# 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

New Zealand (n=1). We chose this design because implementation of the intervention required changes to the provision of care at the unit level. Eligible sites had to take care of preterm infants of 33 weeks' gestation or less, from birth, and agree to provide specific resources for families and nurses if they were randomly assigned to receive the intervention. To be eligible, intervention sites were required to provide families with a rest space and sleep room for the exclusive use of parents, comfortable reclining chairs at the bedside, free parking or transport vouchers, and nurses with training on FICare in preparation for the study. The study protocol was presented at a national research meeting in Canada and at one in Australia, and sites were asked to inform the national FICare research team of their interest and eligibility to participate and willingness to be randomly assigned. Ethics approval was obtained at all participating sites. A safety monitoring committee was established, which reviewed the rate of neonatal mortality and morbidities among the enrolled infants at the FICare and standard care sites on a biannual basis during the study.

### Participants

Infants were eligible if born before or at 33 weeks' gestation with no or low-level respiratory support (ie, oxygen by cannula or mask, or non-invasive ventilation such as continuous positive airway pressure [CPAP], biphasic CPAP, and nasal intermittent positive pressure ventilation). Infants were excluded if they received palliative care, had a major life-threatening congenital anomaly, had a critical illness and were unlikely to survive, were on high-level respiratory support (invasive ventilation), were scheduled for early transfer to another hospital, or were born to parents unable to participate because of health, social, or language barriers. Parents were informed about the study soon after NICU admission, further screened once their infant became eligible, and then approached for written informed consent. Both parents and infant were enrolled after consent was provided.

To be enrolled at FICare sites, families needed to commit to having a primary caregiver at the infant's bedside for a minimum of 6 h per day (between 0700 h and 2000 h), 5 days a week, and to attend medical rounds and education sessions for at least 3 weeks. Parents at standard care sites were not screened to determine if they were willing or able to spend 6 h a day in the unit. Parents in the FICare group were encouraged to participate in care and orientated to the resources and tools available for education, charting, and participation on rounds. All enrolled parents, in both groups, were asked to complete questionnaires assessing demographic information and measures of stress and anxiety, at study enrolment and 21 days later.

### Randomisation and masking

We stratified all sites by country, and Canadian sites by unit size (large >200 eligible infants and small <200 eligible infants, per year). SKL randomly assigned them to provide FICare (intervention) or standard care (control) using a computer-generated sequence. Although randomisation was at the unit level, outcomes were measured at the individual level. Site preparation, including staff training, occurred before any patient enrolment. Because of the nature of the intervention, no masking was done.

### Procedures

An implementation team from each FICare site attended a 2-day FICare training workshop, which focused on the implementation of the four pillars of FICare: a parent education programme with small group education sessions, parent coaching at the bedside, and parent involvement in medical rounds; a staff training programme with education about the importance of family involvement in infant care and tools for staff to mentor, coach, and support parents; policies, procedures, and environmental resources to operationalise parent involvement in caregiving and support prolonged parental presence in the NICU; and a programme of psychosocial support that included peer-to-peer and professional support for families while in the NICU.[14] A unique, consistent written protocol and printed educational and training material were provided to all FICare sites. A trial coordinator was appointed at every site to enrol and support parents to complete the questionnaires. At the intervention sites, the trial coordinator had the additional role of introducing the parents to FICare, supporting and, in part, providing the parent education sessions. Parents were taught the skills required to provide many aspects of their infant's care, such as bathing, feeding, providing skin-to-skin care, dressing, diaper changing, administering oral medications, and taking temperature, as well as how to interact with and support their infant's development. Furthermore, parents were encouraged to actively participate on ward rounds, chart their infant's growth and progress, and participate in making clinical decisions about their infant's care with the medical care team. Parents were also informed about tasks they could not actively participate in—eg, adjustment of the infant's CPAP or oxygen levels was the nurses' responsibility. As part of the programme of psychosocial support, parents were provided with emotional support, coping strategies, stress-reducing activities, and other assistance through informal peer-to-peer support and veteran parent and social work involvement in the education sessions. Site visits were done to ensure that each FICare site met the requirements, including the provision of nurse education to more than 90% of active nursing staff, a satisfactory parent education programme, site resources, and psychosocial support. Families and nurses were interviewed at each FICare site to ensure that they felt adequately supported in their role. Further details of the intervention have been described in our previous publication.[13]

### Outcome measures

The primary outcome was infant weight gain at 21 days after enrolment, as measured by change in weight *Z* score.[15] The *Z* score indicates the number of SDs greater or lower than the median, and is used to monitor the growth of the infant relative to the expected intrauterine growth rate. The secondary outcomes examined were weight gain velocity (data collected at enrolment, day 7, day 14, and day 21); high-frequency breastfeeding at hospital discharge, defined as six or more feeds per day at the breast; parent stress and anxiety at enrolment and day 21; NICU mortality and major neonatal morbidities; safety; and resource use, including duration of oxygen therapy and duration of hospital stay. Morbidities assessed beyond the 21 intervention days were included as outcomes because we hypothesised that the FICare effect on parent engagement would persist throughout the rest of the infants' hospital stays. Major neonatal morbidities were necrotising enterocolitis greater than stage 2, according to Bell's criteria;[16] bronchopulmonary dysplasia, defined as oxygen dependency at 36 weeks' postmenstrual age or at the time of transfer;[17] nosocomial infection, as determined by the US Centers for Disease Control and Prevention criteria;[18] retinopathy of prematurity of stage 3 or more, according to International Classification;[19] and intraventricular haemorrhage of grade 3 or higher.[20] Although morbidities could arise, or be diagnosed, before (eg intraventricular haemorrhage) or after (eg bronchopulmonary dysplasia) the 21-day FICare study period, they were included in the study to detect potential positive or adverse long-term effects of FICare.

Feeding data were collected as part of the trial and were abstracted by trained research assistants into the Canadian Neonatal Network or Australian and New Zealand Neonatal Network database platform.[13] We did not implement a predefined feeding protocol at either the intervention or standard care sites and did not prescribe other standards of care, such as the use of probiotics, for the study. Parent stress and anxiety were measured using validated questionnaires (Parental Stress Scale [PSS]:NICU,[21] a 46-item, parent-completed questionnaire, and the State Trait Anxiety Index [STAI]).[22] The PSS:NICU assessed perceived parental stress related to infant appearance and behaviour, communication with staff, altered parenting role, and sights and sounds in the NICU. Scores ranged from 1 (not stressful) to 5 (extremely stressful) and were reported as averages. The STAI measured severity of overall parental state and trait anxiety using a 40-item questionnaire with scores ranging from 1 (lowest anxiety) to 4 (highest anxiety).

### Statistical analysis

We justified the sample size of the trial on the basis of the primary outcome of weight gain at 21 days, as measured by the change in *Z* score (*Z* score at day 21 minus *Z* score at enrolment). We estimated that a sample size of 675 infants per group would achieve an 80% power to detect a clinically significant 25% difference or more (absolute difference of 0·11) in mean *Z* score change, assuming a two-sided significance level of 0·05, intracluster correlation coefficient of 0·01, and a 10% dropout rate.[23]

Analysis was by intention to treat, and no data were imputed for the primary analysis. We summarised distributions of baseline characteristics in the study population using descriptive statistics. We compared outcomes between the two trial groups using linear regression for continuous variables and logistic regression for categorical variables. We used generalised estimating equations to account for the clustering of participants within hospitals. We also used generalised estimating equations in multivariable linear or logistic regression models to adjust for risk factors and potential confounders identified in previous research and observed from the descriptive comparison of baseline characteristics.[24] These factors included gestational age, infant age at enrolment, small for gestational age (below tenth centile), singleton status, surfactant use, and caesarean delivery. The repeated measure outcomes, such as weight or weight change over time, were examined longitudinally using multilevel hierarchical multivariable models to compare the rate of change in the outcomes between infants from the two trial groups. The covariates adjusted in the main multivariable analyses were those identified in previous research and observed from the descriptive comparison of baseline characteristics and using clinical judgment. For the sensitivity analysis, we also used a propensity score method that included the variables sex, gestational age, small for gestational age, Apgar score at 5 min, singleton pregnancy, surfactant use, caffeine use, caesarean section, antenatal steroid use, maternal age, maternal diabetes, maternal hypertension, maternal education level, marriage status, employment status, ethnicity, infant age at enrolment, infant corrected age at enrolment, and infant weight at enrolment.[25] We assessed the intervention effects at day 21 after enrolment using the mixed-effect linear models for repeated measures with random intercept accounting for clustering, and adjusted them for the propensity score.

We did statistical analyses and managed data using SAS software (version 9.3) and R (version 3.1.3).

The study is registered with ClinicalTrials.gov, number NCT01852695.

### Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. SKL and KO'B had full access to all the data in the study, and had final responsibility for the decision to submit for publication.

## Results

Starting on 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.

Between April 1, 2013, and Aug 31, 2015, 3012 infants were assessed for eligibility at FICare sites and 2015 at standard care sites (figure 1). Of these infants, 895 (30%) were enrolled at the 13 FICare sites and 891 (44%) infants were enrolled at the 12 standard care sites. Baseline characteristics of the infants in both groups are shown in table 1. The age at enrolment was similar between the two groups, although a greater proportion of infants in the FICare group were born at a younger gestational age (22–28 weeks) than those in the standard care group (table 1). Also, more parents in the FICare group self-identified as being Caucasian in the demographic survey (table 2).

Infants in the FICare group gained weight better than did those receiving standard care, as indicated by the mean change in *Z* score at 21 days (1·58 [SD 0·51] for FICare *vs* 1·45 [0·49] for standard care; p<0·0001; table 3). The difference in *Z* score remained significant after adjustment for the covariates gestational age, age at enrolment, small for gestational age, singleton, surfactant use, and caesarean delivery (table 3). The effects remained significant after we did the sensitivity analysis (table 4).[25]

The average daily weight gain was significantly higher among infants in the FICare group than for those in the standard care group (table 3). The difference in daily weight gain remained significant after adjusting for confounders (table 3). Furthermore, the difference in weight gain between the FICare group and standard care group showed that the weight gain increased faster and remained higher during 21 days in the FICare group (figure 2).

Data about feeding were collected by the site study coordinator upon infant discharge to home, or transfer. Information about feeding at discharge was available for 536 (60%) of 895 of infants in the FICare group and 789 (89%) of 891 infants in the standard care group. Many more infants in the FICare group than in the standard care group were transferred to a level 2 NICU, where data on breastmilk feeding at discharge were not collected (316 [35%] of 895 *vs* 76 [9%] of 891). These infants were younger at trial enrolment than those who were discharged home directly from the NICU (appendix p4). The rate of any breastmilk feeds on discharge home was high in both groups (396 [75%] of 531 infants in the FICare group *vs* 624 [81%] of 768 in the standard care group; p=0·0040). However, the rate of high-frequency breastmilk feeds (>6 times a day) at discharge home was higher in the FICare group than in the standard care group (279 [70%] of 396 infants *vs* 394 [63%] of 624]; p=0·016). Of infants receiving high-frequency breastmilk feeds, a greater proportion of those in the FICare group were fed at the breast, as opposed to bottle, than those in the standard care group (92 [33%] of 279 *vs* 37 [9%] of 394; p<0·0001)

At enrolment, total stress and anxiety scores among parents were similar in both groups (mean stress score 2·79 [SD 0·75] in FICare group *vs* 2·72 [0·78] in standard care group; p=0·091; mean anxiety score 83·7 [22·6] *vs* 81·5 [21·8]; p=0·062). The mean scores were lower in both study groups at day 21; however, the mean stress and anxiety scores for parents in the FICare group were significantly lower than those for parents in the standard care group by day 21 (figure 3; stress scores 2·3 [SD 0·8] *vs* 2·5 [0·8], p<0·00043; anxiety scores 70·8 [20·1] *vs* 74·2 [19·9], p=0·0045)

There were no significant differences between groups in the secondary outcomes of mortality, major morbidity, duration of oxygen therapy, and duration of stay in hospital (table 3). Furthermore, the differences remained insignificant after adjusting for gestational age, age at enrolment, small for gestational age, singleton, surfactant use, and caesarean delivery (table 3). Intraventricular haemorrhage, which would occur before FICare enrolment, was significantly higher in the FICare group in the unadjusted analysis, but the difference was insignificant after adjusting for confounders (table 3).

As well as the assessment of neonatal outcomes, we originally intended to include an assessment of patient safety in our trial by comparing the rate of all incident

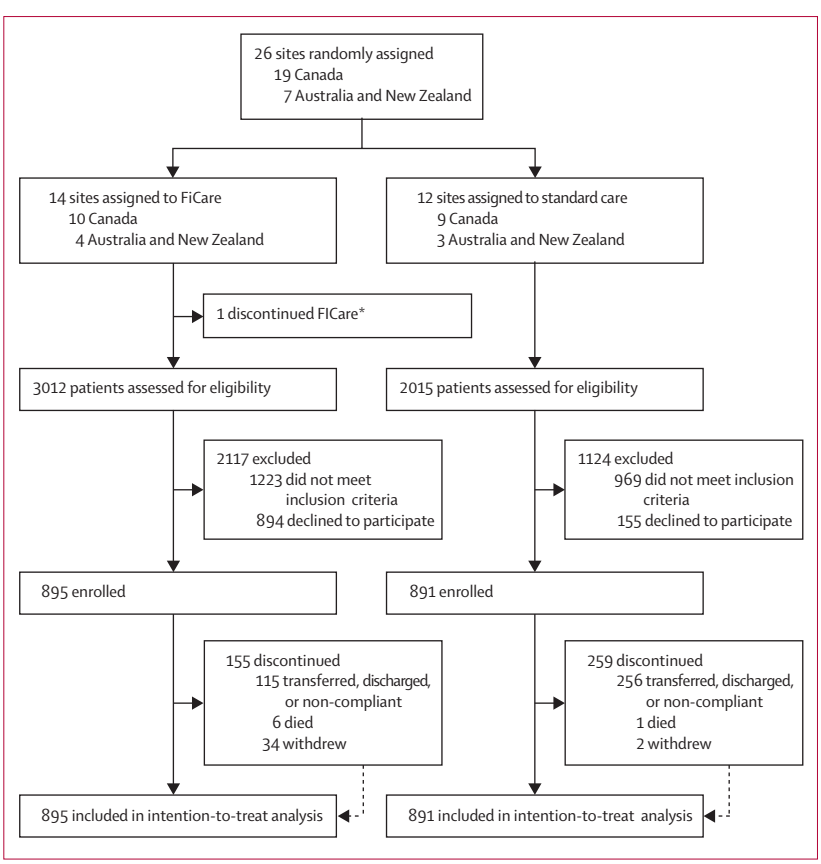


***Figure 1:*** **Trial profile**
FICare=Family Integrated Care. *One site in Canada discontinued because of poor site enrolment.

| | FICare (n=895) | Standard care (n=891) |
|---|---|---|
| Sex | | |
| Male | 497/893 (56%) | 479/890 (54%) |
| Female | 396/893 (44%) | 411/890 (46%) |
| Birthweight (g) | 1219 (413) | 1264 (419) |
| Mean weight at enrolment (g) | 1407 (382) | 1442 (474) |
| Mean weight at enrolment *Z*-score | −0·909 (0·780) | −0·908 (0·792) |
| Gestational age group | | |
| 22–28 weeks | 445/895 (50%) | 377/891 (42%) |
| 29–33 weeks | 450/895 (50%) | 514/891 (58%) |
| Median age at enrolment (days) | 15 (8–28) | 12 (6–23) |
| Median corrected gestational age at enrolment (weeks)* | 32 (30–33) | 32 (30–33) |
| Small for gestational age† | 90/893 (10%) | 105/890 (12%) |
| Apgar score <7 at 5 min | 240/883 (27%) | 236/882 (27%) |
| Singleton | 601/895 (67%) | 538/891 (60%) |
| Surfactant use | 465/895 (52%) | 408/889 (46%) |
| CPAP at enrolment‡ | 398/797 (50%) | 433/859 (50%) |
| TPN at enrolment‡ | 309/797 (39%) | 380/859 (44%) |
| Maternal characteristics | | |
| Mean maternal age (years) | 31·3 (5·5) | 31·4 (5·5) |
| Antenatal steroid use | 797/880 (91%) | 805/878 (92%) |
| Caffeine use | 787/895 (88%) | 785/889 (88%) |
| Caesarean section | 522/894 (58%) | 559/884 (63%) |

Data are n/N (%), mean (SD), or median (IQR). Denominators differ because of missing data, unless otherwise stated. 200 infants had mothers with diabetes (77 [39%] in FICare and 123 [62%] in standard care). FICare=Family Integrated Care. CPAP=continuous positive airway pressure. TPN=total parenteral nutrition. *Defined as gestational age at birth plus chronological age. †Defined as weight below the tenth centile. ‡Canadian sites only; no CPAP or TPN use information at Australian or New Zealand sites.

***Table 1:*** **Infant baseline characteristics of the intention-to-treat population, including relevant maternal characteristics**

| | FICare (n=738) | Standard care (n=705) |
|---|---|---|
| **Employment** | | |
| Student | 27/738 (4%) | 16/705 (2%) |
| Employed | 566/738 (77%) | 516/705 (73%) |
| Homemaker | 54/73 (7%) | 77/705 (11%) |
| Unemployed | 75/738 (10%) | 65/705 (9%) |
| Other* | 16/738 (2%) | 16/705 (2%) |
| **Marriage status** | | |
| Single | 67/731 (9%) | 61/697 (9%) |
| Married or cohabiting | 664/731 (91%) | 636/697 (91%) |
| **Education** | | |
| <10 years | 19/738 (3%) | 20/705 (3%) |
| 10–12 years or some college (incomplete) | 222/738 (30%) | 231/705 (33%) |
| 16 or more years | 497/738 (67%) | 454/705 (64%) |
| **Ethnic groups** | | |
| Caucasian | 546/738 (74%) | 471/705 (67%) |
| Other† | 177/738 (24%) | 221/705 (31%) |
| Unknown | 15/738 (2%) | 13/705 (2%) |

Data are n/N (%). Singletons are indicated in table 1, and the rest of infants were multiples. FICare=Family Integrated Care. *Self-defined by survey participants. †Includes Afro-Canadian or Black, east Asian, south Asian, First Nations, Hispanic or Latino, Middle Eastern, and mixed race.

***Table 2:*** **Maternal characteristics**

reports between FICare and standard care sites. We were unable to complete the analysis because the process for reporting, collecting, and grading incidence reports varied substantially between sites and invalidated any comparisons. However, it is important to note that there were no adverse events attributable to FICare reported during the trial, including medication errors, mishandling of equipment, or serious consequences to the infants.

## Discussion

In this study, FICare resulted in improved weight gain among infants in the NICU and improved mental wellbeing among parents. Given that growth is an important independent determinant of neurodevelopmental outcomes in preterm infants, the increased weight gain and enhanced high-frequency breastmilk feeding in the FICare group are important improvements in preterm care that might have long-term benefits for infant health.[26,27] Furthermore, the improved psychological wellbeing of parents in the FICare group could translate into better long-term mental health for the infant's parents, improved parent–infant bonding, and enhanced outcomes for the infant.[28,29]

Family-centred care is a philosophy that uses principles to guide the provision of care, ultimately focusing on building partnerships between patients, their families, and health-care providers to facilitate shared decision making. FICare draws on all elements of family-centred care, but advances it further by enabling parents to become their infant's primary caregiver and to actively participate in their care.[8,13,14] Parent involvement in infant care creates a more consistent care environment for the infant, which could help protect the infant from trauma associated with the NICU, such as isolation, stress, and lack of support during painful procedures, while also providing a mechanism for parents to build the confidence and skills required to better support their infant after discharge. Unlike other family-centred interventions, FICare combines a care-by-parent model with specific interventions to educate, support, and engage parents at their infants' bedside.[13] Furthermore, FICare aims to facilitate parent involvement by engaging staff and providing both education and support for the nurses and health-care team, which enables the staff to better educate and include parents as partners in their infants' care.

The observed outcomes of this study cannot be attributed to one or the other of these FICare components, but rather to the programme as a whole. Other studies have reported that individual elements of FICare might have specific benefits for infants and their families, but they do not assess all of the elements together.[7,10] Our work with families during the development of FICare suggested that

| | FICare (n=895) | Standard care (n=891) | p value* | Adjusted difference (95% CI); p value† | Adjusted OR (95% CI); p value† |
|---|---|---|---|---|---|
| **Mean weight gain** | | | | | |
| Mean change in *Z* score at 21 days | 1·58 (0·51) | 1·45 (0·49) | <0·0001 | 0·11 (0·06–0·16); p<0·0001 | .. |
| Mean daily weight gain | 26·7 (9·4) | 24·8 (9·5) | <0·0001 | 2·03 (1·10–3·00); p<0·0001 | .. |
| Percentage change in weight at 21 days | 42·6% (15·1) | 38·9% (13·9) | <0·0001 | 3·47 (1·89–4·94); p<0·0001 | .. |
| **Mortality and morbidity** | | | | | |
| Mortality | 11/895 (1%) | 4/891 (<1%) | 0·21 | .. | 2·21 (0·64–7·68); p=0·21 |
| Necrotising enterocolitis | 23/891 (3%) | 15/887 (2%) | 0·25 | .. | 1·34 (0·73–2·45); p=0·27 |
| Bronchopulmonary dysplasia | 167/889 (19%) | 149/887 (17%) | 0·41 | .. | 0·80 (0·44–1·46); p=0·37 |
| Nosocomial infection | 49/895 (5%) | 44/890 (5%) | 0·69 | .. | 0·90 (0·47–1·75); p=0·76 |
| Retinopathy of prematurity‡ | 43/591 (7%) | 33/504 (7%) | 0·84 | .. | 0·94 (0·67–1·31); p=0·73 |
| Intraventricular haemorrhage‡ | 109/756 (14%) | 63/802 (8%) | 0·023 | .. | 1·63 (0·97–2·75); p=0·06 |
| Resource use | | | | | |
| Mean duration of hospital stay (days) | 50 (1·9) | 48 (2·3) | 0·19 | .. | 1·12 (0·81–1·54); p=0·51 |
| Median duration of oxygen support (days) | 4 ( 0–36) | 3 (1–33) | 0·67 | .. | 1·00 (0·75–1·27); p=0·86 |

Data are n/N (%), mean (SD), or median (IQR). FICare=Family Integrated Care. OR=odds ratio. *Based on generalised estimating equations to account for clustering. †Adjusted for gestational age, infant age at enrolment, small for gestational age, singleton status, surfactant use, and caesarean delivery. ‡Of stage 3 or higher.

***Table 3:*** **Assessment of neonatal outcomes and resource use with univariate and multivariable analyses**

| | Adjusted difference (95% CI) | p value |
|---|---|---|
| Mean change in *Z* score at 21 days | 0·10 (0·0–0·18) | 0·015 |
| Weight change at 21 days | 35·4 (1·94–68·9) | 0·038 |
| Percentage change in weight at 21 days | 3·2% (1·12–5·27) | 0·0025 |

Zwt21=*Z* score for weight at 21 days after enrolment. Zw1=*Z* score for weight at enrolment. Wt21=weight at 21 days after enrolment. Wt1=weight at enrolment.

***Table 4:*** **Assessment of neonatal outcomes after adjustment for sensitivity analyses**

the care-by-parent model needed to be multidimensional, with interdependent components that ensure its success. For example, providing a parent education programme without facilitating parent engagement in infant care would lessen the influence of the education programme. Similarly, encouraging parents to care for their infants without providing nurses with the knowledge and skillset to support parents as partners could create conflict at the bedside. By implementing and supporting a culture change within the entire NICU, FICare can help maximise the effect of family-integrated care on the health of the whole family and on staff, who might experience less conflict with parents and greater job satisfaction as a result.

Findings from our study indicate that FICare significantly improves two outcomes important for minimising morbidity in preterm infants: infant weight gain and parental stress and anxiety. Both outcomes are important variables associated with positive neurodevelopmental outcomes. First, infants whose families participated in FICare had a small, but significant, improvement in *Z* score and weight gain. Although the absolute difference in weight gain was small, it compares favourably with the reported effects of specific feeding interventions[30] and also indicates that FICare has the potential to positively affect the physical development of preterm infants. FICare did not aim to change the feeding patterns of infants, but rather to engage parents as caregivers, enabling them to provide more skin-to-skin and developmentally responsive care, as well as empowering them to be active participants in decisions about feeding. Second, parents' responsiveness to their infant is an important determinant of positive neurodevelopmental outcomes; therefore, the reduction of parent stress and anxiety in the FICare group is important for improving both parents' connection with their infant, long-term health outcomes for the entire family, and developmental outcomes of the infants.[10,29] The significant difference in the PSS:NICU scores between the FICare and standard care groups after the intervention is similar in magnitude to that reported by Melnyk and colleagues.[10] Finally, previous reports[27,30] indicated that breastmilk feeding improves neurodevelopmental outcomes, underscoring the importance of the results in our study that suggest that the rate of high-frequency breastmilk feeding at discharge home is increased in the infants receiving FICare. Being able to provide at least six feeds per day of breastmilk is a good indicator of maternal breastmilk supply and is therefore an indicator of long-term breastfeeding success.

To date, most care-by-parent programmes have been studied in lower acuity hospitals.[4] FICare was designed specifically to support parents as primary caregivers for their infant in tertiary care NICUs, and our findings suggest that FICare can be implemented in such units. Ongoing pre-implementation and post-implementation studies of how FICare might be applied in lower acuity units will provide the much needed evidence to establish the feasibility of FICare in these contexts. The intervention

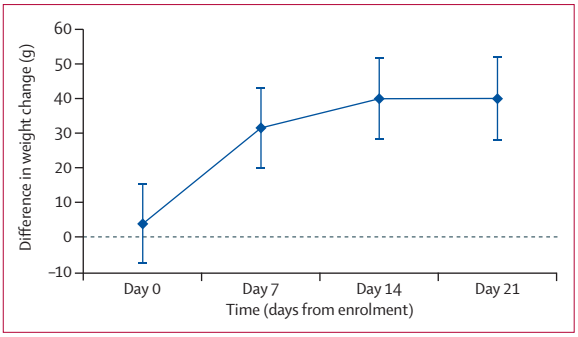


***Figure 2:*** **Adjusted difference in weight change between FICare and standard care groups over time**
Points plotted show the difference between the weight change in FICare and the weight change in standard care, measured as the difference between weight at day of interest and weight at enrolment. Error bars show the 95% CIs. Day 0 is the enrolment date. dWt=(weight at day of interest–weight at enrolment). FICare=Family Integrated Care.

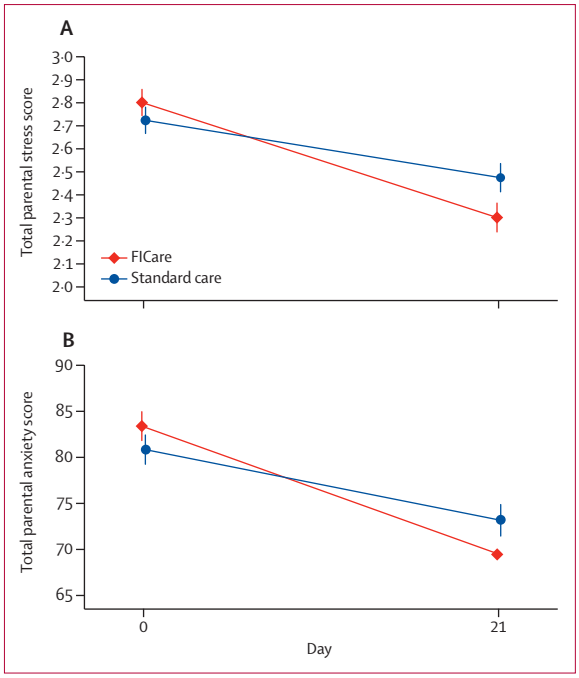


***Figure 3:*** **Total parental stress and anxiety at enrolment and 21 days**
Error bars represent 95% CIs. FICare=Family Integrated Care.

requires that staff communicate effectively with parents, despite language differences, and that education is provided to diverse populations, which are all parts of best neonatal care practices. Our study might be generalisable to units in high-income countries with similar organisation of perinatal health services, but further study is required to assess the practicality of implementing FICare in low-income and middle-income countries. Expansion of the FICare programme will require input from both parents and staff, particularly nurses. In our pilot study, we investigated the attitudes of nurses and parents towards FICare as well as their acceptance of the FICare model, and received mostly positive feedback, although there were also suggestions for improvement.[8] The attitudes of staff and parents will need to be assessed on a larger scale to determine how to effectively promote the expansion of FICare to other types of units.

FICare challenges the current philosophy of neonatal intensive care with three fundamental aims—parent engagement, parent empowerment, and shifting the focus of care to the family. Traditionally, medical professionals have provided care for preterm infants, but actively including parents as integral members in the care team might be a preferable strategy for future neonatal care.[13] Our findings suggest that how care is provided to the family, not just the infant, has a positive effect on the wellbeing of both infant and family.

Cluster-randomised controlled trials are more prone to bias than are individual patient randomised controlled trials because of variations in practice, unbalanced patient populations, and staff cultures that are not captured or measured during the study. For example, our study had a random imbalance in infants younger than 29 weeks' gestation (there were more in the FICare group) and singletons (more in standard care group). To address possible confounding factors in neonatal practice, we stratified sites by country and size before they were randomly assigned. We were unable to control for nutritional policies or resource use. Specific to this study, FICare parents were asked to make a very different commitment than were standard care parents, resulting in the possibility that more committed parents enrolled in FICare; the proportion of families who participated at FICare sites (30%) was different than at the standard care sites (44%). However, our sensitivity analysis, which included family demographic data as well as the infant data, showed that the intervention effects remained significant, regardless of the family demographics. One last potential source of bias from the study design is that over the duration of the study, some standard care sites could have adopted local family-oriented practices that were not recorded and might have biased the results towards a less detectable difference.

Our study had other limitations that were independent of the study design. First, we have less information about the status of infants in the FICare group on discharge home than about infants in the standard care group. The increased rate of transfer of infants from FICare sites to level 2 NICUs before discharge home was not something that we anticipated when assigning sites. These missing data might have resulted in a type I error, which limits our conclusions about the success of breastfeeding in this population. Furthermore, we did not report the difference in weight gain at 36 weeks and at discharge home between infants in both groups because many of the data were missing. Second, some secondary outcomes (eg, intraventricular haemorrhage, nosocomial infection, or bronchopulmonary dysplasia) either occur before trial enrolment or are predetermined at the time at enrolment.

We decided to include these secondary outcomes in our study despite the ir early occurrence because they are neonatal outcomes that are important indicators of the infant's health. Finally, many infants included in the intention-to-treat analysis were transferred before receiving 3 weeks of the FICare intervention, thus resulting in fewer measurements at later timepoints.

In conclusion, both infants and parents enrolled in FICare showed improved outcomes. Further research on the barriers to implementing and sustaining this model of care in NICUs and other hospital settings, and the effect of FICare on long-term neurodevelopment, is warranted.

#### Contributors

KO'B did the literature review. SKL, KO'B, KR, MB, KL, RA, OdS, LMo, MN, EN, AS, XYY, LMi, and WT-M were involved in the design of the study. SKL, KO'B, MC, KL, RA, OdS, LMo, MN, EN, AS, and WT-M were involved in acquisition of data. SKL, KO'B, KR, MB, MC, KL, RA, OdS, LMo, MN, EN, AS, LMi, and WT-M were involved in interpretation of the analysis. KO'B drafted the paper. XYY did the statistical analyses and prepared the figures. SKL, KO'B, KR, MB, MC, KL, RA, OdS, LMo, MN, EN, AS, XYY, LMi, and WT-M approved the paper.

#### Declaration of interests

KO'B and SKL report grants from the Canadian Insitute of Health Research and Ontario Ministry of Health and Long-Term Care during the study. All other authors declare no competing interests.

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# Family Integrated Care for very preterm infants: evidence for a practice that seems self-evident?

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Very preterm birth (28 to 32 weeks gestation) is stressful and traumatic for parents; long-term sequelae include impaired bonding and symptoms of post-traumatic stress disorder.[1] Family Integrated Care (FICare) is a model that aims to ameliorate these and other adverse effects by integrating parents as primary caregivers. Parents are resident in the neonatal intensive care unit for extended periods, learn to provide all care (except intravenous fluid and medications), record observations in medical charts, and participate in ward rounds, with their involvement underpinned by peer support and education.[2] FICare has been in use since the late 1980s in Estonia[3] and low-resource settings;[4] however, there has been a paucity of robust evidence to support it.

In *The Lancet Child and Adolescent Health,* Karel O'Brien and colleagues[5] report results from their international cluster-randomised trial, which is a key addition to the evidence base for FICare. This trial randomised 26 neonatal units, across three countries, to FICare or standard care. The primary outcome was individual infant weight gain 21 days after enrolment; other outcomes included parental stress and measures of breastfeeding. The authors must be congratulated on completing this highly challenging trial: the intervention applied was complex and followed extensive development,[6] and the methodological and logistical challenges must not be underestimated.

O'Brien and colleagues show significant differences in favour of the FICare group in infant weight gain, parental stress and anxiety 21 days after enrolment, and high-frequency breastfeeding (≥6 times a day) at hospital discharge. These results appear to provide robust support for FICare—a holistic approach to care that could be argued to be self-evident. However, neonatal care is littered with so-called truths that seemed self-evident before being found to be ineffective or harmful,[7] hence critical appraisal is warranted. High-quality randomised trials are the gold standard method to determine causality because, alone among experimental approaches, they can eliminate both measured and unmeasured confounders. Fundamental to the integrity of any randomised trial is that comparison groups are identified and treated equally, apart from the intervention of interest. Therefore, it is an important limitation of this trial that one inclusion criterion was applied only to the intervention group: parents in the FICare group had to commit to being a primary caregiver at the infant's bedside for a minimum of 6 h per day (between 0700 h and 2000 h), 5 days a week, and to attend medical rounds and education sessions for at least 3 weeks. This is a considerable commitment and the FICare and standard care groups were different at the outset of the trial. Because of the study design, this limitation might well have been unavoidable; the authors discuss this limitation in the protocol[2] and paper, and adjusted the results to account for baseline differences. Although such an approach is appropriate, it cannot account for unmeasured confounders (such as parental commitment), which are likely to differ considerably between intervention and standard care groups. The degree to which unmeasured confounders explain the differences seen in the study outcomes, rather than FICare per se, might be considerable, particularly in relation to parent-reported stress and anxiety.

The primary outcome was weight gain 21 days after enrolment. Although this surrogate outcome is of some academic interest, it is not clear how it relates to long-term measures of infant development or wellbeing, highlighting the importance of identifying

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core outcomes for neonatal trials that are important to stakeholders, including parents and ex-neonatal patients.[8] In my opinion, the higher rate of high-frequency breastfeeding seen in the FICare group is the key infant outcome because of the long-term benefits of breastfeeding.[9] However, there is an important additional bias that needs to be considered when interpreting this result: breastfeeding was assessed by parent questionnaire at final hospital discharge, and follow-up was considerably lower in the FICare group (60%) when compared to the control group (89%). This differential rate of follow-up might have biased this result in favour of the FICare group; mothers in this group who stopped breastfeeding might not have wanted to disclose this to the study team, and therefore returned their breastfeeding questionnaires at a lower rate than did mothers who stopped breastfeeding in the control group (who did not feel this way because they did not receive the education and support package included in FICare). Again, it is up to the reader to judge how this potential bias influences their interpretation of the study.

O'Brien and colleagues have achieved a remarkable feat, robustly testing FICare in an international, cluster-randomised controlled trial. High-quality cluster trials are sorely needed to investigate the many organisational uncertainties that plague neonatal care. The beneficial effects of FICare that O'Brien and colleagues report, particularly in relation to parental stress and anxiety and breastfeeding, are important—but they need to be interpreted cautiously in light of the risk of bias inherent in the trial. Fundamentally, however, in the absence of detriment, parent choice could be the prime consideration for neonatal units considering implementing FICare.

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