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EFFECTIVENESS AND IMPLEMENTATION FIDELITY OF FAMILY-CENTERED CARE INTERVENTIONS

Close Collaboration with Parents and Couplet Care Model

Ryo Itoshima

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The originality of this publication has been checked in accordance with the University of Turku quality assurance system using the Turnitin OriginalityCheck service.

ISBN 978-952-02-0023-7 (PRINT)
ISBN 978-952-02-0024-4 (PDF)
ISSN 0355-9483 (Print)
ISSN 2343-3213 (Online)
Painosalama, Turku, Finland 2025

To my twin sons, Hotaka and Asahi,
my daughter, Ibuki, and my wife, Saori

UNIVERSITY OF TURKU
Faculty of Medicine
Department of Clinical Medicine
Paediatrics
RYO ITOSHIMA: Effectiveness and implementation fidelity of family-centered care interventions: Close Collaboration with Parents and Couplet Care Model
Doctoral Dissertation, 162 pp.
Doctoral Programme in Clinical Research
January 2025

ABSTRACT

Neonatal intensive care units (NICUs) provide essential treatment and care for sick or preterm infants. Admission to NICU may, however, cause parent-infant separation and expose infants to environments that could harm their development. There is a need for initiatives that promote parent-infant closeness and integrate parents into neonatal care, known as family-centered care.

This thesis included two family-centered care interventions: the Close Collaboration with Parents intervention and the Couplet Care Model. The studies aimed to evaluate the effects of these interventions on family-centered care practices and infant outcomes. Implementation fidelity of the the Close Collaboration with Parents intervention and its effects on family-centered care practices were also evaluated. A comparison study in Japan and Finland aimed to understand how different discharge practices contributed to the differences in the length of stay.

The family-centered care practices, including staff-parent communication and emotional support for parents, improved after the implementation of the Close Collaboration with Parents intervention in six Estonian NICUs. Better implementation fidelity was associated with better improvement in family-centered care practices. The Finnish register study showed that the intervention also promoted growth, shortened the length of stay, and reduced the likelihood of unscheduled outpatient visits after discharge in preterm infants. The comparison study between Japan and Finland showed that the promotion of the parents' readiness for discharge contributed to shorter hospital stays of preterm infants in Finland. After the introduction of the Couplet Care Model, the first parent-infant skin-to-skin was performed earlier and the duration of the parents' NICU presence was extended.

The improvement in the staff-parent communication, NICU architecture and care system are the key components of family-centered care to improve infant outcomes.

KEYWORDS: Care culture, NICU, parenting intervention, prematurity, skin-to-skin contact, staff education, transition to home.

TURUN YLIOPISTO
Lääketieteellinen tiedekunta
Kliininen laitos
Lastentautioppi
RYO ITOSHIMA: Perhekeskeisten interventioiden vaikuttavuus ja käyttöönotto: Vanhemmat Vahvasti Mukaan –koulutus ja vierihoito vastasyntyneiden tehohoidossa.
Väitöskirja, 162 s.
Turun kliininen tohtoriohjelma
Tammikuu 2025

TIIVISTELMÄ

Sairaiden ja ennenaikaisesti syntyneiden vauvojen hoito vastasyntyneiden teho-osastolla johtaa usein vauvan ja vanhemman väliseen separaatioon ja altistaa vauvan ympäristölle, joka on haitallinen hänen kehitykselleen. Siksi tarvitsemmekin lähestymistapoja, jotka edistävät vauvan ja vanhempien välistä läheisyyttä ja osallistavat vanhemmat vauvansa hoitoon sairaalassa oloaikana. Tällaista lähestymistapaa kutsutaan perhekeskeiseksi hoidoksi.

Tämä väitöskirja käsittelee kahta perhekeskeistä interventiota: Vanhemmat Vahvasti Mukaan (VVM, Close Collaboration with Parents) ja vierihoito vastasyntyneiden tehohoidossa (Couplet Care Model). Tutkimusten tavoitteena oli arvioida näiden interventioiden vaikutuksia perhekeskeisiin toimintatapoihin ja keskoslasten toipumiseen. Lisäksi arvioitiin Vanhemmat Vahvasti Mukaan -intervention käyttöönoton fideliteettiä ja sen yhteyttä perhekeskeisten toimintatapojen muutokseen. Japanin ja Suomen välillä toteutetun vertailevan tutkimuksen tarkoituksena oli selvittää, miten erilaiset kotiutuskäytännöt vaikuttivat keskosvauvan sairaalassa olon kestoon.

VVM-intervention käyttöönoton jälkeen perhekeskeiset toimintatavat paranivat kuudessa vastasyntyneiden tehohoitoyksikössä Virossa. Parannusta tapahtui mm. henkilökunnan ja vanhempien välisessä kommunikaatiossa ja emotionaalisen tuen tarjoamisessa vanhemmille. VVM-intervention korkeampi käyttöönoton fideliteetti oli yhteydessä parempaan perhekeskeisten toimintatapojen edistymiseen. Rekisteritutkimus Suomessa osoitti, että VVM-interventio edisti keskosvauvojen kasvua, lyhensi heidän sairaalassa oloaikaa ja vähensi päivystyskäyntien todennäköisyyttä kotiutuksen jälkeen. Japanin ja Suomen välinen vertailututkimus osoitti, että vanhempien varhaisempi kotiutumisvalmius selitti lyhyempää keskosten sairaalahoitoaikaa Suomessa. Vierihoitomahdollisuus vastasyntyneiden teho-osastolla aikaisti vanhemman ja vauvan välistä ensimmäistä ihokontaktia ja lisäsi vanhempien läsnäolon vastasyntyneiden teho-osastolla. Väitöskirjan tulosten perusteella henkilökunnan ja vanhempien välisen kommunikaation, vastasyntyneiden teho-osaston arkkitehtuurin ja perhekeskeisten hoitokäytäntöjen parantaminen ovat keskeisiä ennenaikaisesti syntyneiden vauvojen toipumisen näkökulmasta.

VAINSANAT: Hoitokulttuuri, vanhemmuusinterventiot, keskosuus, ennenaikaisuus, ihokontakti, henkilökunnan koulutus, kotiutus

トゥルク大学
医学部
臨床医学部門
小児科学
糸島 亮：ファミリーセンタードケア介入の効果と実施忠実度：クロースコラボレーションウィズペアレンツ（Close Collaboration with Parents）とカプレットケアモデル（Couplet Care Model）
博士論文、162ページ
臨床研究博士課程プログラム
2025年1月

要旨

新生児集中治療室（NICU）は早産児などへ必要な治療とケアを行う場である。しかしNICUへの入院は、親子分離を引き起こし、新生児を発達に有害な可能性のある環境へ暴露させる。親子分離を減らし、新生児のケアに両親を巻き込む取り組みが求められており、これをファミリーセンタードケアと呼ぶ。

本論文には、クロースコラボレーションウィズペアレンツ（Close Collaboration with Parents）トレーニングとカプレットケアモデル（Couplet Care Model）と呼ばれる 2 つのファミリーセンタードケア介入が含まれている。これらの研究では、介入が NICU のファミリーセンタードケアの実践や児の予後に与える影響を評価することを目的とした。前者の介入の実施忠実度やそれがアウトカムに与える影響も評価した。また日本とフィンランドの比較研究で、異なる退院基準が NICU 入院期間の違いに与える影響を理解することを目的とした。

エストニアの 6 か所の NICU での Close Collaboration with Parents 介入は、医療者と家族のコミュニケーションや両親への感情的サポートを含めた、ファミリーセンタードケアの実践を改善した。介入の実施忠実度が高いほど、ファミリーセンタードケアのレベルがより大きく改善した。フィンランドの登録データを用いた研究では、本介入により早産児の NICU での成長が促進され、入院期間が短縮され、退院後の予定外外来受診が減少した。日本とフィンランドの比較研究では、両親の退院準備を促進することが早産児の入院期間の短縮に寄与する可能性が示された。カプレットケア導入により、初回カンガルーケアがより早期に実施され、両親がより長時間 NICU へ滞在するようになった。

スタッフと両親のコミュニケーション、NICU の設計やケアシステムの改善は、新生児の予後を改善するためのファミリーセンタードケアの重要な要素である。

キーワード：育児介入、カンガルーケア、ケア文化、在宅移行、スタッフ教育、未熟児、NICU.

Table of Contents

Abbreviations

95% CI	95% confidence interval
COPE	Creating Opportunities for Parent Empowerment
IQR	Interquartile range
FICare	Family Integrated Care
FNI	Family nurture intervention
H-HOPE	Hospital to Home Transition-Optimizing Premature Infant's Environment
MITP	Mother-Infant Transaction Program
NBO	Newborn behavioural observations system
NICU	Neonatal intensive care unit
NIDCAP	Newborn Individualized Developmental Care and Assessment Program
PMA	Postmenstrual age
SD	Standard deviation
SENSE	Supporting and enhancing NICU sensory experiences
WHO	World Health Organization

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

I Itoshima R, Varendi H, Toome L, Saik P, Axelin A, Lehtonen L, Moazami Goodarzi A, Ahlqvist-Björkroth S. Outcomes following Close Collaboration with Parents Intervention in Neonatal Intensive Care Units. *JAMA Netw Open*, 2025;8:e2454099.

II Itoshima R, Helenius K, Ahlqvist-Björkroth S, Vahlberg T, Lehtonen L. Close Collaboration with Parents Affects the Length of Stay and Growth in Preterm Infants: A Register-Based Study in Finland. *Neonatology*, 2024;121:351-35.

III Itoshima R, Ojasalo V, Lehtonen L. Impact of discharge criteria on the length of stay in preterm infants: A retrospective study in Japan and Finland. *Early Hum Dev*, 2024;193:10601.

IV Itoshima R, Korhonen K, Axelin A, Ahlqvist-Björkroth S, Hovi A, Lehtonen L. Effect of couplet care on early parent-infant closeness among preterm infants. *Acta Paediatr*. Online ahead of print.

1 Introduction

Neonatal intensive care units (NICUs) provide essential treatment and care for newborn infants. About 10% of newborn infants need admission to NICUs for reasons including preterm birth (Blencowe et al., 2012; Youngran Kim et al., 2021). While admission to a NICU is a necessary procedure for the infant, it may also cause parent-infant separation. Although NICUs have become more open to parents, infants in NICUs still spend most of their time alone without parents. One study showed that infants in a NICU spent 80% of their time alone and most of their interaction was with nurses (Gonya et al., 2018). In addition, even when the parents are present, they are often bystanders. There has been a strong need for an effort to promote parent-infant closeness and include parents in neonatal care in NICUs. One concept and approach to providing neonatal care in partnership with the newborn's family is called family-centered care (Franck & O'Brien, 2019; Gooding et al., 2011).

In the 1970s, Klaus and Kennell showed that increased mother-infant physical contact during the first few postpartum days improved the mothers' bonding and parenting behaviors (Klaus et al., 1972). Since then, many clinical studies have shown the importance and effects of family-centered care (Ding et al., 2019; Puthussery et al., 2018). As a result, nowadays, the World Health Organization (WHO) recommends family involvement in neonatal care as a necessary component of care for all preterm and/or low-birth-weight infants (Darmstadt et al., 2023). The European Foundation for the Care of Newborn Infants (EFCNI) and the National Institute for Health and Care Excellence (NICE) guidelines also state that the parents of newborn infants have the right to play an important role in newborn care as primary caregivers and actively participate in the decision-making process (*Babies, Children and Young People's Experience of Healthcare*, 2021; EFCNI et al., 2022). Family-centered care has become an important foundation of neonatal care.

Although family-centered care is widely advocated by organizations, NICU health care teams, and other stakeholders, its implementation and sustainability in everyday care remain challenging (Franck et al., 2023). One of the reasons is that evidence on the effect of family-centered care is still not regarded as sufficient. Showing more clear effect of family-centered care is important to further promote it in clinical settings. Another reason is that it is unclear how family-centered care

interventions may improve outcomes for infants and parents in NICUs. In particular, no previous studies have evaluated the impact of implementation fidelity, or how an intervention is successfully implemented (Carroll et al., 2007). Understanding fidelity is vital to evaluate the feasibility of interventions in a NICU and their effects correctly.

The studies included in this thesis aimed to fill in the knowledge gap about the effects and implementation fidelity of family-centered care interventions in NICUs. This thesis focuses on two interventions to achieve the set objectives, namely the Close Collaboration with Parents program for the neonatal health care team and the Couplet Care Model to keep the parents and infants together.

2 Review of the Literature

2.1 Definition and classification of family-centered care interventions

No consensus has been reached on the definition of family-centered care. There have been different definitions with a variety of elements. Two literature reviews have mentioned that the core concept of family-centered care is a partnership between neonatal health care staff and parents that mutually shares common goals in the care of the infant which is based on mutual trust (Franck et al., 2023; Mikkelsen & Frederiksen, 2011). There are some principles that support the concept such as participation, information sharing, negotiation and shared responsibility, collaboration, and support for family. These principles are core components of family-centered care.

In this thesis, I define **family-centered care interventions** as models of parent-partnered care according to the definition by Franck and O'Brien. They classified family-centered care interventions into three levels: parent support interventions, parent-delivered interventions, and models of parent-partnered care (Franck & O'Brien, 2019). Family-centered care interventions are mostly comprehensive interventions or models that aim to integrate parents as one of the healthcare team members in NICUs to achieve the best outcomes for infants and their families. As was also defined by Franck and O'Brien, family-centered care interventions are expected to include at least some components of the first two levels of family-centered care (parent support and parent-delivered care and activities, Figure 1) and to be supported by at least one experimental or quasi-experimental study indicating the efficacy of the intervention (Franck & O'Brien, 2019). The target of the interventions can be neonatal health care teams, NICU architecture, policies, or sometimes parents. Prime examples of intervention based on parent-partnered care include comprehensive family-centered care interventions such as the Close Collaboration with Parents intervention (Ahlqvist-Björkroth et al., 2024) and Family Integrated Care (FICare) (Moreno-Sanz et al., 2024). These interventions have been designed to cope with the difficulties in implementing family-centered care in clinical settings. In addition, family-centered care interventions, as defined in this

thesis, also include models of care used in NICUs such as couplet care (Klemming et al., 2023; White, 2024).

Family-centered care interventions target neonatal health care teams and/or NICU architecture and unit policies. For interventions to be sufficiently effective, they should be implemented properly by the neonatal health care team and the NICU. How the intervention is implemented and whether it has been applied as intended is called **fidelity** (Carroll et al., 2007).

Once family-centered care interventions are implemented, the neonatal health care team is expected to change their care or NICU architecture or policies to be more in line with family-centered care. Many of these changes focus on how to support parents in NICUs and, therefore, they are called **parent support**. The components include support for the parents' presence, improved communication between neonatal health care teams and parents, emotional support for the parents, and creating single-family NICU rooms (Figure 1).

When parents receive support from the neonatal health care teams, NICU architecture and policies, they are able to deliver care, interaction, or special activities for their infants, which supports their recovery and development. Such **parent-delivered care and activities** are among those components of family-centered care, that are also referred to as parent-delivered interventions in the previous article (Franck & O'Brien, 2019). Parent-delivered care and activities include caretaking by parents, parent-infant skin-to-skin contact, holding, and the parents' readiness for discharge (Figure 1). These components primarily aim to improve outcomes for infants, e.g. length of stay, growth, outpatient visits and rehospitalizations after discharge.

In this literature review, I have summarized (1) two family-centered interventions: the Close Collaboration with Parents intervention and the Couplet Care Model, (2) the implementation fidelity of family-centered care interventions, (3) the components of family-centered care and their meanings, and (4) some important infant outcomes after these interventions.

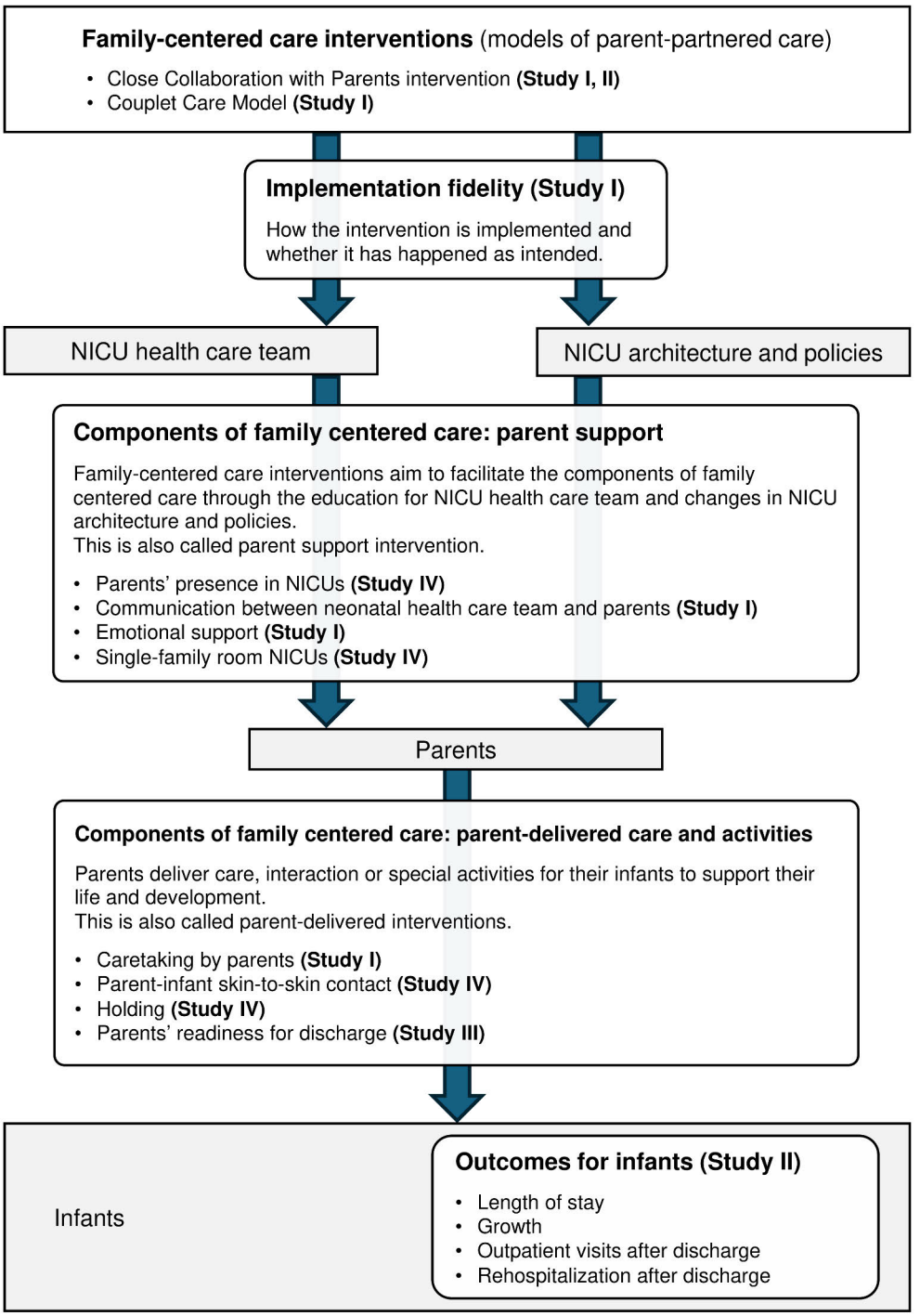

Figure 1. Effect pathway and outcome measures of family-centered care interventions and outcome measures evaluated in this thesis. NICU, neonatal intensive care unit.

2.2 Family-centered care interventions (models of parent-partnered care)

Two family-centered care interventions are included in this thesis: the Close Collaboration with Parents intervention and the Couplet Care Model (Figure 1).
There are other family-centered care interventions. The FICare is a care model that encourages parents to actively participate in the neonatal care of their infants in the NICU as one of the neonatal health care team members (Moreno-Sanz et al., 2024). The Supporting and Enhancing NICU Sensory Experiences (SENSE) aims to provide a supportive NICU environment for better neurodevelopment of infants by performing evidence-based structured sensory intervention with the parents (Roberta Pineda et al., 2024). The Newborn Behavioural Observations system (NBO) is used to help parents learn to observe infant behavior so that the parents understand the competencies, challenges and individuality of their infants and establish a good relationship with their infants (Johnson et al., 2024). The newborn Individualized Developmental Care and Assessment Program (NIDCAP) focuses on the developmental assessment of preterm infants based on their behavioral observation and uses the information in infant care to support the infant and the parents (Vittner et al., 2024). The family nurture intervention (FNI) focuses on helping parents of infants in NICUs to learn how to interact with their infants in ways that better promote the infants' development (Welch et al., 2012). The SENSE focuses more on a comprehensive provision of a better nurturing environment; the FNI focuses more on soothing infants by culming sessions between healthcare staff, parents and the infant; the NBO and NIDCAP focus on the observation of infant behavior for a better environment; and the Close Collaboration with Parents uses the observation of infant behavior to learn about the infant's preferences and stress factors and to learn about them together with parents. The SENSE, NBO, NICAP, and FNI need specialists who carry out infant observation or teach parents about infant observation, better interaction with the infant, and/or better nurturing environment. On the other hand, the Close Collaboration with Parents and FICare target NICU as a whole and contain wider items such as improving staff-parent communication and emotional support using staff training in addition to the observation of infant behavior.

2.2.1 Close Collaboration with Parents intervention

Close Collaboration with Parents program is an evidence-based educational intervention for the entire multi-professional staff of NICUs (Ahlqvist-Björkroth et al., 2017; Ahlqvist-Björkroth et al., 2024; He et al., 2021; Toivonen et al., 2020). It aims to improve the family-centered care culture of the NICU by improving the communication skills of the neonatal health care team to achieve better collaboration

with parents and to provide better parenting support. The details of the intervention are summarized in another section of this thesis (4.2.1).

The Close Collaboration with Parents intervention has been shown to promote the provision of support to parents. A study including eight Finnish NICUs showed that the intervention improved NICU nurses' communication skills in active listening and shared decision-making with parents and emotional support for parents (Toivonen et al., 2021). It was also shown that postpartum depressive symptoms decreased after the intervention among mothers of preterm infants, which continued at least up to two years of corrected age (Ahlqvist-Björkroth et al., 2019, 2022). Another study including nine Finnish NICUs showed that the duration of the parents' presence in the NICU room was longer after the intervention (He et al., 2021). A qualitative study found that the intervention helped NICU nurses change their working style from professional-led care to collaborative care with parents (Axelin et al., 2014).

The Close Collaboration with Parents intervention also promotes parent-delivered care and activities. The study in nine Finnish NICUs showed that the duration of mother-infant skin-to-skin contact was longer after the intervention (He et al., 2021).

However, there have been no studies showing the effect of the Close Collaboration with Parents intervention on preterm infants: length of stay and growth in NICUs, and outpatient visits and rehospitalizations after discharge. In addition, the role of fidelity in the implementation of the intervention and its effects on outcomes have not been well studied.

2.2.2 Couplet Care Model

Couplet care is a concept where hospital care for both a sick newborn infant and the mother is provided while they are in close proximity to each other (Klemming et al., 2023; White, 2024). Although parent-infant physical and emotional closeness is vital for the well-being of both mother and infant, ensuring closeness is often challenging when the infant needs medical care in a NICU. One of the biggest challenges arises in the first days after birth, when both the infant and the mother need medical care (Curley et al., 2023; Patriksson & Selin, 2022). Couplet care tries to minimize parent-infant separation by caring for both infants and their parents, especially mothers, in the same room.

According to a narrow definition of couplet care, it can be defined as rooming-in with preterm infants in the NICU (Waller-Wise, 2012). Typically NICUs need major changes in both architecture and policies to provide care for postpartum mothers close to their newborn infants (White, 2024). A wider definition of couplet care refers to non-separation from birth, including early skin-to-skin contact (Klemming et al., 2023). Early skin-to-skin contact has been shown to reduce neonatal mortality in developing

countries (WHO Immediate KMC Study Group et al., 2021), improve physiological stability in preterm infants (Linnér et al., 2022; Lode-Kolz et al., 2023), reduce the mothers' depressive symptoms, and promote mother-infant interaction (Lilliesköld et al., 2023; Mehler et al., 2020). In 2022, the World Health Organization recommended immediate initiation of skin-to-skin contact after birth for all preterm and/or low-birth-weight infants (Darmstadt et al., 2023).

Couplet care has become more common, especially in North America and the Nordic countries (de Salaberry et al., 2019; Klemming et al., 2023; White, 2024). A recommendation for couplet care was added to the standards of NICU design in 2020 (White, 2020). However, no previous studies have examined the effects of couplet care on early parent-infant physical closeness, including the implementation of parent-infant early skin-to-skin, the parents' presence and their contact with their infants in NICUs.

2.3 Implementation fidelity of family-centered care interventions

Although there have been many interventions to improve family-centered care in NICUs, it has not been well studied how these interventions were implemented and how we could better facilitate the implementation. The way the intervention is implemented and whether it is applied as intended is called fidelity (Carroll et al., 2007). The appropriate evaluation of implementation fidelity is vital to our understanding of the true effects of the intervention on outcome measures (Dobson, 1980). Without the evaluation of implementation fidelity, we can not determine if the lack of effect is due to poor implementation fidelity or defects in the intervention program itself, which is called type III error (Dobson, 1980). In addition, it would be unclear whether some positive effects of the intervention could be further improved if the implementation was facilitated better. In fact, higher fidelity has been shown to be associated with better outcomes (Abbott et al., 1998; Becker et al., 2001; Dane & Schneider, 1998; Forgatch et al., 2005; Keith et al., 2010).

There are five necessary components to implementation fidelity evaluation: adherence to the intervention, exposure or dose, quality of delivery, participant responsiveness, and program differentiation (Carroll et al., 2007; Dusenbury et al., 2003). Adherence is defined as whether the intervention is delivered as it is intended to. Exposure or dosage refers to whether the intervention is delivered to the recipient at the designed frequency, duration et cetera. Quality of delivery is defined as how good quality the intervention program is delivered to the recipient, which is not easy to evaluate: e.g. the quality of the education program as part of an intervention given to the recipients. Participant responsiveness evaluates the outcomes and relevance of the intervention from the perspective of those giving and/or receiving the

intervention program. The last component, program differentiation, is the process of identifying the essential elements of the intervention program, without which the intervention would not give the intended effects.

In summary, the fidelity of family-centered care interventions has not been well studied. There has been only one study that evaluated the fidelity of the Close Collaboration with Parents intervention, which reported the proportion of NICU nurses who received the training (Toivonen et al., 2020).

2.4 Components of family-centered care and their importance

The components of family-centered care can be classified into two categories: parent support and parent-delivered care and activities. The two family-centered care interventions included in this thesis first influence neonatal health care teams and NICU architecture and policies, both providing parent support. Parents who receive parent support then provide (parent-delivered) care.

2.4.1 Parent support

One of the key components of family-centered care is parent support (Franck & O'Brien, 2019), which includes communication between neonatal health care teams and parents, psychological and emotional support, and supportive physical environments and care policies. Parent support is provided by the neonatal health care team and supportive NICU environments and policies. Psychological and emotional support is usually provided by psychologists, nurses, and doctors in NICUs. Supportive physical environments and care policies include a 24/7 visiting policy, break rooms and accommodations for parents, single-family rooms, and sibling visits to the NICU. This thesis focused on support for the parents' presence in NICUs, communication between the neonatal health care team and parents, emotional support, and single-family NICU rooms. The Close Collaboration with Parents intervention (Ahlqvist-Björkroth et al., 2024) and FICare (Moreno-Sanz et al., 2024) include parent support as a component of each intervention.

2.4.1.1 The parents' presence in NICUs

The parents' presence in NICUs is a fundamental basis of any level of family-centered care interventions (Roué et al., 2017): it is a prerequisite for caretaking or interaction between parents and infants or the provision of support to the parents.

There have been a handful of studies showing the importance of the parents' presence in NICUs. A Finnish cohort study showed that daily NICU visits by

mothers were associated with better behavioral outcomes for their infants at seven to eight years of age (Latva et al., 2004). Another study found an association between the parents' frequent visits to the NICU and a better quality of motor movement at term age (Reynolds et al., 2013).

The duration of the parents' presence, however, varies widely between different NICUs and parents (Raiskila et al., 2017; Reynolds et al., 2013). The sociodemographic factors of the families that were associated with the parents' longer presence in the NICU were Cesarean delivery, married couples, higher level of education, fewer other children, and having familial support (Roberta Pineda et al., 2018; Raiskila et al., 2017). These studies showed inconsistent results regarding the effect of the mother's age. NICU architecture may also affect the parents' presence. A meta-analysis has shown an association between NICUs with single-family rooms and parents' longer presence (van Veenendaal et al., 2020). Parents having free access to the NICUs 24/7 is listed as one of the principles of family-centered care (Roué et al., 2017). However, NICU policy alone may not be sufficient to increase the parents' presence. One study showed that liberalizing the visiting policy did not increase the parents' presence, while education for the neonatal health care team and the parents did (Schuler et al., 2024).

Some comprehensive family-centered care interventions targeting neonatal health care teams have also been shown to increase the parents' presence in NICUs (He et al., 2021; Schuler et al., 2024). In addition, the NICU architecture and policies, such as accommodations and lounges for parents and sibling visits, may possibly influence the parents' presence. The effect of single-family NICU rooms is summarized in a different chapter of this thesis (2.4.1.4 Single-family NICU rooms).

2.4.1.2 Communication between neonatal health care teams and parents

Communication between neonatal health care teams and parents is another fundamental basis of family-centered care. Good communication supports parents not only to be present in a NICU but also to have a good partnership with the neonatal health care team. A review has shown that communication is an important determinant of the well-being and satisfaction of parents in NICUs (Labrie et al., 2021). In addition, good communication is said to be one of the necessary items for parents to feel prepared to take their infants back home from NICUs without anxiety (Aydon et al., 2018). A study found four important functions of communication that facilitate family-centered care in NICUs: building and maintaining mutual trusting relationships, exchanging information, shared decision-making, and enabling parent self-management (Wreesmann et al., 2021).

Mutual trusting relationship: Building and maintaining mutual trusting relationships is one of the foundational constructs of family-centered care (Franck et al., 2023). For family-centered care to happen in practice, the neonatal health care team must have trust in the skills, knowledge, and the importance of parents and other family members; and the family members must trust the neonatal health care team (Franck et al., 2023).

Individualized guidance and information, active listening: Exchanging information is the next step for better family-centered care. It also appears to be a big challenge in existing neonatal care, because one study showed that the majority of communication between doctors and parents was dominated by the doctors explaining the situation (Boss et al., 2016). Neonatal health care teams providing sufficient information without jargon will help the parents to participate in care and decision-making. Information provision by neonatal health care teams should be individualized. Individualized guidance and information may be crucial in helping the parents survive their challenging situation in NICUs (Wreesmann et al., 2021). In addition, neonatal health care teams must actively listen to parents so that they can share their information. The parents' experience of being listened to may be essential to building and maintaining a good relationship with the neonatal health care team (Wreesmann et al., 2021). However, it is also recognized that parents sometimes experience difficulty in sharing their information because the neonatal health care team often provides their information before actively listening to the parents (Drago et al., 2021).

Participation in medical rounds, shared decision-making: Shared decision-making is another factor that can be facilitated by communication. For shared decision-making to happen, negotiation and collaboration are required in addition to information sharing, all of which are among the core principles of family-centered care (Franck et al., 2023). Shared decision-making has been shown to be preferred by most parents (Abdel-Latif et al., 2015; Soltys et al., 2020) and to increase their satisfaction (Voos et al., 2011). It is also recommended by guidelines (*Babies, Children and Young People's Experience of Healthcare*, 2021; Boss et al., 2022). In addition, parents prefer shared decision-making rather than having the decisions made only by parents (Caeymaex et al., 2011).

However, shared decision-making poses a big challenge to both the neonatal health care teams and the parents. First, it is a big change from the old neonatal care practices in which most decisions were made by the neonatal health care teams (Drago et al., 2021). In addition, doctors play an important role in facilitating the parents' involvement in decision-making (Axelin et al., 2018); yet their communication was usually not intended to share decision-making with parents (Boss et al., 2016).

The decision-making on medical issues is usually done during medical rounds. Although the parents' participation in medical rounds has become more common in

some NICUs in Europe (Aija et al., 2019), it requires a big effort. The parents' participation in medical rounds is often considered by the neonatal health care team to have a negative impact on neonatal medicine. In one study, more than half of the neonatal health care staff viewed the parents' participation in medical rounds as a factor that inhibits discussion, extends the duration of medical rounds, and is a stressful event for parents (Thébaud et al., 2017). In addition, there are also family characteristics and NICU policies that may inhibit the parents' participation in medical rounds (Aija et al., 2019; Caldwell et al., 2019). Furthermore, the effects of the parents' participation in medical rounds are still unclear.

2.4.1.3 Emotional support

Parents of infants in need of NICU care are at a high risk of mood and mental disorders. Mothers of preterm infants and/or infants admitted to NICUs have been shown to have an increased risk of both short and long-term postpartum depression (Eduardo et al., 2019), anxiety (Bonacquisti et al., 2020; González-Hernández et al., 2019; Trumello et al., 2018), stress (Bonacquisti et al., 2020; Suonpera et al., 2023), and post-traumatic stress disorder (W. J. Kim et al., 2015). One study also showed that the fathers of preterm infants had an increased risk of postpartum depression (Helle et al., 2015). The mothers' postpartum depression was shown to be associated with later impaired mother-infant relationships (Korja et al., 2008), which could negatively affect infant development (Kroska & Stowe, 2020). Emotional support is one of the components of family-centered care that neonatal health care teams could provide for parents and infants to improve their well-being (Roué et al., 2017).

Some comprehensive family-centered care interventions have been shown to be associated with a reduction in the parents' depressive symptoms (Ahlqvist-Björkroth et al., 2022; van Veenendaal et al., 2022), anxiety and stress (O'Brien et al., 2018). One of the possible mediators is emotional support for the parents. These interventions included components that promote emotional support for the parents by the neonatal health care team (Ahlqvist-Björkroth et al., 2024; Moreno-Sanz et al., 2024). However, it is still unclear whether these interventions can actually facilitate emotional support.

2.4.1.4 Single-family NICU rooms

Single-family NICU room architecture is recognized as one of the family-centered care interventions, as it has been shown that NICU architecture such as single-family rooms can promote parent-infant closeness and interaction (Flacking & Dykes, 2013). Single-family room architecture is recommended in NICU design standards to satisfy the parents' needs and support their presence in the NICU (White, 2020).

Couplet care usually requires NICUs to have single-family rooms to enable both the mother and the sick newborn infant to be cared for in the same place (Klemming et al., 2023). However, despite the recommendation of more than 10 years so far, single-family room design has not yet become a common NICU architecture. In an international comparison study among high-resource countries by the iNeo group, only 44 in 331 units (13.3%) provided single-family rooms in 2015 and 28% of preterm infants experienced care in single-family rooms (Lehtonen et al., 2020).

Admission to single-family NICU rooms has been shown to have many positive effects on infants and their parents. A meta-analysis has shown that single-family rooms provide parent support by extending the parents' presence and reducing stress levels in NICUs (van Veenendaal et al., 2020). The same meta-analysis has also shown that single-family rooms promote parent-delivered care and activities such as infant care by parents and parent-infant skin-to-skin contact (van Veenendaal et al., 2020). Another meta-analysis has shown that single-family rooms reduce sepsis and promote breastmilk feeding among preterm infants (van Veenendaal et al., 2019). Single-family rooms may also reduce the length of stay in preterm infants (Lehtonen et al., 2020; O'Callaghan et al., 2019; Örtenstrand et al., 2010).

However, isolation of infants could harm the infants. A study found that preterm infants cared for in private rooms than those in a open-bay rooms were associated with a decrease in normal hemispheric asymmetry, cerebral maturation scores using electroencephalography at due date, and motor and language developmental scores at two years of age (Roberta G. Pineda et al., 2014). This association may have been mediated by less stimuli by parents and health care staff such as touching, visual and sound environment, which is essential for infants' development. Definition of single-family rooms and its necessary effect mechanisms should be further discussed.

2.4.2 Parent-delivered care and activities

Parent-delivered care, interaction, and any other special activities are also among the important components of family-centered care. They target infants and are delivered mostly by parents. Education or guidance is usually required for the parents so that they can deliver appropriate care and activities. The parent-delivered care and activities included in this thesis are caretaking by parents, parent-infant skin-to-skin contact, holding, and the parents' readiness for discharge. The EFCNI and the NICE guidelines emphasize the importance of parents' active participation in infant care and other activities as primary caregivers (*Babies, Children and Young People's Experience of Healthcare*, 2021; EFCNI et al., 2022).

There are a variety of other parent-delivered care and activities that were not included in this thesis. Breastmilk feeding and breastfeeding are beneficial not only for infants but also for mother-infant interaction. Pain management with parents,

baby massage, talking, and singing to the baby are also considered parent-delivered care and activities. In addition, there have been many family-centered care interventions mostly focusing on individualized infant care and creating a developmentally supportive environment based on infant observations by parents and/or the neonatal health care team and on providing developmentally supportive sensory experiences for the infant: the Mother-Infant Transaction Program (MITP) (Achenbach et al., 1993), the NBO (Johnson et al., 2024), the Creating Opportunities for Parent Empowerment (COPE) (Melnyk et al., 2006), the Hospital to Home Transition-Optimizing Premature Infant's Environment (H-HOPE) (White-Traut et al., 2015), the NIDCAP (Vittner et al., 2024), the FNI (Welch et al., 2012), and SENSE (Roberta Pineda et al., 2024). All of these interventions have been shown to have a positive effect on infants and/or their parents.

2.4.2.1 Caretaking by parents

Caretaking of sick newborn infants in NICUs by parents is also considered as one of the key elements of family-centered care. One of the possible beginnings of this idea was an intervention in Estonia encouraging mothers to participate in the care of both preterm and full-term infants (Levin, 1994). In 2022, the WHO added the parents' involvement in infant care as one of the strong recommendations for NICU care (Darmstadt et al., 2023). Behind this recommendation is a meta-analysis showing that the parents' involvement in NICU care reduces their stress, lowers their infants' odds of retinopathy of prematurity, and promotes growth, breastmilk feeding and neurodevelopment (North et al., 2022). Thus, caretaking by the parents benefits both themselves and their preterm infants. Nowadays, caretaking by parents is often used as one of the outcome measures of family-centered care interventions.

2.4.2.2 Parent-infant skin-to-skin contact

Parent-infant skin-to-skin contact is defined as the infant being held by the parent on the bare chest, with only a diaper and a cap if necessary. Skin-to-skin contact is also known as the primary component of Kangaroo Mother Care.

Kangaroo Mother Care was introduced in Bogotá, Colombia by Dr. Edgar Rey Sanabria in 1978 to cope with a chronic shortage of hospital resources and a high mortality rate (Abadía-Barrero, 2018; Charpak et al., 2005). The components of Kangaroo Mother Care included early, continuous, and prolonged mother-infant skin-to-skin contact, exclusive breastfeeding, early discharge from hospitals, and close follow-up after discharge to home (Whitelaw & Sleath, 1985). In addition to the reduction in mortality, skin-to-skin contact enabled infant care without an incubator, which increased mother-infant closeness and reduced the number of

abandoned infants (Whitelaw & Sleath, 1985). Since then, skin-to-skin contact has become a common and standard practice, especially among healthy full-term infants after vaginal delivery. A meta-analysis including preterm and full-term infants showed that any form of Kangaroo Mother Care including skin-to-skin contact reduced sepsis, tachypnea, hypothermia, hypoglycemia and hospital readmission, and increased head growth and exclusive breastfeeding (Boundy et al., 2016). Meta-analyses only including preterm and/or low-birth-weight infants showed that any form of Kangaroo Mother Care improved self-regulation skills later in infancy, shortened the length of hospital stay, and reduced mortality (Akbari et al., 2018; Boundy et al., 2016; Narciso et al., 2022). One of the meta-analyses also showed a positive effect of Kangaroo Mother Care on infants' later self-regulation (Akbari et al., 2018) and a follow-up study after a randomized controlled trial also showed positive effect on infants' development after 20 years (Charpak et al., 2017, 2022). However, another meta-analysis did not find its significant effect on neurodevelopment at one year of corrected age (Sivanandan & Sankar, 2023). More evidence is required to confirm its long-term effect.

As skin-to-skin contact has become a more common practice among preterm and/or low-birth-weight infants in NICUs, research and practical interest are shifting towards its earlier initiation. A randomized controlled study in low-resource countries compared low-birth-weight infants who received an intervention consisting of immediate skin-to-skin contact initiated before stabilization, to those who did not (WHO Immediate KMC Study Group et al., 2021). Those who received the intervention experienced the first mother-infant skin-to-skin contact at 1.3 hours after the birth, on average, compared to 53.6 hours of those in the control group. The immediate skin-to-skin contact significantly reduced the mortality rate within 28 days after the birth: the risk ratio was 0.75 (95% confidence interval [95% CI] 0.64 to 0.89). The feasibility and effects of immediate skin-to-skin contact with preterm infants have also been shown in some studies. More stabilized cardiopulmonary (Linnér et al., 2022) and thermal status (Lode-Kolz et al., 2023) were achieved during immediate skin-to-skin contact. In addition, among those who received or provided immediate skin-to-skin contact, the mothers' postpartum depressive symptoms and impaired bonding decreased and mother-infant interaction improved at six months of corrected age (Lilliesköld et al., 2023; Mehler et al., 2020). WHO Immediate KMC Study Group also plans a two-year follow-up to evaluate its long-term effect on neurodevelopment (Adejuyigbe et al., 2023).

As was shown above, skin-to-skin contact benefits both full-term and preterm infants. However, finding ways to promote immediate or early skin-to-skin contact with preterm infants is still a challenge in clinical practice.

2.4.2.3 Holding

Holding is another way for parents in NICUs to have their infants close and feel close to them. Holding is defined as being held by the parents while the infant has clothes on or is swaddled. The duration of holding varies from unit to unit, although not as much as that of skin-to-skin contact (Raiskila et al., 2017). Holding is beneficial for both preterm infants in NICUs and their parents in that it may promote parent-infant interaction and reduce the trauma caused to the parents by being separated from their infants (Kimkool et al., 2022). Nowadays, early holding in a delivery room shortly after delivery gets attention as an alternative to early skin-to-skin contact. Two studies showed that holding in the delivery room, called delivery room cuddling, succeeded without increasing harm and was also valued by parents (Clarke et al., 2021; Kimkool et al., 2022). Holding shortly after delivery, as well as immediate skin-to-skin contact, can provide invaluable moment for parents and their newborn infants (Clarke, 2017).

2.4.2.4 The parents' readiness for discharge

The parents' proper readiness for discharge is one of the prerequisites for their preterm infants to be discharged home safely without unnecessary prolongation of hospital care. The necessary factors for a successful discharge to home are called discharge criteria, and the parents' readiness for discharge is among them (Arwehed et al., 2024; L Jefferies et al., 2014; Seaton et al., 2016). One study in 2002 showed that 20% of the parents of healthy full-term infants did not have sufficient readiness when their infants were discharged home (Bernstein et al., 2002). Risk factors that have been identified include the parents' mental illness and low-level education as well as impaired communication between the parents and the neonatal health care team (Bernstein et al., 2002; McGowan et al., 2017; Miquel-Verges et al., 2011). The parents' lack of readiness for discharge may lead to increased medical needs and phone calls to the hospital, a higher risk of poor health status of the infant and placing the infant in an inappropriate lying position after discharge (Bernstein et al., 2002, 2013). However, although the parents' readiness for discharge is always one of the discharge criteria in NICUs, the association between the parents' readiness for discharge and the length of stay in NICUs has not been well studied. In addition, although the promotion of the parents' readiness for discharge is thought to be one of the possible mediators for comprehensive family-centered care interventions to reduce the length of stay in NICUs, no previous studies have examined that.

2.5 Outcomes of family-centered care interventions (models of parent-partnered care) and their importance

Outcomes of family-centered care interventions can be classified into three categories: for the infants, for the parents, and for the health care system. Some of the outcomes are possibly relevant to more than one stakeholder: e.g. length of stay affects the parents, infants, parent-infant relationships, and health care system. Among many outcome measures of family-centered care interventions, we focused on the outcomes for infants, especially length of stay, growth, outpatient visits and rehospitalizations after discharge.

2.5.1 Length of stay

Newborn infants, preterm infants in particular, often require long hospital stays in NICUs, which may lead to parent-infant separation. A study mentioned that very preterm infants in a NICU spent 80% of their time without any human interaction (Gonya et al., 2018). Parent-infant separation also negatively affects parents. Mothers of preterm infants and/or infants admitted to NICUs are shown to have an increased risk of postpartum depression, anxiety, stress, and post-traumatic stress disorder, as already mentioned elsewhere (2.4.1.3 Emotional support). Newborn infants in hospitals are also exposed to harmful environmental factors such as nosocomial infections, excess light, and noise (Santos et al., 2015). In addition, long hospital stays require hospital resources, such as hospital expenses and professional care. Thus, reducing the length of newborn infants' hospital stay is meaningful in many ways.

The length of stay is one of the most well-studied outcomes of family-centered care interventions on infants to date. Four randomized controlled studies about family-centered care interventions showed a reduction in the length of stay (Benzies et al., 2020; Hei et al., 2021; Melnyk et al., 2006; Örtenstrand et al., 2010), while the other three did not show a significant effect (Chen et al., 2013; White-Traut et al., 2015; Yu et al., 2017). In addition, one non-randomized controlled study showed that, among preterm infants cared for in single-family NICU rooms, the mothers' higher level of involvement in caretaking was associated with a significantly shorter length of stay in the NICU by 13 days on average (Lester et al., 2016). Many of these studies included only two or three NICUs with less than 300 participants. A meta-analysis, including 3,070 infants in seven studies, failed to show a beneficial effect of family-centered care interventions on the length of stay (Ding et al., 2019). In addition, most of these studies involved preterm infants limited by gestational age or birth weight. Thus, further studies are required to confirm the effect.

Although family-centered care interventions have the potential to reduce the length of stay in NICUs, their mechanism has not been determined yet. We need to examine factors affecting the length of stay of preterm infants in NICUs to understand the mechanisms. Important background factors predicting the length of stay of preterm infants include gestational age at birth, birth weight, and sex (Fröhlich et al., 2021; Seaton et al., 2016). Medical conditions of the infants found after birth, such as sepsis and surgical needs, can unexpectedly extend the hospital stay, making it more difficult to predict the length of stay, especially with extremely preterm infants (Hintz et al., 2010; Seaton et al., 2016). In addition, each neonatal unit has different discharge criteria that cause variation in the length of stay. Some of these discharge criteria are used commonly, such as thermoregulation, control of breathing, feeding skills, specified postmenstrual age (PMA) and weight, and the parents' readiness for discharge (Arwehed et al., 2024; Jefferies et al., 2014; Seaton et al., 2016).

There is a lack of guidelines and criteria for correctly determining when a preterm infant is ready for discharge home from hospital (Arwehed et al., 2024; Maier et al., 2018; Seaton et al., 2021; Smith et al., 2013). Furthermore, it is unclear how much each discharge criterion affects the length of stay in preterm infants, or what the determinants of discharge are (Arwehed et al., 2024). International comparison studies show that the length of stay differs between countries (Maier et al., 2018; Seaton et al., 2021). One of them included 11 neonatal networks in 12 countries and found that the length of stay was the longest in Japan and the shortest in Finland, with a mean difference of 25 days (Seaton et al., 2021).

2.5.2 Growth

The growth of infants in NICUs is important in that it may be associated with the later outcomes for the infants such as neurodevelopment (Levine et al., 2015). Some studies showed that better weight gain during hospitalization in NICUs was associated with better neurodevelopment (Belfort et al., 2011; Ehrenkranz et al., 2006; Franz et al., 2009; Leppänen et al., 2014; Zozaya et al., 2018).

Some studies showed that family-centered care interventions increased weight gain (Chen et al., 2013; Hei et al., 2021; O'Brien et al., 2018; Yu et al., 2017). A meta-analysis has also confirmed that family-centered care interventions increased weight gain in preterm infants (Ding et al., 2019). However, each study included less than 1,000 infants. In addition, to our knowledge, no previous studies have shown an effect on the increase in length or head circumference. Growth in length or height might be a better predictor of later neurodevelopment than in weight (Bergvall et al., 2006; Itoshima, Oda, et al., 2023; Lundgren et al., 2003).

2.5.3 Outpatient visits and rehospitalizations after discharge

Two previous studies evaluated the effect of family-centered care interventions on later emergency department visits. However, neither indicated a significant effect (Benzies et al., 2020; Vonderheid et al., 2016).

Previous studies have shown an inconsistency in the effect of interventions on the risk of rehospitalizations. Three studies showed that family-centered care interventions decreased the possibility of rehospitalization within 30 days of discharge (Bastani et al., 2015; Gonya et al., 2014; Hei et al., 2021). A meta-analysis has also confirmed the positive effect (Ding et al., 2019). However, two other studies did not show any significant effect up to about two months after discharge (Benzies et al., 2020; Karbandi et al., 2015; Vonderheid et al., 2016). In addition to the different results between studies, no previous studies have evaluated the long-term effect of family-centered care interventions, e.g. up to a year after discharge.

2.6 Knowledge gaps

Below is a summary of the knowledge gaps that triggered this thesis.

1. The effects of family-centered care interventions on parent support and parent-delivered care and activities have not been well studied.
2. Implementation fidelity of a family-centered care intervention and its impacts on intervention effects has not been well studied.
3. No previous studies have evaluated the effects of the Close Collaboration with Parents intervention on infants.
4. Previous studies have shown inconsistent results regarding the effects of family-centered care interventions on the length of stay in NICUs and rehospitalization after discharge.
5. The effect of family-centered care interventions on outpatient visits after discharge has not been well studied.
6. It has not been clear how family-centered care interventions reduce the length of stay in NICUs among preterm infants.
7. No previous studies have evaluated how different discharge criteria affect the length of stay in NICUs among preterm infants.
8. No previous studies have evaluated the effect of couplet care on early parent-infant physical closeness, including parent-infant skin-to-skin contact, holding, the parents' presence and overnight stays in the NICU room.

3 Aims

General aims

The general aims of this project were to evaluate the effects of two family-centered care interventions, the Close Collaboration with Parents program and the Couplet Care Model. The outcomes included their effects on parent support, parent-delivered care and activities, and the preterm infants. We also aimed to understand the implementation fidelity of these interventions and its impact on outcomes.

Specific aims

The first aims were to evaluate the effects of the Close Collaboration with Parents intervention on the components of family-centered care; and to understand the implementation fidelity of the intervention and its influence on intervention effects. **(Estonian Study [I])**

The specific research questions included the following:

1. Does the Close Collaboration with Parents intervention improve family-centered care practices in NICUs as rated by the parents and neonatal health care staff?

2. Is a higher implementation fidelity of the intervention, the proportion of health care staff who completed the training, associated with better improvement in the levels of family-centered care practices?

The second aim was to evaluate the effects of the Close Collaboration with Parents intervention on the outcomes for preterm infants. **(Register Study [II])**

The specific research questions included the following:

1. Does the Close Collaboration with Parents intervention shorten the length of stay, improve growth, and reduce the outpatient visits and rehospitalization after discharge to home in preterm infants?

The third aim was to understand how different discharge practices in a NICU in Japan and another in Finland contributed to the differences in the length of stay. **(Discharge Criteria Study [III])**

The specific research questions included the following:

1. What is the last discharge criterion before discharge to home?
2. How much does each discharge criterion extend the length of stay?
3. In which gestational age was each discharge criterion met?

The fourth aim was to evaluate the effect of the Couplet Care Model on parent-infant physical closeness in the NICU. **(Couplet Care Study [IV])**

The specific research questions included the following:

1. Does the Couplet Care Model promote early parent-infant skin-to-skin contact by reducing the time gap between birth and the first skin-to-skin contact?
2. Does the Couplet Care Model extend the duration of the parents' presence, skin-to-skin contact, and holding in the NICU room?
3. Does the Couplet Care Model increase the frequency of the parents' overnight stays in the NICU room?

4 Materials and Methods

This thesis consisted of four different clinical studies. Their methods and limitations are summarized in Table 1.

Table 1. The summary of methods and limitations in each study.

Study no.	I: Estonian Study	II: Register Study	III: Discharge Criteria Study	IV: Couplet Care Study
ClinicalTrials.gov registration	NCT06258655	NCT05765136	NCT06144190	NCT05655104
Design	Before-after intervention study	Register-based study	Comparison study of two cohorts	Before-after intervention study
Sites	6 NICUs in Estonia (2 Level III/IV and 4 Level II)	All 23 NICUs in Finland (5 Level III/IV and 18 Level II)	A Level IV NICU in Japan and a Level III NICU in Finland	A Level III NICU in Finland
Years of data collection	2021 and 2023	2006−2020	2020−2021	2018−2019 and 2022−2024
Population	Infants of any gestational age admitted to the NICUs, their parents, and the NICU health care team	Preterm infants born < 35 weeks of gestation	Preterm infants born between 28 and 31 weeks of gestation and discharged home from the study sites	Parents of preterm infants born < 35 weeks of gestation
Sample size	Parents: before group n=186 mothers and n=21 fathers; after group n=207 mothers and n=52 fathers NICU health care team: before group n=7,448 and after group n=6,717 responses	Intervention group n=2,104; partial intervention group n=515; control group n=11,621	In Japan n=22 In Finland n=49	Before group included 40 infants from 30 families and after group included 66 infants from 58 families
Intervention	Close Collaboration with Parents	Close Collaboration with Parents	NA	Couplet Care Model

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Study no.	I: Estonian Study	II: Register Study	III: Discharge Criteria Study	IV: Couplet Care Study
Outcome measures	DigiFCC-P, a questionnaire to evaluate the level of family-centered care practices from the parents' perspective using nine questions. DigiFCC-N, a questionnaire to evaluate the level of family-centered care practices from the neonatal health care team's perspective using nine questions. Implementation fidelity of the intervention and its association with the change in the level of family-centered care practices.	Length of stay in NICUs Growth (increase in weight, length, and head circumference) Outpatient visits after discharge Rehospitalization after discharge	Last discharge criterion before discharge Potential extending effects of each discharge criterion on length of stay Postmenstrual age when each discharge criterion was met	Timing of the first skin-to-skin contact First skin-to-skin contact within two hours Duration of the parents' presence in NICU room Frequency of the parents' overnight stays Duration of skin-to-skin contact Duration of holding
Limitations	Non-randomized design. Not an optimal tool for evaluating family-centered care in Estonia due to the high baseline ratings. Different ways of presenting the questions to the parents and the NICU health care team. Imbalance in the number of mothers and fathers. Staff responses were provided by all the staff, yet the calculation of the fidelity rate excluded temporary staff, assistant nurses, and special workers, who were not expected to receive the full training. No quantitative evaluation of the implementation fidelity.	Non-randomized design. No reliable information about neonatal morbidities. Small sample size in the partial intervention group. Lower gestational age in the partial intervention group than the other groups.	Small sample size and limited number of NICUs. Limited gestational age group. Excluded those who needed special medical care.	Non-randomized design. Possible effect of items included in moving into the new hospital other than the Couplet Care Model. No long-term outcome measures.

NICU, neonatal intensive care unit.

4.1 Study design, participants and procedure

4.1.1 Estonian Study (I)

The Estonian Study (I) had a non-equivalent two-group design, comparing two different cohorts before and after the implementation of the Close Collaboration with Parents intervention. There are seven NICUs in Estonia: one level IV, one level III, and five level II NICUs. The level III/IV units are combined with pediatric intensive care units and taken care of by anesthesiologists and nurses working there. Infants treated in level III/IV units are usually transferred to level II units after intensive care.

Six NICUs in three hospitals were included, which covered all but one NICU in Estonia. The Close Collaboration with Parents intervention was implemented between September 2021 and December 2022. The data were collected between March and August 2021 before the intervention and between December 2022 and June 2023 after. The aim was to include 50 families in each participating hospital, before and after the intervention, respectively, based on the power calculations to detect the association between the intervention and the change in parents' postpartum depressive symptoms (Ahlqvist-Björkroth et al., 2019, 2022).

The study population consisted of the parents of infants admitted to the NICUs and the neonatal health care staff. All parents were eligible regardless of their newborn infants' gestational age if their infant was admitted to a participating NICU during their first 28 days of life. They were excluded if the expected length of stay in the NICU was shorter than three days or if they could not understand Estonian, Russian or English. All neonatal health care staff working during the study periods were eligible to participate, such as neonatologists, registered nurses, assistant nurses, caregivers, psychologists, and physiotherapists.

Ethical approval was prospectively received from the Research Ethics Committee of the University of Tartu (333/T-21). Each participating parent and neonatal health care staff member gave written informed consent. This trial has been registered at ClinicalTrials.gov (identifier, NCT06258655).

4.1.2 Register Study (II)

The Register Study (II), a retrospective nationwide register-based study in Finland, used the following three registers maintained by the Finnish Institute for Health and Welfare under the Ministry of Social Affairs and Health: the Medical Birth Register, Care Register for Health Care, and Very Preterm Infant Register (Lehtonen et al., 2021). These registers cover all infants born in Finland because all public hospitals are mandated to provide data on their patients to the registers and almost all deliveries in

Finland happen at these public hospitals. There are 23 NICUs in Finland; five are level III/IV NICUs affiliated with a university hospital. In most cases, the delivery and initial intensive care of very preterm infants are provided in the level III/IV NICUs (95% of very preterm deliveries in 2017) (Helenius et al., 2019).

The study population consisted of preterm infants born in Finland below 35 weeks of gestation from January 1, 2006 to December 31, 2020, who required care in a NICU immediately after birth. The following infants were excluded: those who died during the hospitalization in the NICU and those whose discharge information was missing or likely to be incorrect (length of stay of 0 days or discharged below 32 weeks PMA). Those who were still hospitalized at 50 weeks PMA were also excluded as outliers.

Eligible infants were classified into three groups depending on the NICU of the delivery and discharge hospital (Figure 2): into a Full Close Collaboration (Full-CC) group if both NICUs had completed the intervention, into a Partial-CC group if only one of the NICUs had completed the intervention, and into a Control group if neither had started the implementation. The infants were excluded if they were taken into care in a NICU where the intervention was currently being implemented.

No ethical approval or informed consent was required based on national research legislation regarding registered studies, and data were handled and analyzed pseudonymously via a secure remote access platform (Findata Kapseli). This trial has been registered at ClinicalTrials.gov (identifier, NCT05765136).

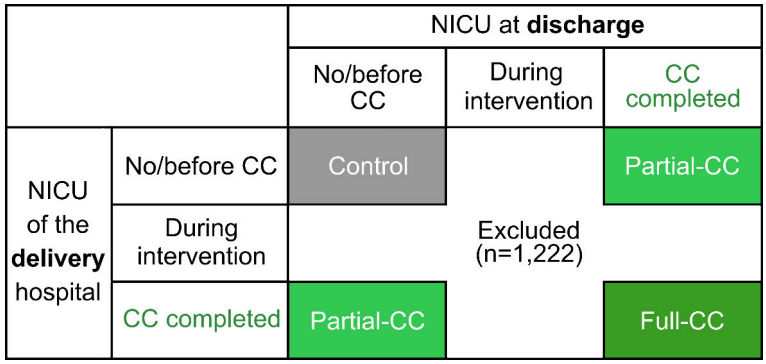

Figure 2. Classification of eligible infants depending on the neonatal intensive care unit of the delivery and discharge hospital in the Register Study (II).

4.1.3 Discharge Criteria Study (III)

The Discharge Criteria Study (III) retrospectively compared two NICUs: Nagano Children's Hospital, a Level IV NICU in Japan, and Turku University Hospital, a Level III NICU in Finland. Both NICUs function as the only tertiary perinatal centers

in their areas. These two study sites are representative of their countries, which may be supported by the following data.

The study site in Japan is one of about 100 Level III/IV NICUs in Japan. It is one of three Level III NICUs in the prefecture and the only Level IV NICU. Among the admitted preterm infants born at 28–31 weeks of gestation in 2020–21, 9% were outborn in the study hospital compared to about 6% in all NICUs participating in the neonatal research network database in Japan in 2020. Infants whose families live in other areas are usually transferred back to the Level II NICU near their home after they have been weaned off from any respiratory support. The study site also functions as a Level II NICU for the local patients. Among 280 infants admitted in 2021, about 25% were preterm infants. The NICU had 24 intensive care beds and 18 step-down beds. There were six hospital rooms in the NICU area and each hospital room accommodated 4 to 10 patients. One nurse on day shift cared for 3 infants in intensive care beds and 7 in step-down beds; this resource is determined by health care fees in Japan. Parents were allowed to visit their infants in the NICU 24/7 before the COVID-19 pandemic. However, their visitations were limited to between 9 a.m. and 3 p.m. since March 2020, except for hospitalized postpartum mothers who could access their infants 24/7. Postpartum mothers are usually hospitalized for four days after vaginal delivery and seven days after Cesarean delivery.

The study site in Finland is one of five Level III/IV NICUs in Finland. It is the only Level III NICU in the southwest Finland region. All very preterm deliveries from the region are centralized in this hospital. During the study period, 86 out of 89 infants (96.6%) born at 28–31 weeks of gestation were born in the Level III NICU in this region, compared to 427 out of 449 (95.1%) in the whole country. The quality comparison data also shows comparable outcomes for all five Level III/IV NICUs in Finland. The study site also functions as a Level II NICU for the local patients. Infants whose families live in other areas are usually transferred back to the Level II NICU near their home after they have been weaned off from any invasive respiratory support. Preterm infants accounted for about 40% of all admissions to the NICU in 2021. The unit consisted of 18 beds, including intensive care and step-down beds. The beds were mostly in single-family rooms, accommodating two patients in the case of twins. There were 14 rooms in the NICU in total. One nurse usually cared for 1–3 infants depending on the intensity of care and the number of working nurses. The parents were allowed to visit the NICU 24/7 and at least one parent could stay overnight in the same NICU room. This policy did not change even during the COVID-19 pandemic.

Eligible infants were those who were born between 28+0 and 31+6 weeks of gestation and discharged home from the study sites between January 2020 and December 2021. Infants were excluded if they had major anomalies at birth or needed home oxygen therapy, tracheostomy, or gastrostomy at discharge. Our study

only included infants born at 28–31 weeks of gestation because 1) we wanted to have comparable patient populations regarding the medical conditions, 2) we wanted to exclude the borderline viability infants (e.g. infants born at 22 or 23 weeks of gestation) to eliminate the confounding effects of possible differences in care approaches, and 3) different centralization strategies were applied in the study sites for those infants who were born after 31 weeks of gestation.

Permission to carry out the study was given by the Ethics Committee of Nagano Children's Hospital (S-04-49) and Turku Clinical Research Centre (T210/2022). Ethical approval with an opt-out approach was given by the Ethics Committee of Nagano Children's Hospital (S-04-49). This study was registered at ClinicalTrials.gov (identifier: NCT06144190).

4.1.4 Couplet Care Study (IV)

The Couplet Care Study (IV) had a non-equivalent two-group design. The study included two different cohorts, before and after the introduction of the Couplet Care Model. The study site was Turku University Hospital's NICU, one of the five Level III/IV NICUs in Finland. All data were collected prospectively. The data from before the introduction of the intervention was collected prospectively to evaluate the effect of single-family NICU rooms (Kainiemi et al., 2021), and was used in this study as a historical baseline. The data after the introduction was also collected prospectively in a similar way.

The study population consisted of the parents of preterm infants born at the hospital below 35 weeks of gestation from March to December 2018 (before the Couplet Care Model) and from December 2022 to March 2024 (after the introduction of the Couplet Care Model). Parents were excluded if (1) the infant's expected length of stay in the NICU was shorter than three days, (2) the infants were triplets or higher order, (3) the parents were not able to understand the informed consent form in either Finnish, Swedish, English, or Russian, (4) the clinical condition of the infant was so critical that his/her survival was uncertain, or (5) the parents did not consent within seven days after birth.

Ethical approval was received for the use of the historical baseline data and the prospective data collection after the introduction of the Couplet Care Model from the Ethical Committee of Hospital District of Southwest Finland (Dnro 44/1801/2022 §432). This study was first submitted to ClinicalTrials.gov on November 30, 2022, and prospectively registered (identifier, NCT05655104).

4.2 Interventions

4.2.1 Close Collaboration with Parents intervention for the Estonian Study (I) and Register Study (II)

Close Collaboration with Parents is an educational intervention for multi-professional staff working in NICUs (Ahlqvist-Björkroth et al., 2017; Ahlqvist-Björkroth et al., 2024; He et al., 2021; Toivonen et al., 2020). It consists of four training phases with the following objectives: Phase I) learning systematic observation of infant behavior and communicating the observations, Phase II) performing joint infant observations with the parents to understand the infant's preferences and to plan infant care together with the parents, Phase III) understanding the family's individual story using a semi-structured discussion, and Phase IV) including the parents in decision-making during daily care, medical rounds and discharge preparation (Ahlqvist-Björkroth et al., 2024). The learning process of neonatal health care teams includes completing the e-learning module and bedside practice combined with reflection on the practice experience with a local mentor. The final goal is to improve the family-centered care culture of the NICU by developing the communication skills of the neonatal health care team to facilitate their collaboration with parents and support parenting.

The "train the trainer" model was used in the implementation. The training team trained local mentors in each NICU, who then trained the other neonatal health care staff (Ahlqvist-Björkroth et al., 2024). Local mentors were mostly chosen from the neonatal health care team working in the NICU. They usually consisted of nurses, doctors, and sometimes psychologists and other professionals. It generally took about 1.5 years for each NICU in Finland and Estonia to complete the implementation, except for one NICU in Finland which implemented the intervention for the first time between 2009 and 2012. In Finland, all of the training sessions for the local mentors were conducted in person (Study II: Register Study), while in Estonia some of them were conducted remotely because of the COVID-19 pandemic (Study I: Estonian Study). When the local mentors trained the neonatal health care staff, the training team offered several support visits per NICU to ensure the quality of the implementation and to help the local mentors cope with problems and difficulties. The implementation period in the Estonian Study (I) (Figure 3) included the training period for the neonatal health care team but not for the local mentors. The implementation period in the Register Study (II) (Figure 4) included the training period for both the local mentors and the neonatal health care team.

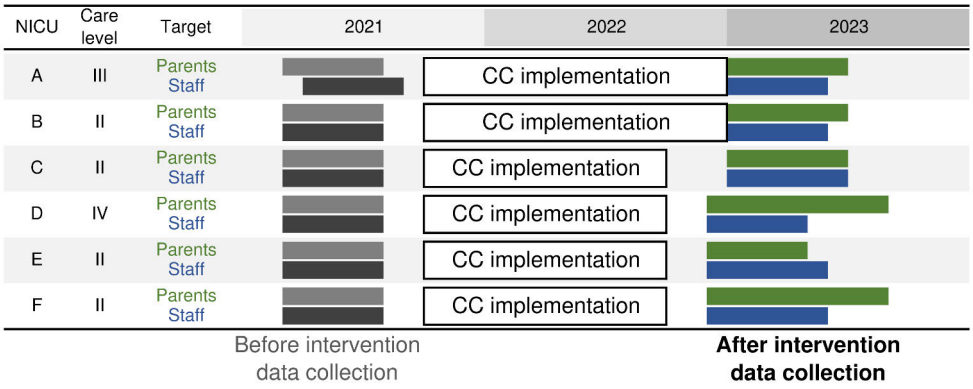

Figure 3. The intervention periods of the Close Collaboration with Parents intervention (CC) and data collection for the parents and neonatal health care staff before and after the implementation in the Estonian Study (I).

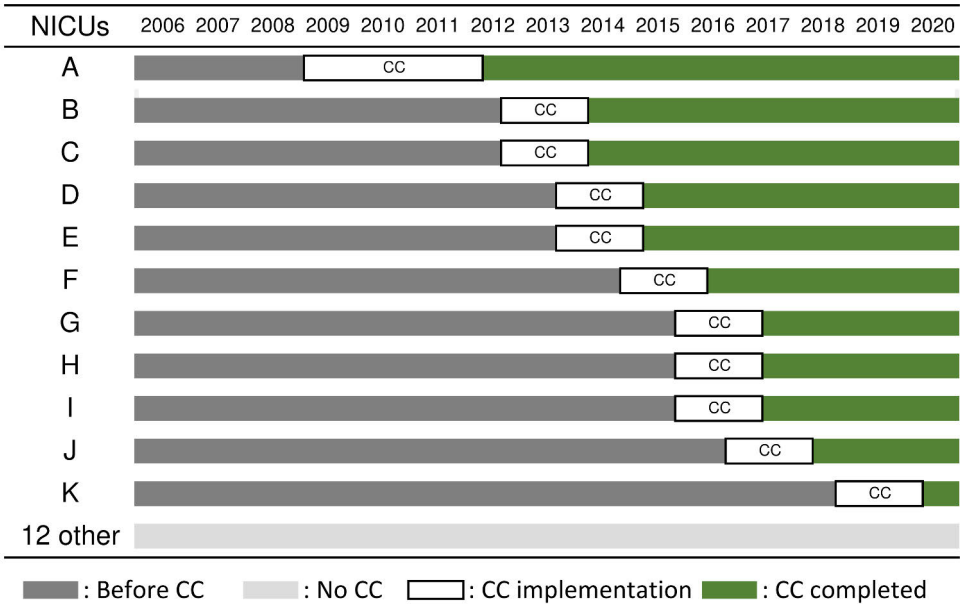

Figure 4. The timing and duration of implementation of the Close Collaboration with Parents intervention (CC) in 11 NICUs in Finland (white square) in the Register Study (II). In addition, there were 12 NICUs without the intervention. Eligible infants were classified into three groups according to the CC implementation status of the NICUs (No/before CC or CC completed). Infants cared for during the implementation period were excluded.

4.2.2 Couplet Care Model for the Couplet Care Study (IV)

The Turku University Hospital NICU started implementing the Couplet Care Model when they moved into a new hospital on February 10, 2022. The Couplet Care Model included (1) stabilizing the infant's condition and providing necessary initial

procedures in the delivery unit to facilitate early parent-infant closeness, (2) providing the mothers' postpartum care in the same NICU room as the infant, and (3) always providing a bed for the father/partner in the NICU room.

Table 2 compares the policies, initial care practices, and characteristics of the facilities in the old hospital before the introduction of the Couplet Care Model and in the new hospital after. Before the introduction, very preterm infants were typically transferred, after minimum stabilization procedures performed at the delivery unit, to the NICU on a different floor, usually within 30 minutes after birth. Further procedures were performed in the NICU room after the transfer. Postpartum mothers and their sick newborn infants were admitted to separate wards on different floors. The NICU room sometimes had to be shared with another family. In addition, the NICU mostly provided only one bed for the parents due to limited space. As a result, in most cases, overnight stays in the infant's NICU room were only possible for one of the parents.

There have been some initiatives to facilitate the implementation of the Couplet Care Model. First, minimizing parent-infant separation was specified as the leading priority in the planning of the new hospital (Reijula et al., 2016). Second, the nurses in the NICU and midwives in the delivery unit had work rotations in the other unit to understand each other's system and to promote future collaboration. Third, neonatal, obstetric, and operation room teams collaboratively made a plan of how to facilitate early parent-infant skin-to-skin contact in the delivery unit. The simulations for early skin-to-skin contact were also carried out.

After the introduction, full stabilization and procedures were carried out in the stabilization room in the delivery unit, such as imaging, surfactant administration, invasive and non-invasive ventilatory support, central line placement, and monitoring. This new practice enabled parents to stay close to their newborn infants in the delivery unit and to have their infants in skin-to-skin soon after birth, irrespective of the infant's condition. Not only the neonatal health care team but also any other related parties and the parents joined the shared decision-making process to decide whether to perform skin-to-skin contact in the delivery unit or not. Postpartum mothers and their newborn infants received care in the same NICU room: the mother from the midwives and the infant from the neonatal health care team. Furthermore, a bed for the father, in addition to the mother was always provided in all NICU rooms. Most NICU rooms in the old hospital and all rooms in the new hospital provided a toilet and a shower for parents. A lounge was provided in both the old and new NICUs. The NICU room structure in the new hospital was exemplified in a previous article (Klemming et al., 2023). The general policies regarding parent-infant skin-to-skin contact and holding carried out in the NICU room did not change after the introduction of the Couplet Care Model; the additional early skin-to-skin contact in the delivery unit before admission to the NICU took place.

Table 2. Comparisons of the policies, the initial care practices, and the characteristics of the facilities in the old hospital before the introduction of the Couplet Care Model and in the new hospital after in the Couplet Care Study (IV).

	Old hospital before the introduction of the Couplet Care Model	**New hospital after the introduction of the Couplet Care Model**
At delivery unit		
Procedures for infant in the delivery unit	Only the initial stabilization procedure.	Full stabilization and other procedures.
Transfer to the NICU	Usually within 30 minutes for further procedures.	Usually with the mother or father about 2 hours after birth.
Early skin-to-skin contact	Rarely used with sick infants.	Actively promoted and considered for all infants.
At NICU		
Mother's postpartum care in the same NICU room as the infant	No	Yes
Mother's bed in the same NICU room as the infant after discharge	Yes	Yes
Father's bed in the same NICU room as the infant	On-demand if possible	Yes
Single-family rooms	Sometimes shared with another family	Always one family in one room

NICU, neonatal intensive care unit.

4.3 Outcome measures and data collection

4.3.1 Estonian Study (I)

The primary outcomes were the parents' and neonatal health care team's ratings of the level of family-centered care practices. Furthermore, we evaluated implementation fidelity in each participating NICU and examined the effect of implementation fidelity on the level of family-centered care practices.

Among the five components of implementation fidelity, dose and amount of the intervention delivery was evaluated using the fidelity rate, which was defined as the proportion of doctors and nurses who completed the full training. Full training was defined as the completion of e-learning module and experiencing at least one bedside training for each training phase. The use of the e-learning module by the neonatal health care staff was automatically recorded. The bedside training progress was manually recorded in an Excel file serving as a training log.

The parents rated their experiences of the level of family-centered care using a questionnaire made from the DigiFCC-P (Axelin et al., 2020). It consisted of nine questions: Q1 active listening, Q2 parent participation in infant care, Q3 individualized parent guidance, Q4 shared decision-making, Q5 the parent's trust in staff, Q6 the staff's trust in parents, Q7 individual information sharing, Q8 emotional support, and Q9 participation in medical rounds. Each question consisted of a Likert scale from 1 to 7, whose higher score indicated a higher level of family-centered care. A response of 0 could be provided if the parent never visited his/her infant in the NICU or never participated in the medical round during his/her hospital stay in the NICU. Parents answered the questionnaire each time their infant was transferred to another unit or hospital or discharged home, the earliest four days before discharge and the latest on the same day. The Cronbach's alpha of the parents' responses was 0.85 before and 0.91 after the intervention.

The neonatal health care staff rated their experiences of the levels of family-centered care practices using the DigiFCC-N (Axelin et al., 2020). It was a web-based questionnaire containing nine questions. The questions were identical to those used for the parents, except presented from the perspective of the neonatal health care team. A response of 0 could be provided if the neonatal health care staff did not have an opportunity to work with the parents or did not participate in the medical rounds. After the working shift of each staff member, he/she answered three questions (out of nine) which were automatically and randomly provided using a computer. Each participating NICU provided one or more computers which were dedicated to this research use.

4.3.2 Register Study (II)

The primary outcome was the infants' length of stay (days) in NICUs before the first discharge to home. The secondary outcomes were the change in growth parameters from birth to discharge (Δ weight z-score; Δ weight, g/week; Δ length, mm/week; Δ head circumference, mm/week); unscheduled outpatient visits (yes/no) and rehospitalizations (yes/no) during the first year of life. The growth data at 42 weeks PMA were only used if the infant was still in a NICU at that point due to the legislative permission to collect data only up until then. The weight z-scores were calculated using Fenton's growth chart and the LMS parameters (Cole, 1990; Fenton, 2003; Fenton & Sauve, 2007).

Eligible infants were identified from the Medical Birth Register. The length of stay was available from all three registers used in the study. If the data were missing or inconsistent, the length of stay was determined following this order of priority: 1. Care Register for Health Care, 2. Very Preterm Infant Register, and 3. Medical Birth Register.

4.3.3 Discharge Criteria Study (III)

The primary outcomes were the last discharge criterion before discharge and the potential extending effects of each discharge criterion on the length of stay. The secondary outcomes included the PMA when each discharge criterion was met.

We classified the discharge criteria into six categories: "temperature criterion" (no need for mechanical temperature control), "respiration criterion" (no need for respiratory support and observation), "feeding criterion" (no need for a feeding tube), "examination criterion" (completion of the necessary examinations), "weight criterion" (exceeding the weight limit), and "family criterion" (parents ready for the transition to home and independent caretaking). The "feeding criterion" and "examination criterion" were not used in the NICU in Finland. The details of the discharge criteria in each study site are summarized in Table 3.

Table 3. Discharge criteria and how they were used and defined at each study site in the Discharge Criteria Study (III).

Discharge criteria	NICU in Japan	NICU in Finland
Temperature	**Definition** No mechanical temperature control (incubator, infant warmer, or heating mattress) • The target body temperature was between 36.5 and 37.5℃	
Respiration	**Definition** No respiratory support (any invasive or non-invasive respiratory support including oxygen, high-flow, or NCPAP) or respiratory monitoring	
	• Apnea observation: no apnea for 2 days. • Definition of apnea: pause in breathing with bradycardia (<100/min.) or requiring stimulation regardless of the duration of the respiratory pause. • The target SpO2: 88–94% between 72 hours after birth and 36 weeks PMA, and ≥ 95% otherwise.	• Apnea observation: no apnea for 7 days. • Definition of apnea: pause in breathing with bradycardia (<80/min.), excluding any bradycardia during feeding. • The target SpO_2: 90–95% until 40 weeks of PMA and ≥ 95% after term age.
Feeding	**Definition** Feeding tube removed permanently	Not used
	• A feeding tube was used at home only if the infant needed it at the due date and the need was estimated to continue for at least several weeks.	• Infants were usually discharged despite having a feeding tube if the other discharge criteria were met and parents were ready for that.
Examination	**Definition** All necessary examinations completed, including a neurodevelopmental assessment	Not used
	• The necessary neurological examinations included brain MRI, a hearing test, Dubowitz and General Movements. They were conducted mostly between 36–40 weeks PMA.	• All the necessary examinations could be conducted in the follow-up clinic after discharge home.
Weight	**Definition** The infant's weight exceeds 2200 g	Not used

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Discharge criteria	NICU in Japan	NICU in Finland
Family	**Definition** The parents and other family members are ready to take their infant home	
	• In most cases, the parents felt ready after using the single-family room (there was only one in the NICU), where the parents stayed overnight with their infant. • In most cases, the neonatal health care team used a checklist to ensure that parents had adequate skills in infant care, which was not shared with the parents. • In most cases, the neonatal health care team confirmed the readiness without asking the parents. • The other NICU beds were open-bay without the parents' bed next to them. The parents had no accommodation in the NICU. The parents' visits to the NICU were limited to the daytime during the study period due to the COVID-19 pandemic. The postpartum mothers had access to the NICU 24/7 even during the COVID-19 pandemic.	• In most cases, the exact date when the parents felt ready was difficult to confirm because they were usually ready long before the infant's condition met the discharge criteria. • Usually, the neonatal health care team and parents filled out a checklist together to ensure that parents were confident in caretaking and that they had adequate infant care skills. Using the checklist was not mandatory. • The parents and neonatal health care team confirmed the readiness together. • Parents were allowed to stay with their infants 24/7, in most cases with at least one bed for a parent. Most NICU rooms were one or two-patient private rooms.

MRI, magnetic resonance imaging; NCPAP, nasal continuous positive airway pressure; NICU, neonatal intensive care unit; PMA, postmenstrual age.

4.3.4 Couplet Care Study (IV)

The outcome measures included in the Couplet Care Study (IV) were the timing of the initiation of the first parent-infant skin-to-skin contact (hours after birth) and the duration of a parent's presence, parent-infant skin-to-skin contact, and holding in the NICU room during the first two weeks of life (average hours per day). We also compared the following outcome measures: the proportion of infants, mothers, or fathers experiencing the first skin-to-skin contact within two hours after birth; the proportion of infants whose first skin-to-skin contact was with their father; and the frequency of the parents' overnight stays in the NICU room (average nights per week). All outcomes were analyzed from the infant's perspective (e.g. having at least one parent present in the NICU room), and the mother's and father's perspectives separately. In cases where the parents had twins, the parents' data were analyzed in terms of being together with or caring for at least one of the twin infants (e.g. caretaking for at least one of the twin infants).

The parents documented the duration and timing of the parents' presence, parent-infant skin-to-skin contact, and holding using the Parent-Infant Closeness Diary (Axelin et al., 2020). The parents drew a line on a paper diary to report the duration of their presence with five-minute accuracy. A parent's presence was defined as being present in the infant's NICU room. Parent-infant skin-to-skin contact was defined as a parent having the infant (or an infant being held) skin-to-skin on the parent's bare chest, with only a diaper and a cap on the infant if necessary. Holding was defined as a parent having the infant (or an infant being held) with their clothes on. An overnight stay was defined as being present in the NICU room for at least 5.5 hours between 0 and 6 a.m.

In the questionnaire, the parents reported when each of them had their own infant skin-to-skin contact for the first time. Their background information was also collected through the questionnaire. A research nurse sometimes supplemented the data from the medical records.

4.4 Statistical Analysis

4.4.1 Estonian Study (I)

The scores of each question were compared using the Wilcoxon rank sum test due to their skewed distribution. The linear regression models were applied to adjust for the following variables to analyze the outcomes for the parents: the infants' birth weight, parents' native language (Estonian/Russian vs. others), the level of NICU care (Level II or III/IV), and the fidelity rate of the NICU ("high" above or "low" below the median). Birth weight was included as it differed between the groups. Gestational age and length of stay were not included in the model as they were well correlated with birth weight. The inclusion of native language was justified by its potential effect on the quality of staff-parent communication. Estonian and Russian are two major languages spoken in Estonia. The linear regression models to analyze the outcomes for the neonatal health care teams only included the level of NICU care and the fidelity rate. Outcome variables in the linear regression models were transformed using Box-Cox transformation to reduce the skewness of the residuals of the models. The model fit of the transformation was evaluated using the Shapiro-Wilk W statistic. Separate linear regression models were used to evaluate the effect of the fidelity rate on the change in the average scores of all questions after the intervention. We excluded the 0 responses in all the analyses. The analyses were conducted using R (R Core Team, n.d.), version 4.2.2 with the R packages of the Tidyverse (Wickham et al., 2019), version 1.3.2; AID (Dag & Ilk, 2017), version 2.9; and lme4 (Bates et al., 2015), version 1.1-31. The visualization used the R

package ggplot2 (Hadley Wickham, 2016), version 3.4.0. P<0.05 were considered statistically significant.

4.4.2 Register Study (II)

Demographics with continuous variables were compared with a 1-way analysis of variance. Further pairwise comparisons between the Full-CC and Partial-CC groups and the Control group were conducted using Dunnett's method. The χ^2 test was used to evaluate the differences in the demographics with categorical variables. The outcome variables were compared between the groups using the linear mixed models and mixed effects logistic regression models. The values of the length of stay, the primary outcome, were natural logarithm transformed due to their right-skewed distributions. The results of the linear regression models were expressed as adjusted geometric mean ratios for the length of stay and as mean differences for the growth parameters, normally distributed outcomes. The results of the mixed effects logistic regression models were expressed as odds ratios with 95% CI for binary outcomes. The following variables were included in the models to adjust for their effects: exposure to at least one dose of antenatal corticosteroid, mode of delivery, year of birth, gestational age at birth, birth weight z-score, sex, multiple birth, and a NICU single-family room (yes/no) (Maier et al., 2018; Seaton et al., 2016). The models also included the random intercepts for the NICU of the delivery and discharge hospital to consider the clustering effects of the NICUs. SPSS version 27 for Windows (SPSS Inc, Chicago, IL, USA) was used for analyses. Two-tailed tests were used, and P<0.05 was considered statistically significant.

4.4.3 Discharge Criteria Study (III)

There was no missing information related to the outcome measures. The potential extending effects of each discharge criterion on the length of stay were estimated as follows. The days of postnatal age when each discharge criterion was met were listed in the following order: the temperature, respiration, (feeding, examination, and weight only in the NICU in Japan), and the family criterion. Then, we calculated the difference in days between each discharge criterion and the most recently met discharge criterion. For example, if the "feeding criterion" was met at 20 days of age and the "examination criterion" at 25 days, the extending effect of the "examination criterion" was 5 days. The extending effect was determined to be 0 days if the discharge criterion was met earlier than the previous criteria. For example, if the "temperature criterion" was met at 16 days and the "respiration criterion" at 14 days, the extending effect of the "respiration criterion" was 0 days. The mean and the standard deviation (SD) were calculated for each extending effect.

The PMA when each discharge criterion was met was compared using the Wilcoxon rank sum test. The R (R Core Team, n.d.), version 4.2.2 with the R packages of the Tidyverse (Wickham et al., 2019) was used for the data analyses. The R package ggplot2 (Hadley Wickham, 2016), version 3.4.0, was adopted for visualization. $P<0.05$ were considered statistically significant.

4.4.4 Couplet Care Study (IV)

The time gap between the birth and the first parent-infant skin-to-skin contact was compared using the Wilcoxon rank sum test due to the skewed distribution. Otherwise, the Student's t-test was adopted for continuous variables and Fisher's exact test for binary variables. The linear regression models and the logistic regression models adjusted for gestational age and plurality (first parent-infant skin-to-skin contact); gestational age, plurality, parity, and distance from the hospital to home (the other measures) (Franck & Spencer, 2003; Giacoia et al., 1985; Roberta Pineda et al., 2018). We did not transform the variables for the time gap between the birth and the first parent-infant skin-to-skin contact in the linear regression models because their residuals could assume normal distributions. The subgroup analyses regarding all outcome measures were conducted for the infants born < 28 and ≥ 28 weeks of gestation. There were no multivariate analyses due to the small sample size. The R (R Core Team, n.d.), version 4.2.2 with the R packages of the Tidyverse (Wickham et al., 2019), version 1.3.2, and lme4 (Bates et al., 2015), version 1.1-31 was used for data analyses. The R package ggplot2 (Hadley Wickham, 2016), version 3.4.0, was adopted for visualizations, including the drawing of kernel density estimation of the first skin-to-skin contact. The kernel density estimation illustrates how the probability of the first parent-infant skin-to-skin contact changed over time from birth. $P<0.05$ were considered statistically significant.

5 Results

5.1 Estonian Study (I)

A total of 99 neonatal health care staff completed the Close Collaboration with Parents program, including 21 doctors (21%), 57 nurses or midwives (58%), and 21 other specialists (21%). As the number of doctors and nurses in all six NICUs was 156 at the beginning of this study, the fidelity rate, defined as the proportion of doctors and nurses who completed all phases of the training, was 50.0%. The fidelity rates were higher than the median in three NICUs (E and F 82.2%; C 72.2%) and lower in the other three NICUs (B 47.1%; A 27.6%; D 13.3%). The training status and the fidelity rates of the NICUs are summarized in Table 4.

There were 326 and 301 families whose infants were admitted to the study sites before and after the intervention, respectively. After considering exclusion criteria, 228 and 235 families were approached, respectively. Finally, the data of 186 and 208 mothers and 22 and 55 fathers were eligible for analyses before and after the intervention, respectively (Figure 5). Among the families included in the analyses, 44 and 28 families before and after the intervention experienced one transfer of their infants to another study site before discharge.

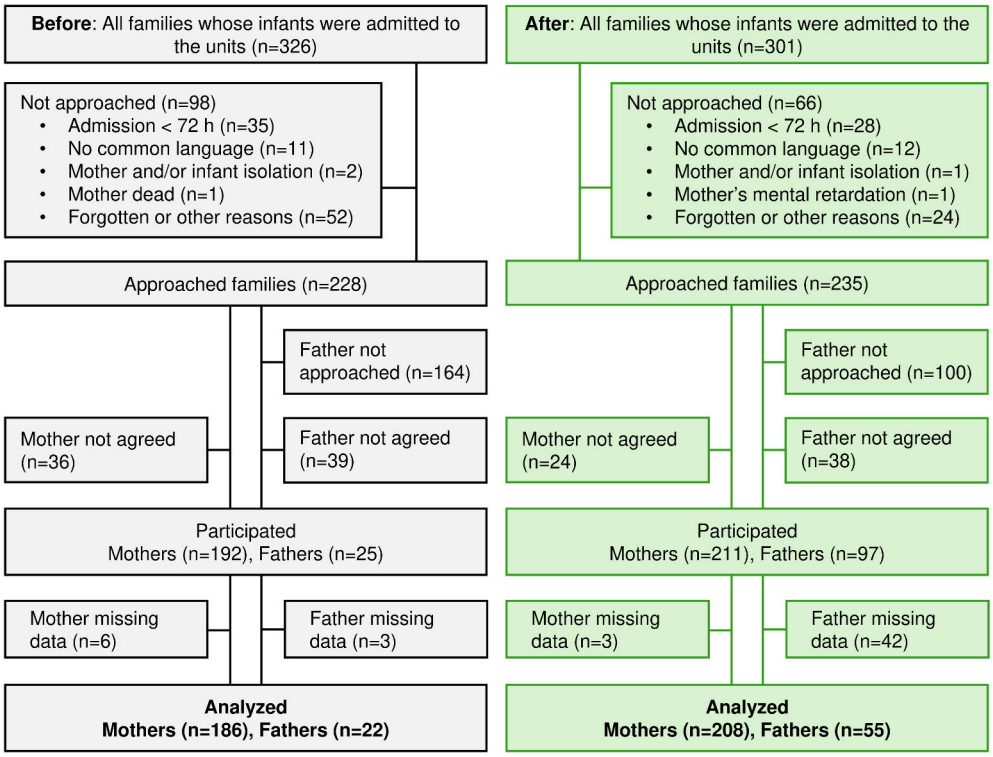

Figure 5. Flow chart of parents' recruitment and participation in Estonian Study (I).

Table 4. The training summary and fidelity rate of the implementation in each NICU in the Estonian Study (I).

NICU	Level of care	Number of doctors and nurses [a]	Number of completed NICU health care staff [b]					Completion rate [c] (%)			
			TOTAL	Doctor	Nurse [d]	Others		Until Phase I	Until Phase II	Until Phase III	Until Phase IV (Fidelity rate [e])
A	III	29	8	0	8	0		69.0	55.2	44.8	27.6
B	II	34	29	3	13	13		79.4	67.6	61.8	47.1
C	II	18	14	6	7	1		111.1 [f]	100.0	88.9	72.2
D	IV	30	4	1	3	0		73.3	63.3	20.0	13.3
E and F [g]	II	45	44	11	26	7		106.7 [f]	97.8	91.1	82.2
TOTAL		156	99	21	57	21		87.8	76.9	62.2	50.0

[a] Doctors and nurses at the beginning of the pre-intervention data collection.
[b] Participation in at least one bedside practice session for each phase and the completion of e-learning.
[c] Calculated by dividing the number of nurses and doctors who completed the intervention by the number of full-time nurses and doctors at the beginning of the pre-intervention data collection.
[d] Including midwives.
[e] The fidelity rate of the implementation of the intervention was defined as the completion rate in all phases (until Phase IV).
[f] The total number of doctors and nurses who completed the training until Phase I was more than those who were working at the beginning of the study.
[g] NICU E and F were merged in the fidelity calculation as there were occasional staff sharing and movements between these two NICUs.
NICU, neonatal intensive care unit.

5.1.1 Characteristics and outcomes for parents (Study I)

The characteristics of the parents are summarized in Table 5. The after-intervention group included more preterm infants than the before-intervention group (before 46.8% vs. after 34.8%), more very-low-birth-weight infants (15.1% vs. 11.6%), more singleton infants (89.2% vs. 96.1%), fewer admissions to the Level III/IV NICUs (30.1% vs. 12.6%), and more single parents (0.5% vs. 2.3%). The other characteristic information was comparable between the groups.

Table 5. The characteristics of the infants and parents in the final study groups in the Estonian Study (I).

	Before	**After**
Infant	(n=186)	(n=207)
Gestational age, median (IQR), weeks	37.4 (34.0, 39.9)	38.1 (35.4, 39.9)
< 37 weeks of gestation, n (%)	87 (46.8)	72 (34.8)
Birth weight, median (IQR), g	2876 (2014, 3618)	3275 (2482, 3778)
< 1500 g, n (%)	28 (15.1)	24 (11.6)
Male sex, n (%)	94 (50.5)	114 (55.1)
Cesarean delivery, n (%)	77 (41.4)	81 (39.1)
Singleton, n (%)	166 (89.2)	199 (96.1)
Admission to level III/IV NICU, n (%)	56 (30.1)	26 (12.6)
Length of hospital stay, median (IQR), days	9.5 (6.0, 25.5)	9.0 (6.0, 19.0)
Parents (mothers and fathers)	(n=186 and 21)	(n=207 and 52)
Single parent, n (%)	1 (0.5)	6 (2.3)
No siblings at home, n (%)	96 (48.2)	137 (55.5)
Age, median (IQR), years	32 (28, 36)	32 (27, 35)
Higher education [a], n (%)	101 (52.3)	141 (57.3)
Estonian/Russian speaking, n (%)	203 (98.1)	244 (94.9)
In paid work, n (%)	158 (77.8)	194 (75.8)
Smoker, n (%)	12 (5.8)	22 (8.6)
Previous depression/anxiety, n (%)	16 (7.7)	23 (8.9)

[a] Bachelor degree or higher.
IQR, interquartile range; NICU, neonatal intensive care unit.

The proportion of good ratings (six or seven) by the parents increased after the intervention in all questions (**Figure 6**). The average score of all questions rated by parents increased significantly after the intervention based on the change in the distribution of the ratings: r=0.07 and P<0.001. However, the median [IQR, interquartile range] did not change due to the high baseline ratings: before 7 [6–7]

and after 7 [6–7] (Table 6). The ratings significantly improved after the intervention in Q1 active listening, Q3 individualized parent guidance, Q4 shared decision-making, and Q8 emotional support. The linear regression models showed significant improvements after the intervention in the same items, except for Q4 shared decision-making.

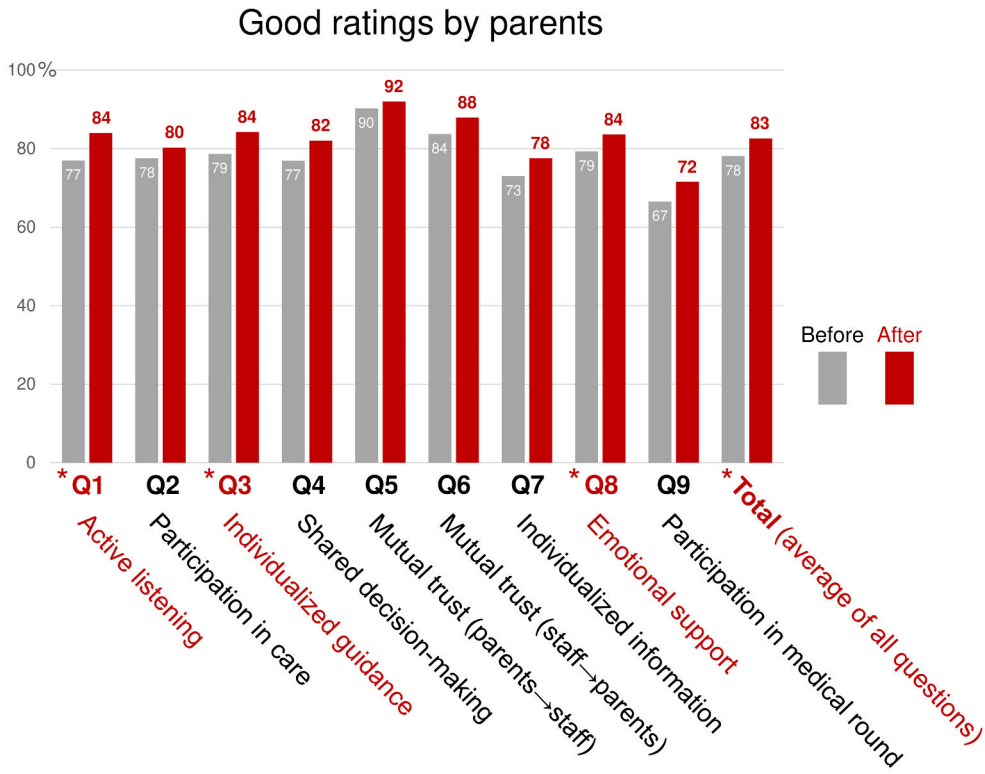

Figure 6. The proportions of good ratings (6 or 7) by the parents for each of the items of family-centered care practice before and after the intervention in the Estonian Study (I). The 0 responses were excluded. * marks the questions with a significant improvement between before- and after-intervention groups based on the linear regression models.

Table 6. Comparison of the parents' ratings of family-centered care practices before and after the Close Collaboration with Parents intervention in the Estonian Study (I).

	Number of responses (missing)		Median (IQR)		Mean (SD)		After vs. before [a]		Linear regression model [b]	
	Before	After	Before	After	Before	After	*r* (effect size)	*P*	*β* (95% CI) [b]	*P*
Parents										
Q1 Active listening	252 (6)	300 (1)	6 (6–7)	7 (6–7)	6.1 (1.1)	6.3 (1.0)	**0.10**	**0.03**	**6.3 (0.62, 12.0)**	**0.03**
Q2 Participation in care	254 (4)	299 (2)	7 (6–7)	7 (6–7)	6.1 (1.4)	6.2 (1.3)	0.00	0.98	-2.0 (-13.0, 8.9)	0.70
Q3 Individualized guidance	253 (5)	298 (3)	7 (6–7)	7 (6–7)	6.1 (1.1)	6.3 (1.0)	**0.10**	**0.02**	**9.5 (1.4, 17.0)**	**0.02**
Q4 Shared decision-making	247 (11)	295 (6)	7 (6–7)	7 (6–7)	6.0 (1.4)	6.2 (1.4)	**0.10**	**0.02**	13 (-0.07, 26.0)	0.05
Q5 Mutual trust (parents→staff)	257 (1)	300 (1)	7 (6–7)	7 (7–7)	6.6 (0.8)	6.6 (0.7)	0.02	0.69	9.6 (-45.0, 65.0)	0.70
Q6 Mutual trust (staff→parents)	246 (12)	298 (3)	7 (6–7)	7 (6–7)	6.3 (1.1)	6.4 (1.0)	0.05	0.23	10.0 (-6.1, 26.0)	0.20
Q7 Individualized information	252 (6)	294 (7)	7 (5–7)	7 (6–7)	5.9 (1.6)	6.1 (1.5)	0.08	0.05	6.4 (-0.91, 14.0)	0.09
Q8 Emotional support	256 (2)	299 (2)	6 (6–7)	7 (6–7)	6.1 (1.1)	6.3 (1.1)	**0.11**	**0.007**	**10.0 (1.8, 19.0)**	**0.02**
Q9 Participation in medical rounds	254 (4)	299 (2)	6 (5–7)	6 (5–7)	5.7 (1.5)	5.9 (1.5)	0.05	0.24	1.6 (-1.9, 5.0)	0.40
Total (average of all questions)	2271 (51)	2682 (27)	7 (6–7)	7 (6–7)	6.1 (1.3)	6.3 (1.2)	**0.07**	**<0.001**	**7.5 (4.0, 11.0)**	**<0.001**

[a] Using the Wilcoxon rank sum test.

[b] Box-cox transformation was adopted for the dependent variables and β was calculated with the transformed variables. The model for the parents adjusted for infants' birth weight, parents' native language (Estonian/Russian vs. others), the care level (level II vs. III/IV) and the fidelity rate of NICU (high vs. low).

95% CI, 95% confidence interval; IQR, interquartile range; NICU, neonatal intensive care unit; SD, standard deviation.

5.1.2 Characteristics and outcomes for neonatal health care team (Study I)

The neonatal health care team gave a total of 7,448 and 6,717 responses before and after the intervention, respectively. The number of responses from each NICU was comparable before and after the intervention, except for NICU A and D, where fewer responses were given after than before (A 47.6%; D 57.0%). The responses were given equally to all questions (Table 7).

Table 7. The number of responses from neonatal health care teams per NICU and per question before and after the intervention in the Estonian Study (I).

n (%)	Before (n=7,448)	After (n=6,717)	After/before
NICU			
A	500 (6.7)	238 (3.5)	47.6%
B	2,762 (37.1)	2,611 (38.9)	94.5%
C	770 (10.3)	910 (13.5)	118.2%
D	1,032 (13.9)	588 (8.8)	57.0%
E	976 (13.1)	1,164 (17.3)	119.1%
F	1,408 (18.9)	1,206 (18.0)	85.7%
Question			
Q1 Active listening	849 (11.4)	743 (11.1)	87.5%
Q2 Participation in care	843 (11.3)	741 (11.0)	87.9%
Q3 Individualized guidance	828 (11.1)	746 (11.1)	90.1%
Q4 Shared decision making	833 (11.2)	741 (11.0)	89.0%
Q5 Mutual trust (parents→staff)	822 (11.0)	732 (10.9)	89.1%
Q6 Mutual trust (staff→parents)	829 (11.1)	723 (10.8)	87.2%
Q7 Individualized information	809 (10.9)	748 (11.1)	92.5%
Q8 Emotional support	843 (11.3)	739 (11.0)	87.7%
Q9 Participation in medical rounds	792 (10.6)	804 (12.0)	101.5%

NICU, neonatal intensive care unit.

The proportion of good ratings (six or seven) by the neonatal health care teams increased after the intervention in all questions (Figure 7). The average score of all questions rated by the neonatal health care teams increased significantly after the intervention: r=0.10; P<0.001. However, the median did not change due to high baseline ratings: before 6 [IQR 5 to 7] and after 6 [6 to 7] (Table 8). The ratings significantly improved after the intervention in eight out of nine questions: Q2 parent participation in infant care, Q3 individualized parent guidance, Q4 shared decision-making, Q5 the parent's trust in staff, Q6 the staff's trust in parents, Q7 individual

information sharing, Q8 emotional support, and Q9 participation in medical rounds. The same items remained significant in the linear regression models. The linear regression models showed significant improvements after the intervention in the same items.

Figure 7. The proportions of good ratings (6 or 7) by the neonatal health care team for each of the items of family-centered care practice before and after the intervention in the Estonian Study (I). The 0 responses were excluded. * marks the questions with a significant improvement between before- and after-intervention groups based on the linear regression models.

Table 8. Comparison of the neonatal health care team's ratings of family-centered care practices before and after the Close Collaboration with Parents intervention in the Estonian Study (I).

	Number of responses		Median (IQR)		Mean (SD)		After vs. before [a]		Linear regression model [b]	
	Before	After	Before	After	Before	After	*r* (effect size)	*P*	*β* (95% CI) [b]	*P*
Neonatal health care team										
Q1 Active listening	849	743	6 (5–7)	6 (6–7)	6.0 (1.2)	6.0 (1.2)	0.04	0.12	0.3 (-1.3, 2.0)	0.70
Q2 Participation in care	843	741	6 (5–7)	7 (6–7)	6.0 (1.4)	6.3 (1.1)	**0.11**	**<0.001**	**8.2 (3.7, 13.0)**	**<0.001**
Q3 Individualized guidance	828	746	6 (5–7)	6 (5–7)	5.7 (1.3)	5.9 (1.3)	**0.12**	**<0.001**	**2.6 (1.1, 4.0)**	**<0.001**
Q4 Shared decision-making	833	741	6 (5–7)	6 (6–7)	5.7 (1.4)	6.0 (1.2)	**0.12**	**<0.001**	**3.4 (1.7, 5.2)**	**<0.001**
Q5 Mutual trust (parents→staff)	822	732	6 (6–7)	7 (6–7)	6.0 (1.2)	6.2 (1.2)	**0.08**	**0.002**	**3.5 (0.6, 6.5)**	**0.02**
Q6 Mutual trust (staff→parents)	829	723	6 (5–7)	7 (6–7)	6.0 (1.3)	6.2 (1.2)	**0.10**	**<0.001**	**5.4 (1.9, 9.0)**	**0.003**
Q7 Individualized information	809	748	6 (5–7)	6 (6–7)	5.6 (1.3)	6.0 (1.2)	**0.15**	**<0.001**	**3.1 (1.9, 4.2)**	**<0.001**
Q8 Emotional support	843	739	6 (5–7)	6 (5–7)	5.6 (1.3)	5.9 (1.2)	**0.10**	**<0.001**	**1.6 (0.7, 2.5)**	**<0.001**
Q9 Participation in medical rounds	792	804	6 (4–6)	6 (5–7)	5.2 (1.7)	5.6 (1.8)	**0.15**	**<0.001**	**3.8 (2.3, 5.3)**	**<0.001**
Total (average of all questions)	7448	6717	6 (5–7)	6 (6–7)	5.7 (1.4)	6.0 (1.3)	**0.10**	**<0.001**	**3.3 (2.6, 3.9)**	**<0.001**

[a] Using the Wilcoxon rank sum test.

[b] Box-cox transformation was adopted for the dependent variables and β was calculated with the transformed variables. The model for the neonatal health care team adjusted for the care level (level II vs. III/IV) and the fidelity rate of NICU (high vs. low).

95% CI, 95% confidence interval; IQR, interquartile range; NICU, neonatal intensive care unit; SD, standard deviation.

5.1.3 Implementation fidelity and family-centered care practices (Study I)

We evaluated the association between implementation fidelity and the change in family-centered care ratings using linear regression models. The NICUs with high fidelity, as opposed to low fidelity, showed significantly greater improvement in the level of family-centered care practices rated by the neonatal health care teams after the intervention: β=2.1 (95% CI, 0.8 to 3.4) and P=0.002. In addition, the neonatal health care staff in Level II NICUs gave better family-centered care ratings than those in Level III/IV NICUs: β=8.6 (95% CI, 9.6 to 7.6) and P<0.001. On the other hand, there was no association between the fidelity rate and the change in the level of family-centered care practices rated by the parents: β=2.6 (95% CI, -4.5 to 9.8) and P=0.47. In the model, the parents in Level II NICUs gave better family-centered care ratings than those in Level III/IV NICUs: β=26.0 (95% CI, 32.0 to 20.0) and P<0.001. The infants' gestational age and the parents' fluency in Estonian and/or Russian did not have any significant effect on the model (Table 9).

Table 9. Impact of implementation fidelity of NICUs and the other factors on overall family-centered care ratings by the parents and neonatal health care team in the linear regression models in the Estonian Study (I).

	Parents [a]		**NICU health care team** [a]	
	β (95% CI)	*P*	*β* (95% CI)	*P*
After-intervention (vs before)	**5.9 (0.4, 11.0)**	**0.04**	**2.3 (1.4, 3.2)**	**<0.001**
High fidelity NICU (vs low)	1.5 (-4.0, 7.1)	0.59	**1.7 (0.8, 2.7)**	**<0.001**
After-intervention (vs before) * High fidelity NICU (vs low) [b]	2.7 (-4.4, 9.8)	0.46	**2.1 (0.8, 3.4)**	**0.002**
Level II NICU (vs III/IV)	**26.0 (20.0, 32.0)**	**<0.001**	**8.6 (9.6, 7.6)**	**<0.001**
Birth weight	0.00 (0.00, 0.00)	0.67	NA	NA
Native language of Estonian and/or Russian (vs no)	-5.2 (-15.0, 4.4)	0.29	NA	NA

[a] Box-cox transformation via the Shapiro-Wilk W statistic was adopted for the dependent variables and β was calculated with the transformed variables.

[b] Interaction between intervention (before-after) and fidelity (high-low). This evaluated the association between fidelity rate and the change in the family-centered care ratings before and after the introduction.

95% CI, 95% confidence interval; NICU, neonatal intensive care unit.

5.2 Register Study (II)

There were 18,107 preterm infants who were born before 35 weeks of gestation in 2006–2020 in Finland (Figure 8). Of those, 2,645 infants were excluded due to death during hospitalization in NICUs (n=729), missing discharge data (n=1,489), length

of stay of 0 days (n=171), discharge before 32 weeks PMA (n=126), or discharged after 50 weeks PMA (n=130, excluded as outliers). The infants were also excluded if they were cared for in the NICU while the intervention was being implemented (n=1,222). The infants were classified into three groups according to their exposure to the intervention: the Full-CC group (n=2,104), Partial-CC group (n=515), and the Control group (n=11,621).

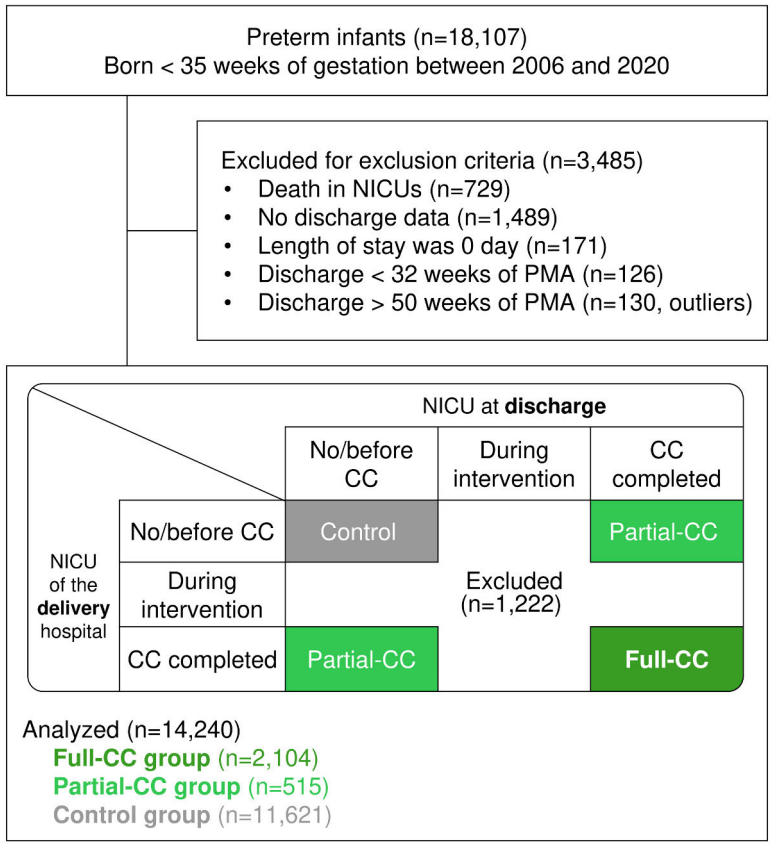

Figure 8. Patient flow diagram and patient grouping in the Register Study (II).

Table 10 summarizes the demographics of the eligible infants. The demographic information was comparable between the three groups, except for a lower gestational age, a smaller birth weight, and a higher rate of Cesarean delivery in the Partial-CC group compared to the Control group.

Table 10. Demographics of the study patients in each study group in the Register Study (II).

	Full-CC (*n*=2,104)	**Partial-CC** (*n*=515)	**Control** (*n*=11,621)
Gestational age, wk, mean (SD)	32.4 (2.5)	31.1 (2.8) [a]	32.4 (2.5)
Birth weight, g, mean (SD)	1914 (631.3) [a]	1631 (598.9) [a]	1874 (587.5)
Birth weight z-score, mean (SD)	0.09 (1.00) [a]	−0.00 (0.99)	−0.00 (0.96)
Male sex, *n* (%)	1173 (55.8)	277 (53.8)	6329 (54.5)
Singleton, *n* (%)	1583 (75.2) [a]	361 (70.1)	8200 (70.6)
Antenatal corticosteroid, *n* (%)	1601 (98.1)	459 (99.6)	7785 (98.1)
Cesarean delivery, *n* (%)	1178 (56.0)	344 (66.8) [a]	6299 (54.2)

[a] *P*-value of comparison with the Control group was <.05 after Bonferroni correction.
SD, standard deviation.
Adapted from Study (II) of this thesis: Itoshima R, Helenius K, Ahlqvist-Björkroth S, Vahlberg T, Lehtonen L. Close Collaboration with Parents Affects the Length of Stay and Growth in Preterm Infants: A Register-Based Study in Finland. *Neonatology*, 2024;121:351-35.

5.2.1 Primary outcome (Study II)

Table 11 summarizes the primary and secondary outcomes of this study. The mean length of stay was 22.9 days (95% CI, 22.1 to 23.8) in the Full-CC group, 35.6 days (33.4 to 37.9) in the Partial-CC group, and 22.3 days (21.9 to 22.6) in the Control group. The adjusted geometric mean length of stay was shorter in the Full-CC group than in the Control group by 1.8 days or 6%: geometric mean ratio 0.94 [95% CI 0.89 to 1.00] and *P*=0.041. No significant difference was found between the Partial-CC and Control groups.

Table 11. Length of stay, growth, and later hospital visits/rehospitalizations in preterm infants compared between the Full-CC, Partial-CC, and Control groups in the Register Study (II).

	Full-CC (*n*=2,104)	Partial-CC (*n*=515)	Control (*n*=11,621)	Full-CC vs. Control	*P*	Partial-CC vs. Control	*P*
	Mean (95%CI) or *n* (%)						
Primary Outcome							
Length of stay, days							
Unadjusted	22.9 (22.1, 23.8)	35.6 (33.4, 37.9)	22.3 (21.9, 22.6)	1.03 (0.98, 1.08) [a]	.54	**1.60 (1.45, 1.76)** [a]	**<.001**
Adjusted	30.1 (27.5, 32.9)	30.9 (28.1, 34.1)	31.9 (29.4, 34.6)	**0.94 (0.89, 1.00)** [a]	**.041**	0.97 (0.89, 1.05) [a]	1.00
Secondary Outcomes							
Δ Weight z-score [b]							
Unadjusted	−0.71 (−0.78, −0.65)	−0.89 (−1.00, −0.77)	−0.83 (−0.86, −0.81)	**0.12 (0.04, 0.20)** [c]	**.001**	−0.06 (−0.18, 0.07) [c]	.86
Adjusted	−0.85 (−0.99, −0.71)	−0.91 (−1.06, −0.76)	−0.89 (−1.00, −0.78)	0.04 (−0.09, 0.17) [c]	1.00	−0.02 (−0.17, 0.13) [c]	1.00
Δ Weight, g/week [b]							
Unadjusted	172.7 (168.1, 177.4)	158.9 (151.5, 166.3)	160.6 (158.7, 162.6)	**12.1 (5.9, 18.3)** [c]	**<.001**	−1.8 (−11.1, 7.6) [c]	1.00
Adjusted	169.2 (157.0, 181.4)	154.9 (141.8, 168.0)	157.5 (147.3, 167.7)	**11.7 (1.4, 22.0)** [c]	**.020**	−2.6 (−14.8, 9.5) [c]	1.00
Δ Length, mm/week [b]							
Unadjusted	9.7 (9.4, 10.0)	9.5 (9.0, 10.0)	9.1 (9.0, 9.2)	**0.6 (0.2, 1.1)** [c]	**.001**	0.5 (−0.1, 1.1) [c]	.21
Adjusted	10.1 (9.3, 10.8)	9.2 (8.4, 10.0)	8.8 (8.2, 9.4)	**1.3 (0.6, 2.0)** [c]	**<.001**	0.4 (−0.4, 1.3) [c]	.57
Δ Head circumference, mm/week [b]							
Unadjusted	8.3 (8.1, 8.6)	8.1 (7.8, 8.5)	8.4 (8.3, 8.5)	−0.1 (−0.4, 0.3) [c]	1.00	−0.2 (−0.7, 0.3) [c]	.83
Adjusted	8.1 (7.5, 8.8)	7.6 (6.9, 8.3)	7.7 (7.1, 8.3)	0.4 (−0.1, 1.0) [c]	.15	−0.1 (−0.8, 0.5) [c]	1.00

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	Full-CC (*n*=2,104)	Partial-CC (*n*=515)	Control (*n*=11,621)	Full-CC vs. Control	*P*	Partial-CC vs. Control	*P*
	Mean (95%CI) or *n* (%)						
Unscheduled outpatient visit to 1 year of age							
Unadjusted	875 (41.6)	188 (36.5)	4868 (41.9)	0.98 (0.89, 1.07) [d]	.59	**0.78 (0.65, 0.94) [d]**	**.009**
Adjusted	–	–	–	**0.81 (0.67, 0.98) [d]**	**.031**	1.20 (0.93, 1.56) [d]	.16
Rehospitalization to 1 year of age							
Unadjusted	353 (16.8)	79 (15.3)	2733 (23.5)	**0.65 (0.57, 0.73) [d]**	**<.001**	**0.57 (0.45, 0.73) [d]**	**<.001**
Adjusted	–	–	–	0.97 (0.78, 1.21) [d]	.77	1.35 (1.00, 1.84) [d]	.052

Eligible preterm infants were classified into three groups according to the NICU of the delivery and discharge hospital: the Full Close Collaboration group (Full-CC group) if the infant had been cared for in a NICU(s) which had completed the Close Collaboration with Parents intervention, the Partial-CC group if the infants had been cared for in one NICU which had completed the intervention and the other which had not started the intervention yet, and the Control group if the infants had been cared for in a NICU(s) without the intervention. Adjusted for the exposure to one or more doses of antenatal corticosteroid, mode of delivery, year of birth, gestational age at birth, birth weight z-score, sex, multiple births, and single-family NICU rooms (yes/no).

[a] Geometric mean ratio (95% CI), the dependent variable was analyzed after natural logarithm transformation. Means are estimated marginal means from the models and are presented as geometric means. A linear mixed model with the random intercepts for the NICU of the delivery hospital and the NICU at discharge. Bonferroni correction was used in pairwise comparisons.

[b] Change in each parameter from birth to discharge or 42 weeks of postmenstrual age. A linear mixed model with the random intercepts for the NICU of the delivery hospital and the NICU at discharge. Means are estimated marginal means from the models.

[c] Mean difference (95% CI). Bonferroni correction was used in pairwise comparisons.

[d] Odds ratio (95% CI). Mixed effects logistic regression model with the random intercepts for the NICU of the delivery and discharge hospital.

95% CI, 95% confidence interval; CC, Close Collaboration with Parents intervention.

Adapted from Study (II) of this thesis: Itoshima R, Helenius K, Ahlqvist-Björkroth S, Vahlberg T, Lehtonen L. Close Collaboration with Parents Affects the Length of Stay and Growth in Preterm Infants: A Register-Based Study in Finland. *Neonatology*, 2024;121:351-35.

5.2.2 Secondary outcomes (Study II)

The weight z-score decreased in all groups from birth to discharge. The decrease in weight z-score was significantly smaller in the Full-CC group than in the Control group in the unadjusted model, whose significance disappeared in the adjusted model (Table 11). The increase in weight and length from birth to discharge was more rapid in the Full-CC group than in the Control group: the adjusted mean difference was 11.7 g per week (95% CI, 1.4 to 22.0; P=0.020) in weight and 1.3 mm per week (0.6 to 2.0; P<0.001) in length. No significant difference was found in the increase in head circumference. There were no differences in increase in any growth parameters between the Partial-CC and Control group.

The proportion of infants who required at least one unscheduled outpatient visit after discharge, up to one year of age, was 41.6% in the Full-CC, 36.5% in the Partial-CC, and 41.9% in the Control group. The adjusted odds of requiring at least one unscheduled outpatient visit were significantly lower in the Full-CC group than in the Control group (adjusted odds ratio 0.81 [95% CI 0.67 to 0.98]; P=0.031). There was no difference between the Partial-CC and Control group.

The proportion of infants who required at least one rehospitalization after discharge, up to one year of age, was 16.8% in the Full-CC, 15.3% in the Partial-CC, and 23.5% in the Control group. In the unadjusted model, the odds of requiring at least one rehospitalization were significantly lower in the Full-CC group than in the Control group (odds ratio 0.65 [95% CI 0.57 to 0.73]; P<0.001). However, the significance disappeared in the adjusted model. There was no difference between the Partial-CC and Control group.

5.3 Discharge Criteria Study (III)

A total of 73 preterm infants were born at 28 to 31 weeks of gestation and discharged home in 2020–2021 from the NICUs in Japan (n=23) and in Finland (n=50). Fewer eligible infants in the NICU in Japan can be explained by the smaller population they cover than that of the NICU in Finland. Two infants were excluded due to exclusion criteria: due to a need for home oxygen therapy in Japan and due to a need for a gastrostomy in Finland. The final analyses included 22 infants in the NICU in Japan and 49 in the NICU in Finland. Table 12 summarizes the characteristics of the infants. The characteristics were comparable between the two countries, except that there were fewer males (36% vs. 61%) and more singleton infants (55% vs. 33%) in the NICU in Japan than in Finland. The severe neonatal morbidities and rehospitalizations up to 6 months of corrected age were comparable between the countries (Table 12).

Table 12. Characteristics of infants and mothers and neonatal morbidities in the Discharge Criteria Study (III).

	Japan (n=22)	Finland (n=49)
Infant		
Gestational age, mean (SD), weeks	30.1 (1.0)	30.2 (1.2)
Birth weight, mean (SD)	1220 (306)	1351 (328)
Small for gestational age [a], n (%)	6 (27)	15 (31)
Male sex, n (%)	8 (36)	30 (61)
Apgar score < 7 at 5 min., n (%)	4 (18)	6 (13)
Neonatal morbidities		
Severe bronchopulmonary dysplasia, n (%)	0 (0)	1 (2)
Patent ductus arteriosus operation, n (%)	0 (0)	1 (2)
Abdominal operation, n (%)	0 (0)	1 (2)
Severe brain damage [b], n (%)	2 (9)	3 (6)
Sepsis, n (%)	0 (0)	4 (8)
Treatment for retinopathy of prematurity, n (%)	0 (0)	4 (8)
Any rehospitalization up to 6 months of corrected age, n (%)	2 (9)	8 (16)
Mother		
Age, mean (SD), years old	29.1 (4.5)	31.4 (4.8)
Age < 20 years of, n (%)	0 (0)	1 (2)
Singleton, n (%)	12 (55)	16 (33)
Antenatal steroid, n (%)	13 (59)	31 (63)
Outborn, n (%)	2 (9)	1 (2)
Cesarean delivery, n (%)	17 (77)	37 (76)
Primipara, n (%)	17 (77)	36 (73)
Fluent in official languages, n (%)	22 (100)	43 (88)
Distance between hospital and home, mean (SD), km	27.4 (18.1)	21.5 (26.6)

[a] Whose birth weight z-score below 10 percentile.
[b] Grade 3 or 4 intraventricular hemorrhage or cystic periventricular leukomalacia.
SD, standard deviation.

5.3.1 Primary outcomes (Study III)

The most common last discharge criteria in the NICUs in Japan and Finland are summarized in Table 13. In Japan, the "family criterion" (n=19; 86%) was the most common last discharge criterion, followed by the "feeding criterion" (n=2; 9%) and the "weight criterion" (n=1; 5%). In Finland, "respiration criterion" (n=43; 88%) was the most common, followed by the "family criterion" (n=5; 10%) and the "temperature criterion" (n=1; 2%). In Finland, the "family criterion" could be determined for only four infants. The details of their "family criterion" included

infants waiting for their twin or triplet siblings to be ready, and an infant waiting for the recovery of the mother.

Table 13. The last discharge criterion before discharge in each infant in the Discharge Criteria Study (III).

Discharge criterion **n (%)**	**Japan (n=22)**	**Finland (n=49)**
Temperature	0 (0)	1 (2)
Respiration	0 (0)	**43 (88)**
Feeding	2 (9)	Not used
Examination	0 (0)	Not used
Weight	1 (5)	Not used
Family	**19 (86)**	5 (10)

Figure 9 illustrates how much each discharge criterion contributed to the hospital stay of each infant. The contribution of each discharge criterion was different in Japan and Finland. In the NICU in Finland, the temperature and respiration criteria (gray area) were dominant. On the other hand, other infant criteria and the "family criterion" (colored area) were dominant in the NICU in Japan. The potential extending effect of each discharge criterion on the length of stay was calculated (Table 14). In the NICU in Japan, the length of stay of preterm infants was extended by 7.9 days (SD 7.0) due to the delay in the parents' readiness for discharge ("family criterion") and by 8.7 days (SD 8.7) to wait for a feeding tube to be removed ("feeding criterion"). The effect of the "examination" and "weight" criteria was small in Japan. The effect of the "family criterion" was small in the NICU in Finland compared to Japan.

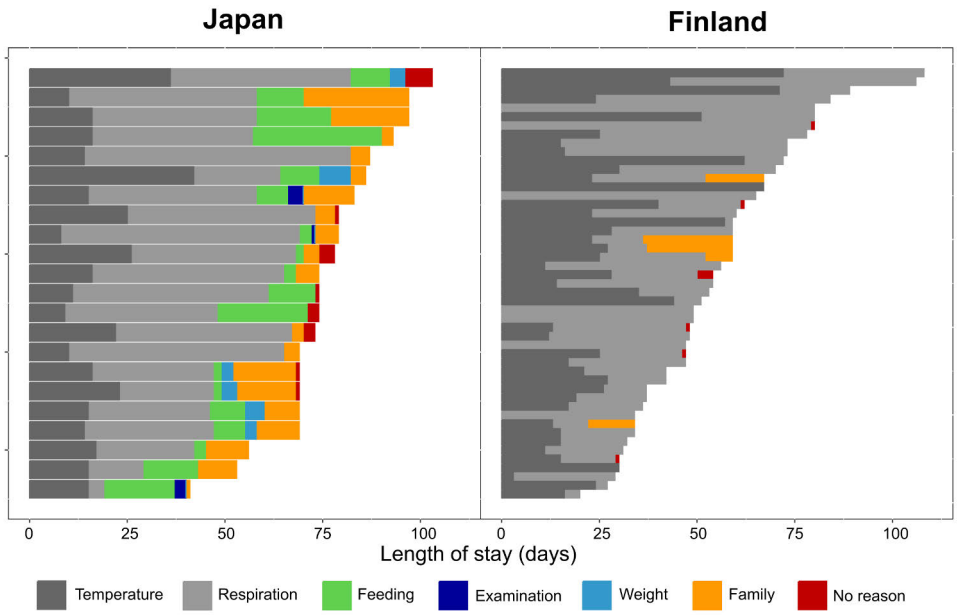


Figure 9. The contribution of each discharge criterion to the hospital stay length of each infant participating in the Discharge Criteria Study (III). Adapted from Study (III) of this thesis: Itoshima R, Ojasalo V, Lehtonen L. Impact of discharge criteria on the length of stay in preterm infants: A retrospective study in Japan and Finland. *Early Hum Dev*, 2024;193:10601.

Table 14. Potential extending effect of each discharge criterion on the length of stay in the Discharge Criteria Study (III).

Mean (SD), days	Japan (n=22)	Finland (n=49)
Feeding	**8.7 (8.7)**	NA
Examination	0.4 (1.0)	NA
Weight	1.2 (2.2)	NA
Family	**7.9 (7.0)**	1.6 (5.2)
No reason	1.0 (1.8)	0.2 (0.6)

SD, standard deviation.

5.3.2 Secondary outcome (Study III)

Figure 10 illustrates the PMA at discharge and at the time when each discharge criterion was met. Preterm infants were discharged home significantly earlier in the NICU in Finland than in Japan. The median PMA at discharge was 40.7 weeks (IQR, 39.9 to 41.3) in Japan and 37.9 weeks (36.9 to 39.0) in Finland (r=0.58; P<0.001). Preterm infants met the "temperature criterion" significantly earlier in the NICU in

Japan than in Finland: the median PMA was 32.7 weeks (IQR 31.7 to 33.8) in Japan and 33.9 weeks (33.3 to 34.8) in Finland (r=0.41; P=0.001). There was no difference in the PMA for the "respiration criterion" between the two NICUs (median 37.9 vs. 37.0 weeks; r=0.18; P=0.13). In the NICU in Japan, the median PMA for the "family criterion" was 40.6 weeks (IQR 39.5 to 41.5). In most cases in Finland, we could not determine the exact date when the "family criterion" was met because the parents were usually ready for discharge before the infant achieved stability. The PMA for the other discharge criteria that were used only in Japan were as follows: 38.6 weeks (IQR 37.9 to 39.7) for the "feeding criterion," 38.3 weeks (37.6 to 39.2) for the "examination criterion," and 36.8 weeks (35.8 to 38.4) for the "weight criterion."

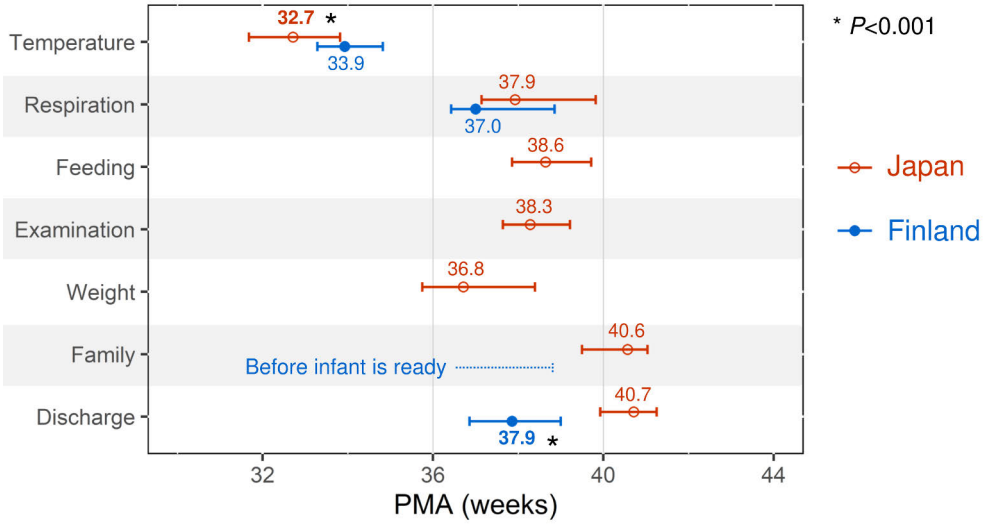


Figure 10. The postmenstrual age (median and interquartile range, weeks) at the time when each discharge criterion was met in the Discharge Criteria Study (III).

5.4 Couplet Care Study (IV)

Out of 67 and 92 families of preterm infants born at the study site, 54 and 84 families were approached and 30 (56% of those approached) and 64 (76%) families participated in the before and after group, respectively. After excluding three infants who had died and three infants whose parents withdrew their consent, the final analyses included 40 infants (100% of those who agreed) from 30 families in the before and 66 infants (91%) from 58 families in the after group (Figure 11).

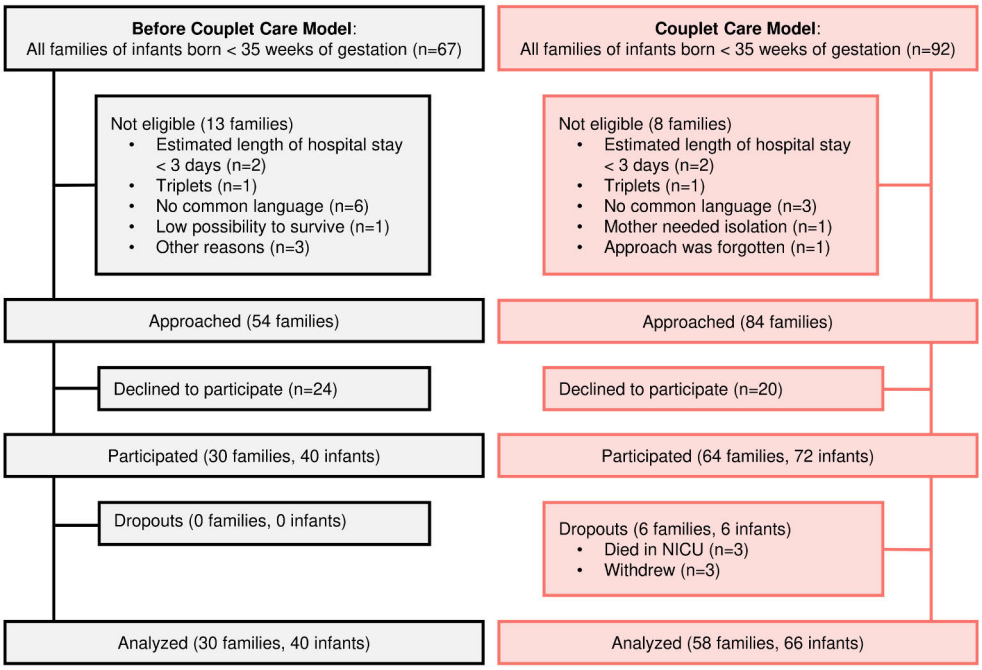


Figure 11. Patient flow chart describing the enrollment process before and after the introduction of the Couplet Care Model in the Couplet Care Study (IV).

Table 15 summarizes the characteristics of the participating parents and their infants in each study group. The ranges of gestational age of included preterm infants were between 23+0 and 34+5 weeks and between 23+2 and 34+6 weeks in the before and after groups, respectively. More preterm infants in the after group were singletons than before (before 47.5% vs. after 75.4%). In addition, parents in the group after the introduction lived further from the hospital than before (median 12.0 km vs. 30.0 km). The other characteristics were comparable between the two groups.

Table 15. Characteristics of the infants and parents in the Couplet Care Study (IV).

	Before Couplet Care	Couplet Care Model
Infant	(n=40)	(n=66)
Gestational age, median (IQR), weeks	32.0 (29.3−33.9)	31.9 (28.5−34.0)
< 32 weeks of gestation, n (%)	6 (15.0)	15 (22.7)
Birth weight, median (IQR), g	1560 (1269−2008)	1560 (1220−2051)
< 1500 g, n (%)	6 (15.0)	11 (16.7)
Male sex, n (%)	20 (50.0)	34 (51.5)
Cesarean delivery, n (%)	29 (72.5)	42 (63.6)
Singleton, n (%)	19 (47.5)	49 (75.4)
Mother	(n=30)	(n=58)
Single parent, n (%)	2 (6.7)	2 (3.5)
First child, n (%)	14 (58.3)	18 (46.1)
Distance between home and hospital, median (IQR), km	12.0 (5.0−64.0)	30.0 (9.6−74.0)
Age, median (IQR), years	33 (29−36)	32 (29−35)
Higher education [a], n (%)	21 (75.0)	39 (68.4)
At paid work, n (%)	22 (78.6)	51 (87.9)
Smoker, n (%)	1 (3.3)	1 (1.7)
Father	(n=28)	(n=55)
Age, median (IQR), years	33 (30−36)	35 (31−39)
Higher education [a], n (%)	14 (53.8)	28 (57.1)
At paid work, n (%)	25 (92.6)	50 (90.9)
Smoker, n (%)	3 (11.1)	5 (9.4)

Bachelor's degree or higher.
IQR, interquartile range; NICU, neonatal intensive care unit.

5.4.1 Primary outcomes (Study IV)

The infants' first skin-to-skin contact was initiated at a median [IQR] of 4.0 [0.4 to 24.0] postpartum hours in the after group, while it was 24.0 [17.5 to 52.0] postpartum hours in the before group. The preterm infants received their first skin-to-skin contact significantly sooner in the after group (Z=0.33, P<0.001). The linear regression model also showed a significant difference: mean difference -18.5 [95% CI -34.8 to -2.1] and P=0.03 (Table 16). The mothers' first skin-to-skin contact was initiated at a median of 13.5 [IQR 0.1 to 24.0] postpartum hours in the after group, while was 24.0 [16.3 to 72.0] postpartum hours in the before group. The difference was significant in the Wilcoxon rank sum test (Z=0.29, P<0.04), but the significance disappeared in the linear regression model. The fathers' first skin-to-skin contact was

initiated at a median of 7.0 [IQR 1.0 to 48.0] postpartum hours in the after group, while the median was 48.0 [24.0 to 63.0] postpartum hours in the before group. The difference was significant in the linear regression model: mean difference -25.9 (95% CI -51.2 to -0.6) and P=0.04.

Furthermore, the proportion of preterm infants who received the first skin-to-skin contact within two hours after birth was 8.6% in the before group, which increased to 45.5% after (Table 16). The difference was significant in the logistic regression model: odds ratio 8.7 (95% CI 2.4 to 48.9) and P<0.001. The first skin-to-skin contact within two hours after birth was achieved in 11.5% in the before group and 32.8% in the after group among the mothers; and 4.8% in the before group and 35.2% in the after group among the fathers. These differences were significant in the linear regression models. The infants' skin-to-skin contact was conducted with the fathers in 23.8% of cases before the introduction and 30.4% after. However, the difference was not significant in the linear regression model.

The kernel density estimation illustrated in Figure 12 describes that the probability of the first parent-infant skin-to-skin contact reached its maximum at about 24 postpartum hours in the before group, and at about two postpartum hours in the after group.

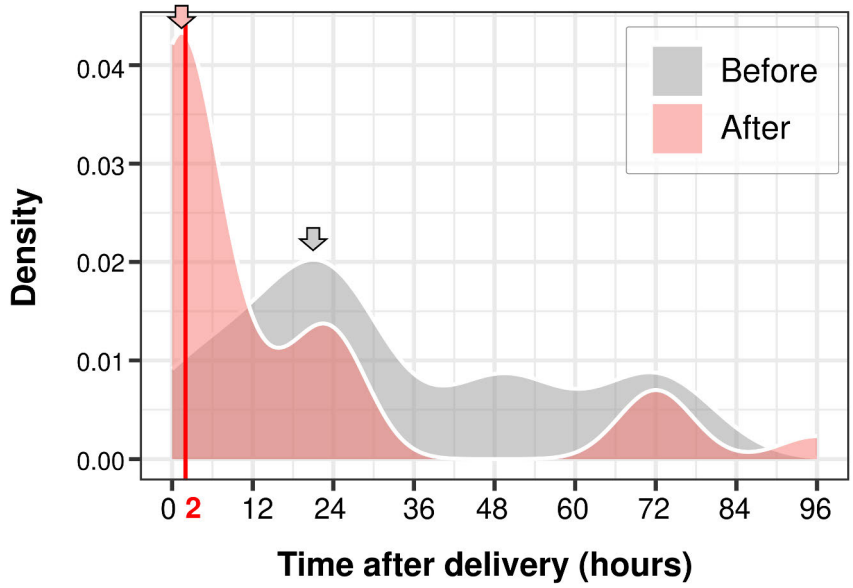


Figure 12. Change in probability of the first skin-to-skin contact over time from birth, using kernel density estimation before and after the introduction of the Couplet Care Model in the Couplet Care Study (IV). The probability reached its maximum at about 24 hours after birth before the Couplet Care Model was introduced (grey area and arrow) and was shortened to about two hours after the introduction (red area and arrow).

Table 16. Comparison of the first skin-to-skin contact before and after the introduction of the Couplet Care Model in the Couplet Care Study (IV).

	Before Couplet Care Model	Couplet Care Model	Z [a] or OR (95% CI)	P value	Linear/Logistic regression model	
					MD or OR (95% CI)	P value
First skin-to-skin contact after birth, median (IQR), hours						
Either parent	24.0 (17.5, 52.0)	4.0 (0.4, 24.0)	**0.33**	**<0.001**	**-18.5 (-34.8, -2.1)** [b]	**0.03**
Mothers	24.0 (16.3, 72.0)	13.5 (0.1, 24.0)	**0.29**	**0.04**	-16.7 (-35.9, 2.4) [b]	0.09
Fathers	48.0 (24.0, 63.0)	7.0 (1.0, 48.0)	**0.29**	**0.01**	**-25.9 (-51.2, -0.6)** [b]	**0.04**
First skin-to-skin contact initiated ≤ 2 hours after birth, n (%)						
Either parent	3 (8.6)	30 (45.5)	**8.7 (2.4, 48.9)**	**<0.001**	**13.8 (3.6, 62.8)** [c]	**<0.001**
Mothers	3 (11.5)	19 (32.8)	3.7 (0.9, 21.5)	0.06	**5.5 (1.4, 29.9)** [c]	**0.03**
Fathers	1 (4.8)	19 (35.2)	**10.6 (1.5, 472.2)**	**0.007**	**19.3 (2.9, 413.7)** [c]	**0.01**
First skin-to-skin contact						
With fathers, n (%)	5 (23.8)	17 (30.4)	1.4 (0.4, 5.6)	0.78	1.6 (0.5, 5.9) [c]	0.68

[a] Effect size of the Wilcoxon rank sum test.
[b] MD (95% CI) of the linear regression model adjusting for gestational age and plurality.
[c] OR (95% CI) of the logistic regression model adjusting for gestational age and plurality.
95% CI, 95% confidence interval; IQR, interquartile range; MD, mean difference; OR, odds ratio.

5.4.2 Secondary outcomes (Study IV)

The time preterm infants spent with at least one parent increased from a mean ± SD of 10.8 ± 4.4 hours per day to 21.2 ± 2.8 hours after the introduction of the Couplet Care Model (Table 17). The difference was significant in the linear regression model: mean difference 10.8 (95% CI 9.1 to 12.4) and $P<0.001$. The duration of the parents' presence in the NICU room also increased significantly from a mean of 9.8 ± 3.9 hours per day to 20.5 ± 2.9 hours for the mothers and from 5.7 ± 3.6 hours to 11.5 ± 6.9 hours for the fathers after the introduction.

The frequency of at least one parent staying overnight in the NICU room increased from a mean ± SD of 1.7 ± 2.3 nights per week to 6.4 ± 1.1 nights after the introduction of the model (Table 17). The difference was significant in the linear regression model: mean difference 4.8 (95% CI 3.9 to 5.6) and $P<0.001$. The frequency of the parents' overnight stays in the NICU room also increased significantly from 1.3 ± 2.0 nights to 6.3 ± 1.1 nights for the mothers and from 0.4 ± 0.8 nights to 3.3 ± 2.8 nights for the fathers after the introduction.

The duration of parent-infant skin-to-skin contact did not change significantly: a mean ± SD of 2.7 ± 2.0 hours per day before and 3.2 ± 2.1 hours after the introduction of the model from the infants' perspective; 2.1 ± 1.4 hours per day before and 2.1 ± 1.4 hours after from the mothers' perspective; 1.3 ± 1.1 hours per day before and 1.2 ± 1.4 hours after from the fathers' perspective, respectively (Table 17). The duration of holding did not change significantly either.

Table 17. Comparison of the parents' presence, skin-to-skin contact, holding and overnight stay before and after the introduction of the Coupet Care Model in the Couplet Care Study (IV).

	Before Couplet Care Model	Couplet Care Model	Cohen's d [a]	P value	Linear regression model [b]	
					MD (95% CI)	P value
Presence, mean (SD), hours/day						
Either parent	10.8 (4.4)	21.2 (2.8)	**2.8**	**<0.001**	**10.8 (9.1, 12.4)**	**<0.001**
Mothers	9.8 (3.9)	20.5 (2.9)	**3.1**	**<0.001**	**10.7 (9.1, 12.4)**	**<0.001**
Fathers	5.7 (3.6)	11.5 (6.9)	**1.1**	**<0.001**	**7.7 (4.7, 10.7)**	**<0.001**
Overnight stay, mean (SD), nights/week						
Either parent	1.7 (2.3)	6.4 (1.1)	**2.6**	**<0.001**	**4.8 (3.9, 5.6)**	**<0.001**
Mothers	1.3 (2.0)	6.3 (1.1)	**2.8**	**<0.001**	**4.8 (4.0, 5.6)**	**<0.001**
Fathers	0.4 (0.8)	3.3 (2.8)	**1.5**	**<0.001**	**3.6 (2.4, 4.7)**	**<0.001**
Skin-to-skin contact, mean (SD), hours/day						
Either parent	2.7 (2.0)	3.2 (2.1)	0.2	0.29	0.9 (-0.2, 2.1)	0.11
Mothers	2.1 (1.4)	2.1 (1.4)	0.05	0.94	0.3 (-0.5, 1.1)	0.48
Fathers	1.3 (1.1)	1.2 (1.4)	0.1	0.61	0.2 (-0.5, 0.9)	0.56
Holding, mean (SD), hours/day						
Either parent	1.2 (1.6)	1.5 (2.2)	0.2	0.40	0.2 (-6.8, 1.0)	0.69
Mothers	1.2 (1.5)	1.3 (1.9)	0.1	0.83	-0.0 (-0.8, 0.8)	0.99
Fathers	0.3 (0.5)	0.4 (0.9)	0.1	0.51	0.3 (-0.2, 0.8)	0.20

[a] Effect size of the student t-test.

[b] The linear regression model adjusted for gestational age, plurality, parity, and distance from the hospital to home.

95% CI, 95% confidence interval; MD, mean difference; SD, standard deviation.

5.4.3 Subgroup analyses (Study IV)

The subgroup analyses included 6 (15%) and 34 (85%) infants born < 28 and ≥ 28 weeks of gestation before the introduction of the Couplet Care Model; and 15 (23%) and 51 (77%) infants born < 28 and ≥ 28 weeks of gestation after the introduction. The timing of the first parent-infant skin-to-skin contact did not change significantly in infants born < 28 weeks of gestation, from a median of 72.0 postpartum hours before and 72.0 hours after. On the other hand, among infants born ≥ 28 weeks, the first skin-to-skin contact happened significantly earlier after the introduction than before (P<0.001), from a median of 24.0 postpartum hours before and 1.0 hours after (Table 18). The proportion of infants who received the first skin-to-skin contact within 2 postpartum hours did not change in infants born < 28 weeks of gestation (20.0% before and 6.7% after), whereas it increased significantly in those born ≥ 28 weeks (6.7% before and 56.9% after, P<0.001). The duration of parents' presence increased significantly both in infants born < 28 weeks of gestation from a mean of 12.2 hours before to 19.7 hours after and in infants born ≥ 28 weeks from a mean of 10.6 hours before to 21.6 hours after. The frequency of overnight stays did not change significantly in infants born < 28 weeks of gestation (2.3 nights per week before and 5.8 after), while it increased significantly in infants born ≥ 28 weeks from 1.6 nights per week before to 6.6 after (P<0.001). The duration of parent-infant skin-to-skin contact and holding in the NICU rooms did not change significantly in both groups.

Table 18. Comparison of the timing of the first parent-infant skin-to-skin contact, parents' presence, skin-to-skin contact, holding and overnight stay before and after the introduction of the Coupet Care Model according to the infants' gestational ages at birth in the Couplet Care Study (IV).

	Before Couplet Care Model (n=40 infants)	Couplet Care Model (n=66 infants)	Z [a], OR (95% CI) or Cohen's d [b]	P value
Infants < 28 weeks of gestation	(n=6)	(n=15)		
First skin-to-skin contact after birth, median (IQR), hours	72.0 (24.0, 72.0)	72.0 (15.9, 108.0)	0.20 [a]	0.40
First skin-to-skin contact initiated ≤ 2 hours after birth, n (%)	1 (20.0)	1 (6.7)	0.3 (0.0, 28.0)	0.45
Presence, mean (SD), hours/day	12.2 (7.2)	19.7 (4.0)	**1.3** [b]	**0.049**
Overnight stay, mean (SD), nights/week	2.3 (3.6)	5.8 (1.9)	1.2 [b]	0.07
Skin-to-skin contact, mean (SD), hours/day	3.1 (2.0)	3.5 (2.3)	0.2 [b]	0.70
Holding, mean (SD), hours/day	0.1 (0.2)	0.01 (0.04)	0.9 [b]	0.18
Infants ≥ 28 weeks of gestation	(n=34)	(n=51)		
First skin-to-skin contact after birth, median (IQR), hours	24.0 (16.3, 48.0)	1.0 (0.1, 14.5)	**0.52** [a]	**<0.001**
First skin-to-skin contact initiated ≤ 2 hours after birth, n (%)	2 (6.7)	29 (56.9)	**17.8 (3.8, 170.3)**	**<0.001**
Presence, mean (SD), hours/day	10.6 (3.9)	21.6 (2.3)	**3.5** [b]	**<0.001**
Overnight stay, mean (SD), nights/week	1.6 (2.1)	6.6 (0.7)	**3.2** [b]	**<0.001**
Skin-to-skin contact, mean (SD), hours/day	2.6 (2.0)	3.1 (2.1)	0.2 [b]	0.37
Holding, mean (SD), hours/day	1.4 (1.7)	2.0 (2.3)	0.3 [b]	0.20

[a] Effect size of the Wilcoxon rank sum test.

[a] Effect size of the student t-test.

95% CI, 95% confidence interval; IQR, interquartile range; OR, odds ratio.

6 Discussion

The four clinical studies described above showed the effects of two family-centered care interventions and the possible mediators in the effects of the intervention. The family-centered care practices improved after the implementation of the Close Collaboration with Parents intervention in NICUs in Estonia. The study in Estonia (I) was the first study to precisely evaluate the implementation fidelity of the Close Collaboration with Parents intervention. Better implementation fidelity of the intervention was associated with better improvements in family-centered care provision rated by the neonatal health care teams. The effects of the Close Collaboration with Parents intervention on the outcomes for infants were first evaluated in the register study in Finland (II). The length of stay was reduced, growth in weight and length was promoted, and the likelihood of unscheduled outpatient visits after discharge was reduced in preterm infants after the intervention. In addition, the comparison study between Japan and Finland (III) showed that the parents' readiness for discharge may be one of the important mechanisms that mediate the effects of family-centered care interventions on infants, especially the reduction in the length of stay of preterm infants. The effects of the Couplet Care Model on early parent-infant closeness were first evaluated in the study in Finland (IV). The first parent-infant skin-to-skin contact started earlier, the parents stayed in the NICU room longer, and they stayed overnights in the NICU room more often after the introduction of the Couplet Care Model.

6.1 Close Collaboration with Parents intervention

In the Estonian Study (I) and the Register Study (II), we evaluated the effects of the Close Collaboration with Parents intervention. We found better family-centered care practices after the intervention as compared to the baseline, especially better communication and emotional support skills by the neonatal health care team. We also found that the intervention improved outcomes for preterm infants: it promoted the growth of preterm infants in weight and length, reduced their length of stay, and reduced their outpatient visits after discharge. The mechanisms for how the intervention could reduce the length of stay are speculated based on the results of the Discharge Criteria Study (III).

6.1.1 Implementation fidelity

The Estonian Study (I) is the first study to evaluate the implementation fidelity of the Close Collaboration with Parents intervention in detail. The effect of implementation fidelity on intervention outcomes has not been studied for any parent interventions either. This study evaluated adherence and exposure.

Our study (I) showed that high implementation fidelity was associated with better improvement in the family-centered care practices rated by the neonatal health care teams, but not by parents. This finding is consistent with previous studies on implementation fidelity reporting that high fidelity was associated with better outcomes (Abbott et al., 1998; Becker et al., 2001; Dane & Schneider, 1998; Forgatch et al., 2005; Keith et al., 2010). Thus, the evaluation of implementation fidelity is vital to correctly understand the different effects of different family-centered care interventions. On the other hand, we could not confirm the association between implementation fidelity and family-centered care practices rated by parents. High baseline ratings by parents may have resulted in that non-significant effect.

We need to understand the factors associated with low/high fidelity to achieve better outcomes in future interventions. There were several factors in this study that have potentially contributed to low fidelity. First, the mentoring team sometimes had to cancel the scheduled training due to the NICU health care staff or their children being ill due to the COVID-19 pandemic. Second, the degree of the doctors' contribution to the project may be another factor. For family-centered care interventions to succeed, we need to facilitate the doctors' contributions (Toivonen et al., 2020). In our study (I), the three NICUs with low fidelity did not have any doctors in the mentoring team, which might have decreased the doctors' involvement in the project. Third, the implementation period may not have been long enough for some NICUs to achieve high implementation fidelity. There were more NICU staff to be trained in the NICUs with low fidelity than in the other NICUs. In fact, more than half of the NICU health care staff completed the training until Phase II even in the NICUs with low fidelity, which possibly means that the training had been implemented smoothly but just needed more time. Lastly, the mentors and the trainees may have had difficulty finding parents to perform joint training sessions with in these NICUs with low fidelity. These NICUs consisted of open-bay rooms, while the other NICUs consisted of single-family rooms. NICUs with open-bay rooms compared to single-family rooms have been shown to be associated with the parents' shorter presence (van Veenendaal et al., 2020).

6.1.2 Parent support and parent-delivered care and activities

Nine questions about family-centered care practices used in the Estonian Study (I) evaluated the quality of the core components of family-centered care, including parent support and parent-delivered care and activities. The Estonian Study (I) showed that both the parents and neonatal health care team reported better family-centered care practices after the Close Collaboration with Parents intervention than before. Both parents and the neonatal health care team reported significantly better average scores of all questions.

Our results (Estonian Study [I]) were in line with three previous reports indicating that family-centered care practices in NICUs improved after the implementation of the Close Collaboration with Parents intervention (Axelin et al., 2014; Toivonen et al., 2020, 2021). The same measuring method was used in one of the previous studies (Toivonen et al., 2021) and our study. The comparison of the results of our study and the previous study is summarized in Table 19.

Ratings by parents

The parents' ratings of active listening and individual guidance improved significantly only in our study. The Close Collaboration with Parents intervention also provides training sessions for neonatal health care teams to learn active listening. The parents' experience of being listened to may function as emotional support and help to build and maintain their good relationships with the neonatal health care team (Wreesmann et al., 2021). In addition to these improvements in the ratings regarding communication between the parents and neonatal health care team, the quality of emotional support also improved in our study but not in the previous study (Table 19). Emotional support can be offered by neonatal health care teams to improve the well-being of parents and infants in NICUs (Roué et al., 2017) but is difficult to improve, along with shared decision-making (Raiskila et al., 2016; Toivonen et al., 2021).

Table 19. Comparison of the improvement in the quality of family-centered care practices as rated by the parents and neonatal health care team between Estonia (Estonian Study: I) and Finland (previous study).

Question		Classification in family-centered care	Estonia [a]	Finland [b]	Estonia [c]	Finland [d]
			Parents		Staff	Nurse
Q1	Active listening	Parent support (communication)	**Sig.**	not sig.	not sig.	**Sig.**
Q2	Participation in care	Parent-delivered care and activities (caretaking by parents)	not sig.	not sig.	**Sig.**	not sig.
Q3	Individualized guidance	Parent support (communication)	**Sig.**	not sig.	**Sig.**	not sig.
Q4	Shared decision making	Parent support (communication)	not sig.	**Sig.** (father)	**Sig.**	not sig.
Q5	Mutual trust (parents→staff)	Parent support (communication)	not sig.	not sig.	**Sig.**	**Sig.**
Q6	Mutual trust (staff→parents)	Parent support (communication)	not sig.	not sig.	**Sig.**	not sig.
Q7	Individualized information	Parent support (communication)	not sig.	not sig.	**Sig.**	not sig.
Q8	Emotional support	Parent support (emotional support)	**Sig.**	not sig.	**Sig.**	**Sig.**
Q9	Participation in medical rounds	Parent support (communication)	not sig.	not sig.	**Sig.**	NA [e]
	TOTAL (average of all questions)		**Sig.**	**Sig.** (father)	**Sig.**	**Sig.**

[a] The results of the Estonian Study (I) using the linear regression models that adjusted for gestational age, fluent language, care level and fidelity rate of the NICU.
[b] The results of the previous study in Finland (Toivonen et al., 2021) using the linear mixed models that adjusted for gestational age and handled NICU as a random factor.
[c] The results of the Estonian Study (I) using the linear regression models that adjusted for care level and fidelity rate of the NICU.
[d] The results of the previous study in Finland (Toivonen et al., 2021) using the linear mixed models that adjusted for gestational age and handled NICU as a random factor.
[e] Q9 "participation in medical rounds" was not included in the previous study in Finland (Toivonen et al., 2021).

Ratings by neonatal health care team

The neonatal health care team reported improvement in all but one item in our study (Estonian Study [I]) (Table 19). Compared to the earlier study from Finland, the effect was seen in a larger number of items. Five items improved only in our study: individualized guidance and information, trusting relationships from the neonatal health care team to parents, shared decision-making, and the parents' participation in care. The differences in the population size and the analytic methods may have contributed to the difference in results. Our study included more responses than the

previous study; our study compared the median due to skewed distribution while the previous study compared the mean. In addition, more doctors completed the implementation in our study (22% of the neonatal health care staff) than in the previous study (6%). The doctors' involvement is a meaningful factor in practicing family-centered care (Benzies et al., 2019; Toivonen et al., 2020).

On the other hand, in both studies, improvements were found in the skills of the neonatal health care team to provide emotional support and the level of the parent's trust in the neonatal health care team. On the other hand, active listening as rated by the neonatal health care team themselves did not improve even though the parents reported an improvement in our study. While the previous study only included nurses as NICU staff, our study also included doctors, who prefer providing information rather than listening to the parents (Boss et al., 2016).

The neonatal health care team reported better skills in shared decision-making after the Close Collaboration with Parents intervention in Estonia, while the change was not significant in the study in Finland. The Close Collaboration with Parents intervention includes training sessions for neonatal health care teams to learn communication skills that facilitate shared decision-making and help them understand its importance. Shared decision-making is recommended by guidelines as one of the important parts of neonatal care in collaboration with parents (*Babies, Children and Young People's Experience of Healthcare*, 2021; Boss et al., 2022). Shared decision-making could improve the parents' outcomes. Some previous studies showed that shared decision-making promoted the parents' autonomy, improved their feelings of closeness toward their infants and parenting behavior, and increased their communication satisfaction (Treherne et al., 2017; Voos et al., 2011). However, the ratings by the parents and the health care team in both studies showed different results. The difficulty in promoting shared decision-making has also been shown in the previous articles (Raiskila et al., 2016; Toivonen et al., 2021).

Comparison of ratings by parents and neonatal health care staff

In our study, more items improved after the implementation of the Close Collaboration with Parents in the neonatal health care team's rating than in the parents' rating. This difference could be explained by the fact that the parents' baseline ratings were already close to the maximum. In addition, the change in the mindset of the neonatal health care staff may have happened first, followed by the change in their behavior towards the parents. In healthcare behavioral change, it is generally said that a change in mindset occurs first (Prochaska et al., 1997). Furthermore, the neonatal health care staff may have expected the improvement as they were the recipients of the intervention. The quality of family-centered care practices might have been rated higher by the health care staff than they actually were.

6.1.3 Growth

Our finding that growth in weight and length was significantly improved (Δ 11.7 g/week in weight and Δ 1.3 mm/week in length) was consistent with the previous studies. The FICare promoted growth in two different studies. Preterm infants in the FICare group demonstrated better weight gain than those without FICare by 2.03 g/day in Canada, Australia and New Zealand (O'Brien et al., 2018) and by 5.43 g/kg/day in China (Hei et al., 2021). Two family-centered care interventions in Taiwan demonstrated an increasing weight gain of 2.0 and 3.3 g/day (Chen et al., 2013; Yu et al., 2017). A meta-analysis has shown that family-centered care interventions increase weight gain by 4.57 g/day (Ding et al., 2019).

We speculate that parent-infant skin-to-skin contact may be one of the factors mediating the effect of the Close Collaboration with Parents intervention on the promotion in growth. The Close Collaboration with Parents intervention was shown to be associated with a longer duration of parent-infant skin-to-skin contact (He et al., 2021). Several randomized controlled studies have shown that skin-to-skin contact including Kangaroo mother care promotes growth in weight, length, and head circumference (Acharya et al., 2014; Boo & Jamli, 2007; Cattaneo et al., 1998; Gathwala et al., 2010; Rao PN et al., 2008; Rojas et al., 2003). There might be another mediating factor such as the promotion of breastmilk production between skin-to-skin contact and growth promotion.

6.1.4 Length of stay

The Register Study (II) showed that the Close Collaboration with Parents shortened the length of stay of preterm infants in NICUs. This finding was in line with some previous studies on family-centered care interventions (Benzies et al., 2020; Hei et al., 2021; Melnyk et al., 2006; Örtenstrand et al., 2010). However, the decrease in the length of stay in this study (1.8 days or 6%) was more modest than in the previous studies. The COPE intervention shortened the length of stay by 3.8 days or 11% in infants born at 28 to 34 weeks of gestation in two NICUs in the USA (Melnyk et al., 2006). The FICare intervention shortened the adjusted length of stay by 6.8 days or 19% in infants born at 29 to 34 weeks of gestation in 11 level III NICUs in China (Hei et al., 2021). The Alberta FICare intervention shortened an adjusted length of stay by 2.6 days or 13% in infants born at 32 to 34 weeks of gestation in 10 level II NICUs in Canada (Benzies et al., 2020). A study in two NICUs in Stockholm showed that a new model of family care, including the transition to single-family rooms, reduced the length of stay by 5.3 days or 16% in infants born < 37 weeks of gestation (Örtenstrand et al., 2010). The modest effect in the Register Study (II) may be attributed to the short baseline length of stay in Finland: an international comparison

study by the iNeo group among 11 high-resource countries showed that the length of stay of extremely preterm infants was the shortest in Finland (Seaton et al., 2021).

6.1.4.1 Discharge criteria and length of stay

It is still unclear how family-centered care interventions reduce the length of stay of infants in NICUs. Although this thesis did not prove the mechanism either, the Discharge Criteria Study (III) considered some possible effect mechanisms.

In the Discharge Criteria Study (III), we compared discharge criteria in NICUs in Japan and Finland. The length of stay of preterm infants in these two countries was at the opposite ends of the variation in the previous international comparison study, resulting in a 25-day difference in the mean hospital stays of preterm infants born before 29 weeks of gestation (Seaton et al., 2021). We found that parents' readiness for discharge and tube feeding at home as a common practice were the two major reasons explaining the difference in the length of stay between the NICUs. Therefore, these might be the factors that could reduce the length of stay through family-centered care.

Parents' readiness for discharge

In Japan, among the six major discharge criteria used, the parents' readiness was the most common last discharge criterion before discharge from the hospital. There are some factors that may explain why it took a long time for the parents to get ready for discharge in the NICU in Japan. First, it was a common practice that the parents would stay at least one night in the family room with their infant before discharge. As the NICU only had one family room, the parents sometimes had to wait for a long time for the opportunity to use the family room. Second, and most importantly, family-centered care in the hospital in Japan had not been promoted as much as in Finland. The parents in Japan usually needed more time at the end of the hospital stay to get ready for discharge. In the NICU in Finland, the parents usually became competent in infant care before their infants achieved physiological stability.

Some of the differences in the way the parents are prepared for discharge in Japan and Finland could have resulted from the Close Collaboration with Parents intervention, which had been implemented by the NICU in Finland. The intervention includes components focusing on facilitating the parents' readiness for discharge from the early stages of the hospital stay (Ahlqvist-Björkroth et al., 2024). In addition, the effect of the Close Collaboration with Parents intervention on the length of stay could be mediated by the parents' increased presence in the NICU (He et al., 2021). Spending more time in the NICU may allow the parents to understand their infant better and to start participating in infant care earlier. Our study showed that

the length of stay of preterm infants in the NICU in Japan could have been eight days shorter if the parents were ready by the time the infant reached physiological stability.

Different NICU architectures in the NICUs in Japan and Finland could also explain the difference in time needed for the parents to get ready for discharge. In the NICU in Finland, most patient rooms accommodated one or two infants, with at least one bed for a parent. Recent studies showed that NICUs with single-family rooms were associated with longer parental presence and better involvement in infant care (Kainiemi et al., 2021; van Veenendaal et al., 2020). In addition, the COVID-19 pandemic and related hospital visiting policies may have affected the parents' readiness. During the COVID-19 pandemic, the NICU in Japan allowed the parents to stay beside their infants for only six hours during the day, while they could stay in the NICU 24/7 in Finland. Therefore, the parents in Finland were likely to have sufficient time to prepare for discharge. Furthermore, the social support and medical care after discharge could have been other factors affecting the parents' readiness for discharge, but these were not compared in detail in the Discharge Criteria Study (III).

Tube feeding at home

Feeding management is another important factor affecting the difference in the length of stay of preterm infants in Japan and Finland. In the NICU in Finland, tube feeding was commonly continued at home after discharge, whereas it was not a common practice in Japan. Our study (the Discharge Criteria Study [III]) showed that the length of stay was extended by nine days in Japan due to this difference. The effect of early discharge with a feeding tube on the length of stay has been studied in Sweden and Denmark. The length of stay of preterm infants was shortened after the introduction of early discharge with a feeding tube (Ahnfeldt et al., 2015; Örtenstrand et al., 1999). It has become a more common practice nowadays, as a recent survey in the Nordic countries indicated that 86% of NICUs discharged very preterm infants even if they needed a feeding tube (Arwehed et al., 2024). Parents were shown to prefer this practice as well (Schuler et al., 2020). Early discharge with a feeding tube has also been shown to reduce respiratory infections and promote breastfeeding among preterm infants (Ahnfeldt et al., 2015; Kliethermes et al., 1999; Örtenstrand et al., 1999; Schuler et al., 2020).

For early discharge with a feeding tube to function well, the NICU should have a good family-centered care culture. The parents need to be confident in their skills related to tube feeding well before the discharge from the NICUs. Neonatal health care teams should appropriately support the development of the parents' skills, which is part of the parent support provided by neonatal health care teams to promote the parents' readiness for discharge.

6.1.5 Unscheduled outpatient visits after discharge

Our study (the Register Study [II]) showed that the likelihood of unscheduled outpatient visits after discharge decreased after the implementation of the Close Collaboration with Parents intervention. Our findings were different from the previous studies which failed to reduce emergency department visits up to two months of corrected age in infants born at 29 to 34 weeks of gestation (Benzies et al., 2020; Vonderheid et al., 2016). Our study population had a lower average gestational age and received longer follow-up, which may explain a higher need for unscheduled/emergency outpatient visits: the proportion of infants with unscheduled/emergency visits was 41.9% in the control group of our study compared to 25.5% in the Alberta FICare study and 23.1% in the H-HOPE study. The Close Collaboration with Parents intervention has components that promote the parents' readiness for discharge (Ahlqvist-Björkroth et al., 2024), which should help parents take care of their infants at home even after discharge to reduce unnecessary outpatient visits.

6.1.6 Rehospitalizations after discharge

Similarly to the Alberta FICare or H-HOPE interventions, the risk of rehospitalization was not changed by our intervention (Benzies et al., 2020; Vonderheid et al., 2016). However, the FICare intervention in China reduced the rehospitalization rate from 7.5% to 3.7% within 30 days post-discharge in infants born at 29 to 34 weeks of gestation (Hei et al., 2021). These participants with the FICare intervention possibly had a low risk of physical illness requiring later hospital admission because the intervention improved weight gain, promoted breastfeeding, shortened the duration of the need for supplemental oxygen, and reduced nosocomial infections (Hei et al., 2021).

6.2 Couplet Care Model

In the Couplet Care Study (IV), we showed how couplet care affected early parent-infant physical closeness among preterm infants in a Level III NICU. After the introduction of the Couplet Care Model, the first parent-infant skin-to-skin contact happened earlier and the parents stayed in the NICU room longer than before. However, the mean durations of skin-to-skin contact and holding in the NICU room did not change. In summary, early parent-infant physical closeness was facilitated after the introduction of the Couplet Care Model during the first postpartum weeks, regarding the timing of the first parent-infant skin-to-skin contact and the duration of parents' presence and overnight stays in the NICU rooms.

6.2.1 Parent support

Facilitating the parents' presence in the NICUs is one of the important components of parent support. The Couplet Care Model successfully encouraged parent-infant closeness in the NICU room, as the parents stayed there longer. This success was achieved regardless of the infants' gestational age. There are some possible explanations for how the Couplet Care Model extends the parents' presence in the NICU room. First, the Couplet Care Model notably promoted parent-infant closeness during the first hours after birth compared to the previous practice as was shown in the same study (IV).

Another explanation for the parents' extended presence after the introduction of the Couplet Care Model was the provision of overnight accommodation for both parents. Our study showed that the frequency of overnight stays of both parents increased significantly after the introduction of the Couplet Care Model. As a permanent bed for a parent in the NICU room is a non-verbal signal that he/she is welcome (Flacking & Dykes, 2013), having two beds available permanently in the Couplet Care Model may have encouraged fathers as well as mothers to stay. In this situation, the parents had to make an active decision to "leave" the NICU room. On the other hand, if parents do not spend enough time together with their infants, their decision would be to "come and stay," which was the usual case in the old hospital before the introduction of the Couplet Care Model.

We also found that, after the introduction, the mothers stayed in the NICU almost all nights, while the fathers stayed about half the nights. If parents have other children at home when they also have their newborn infant at the NICU, the father is more likely to be taking care of the other children than the mother. Nevertheless, the increase in fathers' presence in the NICU room may be psychologically important for the mothers. Support provided by husbands or partners has been shown to be associated with fewer postpartum depressive symptoms (Gremigni et al., 2011; Milgrom et al., 2008).

6.2.2 Parent-delivered care and activities

In the Couplet Care Study (IV), among the components of parent-delivered care and activities, we evaluated parent-infant skin-to-skin contact in the delivery unit (early skin-to-skin contact) and skin-to-skin contact and holding in the NICU room.

Early parent-infant skin-to-skin contact in the delivery unit

The Couplet Care Study (IV) showed that preterm infants experienced their first skin-to-skin contact with their parents significantly earlier after the introduction of the Couplet Care Model than before. One of the important factors in the successful

implementation of early skin-to-skin contact is the change in the design and care system in the delivery unit (Klemming et al., 2023). The new facilities and care system in the delivery unit allowed infants to receive all necessary procedures before admission to the NICU and allowed the mothers to spend postpartum time close to their infants.

Our study also emphasized the fathers' role in early skin-to-skin contact. The first skin-to-skin contact happened earlier after the introduction of the Couplet Care Model among the fathers, while it did not change significantly among the mothers in the linear regression model. The difference can be explained by the mothers' high levels of involvement in the early skin-to-skin contact before the introduction. The proportion of parents who had their infants in skin-to-skin contact within two postpartum hours was 11.5% and 4.8% among the mothers and fathers before the introduction, but 32.8% and 35.2% after. After the introduction, the mothers and fathers were both equally engaged in providing skin-to-skin contact. Two previous studies also emphasized the importance of the fathers' role in early skin-to-skin contact, especially after Cesarean delivery which makes mother-infant skin-to-skin contact more difficult shortly after delivery (Linnér et al., 2022; Lode-Kolz et al., 2023). The healthcare staff in the Couplet Care Model successfully encouraged fathers to be involved in early parent-infant skin-to-skin contact.

The Couplet Care Study (IV) also showed that the effect of the Couplet Care Model on the timing of the first parent-infant skin-to-skin contact was dependent on infants' prematurity. Our finding was consistent with the previous literature showing evidence for immediate skin-to-skin contact for preterm infants born ≥ 28 weeks of gestation (Brimdyr et al., 2023). Future studies should focus on the facilitators, barriers and effectiveness of early parent-infant skin-to-skin contact in extremely preterm infants.

Parent-infant skin-to-skin contact and holding in the NICU room

The duration of skin-to-skin contact and holding was not affected by the introduction of the Couplet Care Model even though the duration of the parents' presence increased. The result could be caused by the fact that the Couplet Care Model does not have a component to promote skin-to-skin contact or holding provided in the NICU room. However, the parents may have used their time for different types of care and activities. These other activities are also beneficial to their infant: daily infant care (Kato et al., 2023; Lester et al., 2016; Vittner et al., 2019), verbal interaction (Aija et al., 2024; Caskey et al., 2014; McGowan et al., 2023), or maybe even sleeping close to their infant.

6.2.3 Better implementation of the Couplet Care Model

Our findings, that early parent-infant skin-to-skin contact, parents' presence and overnight stays in the NICU room were promoted after the introduction of the Couplet Care Model, meant that the model was implemented successfully. The key factors for the successful implementation of the Couplet Care Model are discussed here.

The change in attitude and provision of education are needed as well as architectural changes for the successful implementation. Firstly and most importantly, couplet care requires a good family-centered care culture as a solid foundation for its successful implementation (Klemming et al., 2023). The study hospital NICU had implemented the Close Collaboration with Parents intervention between 2009 and 2012. This intervention is expected to have functioned as a good foundation to understand the importance of early parent-infant closeness and to think about how to promote it.

The successful implementation of couplet care can also be promoted by the changes in architecture and care system (Klemming et al., 2023). In addition, multi-professional leadership of both neonatal and obstetric care promoted couplet care (Klemming et al., 2023; Toivonen et al., 2020). Early parent-infant closeness was described in the functional plan of the new hospital as one of the top priorities (Reijula et al., 2016). The leadership also facilitated the collaboration between obstetric, neonatal, and operation room teams. Good multi-professional collaboration is an essential factor for the successful implementation of couplet care (Klemming et al., 2023). In addition, education and simulation were emphasized in the previous literature as an important but challenging components of early parent-infant skin-to-skin contact (Klemming et al., 2023). The neonatal health care staff in the study site had enough time before the move and during the first year in the new hospital to provide sufficient education and simulation to the healthcare teams.

The changes in facilities and care systems in the delivery unit and the NICU also strongly facilitated the implementation of the Couplet Care Model. As mentioned above, the change in the facility and the care system in the delivery unit was a prerequisite for the first parent-infant skin-to-skin contact carried out within two hours after birth. To care for postpartum mothers in the NICU rooms, they changed the care system so that midwives could regularly work in the NICU. Single-family NICU rooms are not necessary for couplet care, but the transition to the spacious single-family NICU rooms with two adult beds for both parents in the new hospital should have facilitated its implementation.

6.3 Limitations

The non-randomized study design was one of the biggest limitations of the Estonian Study (I), Register Study (II), and Couplet Care Study (IV). The analyses of these studies might have included the influence of other factors possibly associated with the outcome measures other than the interventions. At least some of the characteristics of the patients in each study were not comparable between the groups. To reduce these influences, multivariate analyses were performed in all of these studies to take them into account. The effect of time might have also affected the outcomes, which was also included in the multivariate analyses in the Register Study (II).

In the Estonian Study (I), the questions with a Likert scale from 1 to 7 might not have been a sufficiently sensitive tool to evaluate family-centered care in Estonia due to the high baseline levels, especially in the parents' responses. This ceiling effect may have caused non-significant changes or small effect sizes. It is said that the self-assessment questionnaires may not be optimally sensitive tools to evaluate family-centered care (Kainiemi et al., 2022). To validate the changes in family-centered care, there is a need to develop more appropriate tools or conduct ethnographic observations. Second, the way the questions were presented to the parents and the neonatal health care team was different. We chose a one-point questionnaire for parents based on a previous study showing that daily answers may not be more sensitive than a one-point measurement (Axelin et al., 2021). Third, there was an imbalance in the number of mothers and fathers due to the fathers' limited access during the COVID-19 pandemic (Itoshima, Tuura, et al., 2023). Fourth, the staff responses were provided by all the NICU health care staff, while the fidelity rate calculation excluded temporary staff, assistant nurses, and other special workers, who were not expected to complete the full training. Fifth, there was potential response bias in the staff responses in NICU A and D where the number of staff responses decreased by about half after the intervention. Furthermore, the evaluation of the implementation fidelity was done quantitatively. The quality of intervention delivery and participant responsiveness should be evaluated in future studies, as they are also among the components used to evaluate fidelity.

In the Register Study (II), the adjusted models could not include neonatal morbidities due to the low quality of the data. Therefore, we cannot conclude whether morbidities were mediating factors for shorter LOS (Seaton et al., 2021) and better growth (Greenbury et al., 2021). The small number of infants in the Partial-CC group limited the significance and overall reliability of the analyses comparing the Partial-CC and Control groups. In addition, the infants in the Partial-CC group were born at smaller gestational ages and birth weights. However, this is logical because all the infants in the Partial-CC group needed neonatal transfer. The deliveries of very preterm infants are centralized to Level III/IV NICUs in Finland

according to the national guidelines. In other words, most preterm infants who need neonatal transfer were likely to be born very preterm.

For the Discharge Criteria Study (III), the small sample size is one of the biggest limitations. In addition, only two NICUs with a limited gestational age group were included. These study sites may not represent all of the existing variations in discharge practices in each country and at each gestational age. In addition, our study analyzed only those infants who did not have special medical needs at discharge. Future studies should consider the same outcome measures with other patient variations.

In the Couplet Care Study (IV), the transition to the new hospital included factors other than couplet care: e.g. the sophisticated design, brand-new furniture, and spacious NICU rooms. Further studies might want to document the effects of different hospital designs and policies to provide evidence for future planning teams. Lastly, the long-term effects of couplet care on parents and infants were beyond the scope of this study.

6.4 Family-centered care interventions and mediators in intervention effects

6.4.1 Improvement in infant development as the final goal of neonatal care

Among all outcome measures, better infant development is one of the final goals of neonatal care including family-centered care interventions. Appropriate support for the sensory system after birth is vital for better infant development. Compared to the intrauterine environment before delivery, infants who need admission to a NICU after birth could be exposed to a harmful environment in terms of infant sensory development: excessive chemicals, light, sound, and nociceptive pain; and insufficient speech and touch (Santos et al., 2015). The exposure of preterm infants, who have immature coping skills, to toxic environments may destabilize their physiology and harm their growth and development (Roberta Pineda et al., 2019). At the same time, however, an appropriate nurturing environment in NICUs may support and promote the development of preterm infants. Family-centered care interventions could provide this supportive environment for any infants cared for in NICUs.

Next, I will speculate on the mechanisms of how family-centered care interventions and the outcome measures included in this thesis could improve the development, especially neurodevelopment, of preterm infants.

6.4.2 How family-centered care interventions improve infant neurodevelopment

Typically, the human sensory systems do not become functional at the same time. Instead, they develop according to the following order: somesthetic, vestibular, taste, olfactory, auditory, and visual stimulation (Gottlieb, 1971; Lickliter, 2011). As the development of the sensory systems of infants starts in the early pregnancy period, preterm births may affect the developmental process of the sensory systems, especially those that develop quickly. The mechanisms of the effect of preterm births on the development of the sensory systems have not yet been well understood. Nevertheless, family-centered care could effectively mitigate the negative effects of preterm birth and promote the development of the entire central nervous system.

Some family-centered care interventions have had a positive impact on infant neurodevelopment, especially those focusing on offering developmentally supportive sensory experiences to preterm infants. The MITP aims to enable mothers of low-birth-weight infants to interact with their infants based on their observations of the infants' behavior (Achenbach et al., 1993). After the randomized controlled trial, low-birth-weight infants in the intervention group showed better intelligence than those in the control group at least up to nine years of age, at the same level as normal-birth-weight infants (Achenbach et al., 1993). Another randomized controlled trial also showed that a modified version of the MITP improved the intelligence quotient at five years of corrected age in infants with birth weights of < 2000 g (Nordhov et al., 2010). The FNI focuses on teaching mothers of preterm infants in NICUs how to create a better nurturing environment through appropriate tactile, verbal, and olfactory stimuli (Welch et al., 2012). A randomized controlled trial showed that the FNI improved cognitive and language development at 18 months of corrected age among those whose Bayley-III scores were greater than 85 (Welch et al., 2015). The NBO focus on helping parents observe their infants to provide more individualized care and establish good prent-infant relationships (Johnson et al., 2024). A randomized controlled trial showed that neurodevelopment was promoted by the NBO up to six months of age (McManus et al., 2020).

Parent-delivered activities can be one of the effect mechanisms of family-centered care interventions on infant neurodevelopment. Parent-infant physical close contact, especially skin-to-skin contact, allows preterm infants to be exposed to their parents' skin, smell, voice, face, and possibly breastmilk if in contact with the mother. Mother-infant skin-to-skin contact was shown to be associated with better development at six months of corrected age (Feldman et al., 2002). Caretaking by their parents also provides infants in the NICU an opportunity to be exposed to an appropriate environment such as being touched and talked to by their parents, and smelling or looking at their parents (Roberta Pineda et al., 2019). In addition, the parents' readiness for discharge is important for infant development in that their life continues smoothly

after discharge home from the NICUs. The parents' readiness for discharge includes understanding their infants through infant observation and decision-making based on this understanding, which is also meaningful after discharge.

Parent support could indirectly improve infant neurodevelopment. The parents' longer presence in the NICU is a good foundation for parent-delivered care and activities. For example, the parents may have more opportunities to talk to their infants. Research on the effect of language environment on later neurodevelopment has progressed in recent years. One observational study showed that a language environment with more adult words was associated with better language development at 18 months of corrected age (Caskey et al., 2014). In addition, a randomized controlled trial showed that a parent-driven language intervention increased the number of words parents spoke to their infants and, thus, improved the language development of preterm infants (McGowan et al., 2023).

In addition, better staff-parent communication could also promote parent-delivered care and activities. In the Close Collaboration with Parents intervention, the neonatal health care staff learn the collaborative observations of the infant and shared decision-making together with the parents using their communication skills. The staff may be able to encourage parents to focus on understanding the individual needs of their infants and provide individual care for their infants based on their observations. Then, the parents could be more competent in creating a supportive environment for the better development of their infants.

Further studies are required to understand if parent support and parent-delivered care and activities mediate the effects of family-centered care interventions on infant development. We also need to discover better ways to support infant neurodevelopment through supportive environments for the sensory systems.

6.4.3 Conceptual diagram of effect mechanisms of family-centered care interventions

Figure 13 summarizes the possible components that mediate the effect of family-centered care interventions and infant outcomes mentioned in this thesis. In addition to our findings, some important mechanisms that have been found in the previous studies are also listed in the figure. Implementation fidelity may also affect the components of the mechanisms as we showed.

We found in the figure that there is a lack of evidence for mediators connecting parent support and parent-delivered care and activities. Future studies should focus particularly on how parent support by neonatal health care teams could promote parent-delivered care and activities. In addition, the association between the reduction in the length of stay in NICUs and later neurodevelopment could be of interest for further study.

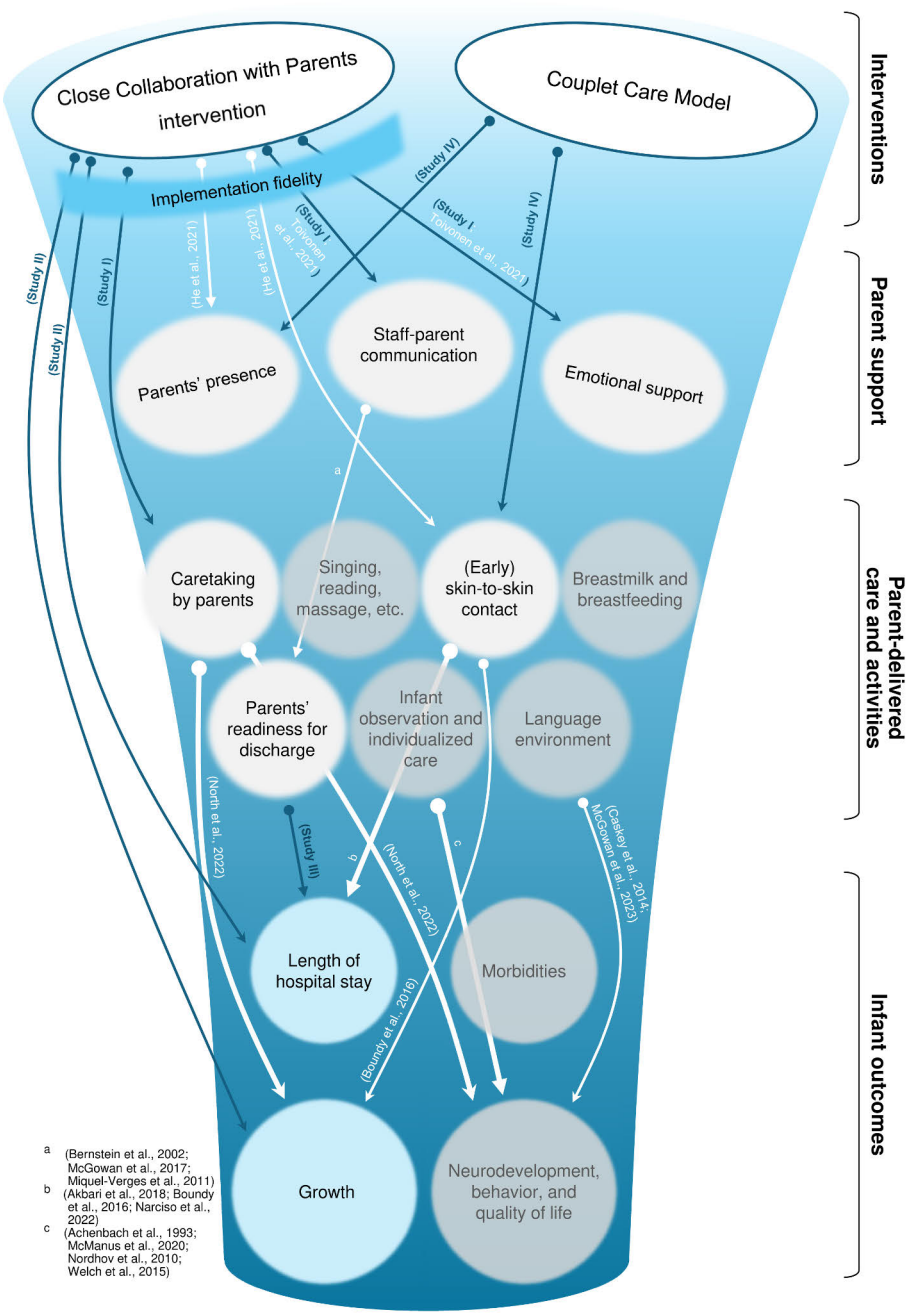


Figure 13. Conceptual diagram of effect mechanisms of family-centered care interventions in this thesis. Implementation fidelity, parent support, and parent-delivered care and activities mediate the effects of family-centered care interventions on infants. The items with a grey circle are the outcomes not considered in this thesis. White arrows indicate clinical findings not included in this thesis.

6.5 Prospects for the future

This thesis added some important insights into the effectiveness and fidelity of family-centered care interventions. However, further studies are required for their better understanding.

Our study in Estonia showed the importance of measuring implementation fidelity, which is not easy. Among the five necessary components of fidelity, which are adherence, exposure, quality of delivery, participant responsiveness, and program differentiation (Carroll et al., 2007; Dusenbury et al., 2003), the Estonian Study (I) evaluated adherence and exposure. Quality of delivery is difficult to measure. We might want to use a self-report questionnaire for the mentors, who deliver the intervention, to assess their ability and competency after every training session. A qualitative study using a video recording method may also be useful to assess the quality of delivery. Participant responsiveness could be evaluated using a self-report questionnaire after every training session. Program differentiation could be assessed by using very short-term outcomes after every training session to compare the effectiveness of each training phase.

As was shown in our study, better fidelity may lead to better outcomes. Achieving better fidelity should be emphasized not only when we design an intervention but also when we plan the implementation of the intervention. The Close Collaboration with Parents intervention has the flexibility to change the implementation plan depending on the characteristics of the unit. Although the evidence-based content of the training is constant regardless of the unit, each unit needs to find the best ways for them to implement the training effectively. The "train the trainer" system of the intervention significantly contributes to more effective implementation because local mentors, who understand the unit's healthcare team members and the working environment well, should be responsible for the implementation planning. For the training team supporting the local mentors and their implementation process, it is important to experience many different scenarios and to understand the characteristics of each unit to help the local mentors plan the best implementation. In addition, the unit administrators also play an important role in supporting the local mentors in that they know the facility well. Thus, implementation fidelity of the Close Collaboration with Parents interventions can be increased by the collaborative work between the training team, local mentors, and local administrators. Our study validated the necessity of all the efforts to achieve high implementation fidelity of the intervention. Future studies should evaluate and summarize how to better implement the Close Collaboration with Parents intervention. We might want to summarize and evaluate the previous implementation process for a better understanding of the key components for successful implementation.

Our studies also showed that the level of parent support and parent-delivered care and activities improved after the implementation of the Close Collaboration with Parents intervention or the Couplet Care Model. Parent support and parent-delivered care and activities are included in the proximal outcomes of family-centered care interventions, whereas one of the final goals of the interventions is to improve infant outcomes. The improvement in the level of parent support and parent-delivered care and activities could theoretically lead to better outcomes for infants and their parents. However, its mechanisms have not been clearly shown yet. The factors mediating the effects of parent support and parent-delivered care and activities on infant outcomes should be further studied. Mediation analyses may be effective in understanding the mediating effects.

Although we showed that some infant outcomes were improved by the Close Collaboration with Parents intervention, there are other outcomes to be evaluated. Infants' long-term outcomes such as growth, neurodevelopment, behavior, and quality of life are among the final goals of neonatal care in NICUs. A randomized controlled study design is ideal for evaluating long-term outcomes because there are many other factors that are strongly associated with the outcomes. The randomized controlled study should include each NICU as a cluster because the Close Collaboration with Parents is a NICU-wide intervention. In addition, as the implementation of the intervention requires at least 1.5 years for each NICU to be complete, a stepped wedge cluster randomized controlled study design would be one of the best (Hemming et al., 2015). This is an effective study design when interventions are implemented in each cluster step by step, and the order of the implementation in each cluster is determined randomly. This pragmatic study design seems to be well suited for the implementation process of the Close Collaboration with Parents intervention.

Couplet care also needs further studies. As was mentioned before, definitions of couplet care vary. Couplet care usually contains several components, but it is still unclear how each component affects outcomes. Comparing the different outcomes from different definitions of couplet care could explain the impact of each component of couplet care on outcomes. In addition, the long-term effects of couplet care should be studied in future studies.

7 Conclusions

This thesis aimed to evaluate the effects of two family-centered care interventions, the Close Collaboration with Parents intervention and the Couplet Care Model, on family-centered care practices and preterm infants. This thesis also evaluated the implementation fidelity of the Close Collaboration with Parents intervention and its effect on family-centered care practices.

In the Couplet Care Model, the first parent-infant skin-to-skin contact happened earlier and parents stayed in the NICU room longer than before the introduction of the model.

The Close Collaboration with Parents intervention increased the level of family-centered care practices in NICUs as rated by both the parents and the neonatal health care team. Implementation fidelity was shown to be an important factor in achieving better outcomes.

The Close Collaboration with Parents intervention also improved outcomes for preterm infants. The growth in weight and length in NICUs was promoted, the length of stay was shortened, and the likelihood of having at least one unscheduled outpatient visit was reduced among preterm infants after the implementation of the Close Collaboration with Parents intervention.

Japan-Finland comparison study showed that early parents' readiness for discharge and different feeding tube management contributed significantly to the shorter length of stay of preterm infants in the NICU in Finland.

Thus, these two family-centered care interventions improved family-centered care practices, promoted parent-infant closeness, and improved short-term infant outcomes. This thesis showed that the changes in staff-parent communication, NICU architecture and care system were key elements to improve family-centered care and infant outcomes. In addition, better implementation fidelity of the interventions reinforces the effects.

Acknowledgements

First of all, I would like to acknowledge my wonderful and powerful supervisors, Professor Liisa Lehtonen and Docent Sari Ahlqvist-Björkroth, for their great contribution to my learning and life in Turku, Finland. Without their support, I couldn't have come this far. They offered me many opportunities to try new things as a scientist: joining the training team of the Close Collaboration with Parents, making scientific presentations, and networking. Meeting Professor Liisa Lehtonen in 2019 was the most significant beginning of my life in Finland. I also thank Dr. Kjell Helenius and Kalle Korhonen, who helped me carry out clinical studies, analyze data, and write manuscripts. They are like my kind older brothers. There are some other research members in Turku who I want to acknowledge. Associate Professor Anna Axelin helped me a lot as an expert in family-centered care. Mr. Tero Vahlberg and Ali Moazami Goodarzi gave me a lot of advice on the data analyses from experts' perspectives. Ms. Minna Paaso, a research nurse at Turku University Hospital, helped me a lot with patient recruitment and data collection. I also worked together with two medical students, Venla Ojasalo and Anna Hovi. My experience of supervising them was also meaningful to me. In addition, Professor Heikki Lukkarinen and Dr. Lauri Ivaska are the advisory committee members of my PhD thesis. They also helped me with my journey to PhD. Dr. Simo Raiskila, who studied family-centered care when he did his PhD, reviewed this thesis and gave many valuable comments. Language proofreading of this thesis was done by Ms. Henna Raudaskoski. I really appreciate her quick and accurate work.

I want to thank many collaborators in Tallinn and Tartu in Estonia. Dr. Liis Toome, Heili Varendi, and Pille Saik are neonatologists in Estonia. Our collaborative project succeeded thanks to their contributions as directors of each department and as experts in neonatology. There are neonatal health care team members who made significant contributions to the implementation of the Close Collaboration with Parents intervention, patient recruitment and data collection in Estonia: Vera Nikolajeva, Õnne Uus, Ellen Majorskih, Kerli Hiiemae, Birgit Kiilaspää, Merilin Lumpre, Kadri Madar, Kertu Lepla, Kaija Piller, Karoliina Sikkal, Jaanika Kuld, and Darja Samulina.

I would like to acknowledge Professor Tomohiko Nakamura and Dr. Arata Oda. Their encouragement has been my motivation to come to Finland to study and continue my learning as a PhD student. Professor Tomohiko Nakamura also helped me financially as Director of Nagano Children's Hospital. Dr. Arata Oda studied in Finland before I came here, which has been a great foundation for my study and life in Finland. Makiko Noda, Yuko Tanaka, and Kanae Hatta in addition to Dr. Arata Oda are local mentors of the Close Collaboration with Parents intervention in Japan. It has also been my valuable experience and a great motivation to work with them on this big project. There have been over 60 visitors from Japan to visit Turku University Hospital NICU so far. My experience of hosting them was also meaningful for me in that it got me thinking about how to promote family-centered care in the future in Japan.

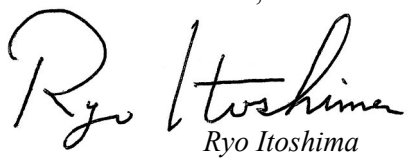
There have been three projects I have joined during my stay in Finland related to the implementation of the Close Collaboration with Parents intervention in Tallinn and Tartu in Estonia, Azumino in Japan, and Kaunas in Lithuania. I really appreciated working with training mentors in Finland, Hannele Haapala, Sanna Pick, Siw Hellsten, and Mariia Aro-Panula in addition to Sari Ahlqvist-Björkroth. My experience in these projects will be beneficial for our future project to spread the Close Collaboration with Parents intervention in Japan.

Katarzyna Piatek, or Kasha, was my great colleague from Poland. We are both PhD students and working at the same office. Her peer support helped my PhD journey in many ways. In addition, she had helped me even before I came to Finland.

I also want to thank people in Finland for their kindness to us. I have learned the importance of respect and trust from them, which are also the core components of family-centered care.

Lastly, I would like to give my greatest thanks to my wife, Saori, my twin sons, Hotaka and Asahi, and my daughter, Ibuki. Saori didn't hesitate to decide to come to Finland when I told the plan in 2019. She also started her PhD study in 2021 together with me, which also motivated me. She was my equal partner as a doctor, PhD student, and parents of our cute children in addition to being a great mother. My children, Hotaka, Asahi, and Ibuki also supported my life in Finland. Seeing their growth and happy faces has been my greatest happiness and motivation as a PhD student and as a father. I won't forget our life in Finland, including traveling around about 20 countries, taking my children to their school and preschool by bike, and eating dinner together. I am truly proud of my brave decision to live in Finland with my family. It's like a dream come true.

August 29, 2024
Turku, Finland



Ryo Itoshima

Ryo Itoshima

I did my medical school at Shinshu University in Matsumoto, Japan. I started my career as a physician in Sapporo, Japan in 2012. After completing my pediatric residency in Sapporo, I started my fellowship in neonatology at Nagano Children's Hospital in Azumino, Japan in 2017. During my fellowship, I started to get interested in the importance of supporting family as a neonatologist, not just treating babies. I have been staying in Finland since 2020 to learn more about my interests.

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TURUN
YLIOPISTO
UNIVERSITY
OF TURKU

Painosalama, Turku, Finland 2025

ISBN 978-952-02-0023-7 (PRINT)
ISBN 978-952-02-0024-4 (PDF)
ISSN 0355-9483 (Print)
ISSN 2343-3213 (Online)