Impact of Single-Family Room design on very preterm infants and their parents

Bente Silnes Tandberg

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Table of Contents

SCIENTIFIC ENVIRONMENT

This dissertation is originated from the Department of Clinical Science 2 at the faculty of medicine and Dentistry at the University of Bergen. The supervision was undertaken by Dr med., Phd, Atle Moen, Professor René Flacking and Professor Trond Markestad. The main research environment was at Department of Paediatric and Adolescent Medicine, Drammen Hospital, Vestre Viken Hospital Trust.

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LIST OF PAPERS INCLUDED IN THE DISSERTATION (I – IV)

I. Tandberg, B. S., Frøslie, K. F., Flacking, R., Grundt, H., Lehtonen, L., & Moen, A. (2018). Parent–infant closeness, parents' participation, and nursing support in single-family room and open bay NICUs. The Journal of Perinatal & Neonatal Nursing, 32(4), E22-E32. doi: 10.1097/JPN.0000000000000359

II. Tandberg, B. S., Frøslie, K. F., Markestad, T., Flacking, R., Grundt, H., & Moen, A. (2019). Single-family room design in the neonatal intensive care unit did not improve growth. Acta Paediatrica. doi: 10.1111/apa.14746

III. Tandberg, B. S., Flacking, R., Markestad, T., Grundt, H., & Moen, A. (2019). Parent psychological well-being in a single-family room versus an open bay neonatal intensive care unit. PloS One, 14(11) e0224488. doi: 10.1371/journal.pone.0224488

IV. Grundt, H., Tandberg, B. S., Flacking, R., Drageset, J., & Moen, A. Effects of single-family room care on breastfeeding initiation and duration in preterm infants. Submitted to Journal of Human Lactation in December 2019.

The articles are referred to by their Roman numerals throughout the thesis.

ABBREVIATIONS

BSES-SF	Breastfeeding Self-Efficacy Scale, Short Form
CPAP	Continuous Positive Airway Pressure
CI	Confidence Interval
DAGs	Directed Acyclic Graphs
EFCNI	European Foundation for the Care of Newborn Infants
EPDS	Edinburgh Postnatal Depression Scale
FCC	Family-Centred Care
FDA	Functional Data Analysis
FiCare	Family-integrated Care
GA	Gestational Age; time from the first day of last menstrual period measured in whole weeks and days
HUH	Haukeland University Hospital
ICS	International Closeness Survey
MPAS	Maternal Postnatal Attachment Scale
NICU	Neonatal Intensive Care Unit
NIDCAP	Newborn Individualized Developmental Care and Assessment Program
OB	Open Bay
OR	Odds Ratio
p-value	Statistical Significance
PMA	Postmenstrual Age; the sum of gestational age and days from birth
PSI	Parenting Stress Index – short form
PSS: NICU	Parent Stressor Scale: Neonatal Intensive Care Unit questionnaire
Q	Quartile (Q 1, Q3) = (The first quartile, the third quartile)
SCENE	Separation and Closeness Experiences in the Neonatal Environment; research network
SFR	Single-Family Room
SMS	Short Message Service
SSC	Skin-to-Skin Contact; parent holding infant skin to skin in an upright position on their naked breast
STAI SF-Y	State–Trait–Anxiety Inventory, Short Form Y
SD	Standard Deviation
VPT	Very PreTerm infant
VVHT	Vestre Viken Hospital Trust
WHO	World Health Organization
Z-score	Number of standard deviations from the mean of a value

THESIS SUMMARY

Over the last decade, parental involvement and family-centred care have been increasingly applied in the care of hospitalised newborn infants. In 2012, Vestre Viken Hospital Trust opened a new neonatal intensive care unit (NICU) designed as a Single-Family Room (SFR) unit. The unit allowed parents to live together with their infant at all times, from birth to discharge, and to take part in daily care and provide unrestricted skin-to-skin contact.

The **overall aim** of this thesis was to study potential benefits and disadvantages for preterm infants and their parents when care is provided in the SFR compared to a traditional open bay (OB) unit. Comparisons were made on parental presence, involvement in care and the provision of skin-to-skin contact, infant growth, extent of breastfeeding and parental psychological well-being during hospitalisation and after discharge at four months post-term.

Method Care at the SFR unit at Vestre Viken was compared with care at the OB unit at Haukeland University Hospital. At both units, eligible preterm infants and their parents were consecutively recruited to two prospective studies. During 2013-2014, parents of hospitalised infants born at ≤ 35 weeks' gestational age reported the duration of parental presence and the provision of skin-to-skin contact. They also responded to nine random questions received as text messages about their perceptions of the quality of family-centred care, their involvement in care and emotional support. In a similar way, nurses in the two units responded through a website about their own assessment of providing parental support and involving parents in care. During 2014-2016, infants born at 28+0 – 32+0 weeks of gestational age and their parents were followed from birth until four months post-term. Parents recorded the duration of their presence and skin-to-skin contact each day until 34 weeks' postmenstrual age. The infants' weight, length and head circumference, vital signs and morbidities, and nutrition, provision of breast milk and extent of breastfeeding were measured at predefined time points. The mothers' milk volume was also measured. They also completed standardised questionnaires on psychological well-being and emotional

distress in terms of depression, anxiety and stress, as well as on breastfeeding self-efficacy and attachment.

Results In the first study, 115 parents of 64 infants and 129 nurses participated. The parents in the SFR unit spent significantly more time with their infant than the parents in the OB unit; a median of 20 versus 7 hours per day for the mothers (p = .001), and 8 versus 4 hours (p = .001) for the fathers. The parents in the SFR unit also provided earlier skin-to-skin contact: at a median of 4 versus 12 hours (p = .03) after birth for the mothers, and after 3 versus 40 hours (p = .004) for the fathers. The respective total time of providing skin-to-skin contact per 24 hours during the first two weeks was 180 minutes in the SFR unit versus 120 minutes in the OB unit for the mothers (p = .02), and 67 versus 31 minutes (p = .05) for the fathers. The SFR parents rated both their participation in medical rounds (mothers: p = .001; fathers: p = .01) and emotional support higher (mothers: p = .05; fathers: p =.001) than did the OB parents. The nurses´ assessment of their own care was similar in both units, but the OB nurses believed that the parents had greater trust in their nursing care of the infants more so than did the SFR nurses (p = .02).

In the second study, 132 parents and 77 infants participated. From birth until a postmenstrual age of 34 weeks, the parents in the SFR unit maintained an average presence of 21 hours for the mothers and 16 hours for the fathers, compared to 7 and 5 hours, respectively, in the OB unit. The respective mean daily hours of providing skin-to-skin contact were 6 and 4 hours (p = .001). There were no differences in mothers' milk volume, nutrient intake, or in the proportions of infants receiving breastmilk and regular formula after the first week until the postmenstrual age of 34 weeks, at discharge, term date and at four months after term date. The growth rate of all anthropometric parameters was the same in both units. The mothers in the SFR unit first expressed milk at a mean of 8 hours after birth as opposed to 33 hours in the OB unit (p =.001). The respective mean time the infant first attempted breastfeeding was 72 and 166 hours (p = .001). However, the mothers' reports of breastfeeding self-efficacy did not differ at discharge. More infants from the SFR than from the OB unit received all mother's milk directly from the breast until four months corrected age (odds ratio 8.2 95% CI 2.9, 23.1, p = .001). In terms of the parents´ psychological

well-being, mothers in the SFR unit had a significantly lower depression score (-1.9 95% CI -3.6, -0.1, p = .03) from birth to four months corrected age compared to mothers in the OB unit, and 14% versus 52% scored above a cut-off point considered as being at high risk for depression during hospitalisation (p = .005). Both the mothers and fathers in the SFR unit reported significantly lower stress levels during hospitalisation. There were no differences between the groups in anxiety, stress or attachment scores after discharge.

Conclusion SFR care facilitated parent–infant closeness through earlier and more extensive presence and the provision of skin-to-skin contact, as well as earlier breast milk expression and exclusive breastfeeding by breast, but did not contribute to improved growth in very preterm infants. The SFR significantly increased parental involvement and parents' psychological well-being.

1 Introduction

This study was conducted to compare the medical and psychological effects of a Single-Family Room (SFR) and an Open Bay (OB) design on preterm infants and their parents. For the premature infant, the immediate hospitalisation usually includes separation from the parents and exposure to the physical environment in the Neonatal Intensive Care Unit (NICU), with loud noises, bright lights and painful procedures. This may disturb the normal sleep-wake cycle and induce chronic stress, with possibly adverse impacts on neurodevelopment and growth trajectories (1). Environmental factors and the NICU experience may also influence parents' psychological well-being, parent–infant bonding and the neurobehavioural outcome of the infant (2, 3). There are distinct features in an NICU that differ from paediatric or adult intensive care units, e.g. the fragility of the patient and the need for advanced medical care from birth. In adult intensive care units, family members visit for shorter periods, whereas extensive parental presence is important in the NICU for proper bonding and attachment between the infant and its parents. Hospitalisation of the infant affects its family, including siblings, and the involvement of parents and family-centred care (FCC) has been increasingly accepted as an important part of care.

1.1 Significance of preterm birth

Each year, about 6000 infants are admitted to NICUs in Norway, which is approximately 10% of all newborn infants (4). Among them, 40% are born premature, i.e. before a gestational age (GA) of 37 completed weeks. There are major differences in prematurity rates internationally, but in Norway the incidence rate is stable, around 6% (4). There is no evidence of geographic variation in postnatal morbidity among newborn infants in Norway, although prematurity rates do show a moderate geographic variation of about 30% (4).
Categories of preterm birth are defined by gestational age (5):

- Late preterm – GA between 34 weeks and 36 6/7 weeks
- Moderate preterm – GA between 32 weeks and 33 6/7 weeks
- Very preterm – GA between 28 weeks and 31 6/7 weeks

- Extremely preterm – GA less than 28 weeks

Morbidity increases with decreasing gestational age and weight, and includes acute and chronic lung disease, life-threatening infections, gastrointestinal disease, cerebral haemorrhage or infarction, and impaired neurodevelopment (5). Improvements in care over the last 40 years have resulted in the increased survival of smaller infants and less severe morbidity among preterm infants (6). The mortality and morbidity rates of preterm infants born at a gestational age of 28 weeks or more are relatively low (4, 7). However, preterm infants may need short-term mechanical ventilation and more long-term non-invasive respiratory support; additionally, they need appropriate nutrition, assistance in developing eating skills and developmental support. Long-term studies from both Norway and Sweden have documented increased morbidity, particularly in terms of cognitive, behavioural and mental challenges, and reduced quality of life for preterm infants, from childhood to adolescence and adulthood (8-11). Whether this situation will improve for preterm infants born today remains to be seen, but it has been argued that preterm birth should be recognised as a chronic condition requiring long-term follow-up to determine the presence of any adverse consequences for adult health (8). On the other hand, it is also well documented that most preterm infants exhibit normal cognitive and motor skills as adults (12). Therefore, although prematurity should be considered a risk factor for later health problems, the actual incidence of such problems is subject to large variations and may at any rate be ameliorated by higher birth weight and GA and decreased initial morbidity.

The main population in the current study was limited to infants born at 28–32 weeks of postmenstrual age (PMA). For these infants, severe neurobehavioural impairment is relatively low. In recent studies on survivors of very preterm (VPT) births, approximately 17% exhibited cognitive or motor delays (13); mild delays were more common. Severe morbidity is strongly associated with GAs lower than 26 weeks (14). Large variations in moderate to severe neurodevelopmental outcomes have been reported in Europe, suggesting that there may be differences in attitudes towards the provision of life support and care practices, as well as divergent follow-up methods

(15). In addition, even though the risk of severe morbidity is low in VPT infants, the spectrum of developmental risks caused by stress during NICU hospitalisation remains poorly understood. Although an infant’s brain develops well into adulthood, essential structures emerge during the last trimester of pregnancy, e.g. the myelination of the neurons in the central cortex (16). Although brain development is a genetically driven process, there is increasing evidence that early experiences and stimulation influence long-term outcomes. Stressors during the NICU stay may affect the regulation of the hypothalamic-pituitary-adrenal axis, our central stress response system, and general brain development (17, 18). Worse, VPT infants have lower tactile thresholds, which in turn induces oxidative stress and inflammatory reactions (19). This may result in chronic toxic stress, thereby increasing short- and long-term morbidity (1, 19-21).

Studies suggest that the presence and involvement of parents may ameliorate their infants' neuroendocrine stress responses and accordingly mitigate or even prevent toxic stress (22). Early stressors, both physical and emotional, affect neural networks and may contribute to a cascade effect, resulting in an impaired ability to adapt to later challenges in life (16, 23). On average, infants born at less than 34 weeks’ GA have been found to spend 38 days in Norwegian NICUs before discharge – but again there are large variations in this figure (4). During these 5-6 weeks of hospitalisation, the infants’ brains develop at a pace that is unprecedented in later life (23), underscoring the need to optimise treatment and care during this period in order to improve long-term outcomes (16).

1.1.1 Nutrition and growth

Growth can be seen as a ‘maker’ of health and disease in preterm infants (24). Most preterm infants are exposed to some degree of extra uterine growth restriction, and poor postnatal growth is associated with less beneficial neurologic outcomes (25-27). Klingenberg et al. reported that, in Norway, 14% of preterm infants born before 30 weeks’ GA were growth-restricted (weight < 10th centile) at discharge (28).

Preterm infants have higher nutritional requirements than full-term infants due to low storage, a physiologically immature gastrointestinal tract, and a lower tolerance for macronutrients and milk volumes (5). The substantial health benefits of human milk, preferably the mothers´ own milk, and breastfeeding preterm infants are recognised by the World Health Organization (WHO) (29). Mother's milk reduces gastrointestinal complications and has beneficial effects on immunologic defence in preterm infants (30, 31). Further, nutrition with mother's milk is associated with improved neurological outcome and may also play a role in the development of cerebral white matter (23). However, to correct for growth restriction and to achieve an appropriate growth velocity, it is generally recommended that mother's milk be fortified with protein, energy, minerals and micronutrients (30). If mother's milk is not available, fortified banked breast milk is the preferred choice, with preterm formula representing a secondary option.

Although there is strong consensus that mother's milk is the preferred type of enteral nutrition for preterm infants, there is no such agreement on how to most effectively implement currently available evidence. The determination of the optimal timing and magnitude of catch-up growth is debated (32). Diverse practices are employed with respect to the fortification of mothers' milk and to the administration of appropriate volumes, even between units in the same country (33). Different practices make comparisons difficult when assessing both growth and neurodevelopmental outcomes. In recent literature, there are reports on how an increased focus on nutritional practices has resulted in better growth trajectories in preterm infants (34). As we strive to achieve a balanced nutritional schedule, one which would account for the risk of potentially adverse effects and long-term metabolic consequences, it is reasonable to ask whether there may be other factors that could optimise preterm infants' growth.

The rationale behind this study rests on a specific historical precedent. Until 2012, the NICU at Vestre Viken Hospital Trust (VVHT) was a traditional OB unit, but thereafter it was converted to a new SFR unit. Growth parameters were consecutively followed seven years prior to the conversion and for the first year thereafter, and the nutritional policy employed by the unit was not changed during this time. Despite this, the mean weight of infants at discharge increased by 300 grams and was 155 grams higher at 40 weeks' PMA for infants in the SFR unit. The corresponding increase in length and head circumference was 0.8 cm (unpublished results). Our hypothesis is that more involvement and support by parents had a impact on growth. It has been suggested that reducing environmental stressors may improve neurobehavioural outcomes (35-37). That said, there is no conclusive data to show a similar effect on growth, although some early reports suggested that increased parental presence and involvement facilitated faster weight gain and increased weight at discharge (38, 39). Our observed parallel improvements in growth at 40 weeks' PMA coupled with the change in care practice from OB to SFR care were compelling enough to justify the exploration of a potential causative relationship (Figure 1).

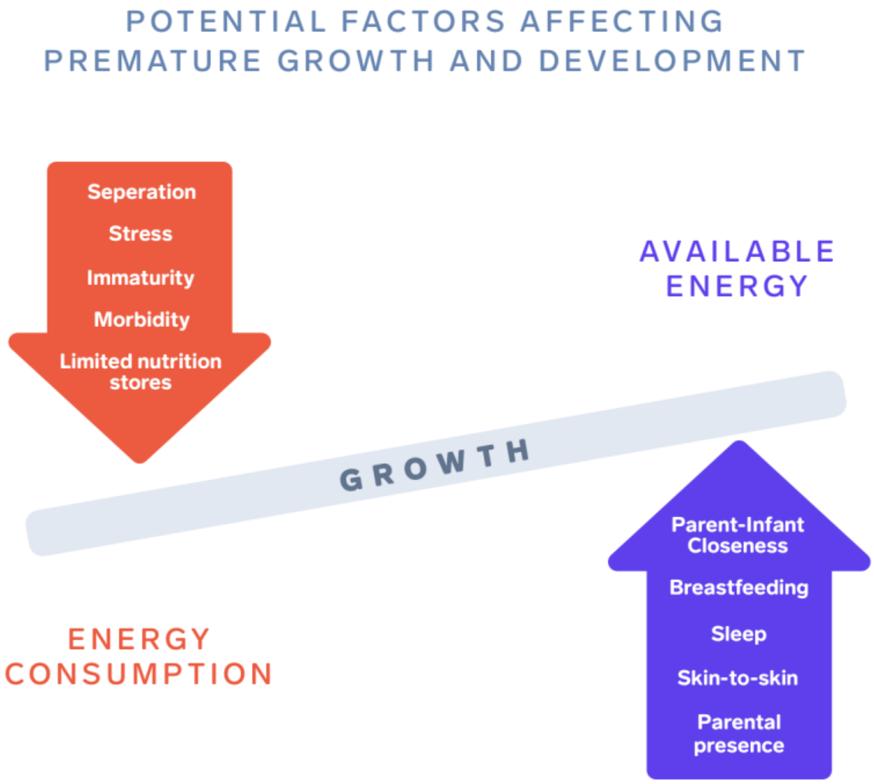

Figure 1. Visualisation of the hypothesis of a correlation between factors that may potentially affect growth in premature infants.

1.1.2 Breastfeeding the preterm infant

The infant's ability to coordinate breathing, sucking and swallowing is a prerequisite for breastfeeding. Immaturity and morbidity are limiting factors (40). Breastfeeding is increasingly stimulated as the infant matures, but the time point at which breastfeeding is accomplished differs and is not necessarily related to GA. Some infants may be able to search for and latch onto the breast as well as to suck actively as early as 28 weeks; other infants have the capacity to breastfeed from 32 weeks PMA (41). Following a preterm birth, the mother's ability to produce milk may be hindered by limited milk-producing tissue (42) and lack of stimulation by the infant. Therefore, these mothers must be encouraged to stimulate and pump the breast to initiate and maintain milk production. Early initiation of pumping or hand milking (within the first 6 hours of giving birth) is a contributing factor to the establishment of breastfeeding in preterm infants (43). However, maintaining milk expression for weeks has been reported to be emotionally challenging for mothers (44).

Breastfeeding the preterm infant is not only about optimal nutrition; it also plays an important role in the development of the mother–infant relationship. Breastfeeding is influenced by many factors related to the condition of the infant, to the disposition of mothers and staff, and to the relational factors between them (45). Factors that negatively affect breastfeeding progression include separation of the infant from the mother, the mode of delivery, multiple births, the infant's sex (i.e. being born a boy), the mother's level of education, smoking, poor physical and mental health, lack of previous breastfeeding experience, poor motivation, and negative expectations of coping with breastfeeding (43). Mothers require considerable breastfeeding support, both practically and emotionally, to optimise successful breastfeeding. To provide such support, nurses must possess theoretical knowledge on how preterm infants develop the skills needed to enable them to breastfeed (46); moreover, nurses must adopt strategies to support parent–infant relationships during the process (45). Mothers' perceived expectation of their own capacity to cope with breastfeeding is commonly referred to as 'breastfeeding self-efficacy'. This perceived capacity may influence the efforts mothers undertake to successfully breastfeed, with a higher level of self-efficacy being associated with greater success (47).

In Europe, the prevalence of breastfeeding in preterm infants at discharge varies between 19% and 70% (48). It is notable that, in Sweden, the prevalence of breastfeeding preterm infants has decreased significantly over the last 10 years despite parental access to NICUs has actually increased (49). Solid evidence on how to facilitate an optimal breastfeeding process is lacking, but there is growing evidence that early parental involvement (50, 51), extended physical contact and daily skin-to skin contact (SSC) (52, 53) are all factors contributing to the early initiation of breastfeeding. The early initiation of SSC is also a decisive factor for successful breastfeeding at discharge (43) and has been suspected to positively impact the duration of breastfeeding beyond discharge as well (54).

1.2 Psychological well-being of parents in the NICU

The expecting mother usually looks forward to the postpartum period, anticipating joy and closeness with the infant. However, this period may be very different for parents of a preterm infant in an NICU. When entering the NICU, parents encounter an unfamiliar world with monitors, high-technology equipment and procedures that may increase their worry and concern for their infant. Preterm birth is in itself a stressful experience for parents (55-58), and regardless of the actual degree of prematurity and/or illness, most parents experience anxiety about the consequences of prematurity for short- and long-term outcomes and development (59). The level of stress has been shown to correlate with the risk of depression (60-62), although the actual occurrence of clinical depression among NICU parents is not well described (63). A Swedish study screened mothers for symptoms of clinical depression one month post-discharge and reported a large difference in clinical depression (23% versus 8%) between two different units. The study suggested that variations in NICU environments and care practices could at least partly explain differences in the incidence of clinical depression (64). In a Norwegian study of psychological distress in mothers of preterm infants two weeks after birth, Misund et al. found that 52% experienced high levels of post-traumatic stress, defined by a score ≥19 on the Impact of Event scale, which was perceived as clinically important stress-related cognition and behaviour. Further, 28% of the mothers scored at a level indicating clinical depression, while 17% scored at a level indicating anxiety (65).

Studies indicate that fathers of preterm infants experience less stress compared to mothers (66, 67). This difference may be related to the degree of parental involvement as well as to cultural and social expectations about parental roles (68, 69). One study showed that increased involvement by fathers increased their level of stress (70). A comparison of mothers' and fathers' experiences with the attachment process found that mothers experienced the need to regain the temporarily lost relationship with their infant, whereas fathers experienced the beginning of a new relationship (71). Nevertheless, both parents require emotional support and guidance from competent nursing staff to properly care for their infant. The responses (i.e., well-being, discomfort) from preterm infants are fewer and more vague than those of full-term infants, and they may be more difficult to identify, interpret and address by inexperienced parents (72, 73). NICU parents develop their parenting skills while interacting with the infant and receiving support and guidance from the staff (55, 74, 75). Whether SFR care is of benefit for parents' psychosocial well-being is not established, as studies have shown that whilst increased participation in care may be perceived as positive by parents (51), they may also experience increased stress and isolation in SFRs (51, 76).

1.3 Involvement of parents in the neonatal intensive care unit (NICU)

During the last 50 years, neonatology has developed into advanced intensive care medicine with increased survival rates for preterm infants (77). This continuous development of knowledge and advancement in medical technology have increased the need for professional competency, quality, continuity and efficient treatment and care of infants and their families throughout their hospital stay. Even though the focus in neonatology has shifted from increased survival to continuous improvement in long-term outcomes, infants are still separated from their parents. The realisation of the consequences of separation emerged as early as the 1950s, when Bowlby showed that hospitalised children who were separated from their mothers rapidly developed abnormal behaviour and delayed development (78). This finding established the theory that attachment constitutes the basis for understanding infants' psycho-social development (78, 79).

In the 1980s, the need for infants to have a parent caregiver present was increasingly recognised (80), together with a renewed focus on attachment within psychology. This yielded new knowledge about how infants' early attachment experiences shape their understanding of the world and of themselves, as well as their expectations of other persons and surroundings (81). Parents and staff in the NICU are fundamental to the preterm infant's initial communication experiences and perceptions of the outside world (81). Also during the 1980s, the concept of 'human neonatal care' emerged in Estonia. Due to a lack of resources and nurses, preterm infants and their parents were assigned to the same rooms. Parents were taught to provide care for each other in addition to receiving input from nurses. Breastfeeding, minimal use of technology, and little contact between the infant and medical and nursing staff, undertaken to reduce exposure to pathological microbes, were promoted whenever possible. This approach resulted in fewer infections, increased competence in parents and the maintenance of the biological and psychological ties between the mother and infant, as claimed in a paper published in 1994 (82).

In the 1990s, NIDCAP® (the Newborn Individualized Developmental Care and Assessment Program) achieved widespread recognition, particularly among neonatal nurses (73). The programme emphasises systematic observations of the preterm infant's adaptation to the extrauterine environment through autonomic, motor and sleep behaviour, and via self-regulatory subsystems. The infant communicates with the outside world through these subsystems. Through observations, the staff interpreted the infant's signals and fine-tuned their responses in a more conscientious and gentler way, in accordance with the individual infant's degree of adaptation and level of development. This was achieved by limiting light and sound levels, enhancing supportive positioning and better acknowledgement of the infant's rest and sleep periods. The programme also emphasises the importance of the role of parents as the primary caregivers, although this emphasis was not embraced during the early development of the programme, as explained in later publications (83).

During the last 20 years, a large number of studies have documented the effect of various programmes aiming at sensitising parents to the preterm infant's signals and thereby increasing attachment and interaction (84-87). There is now a general acceptance among NICU staff that both parents have the right and need to be involved in care and decision making. The concept of family-centred care (FCC) is generally accepted as the working platform for NICU professionals, although the degree of implementation may differ significantly (74, 88, 89). The philosophy of FCC is that the family, including siblings, are affected when a child is hospitalised, and that parents can assume a central role by sharing responsibility for their infant's care with professionals (90).

The FCC concept may be defined as:

> *A way of caring for children and their families within health services which ensures that care is planned around the whole family, not just the individual child/person, and in which all the family members are recognized as care recipients* (91, p 1318).

In 1992, the Institute for Patient- and Family-Centered Care® defined four core elements in FCC: (1) Dignity and Respect, (2) Information Sharing, (3) Participation and (4) Collaboration. These elements apply to all health care providers, including health care managers, at all levels of health care services for patients and their families.

The FCC initiative was acknowledged as a national standard by the American Paediatric Association in 2003. The concept has since developed further, and several new concepts are emerging, e.g. patient/person-centred care, compassionate family care and family collaborative care. During the last decade, the concept of family-integrated care (FiCare) has emerged. The Canadian Change Foundation promoted FiCare in 2010, providing evidence for the positive impact of involvement by parents (51). FiCare promotes the same core values as FCC, but it also emphasises decision sharing by increasing knowledge for families through education sessions, better staff communication capacities and the involvement of veteran parents to support new parents. However, whether new conceptual terminology actually contributes to increased clarity regarding the concept of family involvement itself is doubtful – indeed, such terms may only heighten confusion and reduce clarity about the FCC concept and how it should be operationalised in practice.

A common feature of the concepts just mentioned is active parental participation in care. It is not sufficient to just centre care towards families; they should also be involved as equal partners in decisions regarding their infant's treatment and care. Professionals hold expert competence in their disciplines, but families are experts in their own lives and about their own resources. An updated definition of FCC has hence been suggested:

> *FCC is the professional support of the child and the family through a process of involvement and participation, underpinning empowerment, and negotiation. FCC is characterized by the relationship between healthcare professionals and the family, in which both parts engage in sharing the responsibility for the child's health care* (90, p 1159).

This understanding of the FCC concept acknowledges that parents will evolve as experts in their infant's care, and that the staff's role is to support this development. Another contribution to the implementation of FCC in recent years was the publication of eight practical principles in the NICU (92). These principles may also serve as a framework for benchmarking NICUs as part of quality improvement. Emotional support, parents' participation in decision making and fathers' participation in infant care were reported as the weakest aspects of FCC among European parents and nurses at 11 centres in six different countries (93). There is therefore room for substantial improvements in terms of emotional support, consistency in health care provider communication and FCC practices (94). However, it is important to consider economic and socio-cultural differences in health care services, within not just Europe but the US as well, when interpreting results. What is included and perceived as quality in standard NICU care differs. Recently, parents in six different Norwegian NICUs were asked via survey about their satisfaction with regard to core elements of FCC. Most of them, 76%, reported high satisfaction overall, while 99% reported being satisfied with the care of their infant. Areas identified as being in need of improvement were related to ongoing continuity during patient care pathway, including follow-up. In addition to care for the whole family (including siblings). The need for more targeted guidance and training about their infant's specific needs was also highlighted. In addition, parents reported that involvement in decision making as well as respect and empathy from staff were integral to their satisfaction (95).

In 2018, the European Foundation for the Care of Newborn Infants (EFCNI) launched European standards of care for newborn infants' health. FCC and a physical environment that allows for extensive parental presence and participation were considered primary standards of care for hospitalised newborn infants in Europe (96, 97). Although NICUs claim to align their practices according to the principles of FCC, and while the levels of standard care provided are perceived to be good or excellent by many parents, possibilities for improvement remain. The degree of involvement by parents is still highly variable (98, 99), and parental involvement in the form of active participation in medical rounds (e.g. parents representing the patient) is still considered controversial by many professionals.

1.3.1 Parent–Infant closeness

Increased parental presence and involvement in making decisions also provide opportunities and encourage parent–infant closeness. Physical closeness in terms of skin-to-skin contact (SSC) may be among the most effective general stress-reducing interventions available for preterm infants.

SSC involves the infant, wearing only a diaper, being situated frontally in an upright position on the mother's or father's bare chest. SSC is recommended for preterm infants by the WHO (2003), and guidelines for the implementation of SSC in the NICU environment exist (100). SSC is associated with a reduction in mortality, severe infections, hypothermia and severe illness, as well as a shorter length of hospital stay, increased weight gain, increased head circumference and length, an increased breastfeeding rate and maternal satisfaction (101, 102). It has also been suggested that even limited SSC may improve psychological and cognitive outcomes up to 20 years after intervention (103, 104). However, one should bear in mind that many of the studies that are often referenced were performed in low-resource countries where SSC is lifesaving, as other lifesaving equipment, like incubators and ventilators, are often absent or scarce. In high-resource health care systems, SSC is mostly used intermittently, but even intermittent SSC has been convincingly shown to generate positive health benefits for preterm infants. SSC contributes to short-term clinical stability, better sleep patterns and reduced autonomic pain responses (105, 106). SSC is also associated with hormonal effects that reduce stress in parents and their infants while increasing bonding (107, 108).

SSC is part of standard care in all Norwegian NICUs, but the degree of implementation varies (109). Whereas early (immediately after delivery) and extensive SSC are considered important in some units, other units may not apply SSC during the first week. Decreasing GA often correlates with later initiation of SSC. Staff attitudes and scepticism are often related to safety issues – for example, during transfer in and out of incubators (110). However, studies have shown that SSC can also be safely used in extremely preterm infants (111-113). Despite its common use and reported benefits, neither the biological mechanisms by which SSC actually exerts its effects (18) nor dose–response relationships are fully understood (50).

1.4 NICU design

An intensive care unit is defined as:

> *…an inpatient unit that provides medical care to patients with severe or life-threatening illnesses. The equipment and insensitivity of supervision are at a*

> *level of sophistication that addresses potential medical crises and the frailty of the patient* (114, p 13).

Since children have special environmental needs based on their development and psychosocial well-being, and as they require specialised treatment and care, specialised intensive care units exist for children 0–18 years. Treatment of sick full-term infants and preterm infants is recognised as a medical subspecialty in paediatric care. Therefore, the infants are admitted to specialised NICUs. The awareness of the infants' sensitivity to environmental stimuli is salient in the NICU's design. The physical environment in a traditional NICU is characterised by a room with multiple incubators and cots and around-the-clock activity by parents, visitors and staff, as well as alarm-capable monitors and medical devices. The American Paediatric Association published a recommendation for decreasing the amount and level of noise in NICUs in 1997 (115). One of the pioneers of single-room NICU care, Dr. Robert White, stated that '*in no other part of the hospital is providing an optimal physical environment more important than in the NICU, because nowhere else will adverse effects of noxious physical elements have more profound effects'* (114, p 72).

The infant's immature brain needs undisturbed sleep and positive stimulation without unnecessary stress and pain. The awareness of the critical impact of disruptions in the natural environment for the infant (i.e. the womb) followed by the separation of the infant from the mother is a crucial consideration in the design of an NICU (114). In traditional NICUs, premature and sick newborn infants spend their first weeks separated from their parents. Parents have access to their infants for most of the day, but they cannot sleep in the unit, meaning that they are separated for many hours during a 24-hour period. The recognition of the possibly severe consequences of separating infants and mothers is one of the main reasons for promoting and building SFRs in NICUs (114). An SFR in the NICU provides a more stress-reduced environment with suppressed noise and the potential opportunity for parents to stay with their infant in more private conditions.

The bonding between a mother and her infant after birth is an important biological and physiological process (72). The post-partum emotional response of both the mother and the infant is rooted in instincts programmed by evolution to secure the survival and safety of mammalian offspring, and thus separation may induce distress and fear in both mother and child (1). Compared to other mammalian species, the human brain is larger and more adaptable at birth, but it is also more immature and more dependent on caregiving behaviours and a nurturing environment (116). Early positive caregiving (e.g. SSC, breastfeeding, holding) may protect the hypothalamic-pituitary adrenal axis from dysregulation and thereby shield the infant from stressors (separation, noise, pain) (117-120). Current knowledge supports the assumption that the physical NICU environment, stress exposure and disruption of mother–infant attachment may negatively influence brain development (121, 122).

In spite of this knowledge, the transition towards SFRs has been slow in NICUs. There might be several explanations for this, among them being reluctance on the part of NICU staff to embrace SFRs due to questions about safety issues. NICU staff are accustomed to having direct access to all patients at all times. Whether or not the values of SFR, such as privacy, are as important in the NICU as adult care has also been questioned (114).

However, understanding of the multiple pathways involved in infants' adaptive/maladaptive responses is growing. The NICU environment and associated experiences influence physiological processes, e.g. immunological inflammation responses to oxidative stress and socio-psychological processes, such as bonding and attachment, which might impact later outcomes in preterm infants (21, 123, 124). The first single-room NICU opened in the state of Arkansas, in the US, in 2000. Since then, SFR units have opened in many other US states. In Europe, a few NICUs have integrated SFR care into their design, although the number is increasing. The SFR unit at Drammen Hospital was the first to provide SFRs to all infants and their parents throughout their entire stay – but, currently, several NICUs in Norway are restructuring in an effort to provide more SFRs in their units.

1.5 Previous research on SFR design

When we initiated this study in 2013, the implementation of SFR care had just started, and research on the impact of SFR NICU design had just begun to emerge. In 2011, Lester et al. published a theoretical model of the potential effects of maternal care in SFRs, including those effects which could improve infants' neurobehavioral status. This model identified mediating factors that are likely to occur when rebuilding or changing the OB into an SFR unit. These mediating factors include FCC practices, level of developmental care, parenting and family factors, staff behaviour and attitudes, and medical practice. The contribution of physical factors in SFRs, e.g. stress reduction, was expected to have an impact on mediating factors, which would in turn contribute positively to the infants' outcomes. Lester and colleagues hypothesised that SFRs constituted a preventive intervention with the potential to improve the neurobehavioural outcomes of infants at discharge (125), but they also underlined the complexity of assessing the research-based effects of the impact of an SFR design.

The first studies conducted in this regard were aimed at documenting the effects of architectural layout on physical factors like noise and light reduction. These studies reported a reduction of noise and unnecessary light exposure, with potential stress reduction effects on respiratory and circulatory outcomes (126-128). However, the only randomised controlled study to document the effects of an SFR design on infant outcomes was 'the Stockholm study', which found a reduction in the length of hospital stays by 5.3 days in an SFR compared to an OB unit. No differences in infant morbidity were found, except for a reduced risk of moderate-to-severe bronchopulmonary dysplasia, although the authors underlined the need for further research before drawing conclusions about the effects of room type on morbidity (129).

Some early studies explored feeding and growth as outcomes and found that infants in SFR units reached full enteral nutrition 2.5 days sooner than infants in OB units, although no differences in weight gain per day or weight at discharge were observed

(128, 130). Effects on breastfeeding rates were inconsistent; some studies documented increased breastfeeding, while others did not (39, 128, 131).

Studies have also shown improved parental and staff satisfaction with an SFR design, but not all experiences have been unambiguously positive. Nurses have reported increased job satisfaction but also fewer opportunities to communicate with colleagues within the team (127, 132, 133). Parents' reports have also been inconsistent; the overall assessment of the NICU environment and care has been positive, but parents' limited ability to learn from and interact with other parents and staff also contributed to a feeling of isolation (127, 131, 132).

Pineda et al. conducted a quasi-experimental study that explored the relationship between SFR versus OB care on parental visitation, the holding of infants, SSC, breastfeeding and maternal health. They found a large variability in these outcomes and thus raised the question of whether parental behaviour was more related to individual factors than to physical features of SFR facilities (131). However, a spill-over effect could have occurred, which would represent a bias considering that both types of rooms were within the same unit and were managed by the same staff. In a follow-up study, Pineda and colleagues found that more frequent parental visitations were associated with significantly better neurobehavioural scores at term date, irrespective of SFR or OB care (134).

In 2013, O´Brien et al. published a pilot study that explored the feasibility, safety and outcomes of implementing the concept of FiCare. Infants born at 35 weeks of gestation or less and who received Continuous Positive Airway Pressure (CPAP) or less respiratory support and had a primary caregiver who was willing to spend at least eight hours a day with the infant were eligible. Mothers of 31 infants completed the study. The growth rate until 21 days after enrolment, as well as the breastfeeding rate at discharge, were significantly higher in the FiCare group compared to controls. Feedback from the parents and nurses indicated that the implementation of the FiCare model was both feasible and safe (39).

Methodological issues have hampered the interpretation of results published before 2013. All such studies, except for the Stockholm study (129), were either observational, had a pre- and post-implementation design, or included small numbers of families and infants (127, 128, 130-132). The main weakness with the pre/post-test design is a lack of control of external factors that might contribute to the outcomes. For instance, positive or negative attitudes and expectations on the part of staff can bias the results in randomised, pre- and post-design studies. Stevens et al. emphasised that the SFR environment appears more conducive to the provision of FCC, and that FCC might be the key element culminating in improved parental satisfaction with care, not the SFR environment (135). However, neither Stevens and colleagues nor other researchers have, to our knowledge, reported data on changes in care culture or treatment procedures. A careful description of the treatment and care provided in both types of units is necessary in order to fully trust the results.

1.6 Knowledge gaps when this study was initiated

In 2013, knowledge about how SFRs might affect infant outcomes, parental involvement and well-being, and staff satisfaction was limited. All previously mentioned studies were conducted in North America, except for the Stockholm study. Inherent mechanisms regarding the effects of SFR design may differ between different cultures and health care systems. Differences in the financing of health care services, social benefits related to pregnancy and childbirth and cultural norms may also influence interpretation of results of infant and parental outcomes. Registration of the actual degree of parental presence and of parental behaviour, such as the extent of holding and the provision of SSC, was often lacking in earlier SFR studies, e.g. in the Stockholm study. Furthermore, parental involvement was low compared to that expected in a Nordic NICU (131, 134). At the time our study commenced, evidence remained lacking on whether the degree of parental presence and involvement in the NICU impacted growth, the successful attainment of breastfeeding, or parental attachment at or beyond discharge, and only a few studies had at that time reported on infant outcomes (126, 128-130).

2 Aim and hypotheses

The overall aim of the study was to describe and compare premature infants´ growth and breastfeeding, parents' involvement and well-being, and staff perceptions of FCC during and after hospitalisation in an NICU with an SFR design versus an OB design. Our hypotheses were:

- SFR design increases parent–infant closeness through more extensive parental presence, greater provision of SSC, more substantial involvement in care and greater support to parents in comparison to OB care.
- SFR care leads to improved growth through close parent–infant interaction, including more SSC.
- Parents who participate actively in care through continuous presence in an SFR unit do not experience more emotional distress than parents in an OB unit who spend less time with their infant.
- SFR care leads to increased breastmilk volumes, earlier direct breastfeeding and improved self-efficacy after a preterm birth.

Paper I aimed to prospectively measure and compare parent–infant closeness as parental presence and SSC. Parental participation in decision making, daily care and medical rounds, as well as support from nurses, were measured through parental experiences concerning information, guidance and emotional support via self-reports. Furthermore, this study also aimed to measure and compare nurses' perceptions of the support they provide for parents in both the SFR and OB units.

Paper II aimed to compare growth in very premature infants admitted to either an SFR or an OB unit.

Paper III aimed to compare emotional distress in the form of depression, anxiety, stress and attachment scores among parents of VPT infants admitted to either an SFR or an OB unit.

Paper IV aimed to compare the initialisation of milk expression and breastfeeding, volumes of mother's milk produced, the extent to which infants received mother's milk, the occurrence of direct breastfeeding, and breastfeeding self-efficacy in an SFR unit versus an OB unit.

3 Research design and methods

Table 1 gives an overview of the study characteristics, design and methods.

Table 1. Study characteristics

	Study population I	Study population II		
Study populations	Infants with Gestational age ≤ 35 weeks and their parents Nursing staff in the two units	Infants with Gestational age 28+0 – 32+0 weeks and their parents.		
	Paper I	**Paper II**	**Paper III**	**Paper IV**
Design	Prospective comparison	Prospective comparison	Prospective comparison	Prospective comparison
Method	Observations Questionnaires	Observations	Questionnaires	Observations Questionnaire
Times of data collection	During hospitalisation	During hospitalisation At discharge Post-discharge term date At 4 months' post term	During hospitalisation At discharge Post-discharge term date At 4 months' post term	During hospitalisation At discharge Post-discharge term date At 4 months' post term
Types of data	Parents' Closeness Diary Parents' report on SMS questions Nurses' report on Web questions	Parents' Closeness Diary Daily nutrition Registration of infants vital measurements: Weight, length and head circumference	Parents' self-reported questionnaires	Registration of mothers' milk volume Breastfeeding occurrence Mothers´self-reported questionnaire
Data analysis	Descriptive statistics Bivariate analyses Explorative analysis	Descriptive statistics Bivariate analyses Linear regression Functional Data Analysis	Descriptive statistics Bivariate analyses Linear regression Mixed model	Descriptive statistics Bivariate analyses Logistic regression Mixed model

3.1 Setting

Two units participated in this study: The SFR unit at Drammen Hospital, VVHT, and the OB unit at Haukeland University Hospital (HUH) in Bergen. Both units were located in maternity hospitals and provided care for all infants born with a PMA from 28+0 weeks within their hospital referral area until discharge. Included infants represented the eligible cohorts of preterm-born infants from these two catchment areas.

3.1.1 The SFR unit

The SFR NICU unit provides care from birth for infants in need of special care, including prematurely born infants from a PMA of 28 weeks. The average admission rate is 390 infants per year. Infants are delivered in the same building and close to the NICU. This unit was opened in 2012 and has 17 single rooms and no open bay areas. Parents and infants are encouraged to stay together from birth until discharge, and siblings can visit without limitations. Both parents are encouraged to stay with their infant for as long as they wish, but mothers must stay in the obstetric ward during the night until 48 hours after giving birth. Each room has two separate areas: one infant area with a space for an incubator or cot, technical equipment, a sink and a bench; and one parent area with two high-quality hospital beds, 105 cm wide, that are electronically adjustable. All rooms have separate bathrooms. In the daytime, there is no physical separation between the parent and infant areas, and equipment are mounted on flexible arms, allowing the secure transfer of the infant from the incubator to the parents' bed without disconnection. During the night, parents can use flexible folding doors to enclose the sleeping area, and nurses still have direct access to the infant without disturbing the parents. All meals are provided without cost to both parents. At the time of the study, parents had access to a psychologist in the unit and to weekly meetings with other parents. During the study, the unit had 62 nurses, 15 (24%) of whom had a postgraduate education in intensive care, paediatrics or neonatal nursing. The SFR unit had five fully-trained lactation support providers.

Photo credit: The SFR NICU unit, Drammen Hospital, Vestre Viken Hospital Trust

3.1.2 The OB unit

The OB unit was located at a university hospital and provided care from birth for all infants requiring intensive and intermediate care. The unit was built in 1979 and had been only modestly upgraded until the end of this study. The obstetric department was located in a different building 500 meters from the NICU, and all infants requiring NICU care were transferred by ambulance. Mothers were accommodated in another building in the hospital after discharge from the maternity ward. The unit had 21 beds and admitted approximately 500 infants per year. Except for one single-room used for high-intensive or end-of-life care, the unit had two open bay rooms: one for intensive- and intermediate-level patients, and one for low intensive-care patients. The rooms were crowded, but one reclining armchair could be placed between incubators or cots, and moveable screens could be placed around the family to provide some privacy. The parents had unlimited access at all hours, but they could not stay overnight in the unit, and meals were only provided for the mothers. A psychologist was available upon special request. The unit had 67 nurses, 43 of whom (64%) had postgraduate education similar to that of nurses in the SFR unit. The OB unit had six fully-trained lactation support providers.

Pictures: The OB NICU, Haukeland University Hospital, in 2013. Copyright: Private photo, Hege Grundt.

Although the facilities available for parents to room in were different, both units had an explicit policy of allowing parents unlimited access to stay with their infant for as long as they wanted. SSC was an established practice and had been strongly encouraged in both units for years before the initiation of this study. Both units promoted and offered guidance by breastfeeding consultants for early breastfeeding. In Norway, hospital care is financed through a public health insurance system and is free of charge for all citizens irrespective of income. No private neonatal intensive care is available. Parents have extensive publicly financed social security benefits during pregnancy and when giving birth. Both parents are generally entitled to job leave with full economic compensation during hospitalisation of their infant. There is also good overall coverage of kindergartens, approximately 90%. The social norm is that fathers are expected to, and do, participate in their infants' life from birth (136).

3.2 Study population I (Paper I)

In 2013-2014, both the SFR and OB units participated in a multi-centre prospective survey, the International Closeness Survey (ICS), which was conducted in 11 NICUs in six different countries. The ICS was aimed at benchmarking similarities and differences in FCC practices and infant–parent closeness across Europe (98, 137). The international multidisciplinary research network Separation and Closeness Experiences in the Neonatal Environment (SCENE) (https://www.utu.fi/scene) was responsible for the study. The Norwegian data were analysed and compared separately, as detailed data from the two Norwegian units were not fully explored in the multi-centre international comparison.

The sample size was based on convenience sampling and on the inclusion of a predetermined number of patients. The aim was to include 30 families in every unit, and the study lasted from 1 September 2013 to 30 April 2014. Parents of preterm infants born ≤35 weeks' GA were consecutively invited to participate during the first six days after birth. Families were excluded from the study if they did not understand Norwegian or English, if the infant was one of a set of triplets or more, or if the infant was likely to die. Families were not approached if the anticipated hospital stay was shorter than one week or if the infant was transferred to another hospital. In total, 115 parents of 64 infants were followed for two weeks after inclusion in the study or until discharge, if it occurred before 14 days. Twenty-three of 131 eligible families declined participation. Thirty-three infants from 29 families in the SFR unit and 31 infants from 29 families in the OB unit participated (Figure 2). All nurses (n = 129) in the two units were invited to attend, and 62 nurses in the SFR unit and 67 in the OB unit participated anonymously. Recruitment of nurses and patients started at the same time, but the duration of recruitment lasted longer than planned in order to achieve a sufficient number of patients in both units

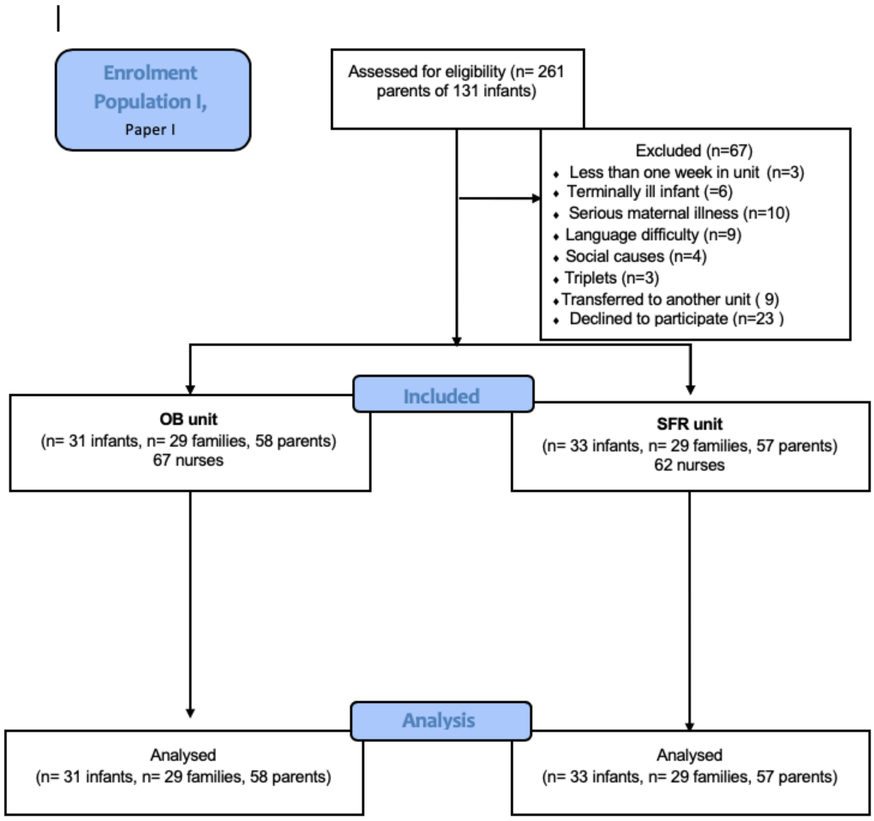

Figure 2. Flow diagram of participant recruitment. OB indicates open bay; SFR indicates single-family room; and SMS refers to short message service.

3.3 Study population II (Papers II, III and IV)

Inclusion in the main study (Papers II, III and IV) started on 1 May 2014 and ended on 31 July 2016, when the OB unit was relocated to another building.

The power calculation of the study was conducted with weight at discharge as the primary outcome and an expected difference of 300 grams, which was the observed mean difference in similarly obtained weight during the year after and the seven years before the establishment of the SFR unit at VVHT (page 17). The number needed to detect such a difference was only 10 in each group. However, in order not to underestimate the number needed to detect a clinically significant difference and to increase the possibility of detecting significant differences in secondary outcomes, we decided to include a higher number of infants.

To ensure comparable cohorts, we recruited infants born at GAs of 28+0 through 32+0 weeks and their parents. The reasons for this choice were that both units had the sole responsibility of providing care for these infants within their regions, and that these infants and their parents were assumed to have stayed long enough in the units to make valid comparisons. The families were consecutively recruited at admission. Two families in the SFR unit and six in the OB unit declined to participate. In addition, two families withdrew from the study. The exclusion criteria were as follows: born in another hospital or transferred to another hospital within the first 48 hours, major congenital malformations, intraventricular haemorrhage grade III/ IV, necrotising enterocolitis or a birth weight below 800 grams. We also excluded infants of parents with a major mental illness, parents who did not understand the Norwegian language, infants of mothers who had used illicit drugs or were on methadone during pregnancy, and infants in the custody of Child Protection Services from birth. Thirty-five infants in the SFR unit and 42 infants in the OB unit completed the study (Figure 3).

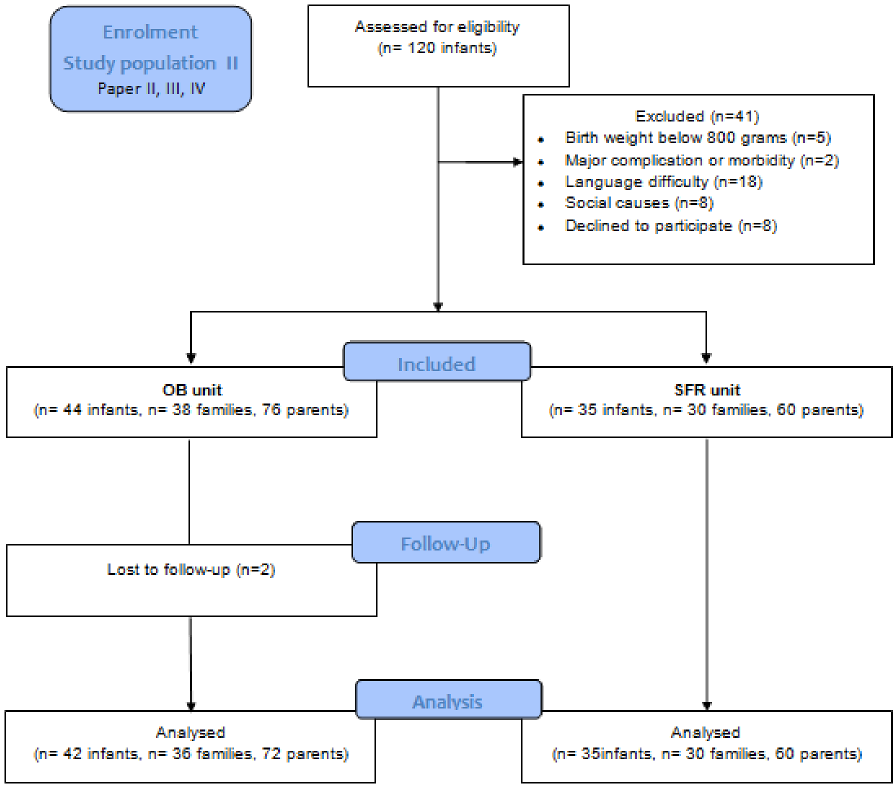

Figure 3. Flow diagram of participant recruitment. OB indicates open bay; SFR indicates single-family room.

In both units, GA was based on ultrasound assessment at 17-18 weeks of pregnancy or, alternatively, on the first day of last menstruation if ultrasound assessment was not available. Parents received oral and written information and were included if both gave written consent by the end of the second day. The candidate (BST) was responsible for recruitment, data collection and follow-up in the SFR, while a research nurse, Hege Grundt (HG), was responsible for the same tasks in the OB unit.

3.4 Data collection

3.4.1 Study population I

We evaluated parents' rating of the core principles of FCC: parental presence, individualised support, respect, information, collaboration and empowerment (88). Parents were asked about their extent of parental participation in decision making, daily care and medical rounds, as well as whether they perceived support through information, guidance and emotional support provided by the nurses. Furthermore, the nurses rated their perception of their own support to parents (Appendix 1: FCC core element questions). The general design and choice of data were decided by the ICS study. The clinical and demographic characteristics are described in Table I in Paper I. Families of infants born at or below 35 weeks PMA were included. Contrary to the SFR unit, the OB unit also treated extremely preterm infants – consequently, the groups differed somewhat in GA, with more premature infants in the OB unit, with a mean of 33+0 versus 31+1 weeks PMA ($p = .03$). Only five infants in the OB unit were below 28 weeks PMA. There was a significant difference between the groups in the rate of caesarean section – 58% in the SFR unit versus 29% in the OB unit ($p =.02$) – and in the number of twins: 10 in the SFR unit versus two in the OB unit ($p = .01$). The SCENE group designed a ‘Closeness Diary’ for prospective registration of parental presence and provision of SCC (Appendix 2: The Closeness Diary). In this diary, parents recorded their presence in the NICU and the duration of SSC each day. Diary entries were made daily for the first 14 days following inclusion in the study or until discharge, if discharged earlier. The diaries were kept in a closed folder next to the infants' bed. Presence was defined as parents being within the NICU unit, while SSC was defined as the infant wearing only a diaper and being situated in an upright position on the mother's or father's bare chest.

Parental participation and nursing support were measured by daily text messages through short message service (SMS). The SMS questions were sent to the parents' mobile phones through a protected website. Nine different questions were sent in random order. The Parents received one question every evening at 9 p.m. for the duration of their infant's hospital stay or until they stopped responding. If they did not respond, they received one reminder the next evening. If that SMS also went unanswered, they received no more messages. The validity of the content of the SMS questions was based on previously published literature (90, 138). SMS and web questions were translated from English to Norwegian according to the standardised guidelines for translation and cultural adaptation (139).

A website was used to collect responses from nurses. They were asked questions corresponding to those asked of parents (except for the question about participation in medical rounds), and in random order. Each nurse answered the questions, available via a website link, on an iPad after his/her work shift. After the answers were submitted, new questions appeared for the next nurse. Nurses answered the questions anonymously, and the questions were not linked to specific parent answers. The survey continued for three months. In their answers, nurses assessed their support to parents on that particular day. Both parents and nurses responded on a scale from 1 (not at all) to 7 (very much). The response rate for parents was 65% and 68% and for nurses 67% and 61% in the SFR and OB units, respectively.

3.4.2 Study population II

Parents recorded their presence and duration of SSC in diaries, in the same way as described for study population I. However, the recording was ongoing from birth until the infant reached a PMA of 34 weeks.

Both units adhered to the same protocol for nutrition based on the European Society of Paediatric Gastroenterology, Hepatology and Nutrition Committee on Nutrition recommendations (140), with both current practical nutritional procedures and minor local adjustments (Appendix 3 a: Feeding protocol if infants < = 1250 grams; Appendix 3 b: Feeding protocol > 1250 g; and Appendix 4:Data collection protocol). Macro nutrients were calculated according to published standards for breast milk and formula (141). The protocol is described in Paper II. Type of nutrition (parenteral, mother's milk, banked breast milk), mode of increment until full enteral feeds, and timing of fortification of breast milk were consecutively recorded. Intake of macro nutrients per day based on body weight was calculated each day from birth to at 34 weeks' PMA (Appendix 6: Nutritional calculation template).

Weight was measured daily from birth to 34 weeks' PMA. Crown-to-heel length and head circumference were measured weekly with a no-stretch measuring tape when the infant was cared for in an incubator. Length was measured with a stadiometer at 34 weeks' PMA, at discharge, at expected term date and four months after term date (four month-corrected age). Measurements were standardised and performed by the infant's nurse during hospitalisation and by BST and HG at each respective unit after discharge.

Mothers reported the first time they expressed milk in the hours postpartum. At day 7, day 14, and at a PMA of 340 weeks, they reported the total volume of milk expressed and/or directly breastfed during a 24-hour period. Directly breastfed volumes were measured with test weighing: one gram of infant weight gain was considered equivalent to one millilitre of milk. Both units used the same brand of electric breast pumps. The numbers of breastfeeding attempts from 32–34 weeks' PMA, the use of nipple shields, PMA at full enteral feeds and PMA at accomplished breastfeeding were registered. Data on exclusive and partial breastfeeding were retrieved from the infants' medical charts from birth and at discharge, and as reported by mothers at term date and at four months' corrected age using the WHO definition. According to the WHO, breastfeeding is classified as exclusive (allows drops, syrups, medicine), full (allows liquids, ritual fluids, drops and syrups, but not non-human milk or food-based fluids) and partial (breast milk supplemented with other nutrition) (29). For infants who have an immature feeding behaviour, e.g. premature infants during early care, the same definitions are commonly used with reference to the type of nutrition, even if it is provided by methods other than the breast, e.g. by gavage, bottle or cup. As commonly used by others, we made distinctions between milk nutrition and breastfeeding, since we regarded the age at which infants acquired the ability to breastfeed and the mother's ability to provide milk by breastfeeding as important outcome measures. Direct breastfeeding was retrieved from the infants' medical chart during hospitalisation and was reported by the mothers at term and at four months' corrected age. This was categorised as exclusively directly breastfed (fed only from the breast), partly directly breastfed (fed from the breast and by gavage/cup/spoon/bottle) and not directly breastfed.

3.5 Questionnaires

Parents were asked to complete questionnaires during hospitalisation at 14 days post-partum, at discharge, at term date and four months after term date (Appendix 7: Questionnaires). If one parent did not participate in a follow-up consultation after discharge, the questionnaires were brought home with the participating parent along with a stamped envelope and were returned by post. The following instruments were used:

(1) *The Breastfeeding Self-Efficacy Scale-Short Form (*BSES-SF) (142). Mothers who direct breastfed (exclusively or partly) at discharge answered the BSES-SF questionnaire. This instrument addresses confidence in breastfeeding. A Norwegian version has been published (143) that identifies breastfeeding mothers of preterm infants at risk of preterm weaning from breastfeeding (144). Through 14 claims, BSES-SF addresses the technical skills of breastfeeding and the mother's personal feelings in the breastfeeding situation ('I can always determine that my baby is getting enough milk') on a 5-point Likert scale; a higher score indicates higher self-efficacy (range from 0–30). The questionnaire has been found to be reliable and valid for preterm and sick newborn infants (145).

(2) *The Edinburgh Postnatal Depression Scale* (EPDS) (146). This instrument aims to identify depressive symptoms in pregnant women or women who have recently given birth. The EPDS was translated into Norwegian and was validated for Norwegian conditions by Eberhard-Gran and Berle (147, 148). EPDS consists of 10 statements, each with four response options. The range of the score is 0–30, and the score increases with an increasing number of symptoms. We applied a score of ≥ 13, as indicative of depressive symptoms in line with a Swedish validation, giving a sensitivity of 77% and a specificity of 94% in detecting symptoms of depression (149).

(3) *The State-Trait–Anxiety Inventory* (STAI) measures symptoms of anxiety in adults (150). It differentiates between the temporary condition of 'state anxiety' and the more general and long-standing quality of 'trait anxiety'. The STAI is one of the most frequently used measures of anxiety applied in psychology research (151). The STAI Short Form Y contains six statements: three items with anxiety present, and three with anxiety absent, which the respondents rate on a scale from 1 to 4 (150-152). The range of the total STAI score is 20–80, and it increases with an increasing number of symptoms. A 'normal' score is below 36 (153). STAI SF has demonstrated reliability and validity in different study samples of parents with sick infants (154).

(4) *The Parental Stressor Scale: NICU* (PSS: NICU) (60, 155) measures the degree of stress experienced by parents during hospitalisation related to alterations in their parental role, the appearance and behaviour of their child, and sights and sounds of the unit. Parents are asked to rate 34 items on a 5-point scale ranging from 'not at all stressful' to 'extremely stressful'. The subscales 'Sights and sounds of the environment' and 'Infant's appearance' are scored as one sub-scale, with scores ranging from 20 to 100. The second subscale, 'Parental role alteration', has a range of scores from 7 to 35 (155). The tool has been shown to predict depressive symptoms (60) and has a moderate correlation with state anxiety (156). It has been validated for European populations (157).

(5) *Parenting Stress Index* (PSI-SF). The short-form version of the PSI (36 questions) is a widely used clinical and research self-report questionnaire to identify stress due to parental factors or the deviant development of the child (158, 159). The questionnaire includes a parent domain (i.e. social isolation, attachment to the child, health, role restriction, depression and partner) and a child domain (i.e. distractibility/hyperactivity, adaptability, how demanding the child is perceived to be, mood and acceptance). The total score ranges from 18 to 90, and higher scores indicate higher levels of parent-related stress. An overall score between 52 and 90 is considered a high-risk level, whereas scores from 18 to 44 are considered low-risk/normal (160).

(6) *The Maternal Postnatal Attachment Scale* (MPAS) evaluates the mother's subjective feeling of attachment ('the emotional tie') to the infant (161). In the current study, fathers were also asked to complete the MPAS. The instrument consists of 19 statements referring to three different factors: patience and tolerance, pleasure in interaction, and affection and pride. The respondents indicate to what extent (never, very rarely, occasionally, frequently, very frequently) the statements match their perceptions. The possible range of scores is 19 to 95, with higher scores indicating better attachment. In Condon et al.'s study, the mean average score was 83 (range 56–95) at term date and 85 (range 59–95) four months post-term (161).

STAI and MPAS tools were translated into Norwegian with forward and backward translation. For PSS: NICU, a former Norwegian translation was used.

3.6 Statistical methods

We used SPSS version 25 (IBM Inc., NY, USA) and R Foundation version 3.5.0 (the function lme in the nlme package) software for the statistical analyses. A p-value less than .05 was considered statistically significant in all analyses. Biostatisticians were involved either as co-authors (Kathrine Frey Frøyslie in Papers I and II) or as consultants (Professor Dag Hofoss at Lovisenberg Diaconal College in Paper III, and Jannicke Igland, statistician at the University of Bergen, in Paper IV).

3.6.1 Analyses based on study population I (Paper I)

Descriptive statistics were performed according to the type and distribution of data, i.e. as means and standard deviations (SDs), medians and quartiles (Q1, Q3), or frequencies (percentages). Groups were compared by bivariate analyses accordingly, with the two-sample t-test or Mann-Whitney test for continuous variables, and the Pearson's chi-square test for categorical data. The primary outcomes in this study included parental presence and physical closeness collected by the Closeness Diary. Estimated differences between groups, based on data from observational designs, will always be subject to potential confounding factors (162, 163) – in particular, it was noted that GA, mode of delivery, multiple births and the proportion of first-born infants differed between the groups, and that all these factors may be considered as confounders for the differences of interest. However, a small number in the subgroups and skewness of the distribution made it unfeasible to make formal adjustments of the differences. Explorative analyses showing the distribution of parental closeness according to the four possible confounding factors are shown in a supplement to Paper I.

Assessment of parental participation and support was collected by parent responses to SMS questions and by nurses' answers to the website questions. We summarised the scores from all the SMS questions from each family and calculated a mean score per question separately for the mothers and fathers. Since the nurses answered anonymously, we could not make a mean score of the website questions for each nurse. Due to skewness of the distribution, we dichotomised the nurse responses (7-point scale) to scores 5 to 7 being the most satisfied (76%), and 1 to 4 being the least satisfied (24%), and compared the differences between groups by cross tables and Pearson's chi-square tests.

3.6.2 Analyses based on study population II (Papers II, III and IV)

Descriptive statistics were performed as for Paper I. There were unequal distributions of GA at birth, mode of delivery (vaginal versus caesarean section) and level of education of the parents. Their potential effects as confounders were assessed in relation to the primary outcomes using linear and logistic regression analyses, mixed models and functional data analyses. We made adjustments for repeated measurements of the various main outcomes.

In Paper II, the primary outcome was mean differences in weight, length and head circumference from birth to four months after the expected term date. To compare the longitudinal growth of each infant, one must take into account the correlation structure within each data set. Growth trajectories were analysed with a linear mixed model with a random intercept and fixed effects for the unit PMA, an interaction term between unit and PMA, and a two-level model with weight, length or head circumference nested within each infant. The interaction term, interpreted as a difference in growth slope (grams or mm per week) between the units, was used to quantify velocities in weight, length and head circumference. In all models, a second-order polynomial term for PMA was added if significant. If such a term was added, we also checked for a corresponding interaction with the SFR versus OB units. Detailed information about the notation of the mixed model is attached as a supplement to Paper II. We used functional data analysis (FDA), a statistical tool developed for analyses of curved data as a function of time (www.functionaldata.org). In FDA, the unit of information is not a single data point, but instead entire curves varying over a continuum. FDA makes it possible to extract information from a temporal process as a whole, instead of point by point (164).

In Paper III, the primary outcome was scores on the EPDS, STAI-SF, PSS: NICU, PSI-SF and MPAS questionnaires. The correlation structure and effect of time from birth to four months after term age was taken into account using a two-level mixed model analysis. Mean scores from the questionnaires were used as level one, and the individual parent as level two. We incorporated the fixed effects for unit, time, mode of delivery and parental education. Results were presented as the mean difference with corresponding 95% confidence intervals between the OB and SFR units.

The statistical methods in Paper IV were much the same as those in Paper III. The primary outcomes were the proportion of nutrition provided as the mother's own milk, mode of feeding, the mother's milk volume and the mother's score on the BSES questionnaire. The time from birth to four months after term age, mode of delivery, parental education and GA were potential confounding factors and were therefore adjusted for. We applied a logistic mixed model for categorical variables (mothers' milk nutrition and mode of feeding) and a linear mixed model for continuous variables (volumes of mothers' own milk). The results are presented as B's (interpreted as the mean difference in the dependent variables) between the OB and SFR units or as odds ratios (OR) with 95% confidence intervals.

3.7 Ethical considerations

Written informed consent was obtained from all parents before inclusion. Parents were explicitly informed that they were free to decide whether to participate or not, and that their decision would not affect infant care or treatment in any way. They were also informed that they could withdraw from the study at any time without explanation. Parents are a vulnerable group in this situation. Even though their option to withdraw at any time without any obligation to explain was underlined, the decision to participate or not could itself cause strain. Further, the repeated questions on the SMS messages throughout the hospitalisation and personal questions in the questionnaires, i.e. 'The thought of harming myself has occurred to me', could represent a potential stressor for the parents during a vulnerable period. On the other hand, parents may appreciate this opportunity to give feedback about the care system. Another concern was that the diary registration of presence and duration of SCC may have potentially led to feelings of being assessed (by staff, researchers) or to the pressure to be present and/or to perform SSC. It is likely that being asked to record information in the diaries was a motivating factor in terms of performance, one which could potentially have caused strain to some parents – that said, it could potentially have also increased the amount of parental stimulation towards infants in both groups, which, in the interest of infants, is essentially positive.

Finally, one could raise the question of whether it is unethical to perform research when launching 24-hour SFR care. In response, it can be asserted that the benefits of examining important outcomes in a controlled design outweigh the potential burden for parents and may lead to significant improvements in neonatal care for many infants and parents alike. The study was approved by the Norwegian Regional Committee for Medical Research Ethics in June 2013: Approval number 2013/1076. The data were stored on the respective research servers at VVHT and HUH and according to the requirements of the hospital and hospital trust. The nurses who participated in the study did so anonymously. The hospitals gave consent on their behalf. The study was registered in Clinical trials; number NT T02452580.

4 Summary of results

4.1 Paper I

The SFR design had a positive impact on infant–parent closeness in terms of parental presence and provision of SSC. The median (Q 1, Q3) presence was 20 (18, 22) hours per day in the SFR and 7 (5, 8) hours per day in the OB unit (p = .001) for the mothers, and 8 (6,17) versus 4 (3, 5) hours (p = .001) for the fathers. SSC was initiated at 4 (0, 12) hours of age by the mothers in the SFR unit and at 12 (0, 28) hours of age in the OB unit (p = .03); for fathers, SSC was initiated at 3 (1, 9) and 40 (20, 53) hours (p = .004), respectively, in the SFR and OB units. The respective median duration of providing SSC care during the first two weeks of life was 180 (60, 300) minutes versus 120 (60,180) minutes per 24 hours (p = .02) for the mothers and 67 (11, 100) versus 31 (0, 60) (p = .05) for the fathers.

The parents in the SFR unit gave higher scores, i.e. higher satisfaction, on the core elements of FCC. On a scale from 0-7, the mothers in the SFR unit reported higher scores on participation in decisions on infant care, median 7 (6, 7)versus 6 (5, 6) (p =

.04); support and guidance from nurses, median 7 (6, 7) versus 6 (5, 6) (p =.02); and information from the staff, median 7 (6, 7) versus 6 (5, 6) (p = .04). Both parents in the SFR unit also reported higher scores on emotional support from nurses, median 6 (5, 6) versus 5 (4, 6) (p =.05) for the mothers, and median 7 (6, 7) versus 5 (3, 5) (p =.01) for the fathers. The parents in the SFR unit reported significantly higher scores on participation in medical rounds, median 6 (5, 6) versus 2 (4, 6) (p = .001) for the mothers, and median 5 (4, 6) versus 3 (2, 4) (p =.01) for the fathers. There were no differences between the units regarding the nurses' evaluation of their own work related to the same FCC elements, but the OB nurses assessed that the parents had greater trust in their unit's care of infants than did the SFR nurses, with a median score of 7 (6, 7) versus 6 (6, 6) (p =. 02).

4.2 Paper II

The infants' growth rates for weight, length and head circumference were the same during hospitalisation and until four months after the expected term date in the SFR and OB units. The adjusted estimate for difference in the infants' growth slope in weight was 4.0 g/week (95% confidence interval (CI): (-5.0, 13.0), p = .38) (Figure 5). Due to an unexpected, temporary lack of banked breast milk in the OB unit during the first week of life, banked milk was replaced by preterm formula with a higher content of protein and carbohydrates, resulting in a moderate but significantly higher protein and carbohydrate intake during the first week. However, this difference did not affect postnatal weight loss or time to regain birth weight. The proportions of infants receiving breast milk and regular formula after the first week until 34 weeks PMA, and at discharge, term date and four months after term date, were similar in both units.

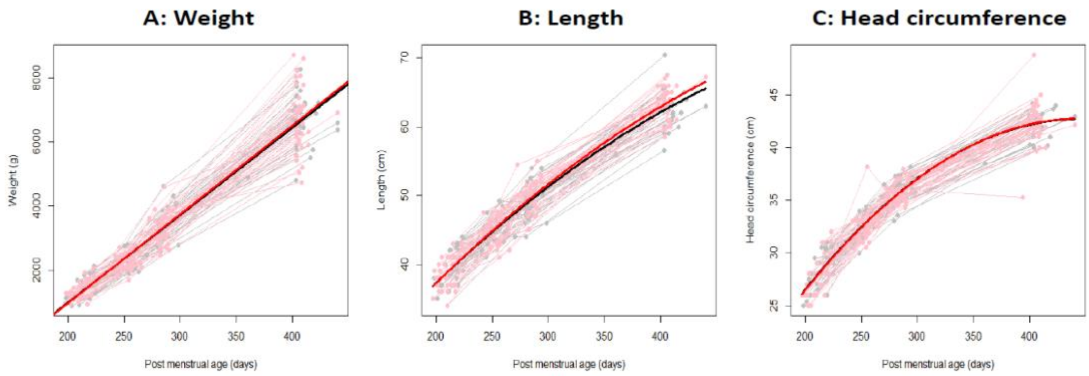

Figure 5. Growth trajectories for weight, length and head circumference from birth until four months after term date. Individual trajectories and mean growth (SFR unit: Black line; OB unit: Red line).

From birth until 34 weeks PMA, the respective mean (SD) presence was 21 hours (5) hours versus 7 hours (3) per 24 hours (p =.001) for the mothers and 16 (6) versus 5 (2) (p =.001) for the fathers. The respective mean duration of providing SSC was 6 (2) and 4 (2) hours (p =.001). In this setting, in which infants received the same nutrition, increased parental presence and provision of SSC had no effect on growth.

4.3 Paper III

The SFR mothers reported a lower risk score for depression (-1.9 points, 95 % CI: (-3.6, -0.1), p = .03) on the EDPS questionnaire from day 14 until four months after term date. The difference was most pronounced during hospitalisation, when 14% of the SFR mothers and 52% of the OB mothers (p = 0.005) scored at a level indicating clinical symptoms of depression. However, four months after term date only 3% of the mothers from both units scored above the cut-off level (p = .65), suggesting a high rate of spontaneous recovery. During hospitalisation, the SFR mothers scored 8 points lower on symptoms of anxiety on the STAI-SF questionnaire, mean sum score and standard deviation (SD): 39 (13) versus 47 (13) (p = .04). However, the scores decreased to levels considered normal (below 36 points) in both units at discharge, and in the mixed model there were no significant differences between the units.

The SFR parents scored lower on stress on the domains ‘Sights and sounds of the environment’ and ‘Infant’s appearance’ on the PSS: NICU instrument during hospitalisation. The mean (95% CI) difference was -5.0 (-9.4, -0.6) (p = .03) for the mothers and -5.3 (-9.5, -1.1) (p = .01) for the fathers. The SFR parents also had lower scores on the domain 'Parental role alteration', with a mean difference of -5.2 (-8.7, -1.7) (p = .004) for the mothers and -7.2 (-10.3, -4.2) (p = .000) for the fathers. However, there were no differences in symptoms of stress on the PSI-SF at term date or four months after term date. Parents in both units reported similar scores just above the high-risk level (score of 52–90), and total stress scores remained in the lower part of the range defined as high-risk level. On the MAPS instrument, mothers and fathers in both units had similarly high scores on parental attachment as well as similar sum scores.

4.4 Paper IV

The mothers first expressed milk at a median (Q 1, Q3) of 6 hours (6, 11) in the SFR unit compared to 30 (27, 40) hours in the OB unit (p =.001). The first attempt at direct breastfeeding occurred at a median of 48 hours (47, 100) after birth in the SFR unit and at 109 hours (96, 183) hours after birth in the OB unit (p = .001). Most mothers initiated and maintained enough milk production to feed the infant exclusively (63% in SFR and 10% in OB) or partly (17% in SFR and 66% in OB) with her own milk until discharge. Neither the mean volume of mother's own milk on day 7 and 14 or at a PMA of 34 weeks, nor the extent to which the infant was fed mother's milk from the PMA of 32.0 weeks until four months after term date differed significantly. The total number of breastfeeding sessions, the use of nipple shields or the sum score on the BSES-SF item did not differ significantly between the two units.

At discharge, 92% of the infants in the SFR unit and 81% of the infants in the OB unit received mother's own milk, either exclusively (77% in the SFR unit and 69% in the OB unit, p = .001) or partially (15% versus 12%, p = .001). Among those who were exclusively fed mother's milk, all were directly breastfed in the SFR unit compared to 10% (p = .001) in the OB unit at discharge. Those who were not exclusively fed from the breast received some mother's milk by bottle or cup. In a logistic mixed model analysis, the odds of achieving exclusive direct breastfeeding were more than eightfold higher in the SFR unit than in the OB unit: odds ratio (OR) = 8.2 (2.9, 23.1) ($p = .001$) from 32 weeks PMA until follow-up at four months after term date.

5 Discussion

5.1 **What is new in this study**

To our knowledge, this study was the first to compare growth in VPT infants when cared for in an SFR unit as opposed to an OB unit, and when controlling for nutritional intake. It was also the first study to describe and compare psychological effects on parents and breastfeeding progression related to the type of NICU unit and parental closeness to the infant in terms of presence in the NICU and the extent of SSC.

5.2 Methodological considerations

The strengths of this study were the prospective inclusion of subjects and the collection of data, the uniform inclusion criteria, the standardisation and control of nutritional intake, the uniform assessment criteria and outcome parameters, and the longitudinal design. The study has several limitations.

In the first study (Paper I), the power calculation was based on convenience sampling. The SCENE group aimed at including 400 patients altogether in the ICS study and decided on an equal number in every unit. This number was 30 patients, which was perceived as a feasible number also in smaller NICU units participating in the international study. Whether the main outcome would have changed significantly if the number of the same types of patients was increased is not known; however, considering the descriptive design and the type of outcomes, this does not seem likely.

The power calculation in the second study (Papers II–IV) was based on an estimated difference in weight gain during hospitalisation. A difference of 300 grams at discharge in favour of the SFR unit was based on the observed difference after changing from an OB to an SFR unit at VVHT. With that assumption, fewer infants needed to be included, but we were very much aware of the uncertainty of this assumption due to possible confounding, and we were also aware that the other outcome measures required a larger number of participants in order to make clinically significantly comparisons. The number needed to make meaningful comparisons was reduced by limiting the inclusion to a narrow spectrum of GAs, i.e. 28–32 weeks, and birth weights, and to infants with low rates of morbidities. The study also had a time limit since the OB unit had to move at a certain date.

A small sample size may result in the rejection of a true null hypothesis (type I errors) (165). As it turned out, the growth trajectories were so similar that we considered it unlikely that a larger study could have disclosed a clinically significant difference. We would also argue that the sample size was sufficient to interpret differences and similarities for the secondary outcomes. We found that SFR care was associated with significant increased closeness to the infant in terms of parental presence, provision of SSC and involvement in the care of the infant. SFR care was also associated with reduced parental stress and maternal depression while in hospital, but not at or after discharge. The SFR mothers also started expressing breast milk and putting the infant to the breast earlier than the mothers in the OB unit. Furthermore, more mothers in the SFR unit managed to give all their milk directly from the breast than did mothers in the OB unit, who more commonly gave some of their milk as express milk by bottle or cup. Overall, the study appeared to be large enough to demonstrate temporary differences in favour of the SFR unit, but the similar results at discharge and at follow-up after discharge on most secondary outcome measures suggests that the study was large enough to exclude type II errors, i.e. that clinically significant differences were not disclosed (164). The study may have been underpowered in other outcomes, e.g. volumes of mother's milk, since the milk volumes tended to be higher for the SFR mothers (Paper IV). The adjusted mean difference in favour of SFR mothers was 102 millilitres throughout all 3 time points (day 7, 14 and at 34 weeks PMA) but was ultimately not statistically significant in the mixed model analysis. On day 14 of hospitalisation, the mean difference in milk volume was 169 millilitres in favour of the SFR unit, which was nearly statistically significant ($p = .06$) and possibly a clinically relevant difference.

The inclusion of two NICU units located far apart and with no other cooperation than the present study may have introduced unrecognised biases, since there may be undescribed differences in staff competency and attitudes, as well as in care practices. For instance, since the OB unit was a tertiary NICU and the SFR unit was a level-II nursery, it is plausible that the OB staff were more experienced and thereby more capable of conveying trust, since the parents may have experienced that their infant was healthy compared to the more immature infants in the unit. On the other hand, the busy and crowded OB unit may have had the opposite effect, since many infants were critically ill, and less attention was provided to families with relatively healthy infants. Randomised studies involving one cohort are generally recognised as the ideal way of assessing the effect of an intervention – in this case, the effect of an SFR design versus an OB design. However, a randomisation within the catchment area of one hospital may introduce significant bias from spill-over effects if one arm of the study is conceived as more desirable from the viewpoint of parents and staff. Applied to the present study, it is likely that the new SFR design would have been viewed as desirable, resulting in negative expectations from the parents and staff, and thereby bias against the OB unit (166). It is also possible that the busy OB unit, which treated many very sick infants, may have caused increased parental anxiety and depression.

The limited information about infant morbidity may have introduced a selection bias in the study population presented in Paper I. All infants born at GA $\leq$ 35 weeks were included, and the OB and SFR units differed in that the OB unit had more immature and sick infants. Although only five infants were born at less than 28 weeks PMA in the OB group, we cannot dismiss the possibility that differences in morbidities may have been large enough to affect the interpretation of the main outcomes: parental closeness and parents' evaluation of FCC. This limitation is noted in Paper I, but we would argue here that the groups were comparable since the number of more immature infants was low. It was considered a strength of this study that only the families of 23 of 131 eligible infants declined to participate, and that there were no differences in background variables between those who participated and those who did not.

In study population II (Papers II–IV), we had no information on those who declined to participate, and therefore we cannot exclude selection bias. However, only the families of 8 of 120 eligible infants declined, which makes a significant selection bias unlikely. Furthermore, we were not able to control for group differences related to maternal morbidity in terms of physical health, psychological factors such as depression and anxiety disorders prior to giving birth, or potentially important psychosocial and sociodemographic factors. It is conceivable that such factors might have had an impact on parents´ assessment of the core values of FCC (Paper I) and their overall distress (Paper III), and even on attitudes towards and the ability to breastfeed (Paper IV). However, considering that the specific study population was close to a population-based sample, it is unlikely that there was a significant difference in maternal health between the groups.

Reliability is a crucial issue when assessing the quality of a study. In this study, reliability related to how well the measurements and the gathered information were free of bias, especially potentially unrecognised bias (165). Such bias may be systematic, which would be a serious problem because it would affect the average of a variable, or it may be random. Random bias is more difficult to detect. It will usually not affect the mean value, but rather the variation around the mean. Information bias may lead to systematic differences in the accuracy of the information collected for comparison between the two groups (167). In most clinical studies, some deviations from protocol may be expected at the discretion of the physician in charge, as was the case in our study, when preterm formula replaced banked breast milk during the first week due to a lack of banked milk in the OB unit. Therefore, it is of utmost importance to control for protocol violations in order to interpret the impact of such bias on the results. However, after the first week, there were no such differences. The impact of this initial small difference was negligible as it did not change either short- or long-term growth trajectories.

Observer bias occurs when there is a difference between the measured and the true value of a variable. Daily measures of growth parameters were performed by the nursing staff. Although measurements may have been prone to minor random observer variations in day-to-day measurements, they would not be expected to be systematic and would therefore most likely be corrected over time. We found no reason to believe that there were systematic observed differences between the groups. Errors may also occur when large amounts of data are typed into a data spreadsheet. Data were therefore continuously recorded and reviewed for missing data and outliers.

There were some random missing data from the diary tool. A few families missed some days or incompletely filled in information for other days, in both groups. Continuous self-report registration over 24 hours for several days is challenging, and so it is only natural that some registrations may be incomplete. However, parents' self-reports on presence and SSC have been shown to be more reliable than registrations recorded by nurses (168).

The validation process of the SMS and website questionnaires are discussed in Paper I. In Paper III, we present the results from the questionnaires. Even though several of the instruments (PSS: NICU, EPDS, STAI Y form, PSI–SF, BSES-SF) have demonstrated good psychometric properties in mother–child populations, only the EPDS, PSI–SF and BSES-SF are validated in Norway. Emotional distress in terms of depression and anxiety are all complex human phenomena – and in retrospect, all the questionnaires should have been translated according to guidelines for translation and cultural adaptation as described in Paper I (139). However, since the objective was to compare two groups, the lack of strict national validation may be of minor significance. Some answers in the questionnaires were also randomly missing. Participants were asked about personal and often sensitive topics that may have provoked unpleasant feelings. To avoid dismissing questionnaires with missing values, we replaced single missing items by inserting a mean score within the subscale, accepting a maximum of two items missing for each scale. This may have caused some inaccuracy, but on a general basis respondents tended to avoid ticking off the most extreme values, instead centring their responses around the mean values (165). Using the mean within subscales is therefore a reasonable way of handling missing values (158).

Observational studies are prone to both under- and overestimation effects (167). There were some baseline characteristics that were unequally distributed in the groups in both study populations. In study population I, mode of delivery, multiple births and the proportion of first-born infants were unequally distributed, which was explored as described in the section on statistics. Except for the difference in participation in medical rounds, the effect sizes on the FFC core values were small to moderate. Assessing the clinical significance of a one-point difference on a scale from 1–7 is difficult, but the purpose was to compare units, not to gain in-depth knowledge about FCC. We do not know how the emotional support was provided or in what way parents participated in medical rounds – we merely reported a difference between the two units.

In study population II, there were baseline differences in that the parents in the SFR unit had a lower level of education, a higher proportion of the infants were born by caesarean sections, and the mean GA was slightly higher (3 days). All these factors were considered as possible confounders and were therefore included in the statistical models as described in the section on statistics. Further, there was a higher proportion of ventilated infants in the OB unit. However, this difference was considered to be due to the need for safe stabilisation before transport after birth, since all the infants had to be transported by an ambulance from the maternity ward to the NICU. The time spent on mechanical ventilation was very short and did not indicate more severe airway disease. There was also a higher number of skin-breaking procedures in the OB unit, which may be due to different routines or to parents questioning the necessity of tests in the SFR unit. No other data indicated differences in disease severity between the two units.

One potential bias was related to unidentified differences in care culture, which could have manifested as residual confounding. The privacy in SFRs creates opportunities for both families and staff in many ways. This study aimed to measure the effects of SFR care on infants, parents and staff. However, there may have been unknown cultural differences that contributed to and in principle modified our conclusions. The care culture is briefly discussed in Paper I, but culture is difficult to elaborate on without involving ethnographic and anthropological methodologies, which were not available in this study.

External validity addresses to what extent the results of a study are representative of the total population in question. The prospective comparative design, strict protocols and reasonable size of the study groups imply that the external validity was likely satisfactory for this selection of premature infants, i.e. moderately premature infants without major illness or morbidities. The OB unit also treated more immature and sicker infants alongside the relatively healthy infants recruited for the present study than did the SFR unit. We cannot rule out that the different care atmospheres and divergent levels of expertise on the part of staff may have introduced bias in terms of reassuring parents of infants with less severe morbidity and with respect to how parents assessed their support and/or their psychological well-being. Whether the results of the study may be representative of more immature or sicker infants and their families is uncertain. Parents' need for involvement and closeness with their infants is a fundamental human instinct, but whether an effect of involvement on the parents' appreciation of FCC, privacy and psychological well-being were related to the extent of presence and participation in care and decisions or to a threshold effect remains unclear. The outcomes were similar or only temporarily different in the two groups despite much more involvement in the SFR unit. However, from an international point of view, the involvement of parents was also extensive in the OB unit. Furthermore, these studies were performed in a setting in which extensive social rights and economic support are provided to both parents during their stay in the NICU, allowing for extensive presence and participation in both units, and therefore the effects on parental presence and psychological well-being must be interpreted with this setting and rights in mind.

6 Discussion of results

6.1 Growth

The main purpose of this project was to study whether a more protected physical environment in an SFR unit could improve growth in preterm infants. We found no such association (Paper II) – an important finding that contradicts those of previous studies.

In 2014, Lester et al. found improved growth after relocating from an OB environment to an SFR unit. They reported that infants with a birth weight below <1500 grams weighed 233 g more at discharge and were younger at full enteral feed after changing to an SFR unit (38). Further, the infants in the SFR unit required fewer medical procedures, had lower rates of septicaemia, scored better on attention, had less physiological stress, less hypertonicity, less lethargy and less pain. The authors claimed to be the first to gain insight into how and why these improvements occur, and for that purpose, they used a structural equation model to determine the effect of mediators. The two mediators were maternal involvement and developmental support. However, it is not entirely clear how the composite variables, involvement and developmental support, were defined and measured. Weight at discharge was related more to developmental support, but the effect size was modest, 49 grams, and they did not explain the majority of differences in discharge weight. There was no effect of maternal involvement. It should be emphasised that the maternal involvement reported in that study was rather minimal compared to that reported in Norwegian conditions, e.g. on average, the mother is present 4.5 days a week in the SFR unit versus 3.6 days in the OB unit. Another recent study by O'Brien and colleagues reported increased growth related to more involvement by parents. Twenty-six tertiary NICUs in Canada, Australia and New Zealand were stratified to provide either FiCare (n = 14 units) or standard NICU care (n = 12 units), with 1786 infants enrolled (51). They also found increased weight gain (measured on day 21 after birth) in the FiCare group compared to the standard care group, with a mean change in z-scores of -0.071 versus -0.155 (p = 0·0002), and they also reported significantly higher daily weight gain (1.9 grams) in the FiCare group. However, neither of these two studies accounted for or reported nutritional intake in relation to improved growth, and it is therefore relevant to question the scientific validity of their results.

After the opening of the SFR unit in 2012 in Drammen, we observed an increase in weight at 34 weeks PMA and at discharge, similar to what Lester and colleagues reported. This led to a preconception about SFR design for preterm infants as being superior with respect to growth. Early papers also suggested increased head growth as a result of SSC and increased growth after increased involvement by parents (39, 50). However, the results in Paper II suggest that improved weight gain after the opening of the new SFR unit was due to unrecognised changes in nutritional practices. This is also an example of why empirical observations should not be accepted as evidence without being confirmed by properly designed research.

When Paper II was published, one of the principal investigators from the Providence group, Dr. Betty Vohr, wrote an editorial comment in Acta Paediatrica (169). She claimed that our finding on the lack of differences in growth trajectories was due to a parental presence above a hypothetical threshold in both units. The possibility of such a threshold has been mentioned in Paper II, but to our knowledge there is no data to support it. The existence of a threshold cannot be completely ruled out, but to assume that parental presence of less than 4–6 hours a day would exert a large effect on growth compared to minimal presence, when 21 hours daily compared to 7 hours has no measurable effect, seems rather unlikely. Nutritional intake is the only documented factor affecting growth in preterm infants, and other mediators compromising growth, like severe morbidity, may exert their effect by altering intake or absorption. We therefore conclude, based on the present evidence, that parental presence and SSC do not change growth trajectories in preterm infants, independent of nutritional intake.

6.2 Impact of parental presence and involvement on developmental outcomes

One of the main reasons for establishing an SFR design in the NICU is to facilitate parental presence and involvement (170). Our study showed that SFR care was associated with a significant increase in parental presence. In an international context, the amount of time present was very high for both parents. In addition, parents initiated SSC much earlier in the SFR unit. Other studies have also suggested that opportunities for parents to stay overnight increase presence and parent–infant closeness (98, 171).

In 2014, Pineda et al. published a two-year follow-up on developmental outcomes, measured by Bayley III in addition to neurobehavioural scores (language and motor scores) and brain maturation (172). They found that infants cared for in SFRs had diminished normal hemispheric asymmetry, a lower language score and a trend towards lower motor scores and more externalising behaviour. Controlling for parent visitation and holding did not alter the findings. However, time and rate of visitation were both low, with a mean of 19 hours for the entirety of the hospital stay. The duration of SCC was even lower, with a mean of 0.7 days over the entire length of stay. This is by no means comparable to parental involvement in Norway and is particularly not representative for the SFR unit in our study. Pineda and colleagues did not report on the nurses' presence with the infants, but without parents' presence it seems likely that the infants were left alone in their rooms without adequate stimulation. The standards of care and parental involvement discussed in that study thus appear to be quite different from those implemented in Scandinavian settings.

Pineda and colleagues later published a follow-up study that determined an association between parental presence, holding and SSC in NICUs and neurobehavioural outcomes in terms of improved development up to 4-5 years (3, 134). The Providence group (Lester and colleagues) also contributed with follow-up studies at 18 months (38, 76, 173). They found that mothers in SFRs were more likely to be in the group of high-level maternal involvement, and to spend more days with high-level maternal involvement, 74% versus 41%, compared to mothers in the OB unit. They found no difference between the two NICU concepts in terms of cognitive, language, communication, and fine and gross motor outcomes on Bayles III, but they did report that infants of mothers who scored high on maternal involvement in both types of units had better cognitive and language scores than did infants with low maternal involvement. SSC and maternal involvement predicted both cognitive and language scores. Infants with one or more symptoms of autism were more likely to have mothers in the low maternal involvement group (76). The Providence group has published 24 months of follow-up data, and contrary to the results at 18 months, SFR care was associated with higher Bayley III cognitive and language scores (173). Indeed, these results are promising, with presence and involvement representing the primary mediators for improved long-term outcomes. Still, the studies from Providence have some methodological issues, e.g. they involved a pre/post-test design and not a real-time control group, exhibited small effect sizes, and used a composite variable to describe presence and developmental care as a substitute for genuine parental presence. There are major problems generalising the results from the Providence study to Norwegian and Scandinavian settings. The group categorised as 'high maternal involvement' was likely to be far less involved than parents in Scandinavian NICUs, irrespective of design, and such involvement was probably significantly lower than in our OB group. Long-term neurobehavioural outcomes were not assessed in our study.

The first meta-analysis on the effect of SFRs on long-term neurodevelopmental outcomes and secondary morbidity and breastfeeding was recently published. Thirteen study populations in 25 papers were included, with a total of 4793 infants. No effect on long-term neurodevelopmental outcomes was found. The authors highlighted the risk for selection bias. They found moderate evidence that SFR care contributed to increased breastfeeding and lower sepsis rates equivalent to a decrease of one sepsis episode per 1000 hospital days if infants were hospitalised in SFR units compared to OB units (174).

6.3 Short-term benefits of parental presence and involvement

In order to provide good evidence-based care, we should focus on the infants' well-being here and now, and on the quality of life during NICU care. There are interventions available to reduce pain and stress, and these can be performed by parents; some can also be carried out by staff: tactile stimulation (SSC and massage), auditory stimulation (music, mothers' voice), kinaesthetic stimulation (physical therapy) and, finally, olfactory/gustatory stimulation (odour, colostrum) and multimodal interventions (175, 176). Instead of increased effort on developing, implementing and testing new interventions, one could argue that engaging parents in all caregiving activities would entail possibilities for positive stimulation of the infant (and the parent). Evidence shows that separation should be avoided (1) and that parents' presence and involvement benefit both infants and their families (20). The importance of parents providing developmentally adjusted sensory stimulation should be emphasised. Such positive stimulation might subsequently even affect hypothalamic-pituitary-adrenalin axis stress responses, e.g. decreased stress responses observed in breastfed infants (177).

SSC is, together with breastfeeding, one of the most researched interventions thus far, and it has been shown to be associated with parental engagement and the regulation of hormones, e.g. oxytocin and cortisol (178). Around-the-clock parental presence also permits parents to respond immediately and more naturally to the infant's signals in a variety of ways other than just performing SSC – for instance, by comforting the infant during procedures by singing and speaking. The mother's voice can stabilise and help the infant to better organise behavioural states (179). Parents staying together in an SFR and having the opportunity to share joy and concerns about the infant's medical situation, as well as the infant's responses and development, are all likely to affect the individual parents, their relationship, and likely their relationship with the infant as well. Qualitative research has contributed to this understanding by, e.g., showing how physical closeness facilitates emotional closeness (89, 180), but more research is needed on what really happens in SFR units and whether – and if so, how – parents naturally provide positive stimulation when they are present.

6.4 Breastfeeding and SFR care

We found that the likelihood of being exclusively direct breastfed was more than eight times higher in the SFR unit than in the OB unit. Since exclusive direct breastfeeding requires physical presence by the mother, this difference may be a direct effect of mothers being present overnight in the SFR unit. In line with other researchers, we found no other differences according to PMA when full enteral feeding was attained

(130). That said, in contrast to other researchers (43), we did not find that the earlier initiation of breastfeeding or the start of milk expression resulted in significantly increased mother's milk volume during hospitalisation. Vohr et al. found that mothers in SFRs produced more milk at four weeks compared to mothers in an OB unit (173). Norway has a social rights policy for mothers which supports the maintenance of breastfeeding; so, in a setting without such a supportive policy as well as a lower overall breastfeeding rate, SFR design may have a greater impact. SSC also facilitates the onset of breastfeeding, as it stimulates both production and sucking (181), and this may also have contributed to the high rates of mother's milk as primary feeding in both units. In line with our results, O´Brien and colleagues found the mothers' presence to be an important contributor to exclusive breastfeeding in that 70% were frequently breastfeeding (more than six feeds per day) at discharge in the FiCare group compared to 63% in the standard care group. The respective occurrence of any breastfeeding was 33% versus 9% (51). Even though other elements might have exerted an impact, e.g. competence and guidance from staff, the results from other studies as well as ours show that SFRs facilitate more exclusive breastfeeding, with parental presence being the key element. These results are in line with a meta-analysis that reported a significantly higher incidence of exclusive breastfeeding at discharge in SFR units (5 studies, n = 410, OR = 1.78, 95% CI = 1.11–2.84, p = .02). This effect was only evident for exclusive breastfeeding. They found no differences in the total number of infants receiving breastmilk at discharge (174).

6.5 Does SFR design impact parents' psychological well-being?

There are factors other than SFR design and presence that may influence parents' psychological well-being during their infant's hospitalisation, e.g. previous life experiences and the dynamics in the parents' relationship. We had no knowledge of these factors in our study, but parents were recruited from the same background population with relatively healthy preterm infants, and there were no indicators that such factors were unevenly distributed between the groups. Prior to our study, there were no reports on parents' psychological well-being when being continuously present over a longer period. We used instruments that measured different aspects of emotional distress in an attempt to screen for risk factors for depression, anxiety, stress and attachment problems. These screening tools are not diagnostic, since a diagnosis of disease would have required a full psychiatric examination, which was beyond the scope of our study. That said, the instruments have frequently been used to evaluate risks (39, 51, 131, 132). Further, we sought to make the scales and instruments relevant for parents of preterm infants, and thus we chose short versions of the instruments in order to make them easier to answer.

We found that mothers in SFRs had significantly lower risk scores for symptoms of depression from birth to four months corrected age, and that both parents scored significantly lower on stress scores during hospitalisation.

Previously, parents have reported greater satisfaction with care in SFRs (135), especially if they had experiences with both types of unit designs (132). In Paper I, parents in the SFR unit gave higher scores on the core elements of FCC, such as emotional support and participation. It is not self-evident that increased satisfaction with care reduces emotional distress, but it is not unlikely that a causal relationship may exist. Pineda and colleagues reported an incidence of 20% of post-partum depression (EPDS), and also that 42% of mothers reported increased anxiety (STAI), but no association with SFR or OB facilities was made. They also reported increased stress (PSI) for mothers in SFRs, and they thus raised the question of whether stress is more related to individual factors and less to the organisation of the NICU per se (131). However, the low parental presence in Pineda et al.'s study might be a plausible explanation for the lack of a difference.

We have documented that parents in SFR units spend all or most of a 24-hour period in the unit, which is highly conducive to becoming very competent in interpreting their infants' specific signals and behaviours. Their participation in medical rounds was also high. There are many reports of distress among parents of preterm infants, but there is still a lack of knowledge about the consequences of such distress or its potential impact on the infant–parent dyad. During the early post-partum period, it is particularly important for parents to bond with their infant (182). The bonding process for mothers of preterm infants has been characterised as being less intimate compared to mothers of full-term infants (183). Early interventions aimed at supporting the parent–infant relationship are associated with improved neurobehavioural development, decreased parental depression, anxiety and stress, and increased attachment (59, 85, 86, 184). Decreased physical stressors and an optimised physical environment may reduce emotional strain and contribute to sensitising parents, thereby contributing to a more positive impact on the infant–parent relationship (185, 186). Emotional distress in terms of depression has been shown to be associated with more behavioural and emotional problems in preterm infants by the age of 3 years, as reported by parents (187). The underlying mechanisms may act through epigenetic mechanisms, modifying brain structures and brain volume in the infant (17, 19). From a biological and evolutionary perspective, not being allowed or capable of protecting and taking maternal responsibility for the infant could be expected to cause emotional distress. This could, in turn, explain the occurrence of more depressive symptoms in mothers. To provide a real opportunity for parents to be present and interact with their infant may therefore be an effective way of relieving stress and discomfort in both infants and parents. Extensive involvement by parents may reinforce parents' feeling of being in control and thereby provide stress relief (3, 51, 131). Our effect sizes of depression and stress scores between the two types of units were rather large compared to those reported elsewhere (66, 131, 188). It may be relevant to speculate about a causal relationship between maternal presence and the risk of developing depressive symptoms. Closeness between mother and infant is enhanced with an SFR design, and this may trigger positive emotions (89). Most parents in the SFR unit are also present during the night. During presence, they rarely leave the infant to the staff, which allows them to provide closeness and care in response to cues from the infant at all times. Thus, a key element to modulate parental distress is the privacy and increased proximity with the infant in the SFR room. Increased duration of SSC in SFRs contributes to a positive parental hormonal response (189-191), but other factors related to parental presence may be equally important. According to Flacking et al. (89), parents state that eye contact, touching, smelling and breastfeeding are all important for feeling emotionally close to their preterm infants. Further, by being engaged in day-to-day care and by being able to promote infant wellness, parents experienced more profound feelings of emotional closeness despite the special condition of parenthood which the NICU represents. Thus, emotional and physical closeness both impact mothers' and fathers' well-being (192).

Parents in our study scored in the lower range on anxiety, indicating that anxiety was not a predominant symptom among parents in either of the units. However, infants had a low risk for both short- and long-term adverse outcomes, and this may have contributed to the low scores. Finally, it should be underlined that after discharge, there was no difference between the units on the stress (PSI-SF) or attachment (MPAS) scales. Even though preterm birth is considered stressful to both parents, they experience gratitude for and self-reliance about being able to cope. They could also experience personal growth and a closer relationship with their partner (193, 194). In our study, both groups maintained moderately elevated stress scores after discharge, but with high attachment scores, it may not have influenced the parent–infant relationship.

6.5.1 Fathers in the SFR unit

To our knowledge, we are the first to report on fathers' psychological well-being over time when an infant is hospitalised in an SFR unit. Interestingly, only 6% of fathers versus 52% of mothers in the OB unit scored above the cut-off of 13 on depression at 14 days, indicating a difference in vulnerability between mothers and fathers immediately after preterm birth. However, others have documented increased emotional distress after preterm birth in fathers (67, 68), and therefore our instruments may not be fully sensitive to fathers' responses. All the instruments were originally developed for and tested on mothers, e.g. there are suggestions that the EPDS cut off should be lower for men, or that it actually does not capture depression in the same way as it does for mothers (195, 196). In Paper III, we argue that the extensive presence by fathers in the SFR unit may provide additional emotional support for mothers. There was no difference between fathers´ scores on depressive symptoms between the two units, but the OB fathers reported significantly increased stress compared to fathers in SFRs. The stress related to the parental role by fathers in the OB unit was particularly high. There are reports on how fathers still feel left out and overlooked by NICU staff. Fathers want to be involved and to take responsibility in the care of the infant. However, they also need to balance this with expectations of being the breadwinners and taking responsibly for the mother and siblings (197). This may in turn provoke increased stress but not necessarily cause symptoms of depression. Paper I reported higher scores on emotional support from nurses in the SFR unit, and this finding was particularly evident for fathers. One could speculate about whether the lower stress scores among fathers in the SFR unit than in the OB unit were related to more emotional support being provided by nurses in the SFR unit or simply that being allowed to be present in the unit satisfied their own expectation of their role as fathers. Still, little is known about how fathers' biological and emotional responses are programmed and developed towards their preterm infant (198). Nor do we have knowledge on how fathers´ increased involvement contributes to and affects the family (199).

6.6 Parent–Staff interaction in the SFR unit

The SFR parents reported significantly higher scores on participation in medical rounds and better support from nurses, especially emotionally, during hospitalisation compared to the parents in the OB unit. The importance of emotional support and an empathic approach from nurses has been described by others as an important aspect influencing the parents´ emotional state (200, 201). The staff´s ability to ease parents' emotional strain and to create opportunities for them to express both medical and emotional concerns are important (202). A previous study from the SFR unit in Drammen described how parents viewed the relationship with nurses as essential for their well-being and coping. A trusting relationship with the nurses strengthened their perception of themselves as being important as parents (203). The clinical experience from the SFR unit in Drammen is that nurses feel closer to the families via an SFR design than they do in an OB setting. When parents are present at all times, there are many opportunities to divulge information, guidance and support. There is a possibility that seemingly well-functioning families are left to themselves too much and thus miss out on guidance. This may be even more common for families perceived as demanding by the nursing staff. There are also reports of parents feeling isolated in SFR units (132). If parents are left alone with their infant in the SFR unit without adequate and competent care, they may feel isolated. Working closely with families is stimulating and ethically the right thing to do, but it can also be challenging for nurses (132), and their professional role may seem less strictly defined when they share responsibility with parents (204). An essential part of the FiCare model is to increase knowledge about infant behaviour and their cues for both parents and the nursing staff. The programme emphasises the staff's need for in-depth knowledge on parents' reactions, training them in supervision and emotional support (51). Nurses need practical communication skills to provide sufficient support to families (205).

The nursing profession has a long tradition of working closely with families, but still many nurses provide care based on the needs of professionals rather than on those of families (206). The nursing staff in the two units scored high on all the core FCC elements. The similarities in the nursing scores may be due to methodological issues, e.g. the instrument may not have been sufficiently sensitive to detect minor differences in nursing care. Alternatively, it can be an indicator that nursing care is not being affected by the type and design of the NICU. In the ICS study, nurses across Europe evaluated their ability to give emotional support lowest on the FCC core elements (93). Involving psychologists in the NICU on a daily basis may be useful (207, 208), and this resource should be used directly for both parents, but it should also be employed to transfer knowledge about infant and parent psychological reactions and responses to the staff. Nurses are around parents day and night, and thus improving their competence has the potential to make a significant difference regarding the quality of care (205, 209, 210). More research is needed to generate a more in-depth understanding about the effects of different approaches than what we can obtain from a survey design in order to more fully comprehend parent–staff interactions during SFR care.

In Paper I, we argue that when parents are involved and allowed unrestricted access, they could participate actively in shared decision making at an informed and competent level, based on their knowledge of the infant. Parents in SFRs are more included in daily rounds, and this may reflect a more advanced level of parental involvement.

Unfortunately, we do not have data to precisely assess how involvement in medical rounds occurs, nor at what level parents participate in discussions about infant treatment and care. Even if the principles of FCC are acknowledged, it could be questioned whether the staff have really changed the way they work (206). Ethnographic research (video observations and interviews with parents, nurses and physicians) in an FCC unit in Finland found that parents, although included in medical rounds, often assumed a passive role, and that the neonatologist conducted the rounds in a one-way information transfer (211). It is therefore of great interest to obtain a systematic description of how collaboration between parents and staff in SFR care impacts parents, and hence this should be further explored in later studies.

Over the last decade, neonatal units have changed towards a more protected physical environment and a more systematic use of SSC. Infants' and parents' rights are better recognised, and the principles of FCC are better acknowledged, which have in turn contributed to the development of different programmes and interventions involving parents. However, there are still considerable variations in content, intensity, setting and degree of parental involvement (212), and much remains to be done to more fully integrate parents and to optimise the care of preterm and sick newborn infants.

7 Conclusion

The SFR design did not contribute to increased growth in VPT infants, but it did facilitate greater parent–infant closeness by near-continuous parental presence, SSC and exclusive direct breastfeeding. The SFR design increased parental involvement and decreased emotional distress, as indicated by lower risk scores of depression for mothers and lower parental stress scores during hospitalisation. There was no difference between the SFR and OB units in terms of anxiety or attachment scores. Regarding the infants, SFRs reduced physical stressors in the environment and prevented separation from parents. This study thereby contributes increased knowledge about how the SFR design impacts infants and parents during the sensitive postnatal period from birth to four months´ corrected age.

8 Implications for clinical practice

Taking into consideration how preterm infants' vulnerability to stress and pain may have long-term consequences for brain development and neuro-developmental outcomes, much remains to be explored concerning the physical and emotional care environment in the NICU. Parents´ protection and positive stimulation may prevent or ameliorate adverse forms of stress for the infant (22). There is enough evidence to conclude that the NICU of the future should be built to minimise infant–parent separation. This goal requires new ways of thinking about infants and parents as well as a reorganisation of medical and nursing care. Based on our results, the SFR design increased parental presence and involvement to a large extent and therefore represents one effective way to plan future NICUs. However, the OB unit also managed to establish practices of parental closeness in terms of SSC despite its outdated architecture. So far, experiences with the SFR design are limited, and as such long-term experiences are needed to disclose potential untoward side effects, such as stress on the part of staff by being so closely involved with parents as well as the economic consequences of the endeavour. Providing the best quality of care for infants in intensive care is highly cost effective, such that the cost-effectiveness ratio is higher than it is for adult intensive care (213).

9 Recommendations for future research

There are major methodological issues in research on the implementation of FCC practices. The main problems are related to the short observation period, the lack of standardisation, and unclear data on long-term outcomes. A clear definition of ethical- and evidence-based care as well as subsequent follow-up studies are thus needed. We must also further explore interventions for positive sensory stimulation related to both short- and long-term outcomes.

Preterm infants are not the only patient group in the NICU. Previous research has for the most part overlooked other vulnerable patient groups with long NICU stays, e.g. newborns with severe congenital malformations, as well as preterm infants with complications requiring prolonged intensive care beyond the term date.

More research is also needed on how to optimise parental support. Studies on how to effectively ease parents' emotional distress as well as how to identify and intervene with the most vulnerable parents are thus warranted. The effects of screening parents systematically for distress with tools similar to those used in our study should be investigated. Importantly, as mentioned above, fathers must be included in research in order to generate knowledge about the challenges they face and their impact on the infant–father relationship. New technology for gentler, non-invasive monitoring is already available, but we need to explore how such technology impacts infants and parents in the NICU.

Even though the obligation of user participation is included in health care legislation and research, parents rarely participate in the actual planning of research. When parents represent the best continuity of care, they may also develop ideas that differ from those of professionals but which are nonetheless relevant and useful in the design of future research projects.

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Papers I–IV with supplements

List of attachment 1 - 5

Attachment 1

FCC core element questions

Attachment 2

The Closeness Diary

Attachment 3

Nutritional protocol

A) Feeding protocol if infants < = 1250 grams

B) Feeding protocol > 1250 g Supplement 3

C) Nutritional calculation template

Attachment 4

Data collection protocol

Attachment 5

The questionnaires

A) During hospitalisation,

B) Post-discharge