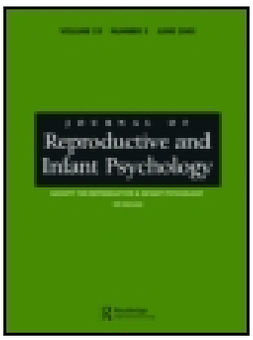

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Evaluating the effect of Family Integrated Care on maternal stress and anxiety in neonatal intensive care units

Chelsea Cheng[a], Linda S. Franck[b], Xiang Y. Ye[c], Sarah A. Hutchinson[c], Shoo K. Lee[a,c,d,e] and Karel O'Brien[a,c,e] on behalf of the FICare Study Group and FICare Parent Advisory Board*

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ABSTRACT

Objective: To identify how Family Integrated Care (FICare) affected maternal stress and anxiety.

Study Design: This secondary analysis of the FICare cluster randomised controlled trial included infants born between 1 April 2013 and 31 August 2015 at ≤33 weeks' gestation. Mothers completed the PSS:NICU and STAI questionnaires at enrolment and study day 21.

Results: 1383 mothers completed the surveys at one or both timepoints. The mean PSS:NICU and STAI scores at day 21 were significantly lower in the FICare mothers than controls (PSS:NICU mean [standard deviation] FICare 2.32 [0.75], control 2.48 [0.78], $p = 0.0005$; STAI FICare 70.8 [20.0], control 74.2 [19.6], $p = 0.0004$). The sights and sounds, looks and behaviour, and parental role PSS: NICU subscales and the state and trait STAI subscales were all significantly different between FIC are and controls at day 21. The magnitude of change in all stress and anxiety subscales was greater in the FICare group than controls. These differences remained significant after adjustment for confounders with the greatest change in the parental role (least-squares mean [95% confidence interval] FICare −0.65 [−0.72, 0.57], control −0.31 [−0.38, −0.24], $p < 0.0001$) and state anxiety subscales.

Conclusion: FICare is effective at reducing NICU-related maternal stress and anxiety.

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KEYWORDS
Preterm infant; NICU; stress; anxiety; FICare

Introduction

Parents with infants in a neonatal intensive care unit (NICU) often have increased stress, anxiety, and depression, not only because of their infants' prematurity or other medical conditions but also because of the complex and technological NICU environment and

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*A complete list of FICare Study Group and FICare Parent Advisory Board participants can be found in the Acknowledgements

Supplemental data for this article can be accessed here.

prolonged physical separation of infants and mothers (Al Maghaireh, Abdullah, Chan, Piaw, & Al Kawafha, 2016; Baia et al., 2016; Busse, Stromgren, Thorngate, & Thomas, 2013; O'Brien et al., 2018). The NICU environment can act as both a physical and emotional barrier between infants and their parents, which prevents parent-infant bonding and leaves parents feeling unprepared to care for their infant both in the NICU and upon discharge (Franck & Axelin, 2013; Franck, McNulty, & Alderdice, 2017; Woodward et al., 2014). The separation of parents from their infant along with their inability to engage in infant care contributes to parent stress, which is known to impact infant behaviour and other long-term outcomes (Treyvaud et al., 2010).

The Family Integrated Care (FICare) model of NICU care was designed to eliminate barriers between parents and their infants by incorporating parents as partners in their infant's NICU care (O'Brien et al., 2013, 2015, 2018). In FICare, parents are supported to work in partnership with the healthcare team and, over time, to perform all of their infant's care in the NICU with the exception of ventilation, adjustment of monitor settings, and administration of IV fluids and medications. Furthermore, the FICare model includes modifications to the policies and practices of the NICU so that the organisational structure fully supports and sustains family integration in caregiving. These modifications include the following: tailored education programmes for parents and the NICU team, integration of parents into medical rounds, environmental changes to support parent presence in the NICU (e.g., access to rest and kitchen areas, screens and breast pumps, comfortable bedside chairs), and parent psychological support through interaction with veteran parents and social workers (http://familyintegratedcare.com/). A multi-centre cluster randomised controlled trial (cRCT) testing the impact of FICare on infants born at ≤33 weeks' gestation and their families found that mothers who participated in FICare had significantly lower stress and anxiety than mothers who received standard care ($p < 0.05$)(O'Brien et al., 2018).

The purpose of the current study was to examine in more detail how FICare affected the subscale measures of NICU-related stress and anxiety so we could better understand the impact of the programme. Our specific aims were the following: (1) to examine if the reduced stress in FICare mothers was attributable to particular subscales of the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS:NICU); (2) to identify if the reduced anxiety in FICare mothers was attributable to particular subscales of the State-Trait Anxiety Inventory (STAI); and (3) to determine if there were associations between the PSS:NICU and the STAI.

Materials and methods

Study design

Our study was a secondary analysis of data collected from infants and their mothers enrolled in the FICare cRCT conducted by O'Brien et al. (2018). Twenty-six tertiary-level NICUs in Canada, Australia, and New Zealand participated in the FICare cRCT. The randomisation occurred at the institutional level, and 14 NICUs were randomised to the FICare intervention, while 12 NICUs provided standard care (Supplemental Figure 1). However, outcomes were measured at the individual level, and maternal stress and anxiety levels were assessed at both enrolment (study day 0) and study day 21.

Infants born at ≤33 weeks' gestation between 1 April 2013 and 31 August 2015 were included in the study. Infants who were receiving palliative care had a life-threatening congenital problem, had a critical illness with a low chance of survival, were scheduled to be transferred to another hospital, or had parents unable to participate were excluded (O'Brien et al., 2015, 2018). The infant characteristics, including severity of illness, were similar between the FICare and control groups.

Intervention

The FICare model consists of four pillars: (i) parent education, (ii) NICU team education and support, (iii) parent environmental support, and (iv) parent psychosocial support (http://familyintegratedcare.com/). The purpose of parent education was to teach parents about the NICU setting and treatments, the importance of parent involvement in their infant's care, and specific ways in which parents can be directly involved in their infant's individual caregiving at all stages of the NICU stay (*e.g.*, feeding and administering oral medications)(O'Brien et al., 2015, 2018). The parent education was provided by nurses and other team members via small group sessions and in individual bedside skills teaching sessions. Parents were invited to participate in ward rounds and contribute to medical decision-making. NICU team education and support consisted of education about the FICare model and providing the staff with the tools to incorporate NICU families into the healthcare team. Parents were also provided environmental support through changes in unit policies and provision of physical resources. These resources included access to lounge and sleep rooms, breast pumps, and parking vouchers. Psychosocial support was delivered to parents in the form of interaction with social workers and veteran parents whose infant(s) were previously admitted to the NICU. Veteran parents provided peer-to-peer support to parents by answering their questions, being available in the NICU and at the bedside, and organising recreational activities that helped to develop a sense of community. Further support, such as psychiatric consultation, was given as needed.

Outcomes and measures

Maternal stress and anxiety were measured by the individual components of the Parental Stress Scale (PSS):NICU and State Trait Anxiety Index (STAI). The PSS:NICU is a validated instrument survey developed by Miles, Funk, and Carlson (1993) that measures NICU-related parental perception of stress. In the FICare cRCT, a revised 34-item PSS:NICU that included a 6-item "sights and sounds' subscale, a 17-item 'looks and behaviour of the infant' subscale, and an 11-item 'parental role' subscale was used to determine maternal stress levels. All items had the same response scale from 1 (not at all stressful) to 5 (extremely stressful). The PSS:NICU questionnaire was then scored using Metric 2 (Overall Stress Level), which took into account all items on the questionnaire to calculate the overall stress score, with items not experienced by the respondent given a score of 1(Miles et al., 1993).

The Spielberger STAI questionnaire (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983) is a validated measure of overall anxiety and was used to quantify maternal anxiety levels. During the FICare cRCT, the STAI Form Y was administered, which

consisted of two 20 item subscales to evaluate state and trait anxiety. Each item on the questionnaire was rated on a scale from 1 (not at all) to 4 (almost always).

Data collection

Information on maternal characteristics and outcomes was collected at FICare and control sites for the study duration. The maternal demographic data for the participants in the FICare cRCT were obtained from the Canadian Neonatal Network (CNN), Australian and New Zealand Neonatal Network (ANZNN) and questionnaires and surveys completed either on paper or electronically (O'Brien et al., 2015). Data from paper forms were entered into the database by the programme coordinator, while data from online forms were automatically entered into the database. Mothers at Australian and New Zealand sites also had the option of submitting answers via smartphone to a web-based dataset collected by the ANZNN Coordinating Centre.

Statistical analysis

The study population was summarised using descriptive statistical methods. Maternal characteristics were compared between FICare and control groups using chi-square test for categorical variables and Student's t-test for continuous variables. To assess the impact of the FICare intervention, we first compared the mean maternal PSS:NICU and STAI scores at enrolment and study day 21 using Student's t-test in the FICare and control groups. To compare the magnitude of change in scores from enrolment to day 21 between the two groups, we used both univariate and multivariable mixed-effect linear models for repeated measures with random intercept to account for the clustering within each NICU. The interaction term between the time period and FICare group was also included in the models. If the interaction term was statistically significant, it indicated there was a significant difference in the magnitude of the score change from enrolment to study day 21between FICare and control groups. The covariates adjusted for in the multivariable models were those potential confounders identified in the univariate analyses ($p < 0.1$) including a number of other children at home, employment, race, and family support (Table 1).

To assess the association between the PSS:NICU and STAI instruments, the Pearson correlation coefficient between the total stress score and total anxiety score were estimated. Similar methods were also used to examine the relationship between the subscales within each instrument. Data management and all statistical analyses were performed using SAS 9.4 (SAS Institute, Inc., Cary, NC, USA). A two-sided p-value of <0.05 was used to indicate statistical significance.

Ethics

The FICare study was approved by the research ethics boards at all 19 Canadian, 6 Australian, and 1 New Zealand participating sites. All data retrieval and usage abided by the Health Information Act and the Personal Information and Electronic Documents Act (PIPEDA) in Canada, the Privacy Act 1988 Sections 95 and 95A in Australia, and the Privacy Act 1993 and Health Information Privacy Code in New Zealand. Data were kept

Table 1. Maternal characteristics.

Characteristics	Control	FICare	p-value[a]
Mothers, N	673	710	
Maternal age, mean (sd)	31.3 (5.4)	31.3 (5.6)	0.86
Married, % (n/N)	91.44 (609/666)	90.6 (636/702)	0.58
Family income group, % (n/N)			0.44
<$20 000	9.98 (64/641)	8.84 (60/679)	
$20 000 – $39 999	15.29 (98/641)	15.76 (107/679)	
$40 000 – $99 999	41.5 (266/641)	45.36 (308/679)	
≥$100 000	33.23 (213/641)	30.04 (204/679)	
# of other children at home			0.04
0	61.22 (412/673)	67.61 (480/710)	
1	24.22 (163/673)	21.13 (150/710)	
>1	14.56 (98/673)	11.27 (80/710)	
Education level (>12 years),% (n/N)	63.74 (429/673)	67.32 (478/710)	0.16
Employed, % (n/N)	72.36 (487/673)	76.76 (545/710)	0.06
Race (White vs Others), % (n/N)	66.57 (448/673)	73.8 (524/710)	0.003
Family support, % (n/N)	60.33 (406/673)	65.49 (465/710)	0.046
Other support, % (n/N)	72.96 (491/673)	74.51(529/710)	0.51

[a]The reported p-values were based on the comparison between the two groups using Chi-square test for categorical variables and Student T-test for continuous variables.
Abbreviations: N, total number in group; n, number in subgroup; sd, standard deviation

secure according to the CNN and the Mount Sinai Hospital research ethics board standards (O'Brien et al., 2015).

Results

Study sample

Of the 1383 mothers enrolled in the FICare cRCT, 1296 mothers completed the PSS:NICU at enrolment, 1029 at day 21, and 995 at both time periods (477 FICare, 518 controls). Similarly, 1332 mothers completed the STAI at enrolment, 1048 at day 21 and 1037 at both time periods (516 FICare and 521 controls). Maternal demographic data for these mothers are presented in Table 1 with 673 mothers in the control and 710 in the FICare group. Mothers in the FICare group had fewer children at home ($p = 0.04$), self-identified as Caucasian ($p = 0.003$), and had more family support ($p = 0.046$) than mothers in the control group (Table 1). The control and FICare group mothers did not differ significantly in age, marital status, family income, education level, employment, or other support (Table 1).

Average stress and anxiety scores

Analysis of the maternal PSS:NICU scores for all mothers indicated that neither the mean subscale scores nor total stress scores measured at enrolment differed significantly between control and FICare group mothers, while all three subscales and the total stress scores were significantly lower in the FICare group at study day 21 than the control group (Table 2). Of note, the greatest subscale change over the study period was the FICare parental role score, which decreased 0.64 points.

At enrolment, the FICare group had significantly higher mean state, trait anxiety subscale and total anxiety scores than the control group (Table 2). Conversely, at study day 21, the FICare group had significantly lower state, trait and total anxiety

Table 2. Stress and anxiety scores in control and FICare mothers.

PSS number		Control	FICare	
Number at enrolment		651	645	
Number at day 21		525	504	
PSS scores		Mean (sd)	Mean (sd)	p-value[a]
Sights and sounds score	Enrolment	2.44 (0.83)	2.51 (0.84)	0.103
	Day 21	2.23 (0.80)	2.12 (0.82)	0.04
Looks and behaviour score	Enrolment	2.72 (0.90)	2.78 (0.88)	0.22
	Day 21	2.50 (0.90)	2.37 (0.85)	0.025
Parental role score	Enrolment	2.90 (0.89)	2.98 (0.86)	0.13
	Day 21	2.61 (0.87)	2.34 (0.87)	<0.0001
Total stress score	Enrolment	2.72 (0.78)	2.79 (0.75)	0.1
	Day 21	2.48 (0.78)	2.32 (0.75)	0.0005
STAI number		Control	FICare	
Number at enrolment		651	681	
Number at day 21		530	518	
STAI score		Mean (sd)	Mean (sd)	p-value[a]
A- State scale score	Enrolment	43.0 (12.2)	44.6 (12.4)	0.02
	Day 21	38.6 (10.9)	36.6 (10.9)	0.003
A-Trait scale score	Enrolment	38.7 (10.6)	40.0 (10.8)	0.02
	Day 21	35.7 (9.9)	34.4 (9.7)	0.03
Total anxiety score	Enrolment	81.5 (21.7)	83.8 (22.6)	0.049
	Day 21	74.2 (19.6)	70.8 (20.0)	0.004

[a]The reported p-values were based on the comparison between the two groups using Student T-tests.
Abbreviations: PSS, Parental Stressor Scale; sd, standard deviation; STAI, State-Trait Anxiety Inventory

scores than the control group. Therefore, the decreases in the anxiety scores from enrolment to study day 21 were greater in the FICare mothers than the control group mothers. Of note, the greatest change was in the state anxiety subscale score for the FICare group, which fell 8 points from enrolment to day 21.

Magnitude of change in stress and anxiety scores

We measured the magnitude of change in both stress and anxiety in the FICare and control groups using a mixed-effect model to perform univariable analyses with paired data from mothers who completed surveys at both enrolment and study day 21. The magnitude of change in all stress subscales and total stress was greater in the FICare group than controls (Figure 1). Similarly, the magnitude of change its state, trait, and total anxiety were also greater in the FICare group than controls (Figure 2).

Multivariable analysis: adjusted maternal stress and anxiety scores

We performed multivariable analyses to determine the difference in stress and anxiety outcomes between FICare and control groups after adjusting for potential confounding factors, including the number of children at home, employment, race, and family support (Table 3). At enrolment, the adjusted mean stress subscale sights and sounds scores, looks and behaviour scores, and total stress scores were significantly higher for the FICare group than the control, but the subscale parental role score was similar between the two groups. At study day 21, the adjusted subscale scores for sights and sounds, parental role, and total mean stress scores were all significantly lower in the

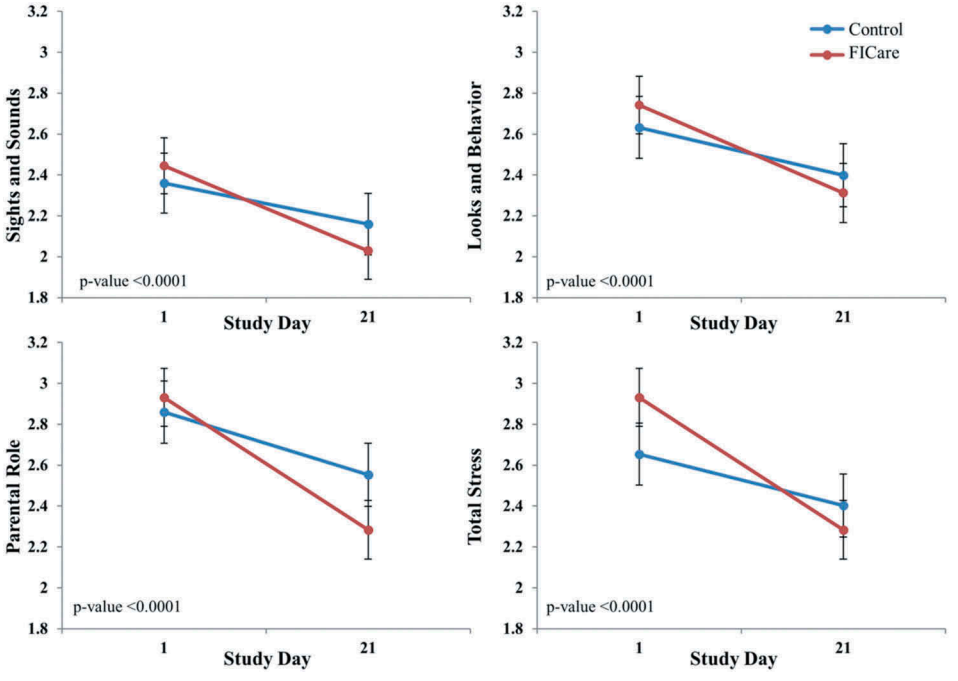

Figure 1. Univariate analysis of parental stress scale scores.

The univariate analysis included mothers who completed questionnaires at enrolment and study day 21 (N = 518 controls, N = 477 FICare). The p-value shows the significance of the interaction term between time period and FICare, which indicates a significant difference in the magnitude of change between FICare and controls.

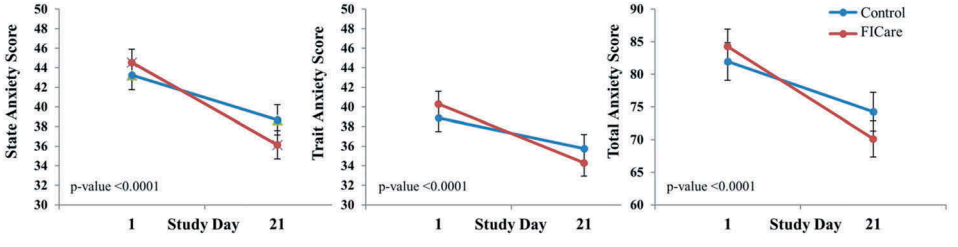

Figure 2. Univariate analysis of State-trait anxiety index scores.

The univariate analysis included mothers who completed questionnaires at enrolment and study day 21 (N = 521 controls, N = 416 FICare). The p-value shows the significance of the interaction term between time period and FICare, which indicates a significant difference in the magnitude of change between FICare and controls.

FICare group than the control group; however, the looks and behaviour subscale score was not significantly different between the two groups. The greatest change over the 21-day period was in the adjusted FICare group parental role score, which decreased by 0.65 points. Similar to the univariate analysis, the magnitude of change in all adjusted stress subscales and total stress scores was significantly greater in the FICare group than the control.

Adjusted state and trait subscale scores and total mean anxiety scores at enrolment were significantly higher in the FICare group than the control group (Table 3). However, at study day 21, the adjusted state, trait, and total anxiety scores were all significantly

Table 3. Adjusted maternal stress and anxiety scores for control and FICare groups.

PSS number		Control	FICare	
Number at enrolment + day 21		518	477	
PSS score		LS mean (95% CI)[a]	LS mean (95% CI)[a]	p-value
Sights and sounds score	Enrolment	2.44 (2.37, 2.51)	2.53 (2.46, 2.61)	0.045
	Day 21	2.24 (2.16, 2.32)	2.13 (2.05, 2.21)	0.023
	Change in score	−0.20 (−0.27, −0.12)	−0.41 (−0.49, −0.34)	<0.0001[b]
Looks and behaviour score	Enrolment	2.75 (2.67, 2.83)	2.85 (2.77, 2.93)	0.048
	Day 21	2.52 (2.43, 2.60)	2.43 (2.33, 2.51)	0.057
	Change in score	−0.23 (−0.30, −0.16)	−0.43 (−0.50, −0.36)	0.0001[b]
Parental role score	Enrolment	2.92 (2.85, 3.0)	3.0 (2.92, 3.08)	0.09
	Day 21	2.61 (2.53, 2.69)	2.35 (2.27, 2.44)	<0.0001
	Change in score	−0.31 (−0.38, −0.24)	−0.65 (−0.72, −0.57)	<0.0001[b]
Total stress score	Enrolment	2.75 (2.69, 2.82)	2.84 (2.77, 2.91)	0.03
	Day 21	2.50 (2.43, 2.57)	2.35 (2.27, 2.42)	0.0007
	Change in score	−0.25 (−0.31, −0.19)	−0.50 (−0.56, −0.44)	<0.0001[b]
STAI number		Control	FICare	
Number at enrolment + day 21		521	516	
STAI score		LS mean (95% CI)[a]	LS mean (95% CI)[a]	p-value
A- State scale score	Enrolment	42.6 (41.6, 43.6)	44.1 (43.1, 45.2)	0.01
	Day 21	38.0 (36.9, 39.1)	35.8 (34.6, 36.9)	0.002
	Change in score	−4.60 (−5.62, −3.58)	−8.42 (−9.45, −7.40)	<0.0001[b]
A-Trait scale score	Enrolment	38.6 (37.7, 39.5)	40.1 (39.2, 41.1)	0.009
	Day 21	35.4 (34.5, 36.4)	34.2 (33.2, 35.2)	0.047
	Change in score	−3.16 (−3.96, −2.34)	−6.00 (−6.82, −5.17)	<0.0001[b]
Total anxiety score	Enrolment	81.0 (79.2, 82.9)	83.6 (81.7, 85.6)	0.02
	Day 21	73.3 (71.3, 75.2)	69.6 (67.6, 71.7)	0.005
	Change in score	−7.78 (−9.51, −6.04)	−14.29 (−16.02, −12.55)	<0.0001[b]

[a]The reported 95% CIs were based on the mixed-effect models for repeated measures with the interaction term between the time period and FICare group adjusted for a number of children at home, employment, race, and family support.

[b]The p-value shows the significance of the interaction term between time period and FICare, which indicates a significant difference in the magnitude of change between FICare and controls.

Abbreviations: CI, confidence interval; LS, least squares

lower in the FICare group than the control. Similar to the univariate analysis, the magnitude of change in all adjusted anxiety scores was significantly greater in the FICare group than the control.

Correlation between maternal stress and anxiety scores

We estimated a Pearson correlation coefficient to determine whether there was a correlation between the PSS:NICU and the STAI scores in this sample. The Pearson correlation coefficient between total stress scores and total anxiety scores was 0.48 ($p < 0.0001$), which indicates a moderate positive correlation between the PSS:NICU and the STAI. There was also a positive correlation between the sights and sounds and looks and behaviour subscales (0.63, $p < 0.0001$), sights and sounds and parental role subscales (0.55, $p < 0.0001$), and looks and behaviour and parental role subscales (0.61,<0.00011). Last, there was a positive correlation between the state and trait anxiety subscales (0.78, $p < 0.0001$).

Discussion

In this study, we analysed the effect of FICare on the dimensions of maternal stress and anxiety as measured by the PSS:NICU and STAI, respectively. To our knowledge, this study is the largest multi-site, multi-country investigation of NICU-related maternal stress and anxiety, and the effects of a family-centred care intervention. Our results show, after adjusting for potential confounders, that the mothers who participated in FICare experienced a greater decrease in total stress and all stress subscales except the looks and behaviour subscale than the control group mothers over a 21-day period. The magnitude of change was greatest for the parental role subscale. Mothers who participated in FICare also experienced a greater reduction in both state and trait anxiety than mothers in the control group over 21 days. Last, our results suggest the PSS:NICU and STAI scores, stress subscales, and state and trait anxiety are positively correlated. Together, our results suggest that FICare decreases maternal stress and anxiety in the NICU and specifically addresses stresses associated with parental role in the NICU setting.

Many NICU interventions have reported that parent education, psychological support, and participation in rounds can all have a positive impact on reducing maternal stress and anxiety (Cano Gimenez & Sanchez-Luna, 2015; Chourasia, Surianarayanan, Bethou, & Bhat, 2013; Davidson et al., 2017; Fotiou et al., 2016; Hane et al., 2015; Matricardi, Agostino, Fedeli, & Montirosso, 2013; Turan, Basbakkal, & Ozbek, 2008; Welch et al., 2016), but these interventions are rarely studied in RCTs or in combination. Although family-centred care has greatly progressed over the years, there is still much room for improvement, particularly in increasing uptake and strengthening the evidence base (Gooding et al., 2011). Currently, family-centred care includes a variety of practices such as kangaroo care, skin-to-skin contact, parental decision-making, and positive environmental and family support systems (Maree & Downes, 2016). The variation in family-centred practices across NICUs and the consequently conflicting results of different interventions on the mother–infant relationship argues for the necessity of developing a streamlined approach to family-centred care (Evans, Whittingham, Sanders, Colditz, & Boyd, 2014; Maree & Downes, 2016). The demand for family-centred care has been

previously explored, for instance, in a thematic analysis looking at parental involvement in neonatal pain management, Franck, Oulton, and Bruce (2012) described parents' desire to become more involved and informed in the care of their infants. Despite the need for family-centred care from the family's perspective, there is currently no comprehensive intervention backed by a strong evidence base that can be easily implemented in NICUs. Thus, the FICare model was designed to incorporate multiple practices that are beneficial to parents in a comprehensive 'care bundle' to address the multiple sources of stress and provide consistency (O'Brien et al., 2013). In agreement with previous studies (Franck, Cox, Allen, & Winter, 2005), our results indicated that mothers' feelings of not being able to fulfil their role as a parent in the NICU were the highest contributor of their overall NICU-related stress.

We found a moderate positive correlation between the PSS:NICU and the STAI, which suggests that it may be insufficient to rely on only one of the questionnaires as an indicator of maternal psychological well-being. Therefore, given the complexity of the parental NICU experience and the need for congruence between intervention and outcome measures, it may be more useful to continue separating the stress and anxiety in future studies designed to investigate the effect of interventions on maternal mental health.

Our findings have important clinical implications for both the implementation of FICare in NICUs and our understanding of the effect of FICare on maternal mental health. Since stress and anxiety scores for all subscales decreased significantly more in the FICare group than in the control group, FICare appears to be a comprehensive approach that is effective at targeting all areas of maternal stress and anxiety in the NICU. However, one cannot implement a single dimension of FICare on its own as the success of FICare likely depends on it being multidimensional. For example, maternal education without facilitation at the bedside might, in fact, result in increasing maternal stress rather than decreasing it, and similarly, maternal engagement in care without nursing support would likely increase conflict between mothers and staff.

Maternal psychological health is a key determinant in long-term infant outcomes. Higher levels of maternal stress have been found to be associated with infant cognitive development delays (Bennett, Schott, Krutikova, & Behrman, 2016) and language and adjustment problems for the child in later years (Woodward et al., 2014). Poor maternal psychological wellbeing, in particular depression and anxiety, was shown to have an adverse effect on infant outcomes, especially with respect to behavioural outcomes (Treyvaud et al., 2010). These adverse infant outcomes may be avoided with the implementation of FICare. Similar family-centred care practices implemented in NICUs have shown positive effects on infants, such as decreased stress cues (Byers et al., 2006), increased neurobehavioral performance (Evans et al., 2014), and significantly improved weight gain (Raiskila, Axelin, Rapeli, Vasko, & Lehtonen, 2014; Yu et al., 2017). Therefore, FICare in the NICU may have a long-term beneficial impact on both infant and family outcomes.

When interpreting the findings of our study, there were limitations that should be considered. First, the mothers who participated in the FICare cRCT were predominantly Caucasian, as were those included in this secondary analysis. Therefore, the results need to be interpreted within this context. We not all mothers who were enrolled in the study completed the PSS:NICU and STAI questionnaires at both enrolment and study day

21. Second, data in this study were only collected at two time points: at enrolment and study day 21. Extended data collection and post-NICU follow-up assessment are needed to determine if improvements in stress and anxiety levels persist in the FICare group. Maternal depression is also an important component of maternal well-being, and future research should specifically investigate if FICare reduces depression as well. Last, paternal stress and anxiety were not measured in this study. Other studies have found that paternal involvement in their infant's care could lead to improved infant outcomes (Matricardi et al., 2013), such as enhanced cognitive development (Yogman, Kindlon, & Earls, 1995) and decreased mental health symptoms (Boyce et al., 2006). Therefore, it would be beneficial to measure paternal stress and anxiety to determine whether they are positively impacted by FICare and how their scores compare to mothers.

Conclusion

In conclusion, FICare is effective at reducing maternal stress and anxiety in the NICU environment, particularly through alteration of stress resulting from the parental role and state anxiety. The FICare approach encompasses aspects of the NICU experience that were previously excluded from other interventions and yielded positive maternal stress and anxiety outcomes. Our results also suggest that models similar to FICare could be used in other areas of care to improve patient mental health outcomes. More research should be conducted to assess the long-term effects of FICare on both parents and infants and to determine how FICare can be adapted to include infants in critical condition and their families.

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References

Al Maghaireh, D. F., Abdullah, K. L., Chan, C. M., Piaw, C. Y., & Al Kawafha, M. M. (2016). Systematic review of qualitative studies exploring parental experiences in the Neonatal intensive care unit. *Journal of Clinical Nursing*, *25*(19–20), 2745–2756.

Baia, I., Amorim, M., Silva, S., Kelly-Irving, M., de Freitas, C., & Alves, E. (2016). Parenting very preterm infants and stress in Neonatal intensive care units. *Early Human Development*, *101*, 3–9.

Bennett, I., Schott, W., Krutikova, S., & Behrman, J. R. (2016). Maternal mental health and child growth and development in four low and middle income countries. *Journal of Epidemiology and Community Health*, *70*(2), 168–173.

Boyce, W. T., Essex, M. J., Alkon, A., Goldsmith, H. H., Kraemer, H. C., & Kupfer, D. J. (2006). Early father involvement moderates biobehavioral susceptibility to mental health problems in middle childhood. *Journal of the American Academy of Child & Adolescent Psychiatry*, *45*(12), 1510–1520.

Busse, M., Stromgren, K., Thorngate, L., & Thomas, K. A. (2013). Parents' responses to stress in the neonatal intensive care unit. *Critical Care Nurse*, *33*(4), 52–59. quiz 60.

Byers, J. F., Lowman, L. B., Francis, J., Kaigle, L., Lutz, N. H., Waddell, T., & Diaz, A. L. (2006). A quasi-experimental trial on individualized, developmentally supportive family-centered care. *Journal of Obstetric, Gynecologic, & Neonatal Nursing*, *35*(1), 105–115.

Cano Gimenez, E., & Sanchez-Luna, M. (2015). Providing parents with individualised support in a neonatal intensive care unit reduced stress, anxiety and depression. *Acta Paediatrica*, *104*(7), e300–e305.

Chourasia, N., Surianarayanan, P., Bethou, A., & Bhat, V. (2013). Stressors of NICU mothers and the effect of counseling-experience from a tertiary care teaching hospital, India. *Journal of Maternal-Fetal & Neonatal Medicine*, *26*(6), 616–618.

Davidson, J. E., Aslakson, R. A., Long, A. C., Puntillo, K. A., Kross, E. K., Hart, J., … Curtis, J. R. (2017). Guidelines for Family-Centered Care in the Neonatal, pediatric, and adult ICU. *Critical Care Medicine*, *45*(1), 103–128.

Evans, T., Whittingham, K., Sanders, M., Colditz, P., & Boyd, R. N. (2014). Are parenting interventions effective in improving the relationship between mothers and their preterm infants? *Infant Behaviour and Development*, *37*(2), 131–154.

Fotiou, C., Vlastarakos, P. V., Bakoula, C., Papagaroufalis, K., Bakoyannis, G., Darviri, C., & Chrousos, G. (2016). Parental stress management using relaxation techniques in a neonatal intensive care unit: A randomised controlled trial. *Intensive & Critical Care Nursing*, *32*, 20–28.

Franck, L. S., & Axelin, A. (2013). Differences in parents', nurses' and physicians' views of NICU parent support. *Acta Paediatrica*, *102*(6), 590–596.

Franck, L. S., Cox, S., Allen, A., & Winter, I. (2005). Measuring neonatal intensive care unit-related parental stress. *Journal of Advanced Nursing*, *49*(6), 608–615.

Franck, L. S., McNulty, A., & Alderdice, F. (2017). The Perinatal-Neonatal care journey for parents of preterm infants: What is working and what can be improved. *Journal of Perinatal Neonatal Nursing*, *31*(3), 244–255.

Franck, L. S., Oulton, K., & Bruce, E. (2012). Parental involvement in neonatal pain management: An empirical and conceptual update. *Journal of Nursing Scholarship*, *44*(1), 45–54.

Gooding, J. S., Cooper, L. G., Blaine, A. I., Franck, L. S., Howse, J. L., & Berns, S. D. (2011). Family support and family-centered care in the neonatal intensive care unit: Origins, advances, impact. *Seminars in Perinatology*, *35*(1), 20–28.

Hane, A. A., Myers, M. M., Hofer, M. A., Ludwig, R. J., Halperin, M. S., Austin, J., … Welch, M. G. (2015). Family nurture intervention improves the quality of maternal caregiving in the neonatal intensive care unit: Evidence from a randomized controlled trial. *Journal of Developmental and Behavioral Pediatrics*, *36*(3), 188–196.

Maree, C., & Downes, F. (2016). Trends in family-centered care in Neonatal intensive care. *Journal of Perinatal Neonatal Nursing*, *30*(3), 265–269.

Matricardi, S., Agostino, R., Fedeli, C., & Montirosso, R. (2013). Mothers are not fathers: Differences between parents in the reduction of stress levels after a parental intervention in a NICU. [Erratum appears in Acta Paediatr. 2013 Mar;102(3):327]. *Acta Paediatrica*, *102*(1), 8–14.

Miles, M. S., Funk, S. G., & Carlson, J. (1993). Parental stressor scale: Neonatal intensive care unit. *Nursing Research*, *42*(3), 148–152.

O'Brien, K., Bracht, M., Macdonell, K., McBride, T., Robson, K., O'Leary, L., … Lee, S. K. (2013). A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit. *BMC Pregnancy & Childbirth*, *13*(Suppl 1), S12.

O'Brien, K., Bracht, M., Robson, K., Ye, X. Y., Mirea, L., Cruz, M., … Lee, S. K. (2015). Evaluation of the Family Integrated Care model of neonatal intensive care: A cluster randomized controlled trial in Canada and Australia. *BMC Pediatrics*, *15*, 210.

O'Brien, K., Robson, K., Bracht, M., Cruz, M., Lui, K., & Alvaro, R.; for the FICare Study Group and FICare Parent Advisory Board. (2018). Effectiveness of Family Integrated Care in neonatal intensive care units on infant and parent outcomes: A multicentre, multinational, cluster-randomised controlled trial. *The Lancet Child & Adolescent Health*, *2*(4), 245–254.

Raiskila, S., Axelin, A., Rapeli, S., Vasko, I., & Lehtonen, L. (2014). Trends in care practices reflecting parental involvement in neonatal care. *Early Human Development*, *90*(12), 863–867.

Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). *Manual for the state-trait anxiety inventory*. Palo Alto, CA: Consulting Psychologists Press.

Treyvaud, K., Anderson, V. A., Lee, K. J., Woodward, L. J., Newnham, C., Inder, T. E., … Anderson, P. J. (2010). Parental mental health and early social-emotional development of children born very preterm. *Journal of Pediatric Psychology*, *35*(7), 768–777.

Turan, T., Basbakkal, Z., & Ozbek, S. (2008). Effect of nursing interventions on stressors of parents of premature infants in neonatal intensive care unit. *Journal of Clinical Nursing*, *17*(21), 2856–2866.

Welch, M. G., Halperin, M. S., Austin, J., Stark, R. I., Hofer, M. A., Hane, A. A., & Myers, M. M. (2016). Depression and anxiety symptoms of mothers of preterm infants are decreased at 4 months corrected age with family nurture intervention in the NICU. *Archives of Women's Mental Health*, *19*(1), 51–61.

Woodward, L. J., Bora, S., Clark, C. A., Montgomery-Honger, A., Pritchard, V. E., Spencer, C., & Austin, N. C. (2014). Very preterm birth: Maternal experiences of the neonatal intensive care environment. *Journal of Perinatology*, *34*(7), 555–561.

Yogman, M. W., Kindlon, D., & Earls, F. (1995). Father involvement and cognitive/behavioral outcomes of preterm infants. *Journal of the American Academy of Child & Adolescent Psychiatry*, *34*(1), 58–66.

Yu, Y. T., Hsieh, W. S., Hsu, C. H., Lin, Y. J., Lin, C. H., Hsieh, S., … Jeng, S. F. (2017). Family-centered care improved Neonatal medical and neurobehavioral outcomes in preterm infants: Randomized controlled trial. *Physical Therapy*, *97*(12), 1158–1168.