nurses and families and by adopting key FCC components in daily practice as respect and dignity, knowledge sharing and shared responsibility.[29,30] FCC is not an explicit integrated part of the clinical practice at the NICU at Herlev Hospital; however, in both hospitals parents can be present 24 h/day and parents are repositioned as the primary caregiver of their infant by upholding the rights of the infant to be cared for with and by their parents. Both hospitals are in the Capital Region of Denmark.

## Quasi-experimental trial

The trial is a prospective non-blinded quasi-experimental trial with a pre and post-test of a couplet care intervention in a NICU.

## Description of the intervention

### *Control group*

Control group families receive standard care defined as current practice where treatment-requiring mother-infant dyads are separated after birth and admitted to the MU and NICU, respectively

### *Intervention group*

In contrast, intervention group families will receive couplet care. Couplet care will be implemented in a period during which the NICU is moving into new facilities with 20 single-family rooms. The intervention comprises several components as illustrated in Figure 2. The key component of the intervention is that treatment-requiring mother-infant dyads are admitted together and receive couplet care provided by neonatal nurses. This family-centered model of care builds on seeing the family as an independent system where family members inevitably influence each other, and why illness will affect the entire family. Therefore, the whole family is considered the unit of assessment and intervention when a family member falls ill.[31]

Figure 3 presents the intervention program theory outlining which activities and mechanisms will inform the intended output, outcome, and impact.

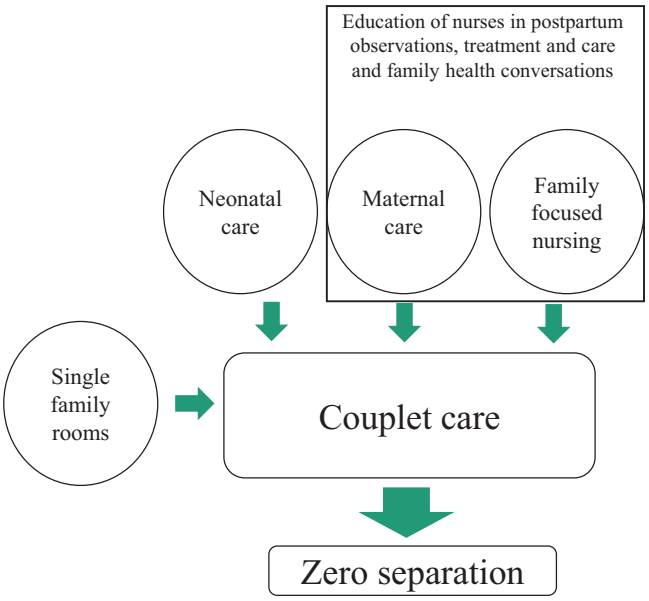


**FIGURE 2** Components of the complex couplet care intervention.

### *Intervention eligibility criteria*

Maternal eligibility criteria are based on the mother having a treatment-requiring condition. A treatment-requiring condition refers to all cases where a mother after birth needs postpartum care and/or treatment, for example, if a mother needs analgesia after a vaginal birth or mobilization after a cesarean section. Mothers will receive their routine postpartum care in the NICU from the NICU nurse. Except, for mothers who require intensive care. Usually, one to two mothers will fall into this category annually.

### *The nurses' competence level and education*

Most of the employed nurses ($n = 41$) have only practiced in pediatric care and considerable education of staff is therefore required to provide sufficient knowledge and skills to implement couplet care. Nurses in Denmark do not have a rotation of maternity care during their nursing education. Consequently, the obstetric specialty is new for most of them. The nurses will participate in a 2-day course about postpartum observations, treatment, and care. The course will be delivered by an obstetrician, a nurse, and a physiotherapist from the MU. Furthermore, the nurses will have a 2-day exchange in the MU before implementation to train clinical skills. During the implementation period, a bedside call will be established to support nurses in their transition to couplet care. An obstetric nurse from the MU will be available 24 h/day if a neonatal nurse needs help or guidance. As the couplet care intervention also consists of delivering family-focused nursing, approximately five nurses will participate in a 6-day family nursing course offered by Linnaeus University, Kalmar, Sweden. The Kalmar trainees

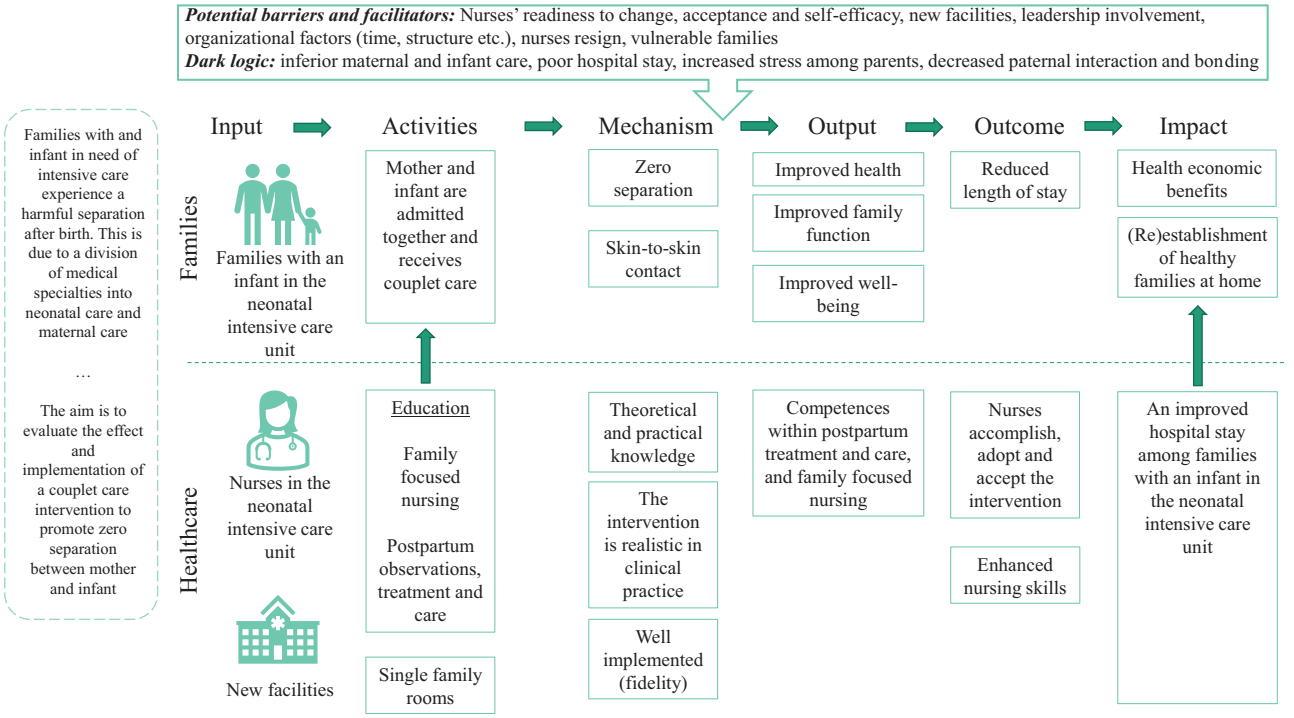


**FIGURE 3** Programme theory of the complex couplet care intervention.

are educated in family-focused nursing based on the Calgary models and the course consists of classes, workshops, and observations in family conversations.[31]

### *Monitoring of potential harm and adverse events*

There is no evidence to indicate that the couplet care intervention would be harmful to the mother and infant. However, any adverse events during the implementation period will be reported and classified in relation to the study intervention as likely, possible, or unlikely.

## Enrolment and eligibility criteria

Families are enrolled in the control group if they meet the eligibility criteria and consent to participate. The families are included approximately 24–72 hours after birth based on the following inclusion criteria: 1) parents speak and understand Danish, 2) mother and infant have been separated after birth, and 3) admission in NICU for more than 1 day. Families are excluded based on the following exclusion criteria: 1) parents do not understand Danish, 2) admission less than 1 day, 3) mother and infant have not been separated after birth, 4) the family is transferred to another hospital, or 5) mother gave birth as an outpatient. The eligibility criteria in the intervention group will be the same as listed above, except for the criteria about separation, as the mother and infant in this group will receive couplet care.

## Outcome measures

### *Primary outcome*

The primary outcome is infant LOS, defined as the number of days from birth to discharge. Data are collected from the infants' medical records.

### *Secondary outcomes*

Secondary outcomes consist of maternal LOS measured as the number of days from delivery to discharge, time to first parental SSC after birth measured in minutes, and time of first breast stimulation after birth measured in hours. Data are collected from mothers' medical records and a self-reported questionnaire. Additionally, four Danish-validated self-administrated questionnaires serve as a measure of family health and well-being and are chosen based on their relevance related to the expected outcome of the intervention and their use in clinical practice. It takes 15 minutes to complete all questionnaires, and permissions were obtained from the authors:

*The Family Centered Care Scale* (FCCS) is a seven-item questionnaire based on FCC principles designed to measure parent's experiences of nursing care.[32] The questionnaire is divided into two parts: (1) the importance of each action and (2) the consistency of the type of care identified as important to parents during their infant's hospital stay. The FCCS is scored on a five-point Likert scale (1 = not at all

important/consistent to 5 = very important/consistent). The scoring is based on the degree of match between the importance and consistency rating, and a total score is calculated as a percentage match score (0–100 percent). The FCCS has good content and internal validity and is internally consistent with Cronbach's alphas of 0.70 for importance and 0.90 for consistency.[32]

*The Edinburg Postnatal Depression Scale* (EPDS) was developed to assess depressive symptoms in the perinatal period. It consists of ten items scored from zero to three with a maximum total score of 30.[33] Higher scores indicate a higher risk of developing depression.[33] A cut-off score of 11 maximizes the combined sensitivity and specificity and is validated to screen for depression.[34] Using a cut-off score of 11 EPDS is a valid and reliable screening instrument with good internal consistency with Cronbach's alpha of 0.82 and a sensitivity of 79.2% and 78.2%.[35] However, when screening for depression in fathers the cut-off score is recommended to be set to a two-point lower cut-off than screening mothers.[36] Therefore, we will use a cut-off score of nine when assessing depression in fathers.

*The Parental Stress Scale* (PSS) was designed to study perceived stress resulting from being a parent.[37] The PSS consists of 18 items scored on a five-point Likert scale (1 = strongly disagree to 5 = strongly agree). Ten of the items address negative and stressful aspects of being a parent and eight items address positive aspects of being a parent. The eight items addressing positive aspects are scored reversely. The score ranges from 18 to 90, with higher scores indicating higher levels of stress. The PSS will be interpreted as two subscales rather than one single score and items 2 and 11 will be removed as recommended by Nielsen et al.[38] The Danish version of PSS has good validity and internal consistency reliability when used as two subscales, measured by the Rasch Model for dichotomous items.[38,39]

*The Pediatric Quality of Life* (PedsQL) was developed to measure the impact of pediatric acute and chronic illness conditions on parents.[40] It consists of eight dimensions focusing on the following aspects; physical functioning, emotional functioning, social functioning, cognitive functioning, communication, worry, daily activities, and family relationships. The PedsQL is scored on a five-point Likert scale (0 = never to 4 = almost always). Items are scored reversely and transformed to a 0–100 scale with a maximum score of 100.[40] The total score is the sum of the 36 items divided by the number of items answered. A total mean score will be computed where higher scores indicate better functioning. The PedsQL has good construct validity and internal consistency reliability with alpha coefficients above 0.70.[40]

## Sample size

The sample size is based on a clinically relevant reduction of LOS by 1 day for the intervention compared with the control group. In pre-existing LOS data collected in 2021 from the intervention setting, the distribution could not be assumed to be normal. Therefore, the sample size calculation is based on the Wilcoxon rank-sum test. The sample size is estimated by simulation based on 1000 repetitions (mean: 10.7, median: 5, standard deviation: 12.5), using the pre-existing data as control and intervention data generated by shifting the control data down 1 day in LOS. This produced a sample size of 239 families in each group ($P < 0.05$; 80% power).

## Data collection

Data collection is ongoing in the control group and commenced on June 12 2022 from Hvidovre Hospital and on February 6 2023 from Herlev Hospital. The self-reported questionnaires are handed over to parents at enrolment. The four validated questionnaires are distributed through a secure Danish digital mail system E-boks when families are discharged and again four months after discharge. The distribution of questionnaires is followed up by two reminders sent by SMS and one phone call.

## Process evaluation

The implementation of the intervention will be analyzed by qualitative process evaluation. Following the MRC guidelines, the process evaluation investigates the components of context, implementation, and mechanism of impact.[25] The process evaluation consists of a field study and two interview studies.

## Field study

The aim of the field study is to explore situations of separation between mother, father, and infant after birth. The field study consists of observations made before, during, and after the intervention is implemented. Before implementation, observations are made at the MU and NICU during the hours after birth. These observations will provide knowledge about the context where the separation between mother, father, and infant arises. The first author will observe parents independently until families are reunited in the NICU using moderately passive participant observation. During and after implementation, observations will be made in the new NICU focusing on the new practice with zero separation and couplet care. The observations will provide knowledge of the context and implementation process with respect to fidelity, adoption, and reach. The exact number of observations cannot be determined in advance. Data collection will continue until patterns are observed and we have enough data to discern a range of

nuances in the observations. The observations will be based on Spradley's methodology of participant observation and will be structured by an observation guide focusing on;[41] places, time, activities, separation/zero separation, couplet care, and communication. Prior to the observations, the first author will have her pre-understanding uncovered in two interviews; one by a nurse researcher and one by a previously admitted mother from the NICU. Awareness of preunderstandings and taking these into account are important when seeking to understand a situation or another human. Proper handling of preunderstandings will allow the researcher to remain sufficiently open throughout the whole process of inquiry.[42,43]

### Focus group interview

The aim of the focus group interview is to explore nurse and physician experience of couplet care, that is, the mechanism of impact and to explore the acceptability and appropriateness. The focus group interviews consist of four interviews with approximately eight HCPs in each group, as recommended in the literature.[44] HCPs are identified by purposive sampling, to ensure knowledge and experiences within the field of interest.[44] The interviews will be based on a semi-structured interview guide. The interviews will be held at the hospital and will be facilitated by the first and the last authors, who have extensive knowledge and experience in facilitating focus group interviews. The interviews will be audio recorded and verbatim transcribed.

### Dyadic family interviews

The aim of the dyadic interviews is to explore and gain deep insight into parents' responses and interaction with the intervention, that is, the mechanism of impact. The interview is a dyadic interview in which both parents are interviewed together giving them the opportunity to support each other's narratives.[45] The sample size will be based on the concept of information saturation, a sample of nine to 17 interviews is suggested to be sufficient to reach saturation, however, due to the nature of qualitative data collection the final number of interviews cannot be decided in advance.[46,47] The sample will be a convenience sample of parents from the NICU. Interviews are held at the hospital and will be facilitated by the first author. The interviews will be audio recorded and verbatim transcribed.

### Health economic evaluation

The health economic evaluation will be conducted as a cost-effectiveness analysis measuring benefits in terms of changes in cost/dyad in relation to infant and maternal LOS, milk supply, number of hospital porters, analgesia, and readmissions. In the evaluation we estimate the direct costs related to the intervention. The evaluation will provide insights into the marginal cost differences between mother-infant dyads receiving the intervention and standard care.[48]

## Analysis

### *Quasi-experimental trial*

Descriptive characteristics of the trial population will comprise demographic, health, neonatal, and gynecological characteristics. Comparison of intervention and control groups on continuous variables will be done by linear regression. Association for intervention/control group with categorical variables will be tested by chi-squared test and the self-administrated questionnaire EDPS by logistic regression. Additionally, potential confounders will be included by including each possible confounder separately and evaluating change in the intervention/control group estimate. If the estimate changes, the variable will be included as a confounder in the given model. Missing data will be handled in the analysis by multiple imputations if missing values exceed 5%. Multiple imputation is achieved by chained equations. When applicable sensitivity analysis and adjustment will be performed. The statistical analysis will be conducted in Stata software (Version 16.1; Stata Corporation). All assumptions will be verified before analysis. All results estimates are given with a 95% confidence interval. A two-sided $P$-value $<0.05$ is considered statistically significant.

### *Field study and focus group interviews*

Field studies are characterized by a continuous and dialectic interaction between data collection and analysis.[41] The time between observations will be used to rewrite field notes and self-reflective notes, and examine them in depth. Field notes from the observation and transcript from the focus group interviews will be analyzed using inductive content analysis.[49] Their approach includes four steps: 1) obtain an overall impression of data, 2) subtract meaning units, 3) transform units into descriptive categories, and 4) interpret and form explanatory themes.[49]

### *Dyadic family interviews*

The dyadic family interviews will be analyzed employing Giorgi's phenomenological method. Giorgi's method of analysis aims to uncover the meaning of a phenomenon experienced by a human.[50] The method comprises four steps: 1) data are read to give an overall impression, 2) meaningful units are identified, 3) meaningful units are transformed into categories, and 4) categories are synthesized to represent the essence of the phenomenon.[50]

All qualitative data will be analyzed and triangulated as a joint effort within the research group during the whole analysis process.

## DISCUSSION

Separation of mother and infant after birth has an adverse impact on family health and wellbeing. This study investigates whether a couplet care intervention may improve health and well-being in families, and it explores the acceptability and feasibility of the intervention from a healthcare perspective. Exploring the effect of couplet care and the implementation process in a NICU may help bridge the gap between current practices and a new model of care in which treatment-requiring mother-infant dyads are admitted together and cared for jointly by neonatal nurses. However, the proposed study has certain limitations that merit mention. First, couplet care is not practical in cases in which a mother needs intensive care treatment, meaning that some families will still be separated after birth. In addition, the current organization of care does not support zero separation after cesarean section, as mothers will need care in a post-surgery unit before transfer to the NICU. However, this is the future goal to achieve zero separation of mothers and their infants directly from birth and cesarean section. The duration of a mother's admission to the post-surgery unit is typically limited to a few hours.

Second, a randomized controlled trial is commonly considered the gold standard in intervention research.[51] However, a quasi-experimental design may generate causal evidence that applies to intervention implementation when a randomized controlled trial is not feasible.[51] Quasi-experimental designs allow the conduct of rigorous studies in implementation science contexts, obtained from analyzing real-world data and the generation of real-world evidence.[52,53] The quasi-experimental design is particularly suitable when the blinding procedure is not possible for either the performer or receiver of the intervention.[51] Furthermore, it is considered unethical to randomize families to either couplet care or usual care due to the vulnerable situation of having an ill or preterm infant. Third, in the pre-existing data used to calculate the sample size many patients had an admission of 2 days; and for some of these patients it may not be possible to reduce LOS further. To obtain a power of 80% the data collection will be completed in two NICUs in the Capital Region of Denmark. This may potentially impact data, as discordance exists between the practice of the two NICUs. This may potentially also impact data when comparing the intervention and the control group as the intervention group will consist of data from the intervention site only. However, this will be adjusted for in the statistical analysis. Fourth, the findings may not be directly reproducible in other NICUs, as NICU organization differs between hospitals; and this model may not be sufficient to change nursing practice without other practice support in the units Finally, we cannot exclude that information bias may affect some outcomes, due to the retrospective nature of way in which data on SSC, first breast stimulation and self-reported questionnaires are collected.

In conclusion, this protocol has outlined the rationale and design we plan to adopt when evaluating an intervention based on zero separation and couplet care in a NICU. The proposed studies enhance our understanding of the process and effect of couplet care while documenting nurses' and parents' experiences with the approach. The results of this study may inform future models of care that best support and enhance family outcomes, as well as recommendations on implementing couplet care in other NICUs. We expect the knowledge gained from the present studies to generate new insights into neonatal care while proposing a new model of NICU care.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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