

Effectiveness of Family Integrated Care in neonatal intensive care units on infant and parent outcomes: a multicentre, multinational, cluster-randomised controlled trial



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Summary

Background Despite evidence suggesting that parent involvement was beneficial for infant and parent outcomes, the Family Integrated Care (FICare) programme was one of the first pragmatic approaches to enable parents to become primary caregivers in the neonatal intensive care unit (NICU). We aimed to analyse the effect of FICare on infant and parent outcomes, safety, and resource use.

Methods In this multicentre, cluster-randomised controlled trial, we stratified 26 tertiary NICUs from Canada, Australia, and New Zealand by country and size, and assigned them, using a computer-generated random allocation sequence, to provide FICare or standard NICU care. Eligible infants were born at 33 weeks' gestation or earlier, and had no or low-level respiratory support; parents gave written informed consent for enrolment. To be eligible, parents in the FICare group had to commit to be present for at least 6 h a day, attend educational sessions, and actively care for their infant. The primary outcome, analysed at the individual level, was infant weight gain at day 21 after enrolment. Secondary outcomes were weight gain velocity, high frequency breastfeeding (≥ 6 times a day) at hospital discharge, parental stress and anxiety at enrolment and day 21, NICU mortality and major neonatal morbidities, safety, and resource use (including duration of oxygen therapy and hospital stay). This trial is registered with ClinicalTrials.gov, number NCT01852695.

Findings From Oct 1, 2012, 26 sites were randomly assigned to provide FICare ($n=14$) or standard care ($n=12$). One site assigned to FICare discontinued because of poor site enrolment. Parents and infants were enrolled between April 1, 2013, and Aug 31, 2015, with 895 infants being eligible in the FICare group and 891 in the standard care group. At day 21, weight gain was greater in the FICare group than in the standard care group (mean change in Z scores 1.58 [SD 0.51] vs 1.45 [0.49]; $p<0.0001$). Average daily weight gain was significantly higher in infants receiving FICare than those receiving standard care (mean daily weight gain 26.7 g [SD 9.4] vs 24.8 g [9.5]; $p<0.0001$). The high-frequency exclusive breastmilk feeding rate at discharge was higher for infants in the FICare group (279 [70%] of 396) than those in the standard care group (394 [63%] of 624; $p=0.016$). At day 21, parents in the FICare group had lower mean stress scores than did parents in the standard care group (2.3 [SD 0.8] vs 2.5 [0.8]; $p<0.00043$), and lower mean anxiety scores (70.8 [20.1] vs 74.2 [19.9]; $p=0.0045$). There were no significant differences between groups in the rates of the secondary outcomes of mortality, major morbidity, duration of oxygen therapy, and duration of hospital stay. Although the safety assessment was not completed, there were no adverse events.

Interpretation FICare improved infant weight gain, decreased parent stress and anxiety, and increased high-frequency exclusive breastmilk feeding at discharge, which together suggest that FICare is an important advancement in neonatal care. Further research is required to examine if these results translate into better long-term outcomes for families.

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Introduction

The modern neonatal intensive care unit (NICU) is a highly medicalised and technologically focused environment, managed by skilled health-care professionals. Despite evidence of improved outcomes from increased parent–infant interaction, parents are not routinely integrated into the caregiver role and are often perceived as visitors in the NICU.¹ Most parents rate their NICU experience as extremely stressful and report feeling anxiety and loss of control.² These feelings of helplessness, anxiety, depression, and fear might

contribute to their inability to assume normal parenting roles.²

Infant–parent separation in the neonatal period limits the bidirectional development of physical, emotional, and psychological bonds between parents and their infants and is detrimental to parents' mental health.³ Studies outside of North America suggest that parents can play a substantial part in providing direct care for their infants while they are in the NICU.^{4,6} Such care-by-parent models have revealed short-term benefits, including improved infant weight gain, decreased nosocomial infection,

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See Online for appendix

Research in context

Evidence before this study

Our study was motivated by published evidence showing the anxiety, stress, and loss of control felt by parents with very preterm infants in the neonatal intensive care unit (NICU); a literature review of the care-by-parent model; direct observation of a care-by-parent NICU in Estonia; and a pilot cohort trial showing that Family Integrated Care (FICare) can help alleviate parental stress and improve neonatal outcomes. Evidence from the literature showed that treating parents like visitors in the NICU added to their feelings of anxiety and helplessness and could contribute to their inability to connect with their infant and assume normal parenting roles. Looking for ways to enable parents to connect with their infant in the NICU, we did a literature review and identified studies that suggested parents can safely be directly involved in the care of their infant in the NICU, and that these interactions might have short-term benefits for both infants and parents. On March 11, 2011, we used the OVID search engine to access MEDLINE, Embase, CINHAL, and CCTR databases. We used the following keywords searches to identify relevant papers: "infant", "low birth weight" OR "infant", "premature" OR "infant", "small for gestational age" OR "infant", "very low birth weight" OR "infant", "extremely low birth weight" AND "hospitals", "maternity" OR "nurseries", "hospital" OR "intensive care units", "neonatal" OR "intensive care", and "neonatal and maternal behaviour" OR "parent-child relations" OR "father child relations" OR "mother child relations" OR "parental behaviour" OR "parents" OR "fathers" OR "mothers" OR "infant care" OR "perinatal care" OR "parenting". We excluded manuscripts that were not published in English, were about animal subjects, and studies that focused only on maternal outcomes. We excluded studies that reported Kangaroo care, early neonatal developmental intervention programmes (eg, Newborn Individualized Development Care and Assessment Program, Creating Opportunities for Parent Empowerment, Parent Baby Interaction Programme, Mother-Infant Transaction Program), or both, because they focus on the outcomes from

specific parental interventions that had already been reported in a meta-analysis as part of Cochrane reviews. Our search identified nine papers that together showed fair evidence for benefit from the care-by-parent model. However, all but one study was done in low-income and middle-income settings, five of the studies were done more than 10 years ago (in the 1980s or 1990s), and some had a poor study design or used retrospective controls. As well as our literature review, direct observation of a neonatal care unit in Estonia, where parents were directly involved in the care of their infant, inspired us to develop the Canadian FICare programme to integrate parents into their infant's health-care team. Our programme was developed in collaboration with parents of infants who had been in the NICU. Together, we designed a programme that enables parents to become integral members of their infant's health-care team in the tertiary NICU setting. We completed a single-centre pilot cohort trial from 2011 to 2012, and showed that FICare is feasible, safe, and potentially beneficial to neonatal outcomes and parental stress levels.

Added value of this study

To our knowledge, this study is the first cluster-randomised controlled trial to assess the effect of integrating the parents of tertiary NICU infants into their infant's health-care team. We show that it is safe to involve parents in the care of their infant in the NICU and quantify the positive effect of parental-infant interaction on infant weight gain, breastfeeding rates at discharge, and parental stress levels.

Implications of all available evidence

Our study further challenges the existing dogma that considers parents as visitors in the NICU and peripheral to their infant's care while in the NICU. We add to the mounting evidence that it is beneficial to both infants in the NICU and their families to incorporate parents into their infant's health-care team and help them assume the caregiver role as soon as possible.

decreased parent stress, fewer readmissions, and improved breastfeeding rates.⁷⁻⁹ The benefits of providing a consistent programme of parent education have also been reported.¹⁰ Although the concepts of family-centred care have been widely promoted in the NICU, most programmes do not integrate parents as part of the care team. This study was conceptualised with the belief that actively involving parents as primary caregivers and integral members of the NICU team might be beneficial. With evidence from the literature and direct observation of an NICU in Estonia,⁵ the Family Integrated Care (FICare) model was developed by a team of parents and health-care professionals for the Canadian NICU.^{11,12} FICare challenges the current dogma of neonatal care by shifting the role of parents from disempowered observers in the NICU to active caregivers and advocates for their infant. Using a multidimensional approach, FICare

catalyses partnerships between families and allied health professionals and facilitates the incorporation of parents into the NICU care team.⁸

Findings from our previous single-centre pilot cohort study of FICare, done between 2011 and 2012, suggested that implementation of the model was feasible and safe and might lead to improved infant weight gain and decreased risk of nosocomial infection.⁸ We describe the results of a multicentre cluster-randomised controlled trial designed to further investigate the effectiveness of FICare, as measured against standard NICU care in Canada, Australia, and New Zealand.¹³

Methods

Study design

We did this multicentre, cluster-randomised controlled trial in 25 NICUs in Canada (n=18), Australia (n=6), and

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