

Implementing Modified Family Integrated Care in a U.S. Neonatal Intensive Care Unit: Nursing perspectives and effects on parents

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Background-original RCT trial

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



*Karel O'Brien, Kate Robson, Marianne Bracht, Melinda Cruz, Kei Lui, Ruben Alvaro, Orlando da Silva, Luis Monterrosa, Michael Narvey, Eugene Ng, Amuchou Soraisham, Xiang Y Ye, Lucia Mirea, William Tarnow-Mordi, Shoo K Lee, for the FICare Study Group and FICare Parent Advisory Board**



FICare Cluster RCT summary

26 NICUs from Canada, Australia, and New Zealand.

Each center randomized to provide FICare or standard NICU care

Infant's inclusion criteria

- <33 weeks GA
- No or low level of respiratory support (NC, CPAP, NIPPV)

Exclusion criteria

- Palliative care
- Life threatening congenital anomaly
- Unlikely to survive
- Receiving invasive ventilation
- Planned early transfer

Parents inclusion criteria

- Present in the NICU for at least 6 h/ day, 5 days/ week
- Attend educational sessions and medical rounds at least 3x/ week
- Actively care for their infant

Exclusion criteria

- Unable to participate due to health, social, language barrier



Elements of original FICare model

- Requires parents commit 6 hours per day, 5 days per week to infant care participation in the NICU
- Consists of:
 - (1) environmental resources designed to enhance parent involvement in caregiving while supporting prolonged parental presence in the NICU,
 - (2) NICU team training and support,
 - (3) Parent psychoeducational support including classes and mentorship at bedside, and parents delivering as much infant care as able with nursing supervision/support,
 - (4) Frequent transparent facilitated communication with parents
 - (5) Design and implementation of all key components in partnership with families.



FICare Cluster RCT results

- FICare: 895 , Standard Care 891 infants
- At day 21 after enrollment, **weight gain** and overall average daily weight gain significantly higher in FICare group.
- The high-frequency **exclusive breast milk feeding** rate(>6 /day) at discharge significantly higher for infants in the FICare group.
- At day 21, parents in the FICare group with significantly **lower mean stress scores and mean anxiety scores.**
- No significant differences between groups in the rates of the secondary outcomes of mortality, major morbidity, duration of oxygen therapy and hospital stay.
- The safety assessment data collection was not completed, however there were no adverse events.



Previously published evidence from outside the US

- Cluster-randomized controlled trial (RCT) reported improved infant and parental outcomes in the group of parents participating in FICare compare to standard NICU care (increased infant weight gain and exclusive breast milk feeding rates as well as lower parental stress and anxiety scores)
- Prospective follow-up from the original RCT showed improved behavioral skills (self-regulation), neurodevelopmental outcomes (motor development), lower maternal stress scores and improved child behavioral outcomes at 18 months post-conceptual age.
- Other studies utilizing this approach similarly reported improved breastfeeding rates and suggested a reduced overall length of stay.
- One center reported higher infant scores on the mental development index and psychomotor development index at 18 months for infants
- Additional qualitative analyses suggested improved parent confidence, communication, increased parental involvement and positive feelings about their role in their infant's care.



Background

- All the studies originating from countries with universal healthcare system and guaranteed paid maternity leave(Canada, Australia, New Zealand, China and Great Britain)
- To date, no studies demonstrating feasibility of FICare implementation and effects on parental outcomes have been published in a US healthcare setting

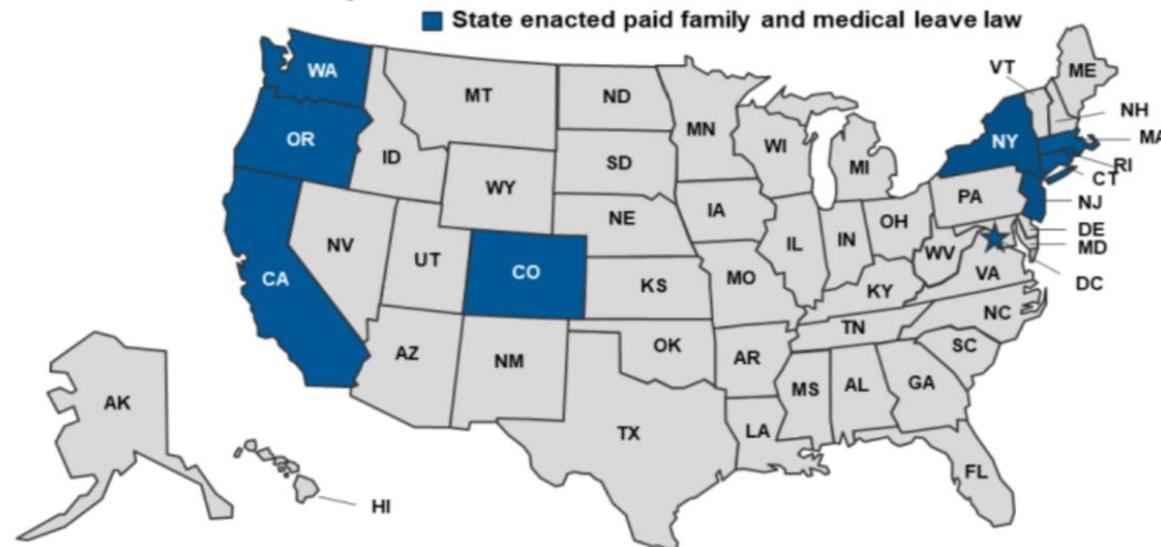


Background

Paid Family Leave in the US

Figure 1

State Paid Family and Medical Leave Laws, 2020



NOTE: Paid family and medical leave laws allow for workers to take time off to bond with a new child or to care for a serious health condition or that of a family member. Law effective dates: CT: Jan. 2021 (premiums)/Jan. 2022 (benefits); MA: Jul. 2019 (premiums)/Jan. 2021 (benefits); OR: Jan. 2022 (premiums)/Jan. 2023 (benefits); CO: Jan. 2023 (premiums)/Jan. 2024 (benefits).
SOURCE: KFF analysis of state paid family and medical leave laws; A Better Balance: [Overview of Paid Family & Medical Leave Laws in the United States](#)



SSH NICU modified FICare model

- Model enabling NICU parents to become active participants in their infant's care, rather than visitors.
- In our setting it includes:
 - 1) providing education for parents utilizing a smart phone application (app)
 - 2) “hands-on coaching” by NICU nurses/multidisciplinary staff
 - 3) daily participation in medical rounds.
 - 4) additional elements: parents support group, “bead program” not part of the study



SSH modified FICare model

- The educational program consists of one-on-one bedside teaching by different disciplines (i.e., nursing, nutritionists, etc.) =“hands-on skills coaching”
- Daily parental participation in multidisciplinary rounds either in person or by speaker phone (NICU parents who overwhelmingly preferred to receive phone calls from the rounding team over tele-video calls).
- Utilization of a mobile phone application (app), *SSH NICU Ficare App*, designed and built by in-house NICU staff while incorporating feedback from former NICU parents.
- The app serves as a supplemental educational resource for parents
- Each section concludes with an optional quiz parents can complete at their leisure.
- The app does not feature any report back or communication with staff capabilities and completion of the educational sections is not a requirement for participation in the FICare program.
- It is offered to all families during prenatal consultation, if conducted, or shortly after an infant’s NICU admission.
- No required number of hours to participate
- No required classes



South Shore Health NICU



 ORIENTATION TO FICARE	 DEVELOPMENTAL CARE
 BASIC SKILLS CARE	 FEEDING YOUR BABY
 DISCHARGE	 TOOLS FOR PARENTS



Tools



- PARENTS' FIC SUPPORT
- LACTATION SUPPORT
- BABY WEIGHT
- DIAPER LOG
- PHOTO BOOTH
- JOURNAL
- FEEDINGS
- KANGAROO CARE TIMER
- PUMPING



Objective

- To evaluate the impact of implementing a FICare model on parental stress levels, parent-staff communication and readiness for discharge home in a US NICU
- To gain nursing perspectives on Ficare model



Design

- Quantitative questionnaire case-control design using both previously validated questionnaires (PSS:NICU) and questionnaires developed *de novo* by the research team
- Parental stress levels after NICU-wide FICare implementation were compared to controls who had completed the PSS(Parental Stressor Scale):NICU prior to FICare implementation as part of another study
- Within FICare group parents stratified by **degree of participation** evaluated associations **with parental stress, parental-staff communication and discharge readiness.**
- Questionnaires captured nursing perspectives on FICare.



Inclusion/exclusion criteria

- Parental inclusion criteria: All parents of infants admitted to the NICU for **at least 7 days** were eligible to participate.
- Parental exclusion criteria: non-English speaking parents, those younger than 18 years of age and NICU length of stay <7 days.
- All RNs working in the NICU at the time of the study



STUDY COMPLETED PRIOR TO FICare IMPLEMENTATION
09/2018-08/2019

FICare IMPLEMENTED
09/2019

CURRENT STUDY POST FICare IMPLEMENTATION
02/21-09/21

SURVEY INSTRUMENTS AND TOOLS		
Survey/tool name	Description	Time of administration
Parental stress questionnaire	The Parent Stressor Scale: NICU (PSS:NICU, version 2015), consists of 26 items, with 3 subscales assessing stress related to infant appearance and behavior (14 items), parental role alteration (7 items), and sights and sounds in the NICU (5 items). Good concurrent and predictive validity, internally consistent with Cronbach alpha with overall reliability coefficient 0.94, subscales: infant appearance 0.92, Parental role alterations 0.90, Sights and sounds 0.80) ¹⁹⁻²⁴ Additional validated questions developed <i>de novo</i> to capture all possible additional stressors in the NICU (social support, financial demands, distance traveled to hospital, infants gestational age, parental characteristics)	Given to parents in both the pre- and post- FICare groups at 30 days of infant age or within 7 days of discharge, whichever came first.

Preceded by 12 months preparatory period:
-FICare app build with support of former parents
-Staff training
-Adding parent's room for support groups and "breaks"

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Infant care bedside skills checklist	The list of 15 "hands-on" skills to be taught to parents by nurses	Collected at discharge in post-FICare group
Parental FICare Questionnaire	Developed <i>de novo</i> to capture parental opinions on FICare with respect to: -frequency and quality of communication -frequency of use and feedback on the FICare app -frequency of participation in daily rounds -psychosocial support -discharge readiness -multidisciplinary team support -physical space in the NICU	Given to parents in post-FICare group. Administered within 7 days of anticipated infant discharge and contained permission to obtain parents' email addresses for the purpose of sending electronic post-discharge follow-up questionnaires. Parents were given one face-to-face reminder for completion.
Infant discharge skills checklist	The list of 6 skills utilized to facilitate parental preparation for discharge	Collected at discharge in post-FICare group
Parental Follow-up Questionnaire	Developed <i>de novo</i> to capture information regarding readmissions, unscheduled hospital and office visits within 1-month post-discharge. It was e-mailed to parents 30 days after an infant's discharge home, with two subsequent email reminders 7 and 14 days later.	Given to parents in post-FICare group. E-mailed to parents 30 days after an infant's discharge home, with two subsequent email reminders 7 and 14 days later.
Nursing FICare questionnaire	Created <i>de novo</i> to capture nursing perspectives on the effects of FICare in the NICU.	Sent to all bedside nurses via secure email link at the end of the study with reminders sent at 15 and 30 days.

Measure: Baseline parental stress levels prior to FICare implementation

Measure: Parental stress level after FICare implementation
Within FICare group parents stratified by degree of participation
Effects of degree of participation on stress levels, communication and discharge readiness



Study tools

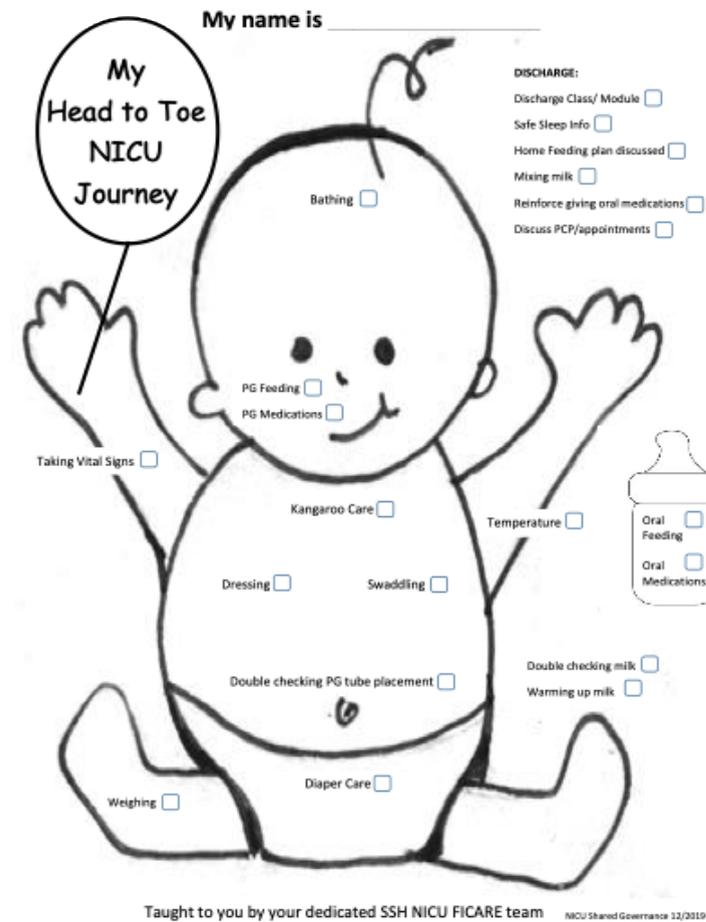
SURVEY INSTRUMENTS AND TOOLS		
Survey/Tool name	Description	Timing of administration
Parental stress questionnaire	Parent Stressor Scale: NICU (PSS: NICU, version 2015) to measure parental stress. Consists of 26 items, which form 3 subscales assessing stress related to infant appearance and behavior (14 items), parental role alteration (7 items), and sights and sounds in the NICU (5 items).	offered to parents at 30 days of infant age or within 7 days of discharge, whichever came first
Parental FICare questionnaire	Created “de novo”, validated, and cognitively pretested to capture parental opinions regarding FICare including communication, psychosocial support, discharge readiness, multidisciplinary team support, feedback on FICare App and physical space in the NICU. Contained permission to obtain parental email address.	offered to parents within 7 days of discharge.
Parental follow-up questionnaire	Created “de novo” validated, and cognitively pretested to capture parental responses regarding readmissions, unscheduled hospital and office visits” within 1 month post-discharge.	offered to parents 30 days’ post infant’s discharge date via email with 2 subsequent reminders 7 and 14 days later
Infant care bedside skills list	List of “hands on” skills completed by parents under nursing supervision during infant’s stay in the NICU and discharge checklist. Routinely utilized in our NICU	collected at discharge



Study tools

Infant Care Bedside Skills Checklist

1. Bathing
2. PG feeding
3. Administering PG medications
4. Taking vital signs
5. Kangaroo care
6. Taking temperature
7. Dressing
8. Swaddling
9. Oral feeding
10. Administering oral medications
11. Double checking PG tube placement
12. Double checking milk labels
13. Warming up milk
14. Weighing
15. Diaper care



Infant Discharge Checklist

1. Completion of discharge class/module
2. Discussing safe sleep information
3. Discussing home feeding plan
4. Discussing mixing milk
5. Reinforcing oral medication administration
6. Discussing follow-up appointments



Definitions

DEFINITIONS	
Metric	Description
Degree of parental participation in FICare	<p>Measured by 3 metrics:</p> <ol style="list-style-type: none"> 1. Parent participation in rounds defined by parental frequency of participation in daily morning interdisciplinary rounds and measured by the highest captured score between questions: "I was able to participate in rounds when I was in the NICU or SCN" and "I was able to participate in rounds via phone/Facetime when I wasn't in the NICU or SCN in person". 2. Utilization of the FICare app defined as parental frequency of App usage and measured by score captured by question "In general, how often did you use the App while your baby was in the NICU?" 3. Infant care bedside skills list completion was defined as parental completion of 15 "hands on" bedside skills measured by aggregate score of 15 skills completed.
Parent staff communication frequency	<p>Defined as frequency of parental communication with 8 providers (nurses, nurse practitioners, doctors, occupational therapists, speech therapists, nutritionists, lactation consultants, social worker), measured as an aggregate (sum) of communication frequency scores with above staff positions captured by question: "How often did you communicate with each staff member"?</p>
Parent staff communication quality	<p>Defined as consistency and clarity in answering parental questions by nurses, nurse practitioners and doctor, measured by aggregate of 2 variables captured by question: "Answers to my questions were easy to understand" and "I received consistent information" from nurses, nurse practitioners and doctors</p>
Parental readiness for discharge	<p>Measured by 3 metrics:</p> <ol style="list-style-type: none"> 1. Parental completion of discharge checklist captured by aggregate score of 6 items completion 2. Parental confidence in seven skills required to care for a baby after discharge home measured by aggregate score captured by the question: "Prior to discharge I felt confident about: feeding my baby, medications/vitamins administration, changing diapers, dressing checking temperature, bathing and overall, I feel well prepared for taking my baby home." 3. Parental follow-up questionnaire capturing parental responses regarding readmissions, unscheduled hospital and office visits" within 1 month post-discharge. It was measured by aggregate score of five parent" after discharge" follow-up questions: unexpected phone calls, unexpected doctor visits, urgent/walk-in clinic visits, emergency room visits, hospital admissions



Results

- 78 parents completed PSS:NICU survey prior to FICare implementation; 90 completed the survey after NICU-wide implementation
- No difference in parental characteristics between groups (age, race, gender, education, support, distance from the hospital, insurance, religiosity)
- Control group: pre-pandemic
- FICare group: Covid-19 pandemic

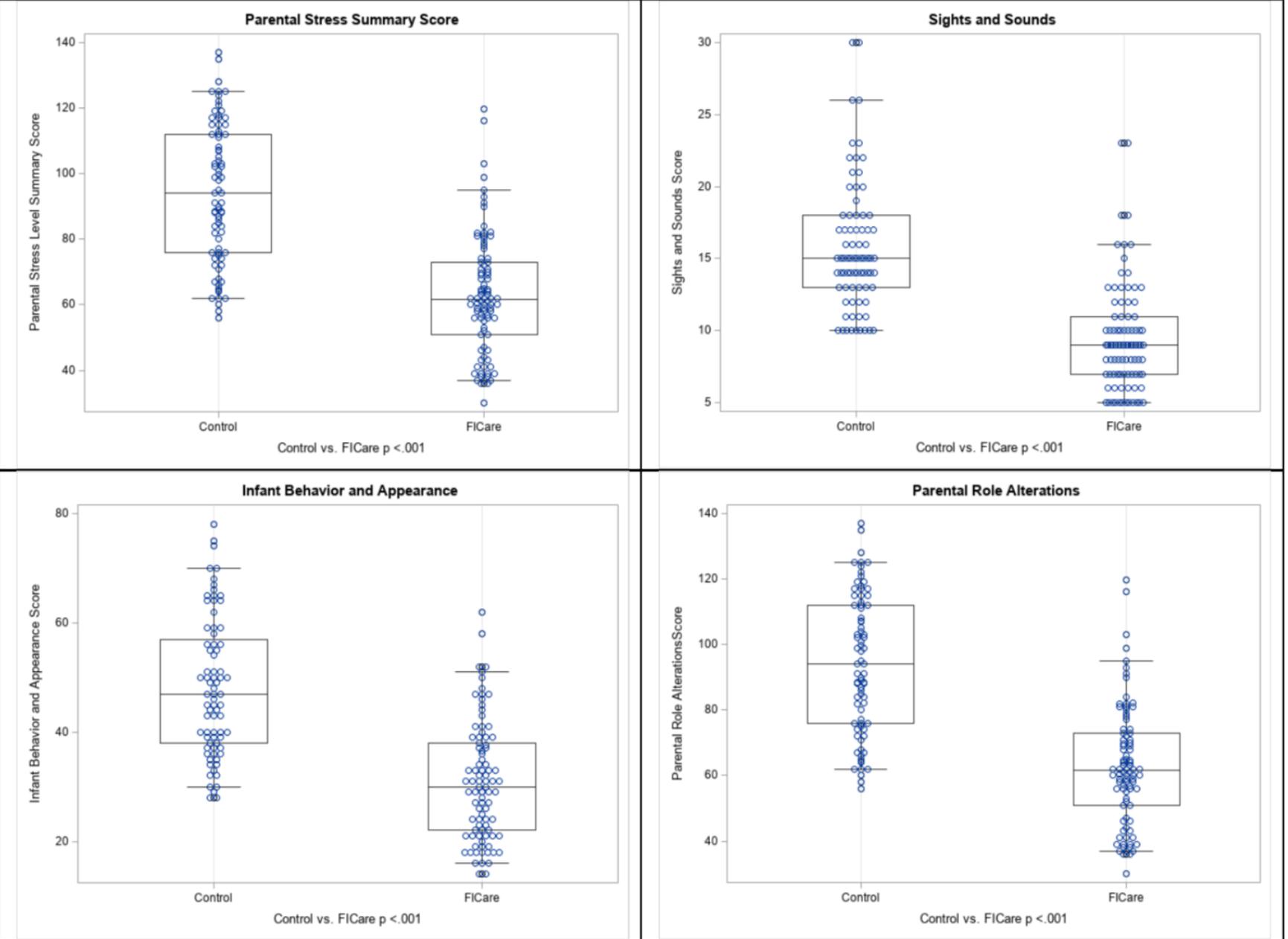


Results: parental stress scores prior and after FICare implementation

- Parental total stress scores after FICare implementation were significantly lower compared to the pre-implementation control group (median stress score 61.5 (IQR 51,73) vs 94 (IQR 75.9, 112) respectively, ($p < 0.001$)
- Parental stress scores in all three subscales of PSS: NICU (baby looks and behaves, sights and sounds, parental role) were significantly lower in post-implementation group. ($p < 0.001$)



Parental Stress Scores (PSS: NICU) Total and Subscales: Prior (Control) and After FICare Implementation



Results: parental stress scores within FICare group

- Parents who reported difficult financial demands and those who had to travel more than 30 minutes from home to hospital had significantly higher PSS:NICU scores ($p < 0.005$ and $p < 0.001$, respectively)
- No associations between parental stress and infant gestational age, length of stay or birth weight
- Mothers/pregnant persons versus fathers/partners and those who self-identified their race as white were found to have higher stress scores ($p = 0.02$ and $p < 0.001$, respectively).



Results

Association of Stress Scores on PSS: NICU with Financial Difficulty and Distance from Hospital		
<u>Financial demands were very difficult</u>	<u>Coefficient Estimate</u>	<u>Pr > Z </u>
Completely disagree	REF	REF
Somewhat disagree	-7.104	0.414
Somewhat agree	-15.351	0.06
Completely agree	-23.467	0.005
<u>Parent-reported driving minutes from home to hospital</u>	<u>Coefficient Estimate</u>	<u>Pr > Z </u>
≤15	REF	REF
16-30	6.9854	0.1074
31-45	15.3472	<.0001
46-60	22.8987	<.0001
>60	34.0859	<.0001



Results: Parental Stress within FICare group stratified by degree of participation

- Parents who learned >5 infant care bedside skills had significantly lower stress levels (median PSS:NICU score 58.0 (IQR 44.0, 63.0), compared to those who learned 1 – 5 skills (median PSS:NICU score 64.5 (IQR 57.10, 78.50), $p=0.008$.)
- 69 out of 74 (93%) of parents reported always participating in daily multidisciplinary rounds and 65 (88%) of parents reported utilizing the educational app during NICU stay.
- Neither parental frequency of participation in daily rounds or frequency of mobile app usage were found to have further stratification effects on parental stress.

Degree of parental participation in FICare	Measured by 3 metrics: (1) Frequency of parental participation in rounds measured by aggregate sum of answers to ordinal scale questions (i.e. 4 = always, 1 = never) (2) Frequency of app utilization by aggregate sum of answers to ordinal scale questions (i.e. 3= every day, 1 = less than once a week) (3) Infant care bedside skills checklist completion	(1) FICare questionnaire captured by responses to the question: “How often did you participate in rounds?” (2) FICare questionnaire captured by responses to the question: “How often did you use the app?” (3) Infant care bedside skills checklist
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Effects of degree of parental participation in FICare on parent-staff communication

- Increased parental utilization of the mobile app significantly increased parent-staff communication frequency (coefficient estimate: 4.9, $p = 0.007$).
- Increased mobile app utilization increased positive scores of parent-reported communication quality (coefficient estimate: 1.8, $p = 0.012$).
- Statistical analysis of the association between communication and parent participation in rounds was not found to be meaningful, as parents overwhelmingly participated in rounds.

Parent-staff communication frequency	Frequency of parental communication with 8 providers measured by aggregate sum of answers to ordinal scale questions reflecting perceived communication (i.e. 4 = always, 1 = never)	FICare questionnaire captured by responses the question: "How often did you communicate with...?"
Parent-staff communication quality	Defined as consistency and clarity in answering parents' questions by nurses, nurse practitioners and doctors as measured by aggregate of two variables	FICare questionnaire captured by responses to the statements: "Answers to my questions were easy to understand" and "I received consistent information from..."



Effects of degree of parental participation in FICare on discharge readiness

- Increased frequency of parent-staff communication significantly associated with parental completion of a pre-discharge checklist (coefficient estimate: 0.58, $p < 0.001$).
- None of the other variables, including participation in rounds, utilization of the FICare app or completion of the infant care bedside skills list was found to have a statistically significant effect on parent-reported discharge readiness.

<p>Parental readiness for discharge</p>	<p>Measured by 3 metrics: (1) completion of the discharge checklist captured by aggregate score of completing up to six items (2) parental confidence in seven infant care skills measured by aggregate score (3) an aggregate score of five questions on the post-discharge follow-up questionnaire</p>	<p>(1) Infant discharge skills checklist (2) Ficare questionnaire captured by the question, "Prior to discharge I felt confident about: feeding my baby, medications/vitamin administration, changing diapers, dressing checking temperature, bathing and overall, I feel well prepared for taking my baby home" (3) Follow-up questionnaire captured by the answers to questions regarding unexpected phone calls, unexpected doctor visits, urgent/walk-in clinic visits, emergency room visits, hospital admissions</p>
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Nursing perspectives

- **Perceived numerous positive effects for parents-nurses did believe that FICARE:**
- Improved quality of care infant receives ($p < 0.0001$)
- Improved parental communication with nurses ($p < 0.0001$)
- Improved parental participation in rounds ($p < 0.0001$)
- Improved parental readiness for discharge ($p < 0.0001$)
- Increased parental confidence in taking baby home ($p < 0.0001$)
- Did not increase parental stress ($p < 0.0001$)
- **With respect to their own work:**
- Nurses **did not believe** that FICare increased nursing work-related stress ($p = 0.009$)
- Nurses **believed** it has resulted in an increase in nursing job-satisfaction ($p = 0.0001$) and has made it easier for them to discharge babies home to their parents ($p < 0.001$)



Conclusions

- We demonstrated that Ficare implementation in the US healthcare setting is feasible
- Any degree of parental participation in FICare has similar effects on decreasing parental stress in the NICU as demonstrated in the original non-US trial, which had stricter enrollment criteria for FICare participation
- In addition, within the Ficare group increased parental participation (completion of the “Infant Care Bedside Skills Checklist”) was found to be associated with a lower parental stress level
- Increased frequency and improved quality of parent-staff communication is another potential benefit of Ficare implementation
- We identified that financial difficulties and longer time to travel to hospital increase parental stress



Ongoing work examining the feasibility and acceptability of the FICare model in the US

Cochrane Central Register of Controlled Trials

Comparison of family centered care with family integrated care and mobile technology (mFICare) on preterm infant and family outcomes: a multi-site quasi-experimental clinical trial protocol

Franck LS, Kriz RM, Bisgaard R, Cormier DM, Joe P, Miller PS, Kim JH, Lin C, Sun Y
BMC pediatrics, 2019, 19(1) | added to CENTRAL: 31 January 2020 | 2020 Issue 01
<https://doi.org/10.1186/s12887-019-1838-3>

Sourced from: [PubMed](#), [Embase](#) | Links: [PubMed](#), [ClinicalTrials.gov](#)







QUESTIONS?

Thank you!

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