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Zhang, R

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**Involvements of parents in the care of preterm infants: A pilot study evaluating a family-centered care intervention in a Chinese Neonatal Intensive Care Unit**

Rong ZHANG, MSc<sup>1</sup>; Rui-wena HUANG, MSc<sup>1</sup>; Xi-ronga GAO, MSc<sup>1</sup>; Xiao-minga PENG, MSc<sup>1</sup>; Li-hui ZHU, PhD, RN<sup>2</sup>; Ramanathan RANGASAMY MD<sup>3</sup>; Jos M. LATOUR, PhD, RN<sup>2,4</sup>.

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<sup>1</sup> Division of Neonatal Medicine, Hunan Children's Hospital, Changsha, Hunan Province, China.

<sup>2</sup> Nursing Department, Hunan Children's Hospital, Changsha, Hunan Province, China.

<sup>3</sup> Division of Neonatology, Los Angeles Children's Hospital and University of Southern California Medical Center and Keck School of University of Southern California, Los Angeles, USA.

<sup>4</sup> School of Nursing and Midwifery, Faculty of Health and Human Sciences, Plymouth University, Plymouth, United Kingdom.

**Corresponding author**

R. Zhang

Neonatal department

Hunan Children's Hospital

Ziyuan Rd, Changsha, 410007, Hunan Province, China

E-mail: [zhangrong8426@163.com](mailto:zhangrong8426@163.com)

Phone: 008618692276520

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## **ABSTRACT**

**Objective:** To evaluate the effectiveness and safety of a Family-Centered Care (FCC) intervention in a Chinese Neonatal Intensive Care Unit (NICU).

**Design:** Pilot study using a RCT design to inform a main RCT study.

**Setting:** Stand-alone tertiary children's hospital in China with a 60-bed NICU serving as a regional NICU center.

**Patients:** Premature infants (n=61) and their parents (n=110)

**Interventions:** Parent education program followed by parents' participation in care as primary caregiver until discharge for a minimum of four hours per day.

**Measurements and Main Results:** Primary outcomes were infants' weight gain at discharge, length-of-stay, and readmission. Parental outcomes were stress, anxiety, satisfaction, and clinical knowledge. Infants in FCC group (n=31) had higher weight gain (886g vs 542g;  $p=0.013$ ); less NICU length-of-stay in days (43 vs 46;  $p=0.937$ ); and decreased readmission rate at one week (41.9 vs. 70.0;  $p=0.045$ ) and at one month (6.5% vs 50%;  $p<0.001$ ) compared to the control group (n=30). Total mean parental stress and anxiety scores was lower in the FCC group (42 vs 59;  $p\leq 0.007$ ); mean satisfaction rates in FCC group were higher compared to control group (96 vs 90;  $p<0.001$ ); and parents in the FCC group had better educational outcomes related to neonatal specialized care skills ( $p<0.05$ ).

**Conclusion:** Involving parents in the care of their infant improved clinical outcomes of infants. FCC also contributed to a better understanding of parent's clinical education, decrease stress levels and increased parental satisfaction. Our study suggests that involving parents in the daily care of their infants is feasible and should be promoted by NICU clinicians.

### **Key words:**

Family-Centered Care; Neonatology; Parents; Premature Infants; Education.

## INTRODUCTION

In the past decades, the percentage of neonatal ward admissions of preterm infants in China has increased from 19.7% to 26.2% and is still rising (1). Preterm birth is the leading cause of neonatal mortality and over one million infants die annually from the related complications (2). It is also the second leading cause of death after pneumonia in children under five years of age.

In most Chinese Neonatal Intensive Care Units (NICUs), parents are not allowed to visit their infant during the entire admission (3). Reason to exclude parents are mainly voiced by the fear of nosocomial infections. Another reason highlighted by NICU professionals in China is the limitation of space. It is recognized that excluding parents in the care of their infant impedes parent-infant interaction and has led to the development of Family-Centered Care (FCC) programs, kangaroo care, and skin-to-skin care across the world (4-6). Family-Centered Care is an integral component of developmental care whereby the parents play an important role in ensuring the health and well-being of the infant (7, 8). This care model encompasses the philosophy that neonatal care incorporates an open and honest communication between parents and professionals. Issues of medical and nursing care as well as possible ethical issues that may arise are shared and discussed with parents. Studies have reported that parental involvement in care might result in increased satisfaction and decreased readmission rates (9, 10), and reduce stress and anxiety (11-13). Allowing parental presence and providing parents with education and support, might also improve preterm infants' outcomes (10, 14, 15). However, changing a closed NICU to an open visiting policy might be a challenge for many NICU healthcare professionals in China. Therefore, this pilot study aimed to determine the effectiveness and safety of a Family-Centered Care intervention in a Chinese NICU.

The FCC intervention was designed to allow parents to visit their infant in the NICU for at least four hours per day. Nurses and doctors were teaching parents specialized care to support parents in becoming the primary caretakers.

## **MATERIALS AND METHODS**

### **Design**

The pilot study, using a RCT design, was conducted between June 2014 and September 2016.

### **Setting**

The study was conducted in a stand-alone children's hospital in Hunan province in the People's Republic of China. The 60-bed NICU serves as a regional tertiary center for all premature infants requiring intensive care treatment. The NICU physicians communicate with parents about their infants' condition three days per week. No visiting policies were in place. Parents are only allowed to visit the infant in special situations such as long-term admissions, critical situations, and withdrawal of treatment.

### **Participants**

Inclusion criteria were parents of infants born at <37 weeks of gestation. Parents were included if they were able to commit spending a minimum of four hours per day with their infant between office hours to enable attendance at medical rounds and education sessions.

Excluded were parents of infants with: 1) major life-threatening congenital anomaly; 2) critical illness and unlikely to survive; 3) respiratory support (CPAP, mechanical ventilation, high-frequency oscillatory or jet ventilation, extra-corporeal membrane

oxygenation). Parents were excluded if they have health, family, social, or language issues that might limit their integration and collaboration with the healthcare team.

### **Recruitment**

Due to the nature of the intervention, which involves changes to unit-level provision of care and interaction between parents, blinding of parents or medical staff was not possible. Parents were recruited by research nurses based on the inclusion and exclusion criteria. Infants were allocated to the intervention group by flipping a coin. The intervention group received the FCC intervention. The control group received standard care. If twins were recruited, both infants were individually randomized. In case one infant was assigned to the intervention group, the parents were also included in the FCC group.

### **FCC Intervention and Standard Care**

In the first week of admission, parents were recruited and assigned to the study groups. In the second week of admission parents in both study groups received the same educational sessions. The content of the educational session included hand hygiene, neonatal resuscitation, daily nursing care (including bathing, feeding, and massage) and respiratory support. The educational sessions (theory and practice) lasted for around 90 minutes per day, 5 days per week, and included question and answer time for parents. Parents in both groups were not able to visit their infants at the bedside but only visit the unit in the parent waiting area.

In the third week of admission, parents in the FCC group were allowed to visit their infant and were encouraged to participate as primary caregivers until discharge for a minimum of four hours per day. We designed a FCC room with two incubators, rest area for parents, bathing area, disinfection equipment, and emergency rescue equipment. This room was located nearby staff's working area isolated with a glass

door to enable NICU staff to observe the condition and ensure safety. If the infant's condition deteriorated and needed positive pressure respiratory support, the FCC involvement was stopped until the infant's condition improved. The parents in the control groups were not allowed to visit their infant during admission but could come to the parent waiting area of the NICU and communicate with the physicians and nurses three days a week.

### **Outcomes and measures**

The primary outcomes were the infants' clinical outcomes, including weight gain at discharge, NICU length of stay, and readmission rate at one week and one month after discharge.

The secondary outcomes were parents' related outcomes; stress and anxiety, parent satisfaction, breastfeeding rate, and knowledge about their baby's progress. Stress and anxiety was measured by the W.K. Zung self-assessment instrument and completed by both mothers and fathers together (16, 17). Satisfaction was measured by the hospital standard parent satisfaction survey completed by both parents. The knowledge about their baby was measured before and after the education sessions using a standard questionnaire testing medical students' skills (resuscitation, hygiene, neonatal care, and respiratory support) and completed separately by fathers and mothers.

The secondary outcomes testing the FCC efficiency and safety were patient's clinical complications; Retinopathy of Prematurity (ROP), Necrotizing Enterocolitis (NEC), Bronchopulmonary Dysplasia (BPD), and neurological outcomes were evaluated the day before discharge using the Neonatal Behavior Neurological Assessment (NBNA) which is widely used in China (18).

## **Data analysis**

The distribution of baseline characteristics of the FCC and the control group are summarized at individual and cluster level, using descriptive statistical methods.

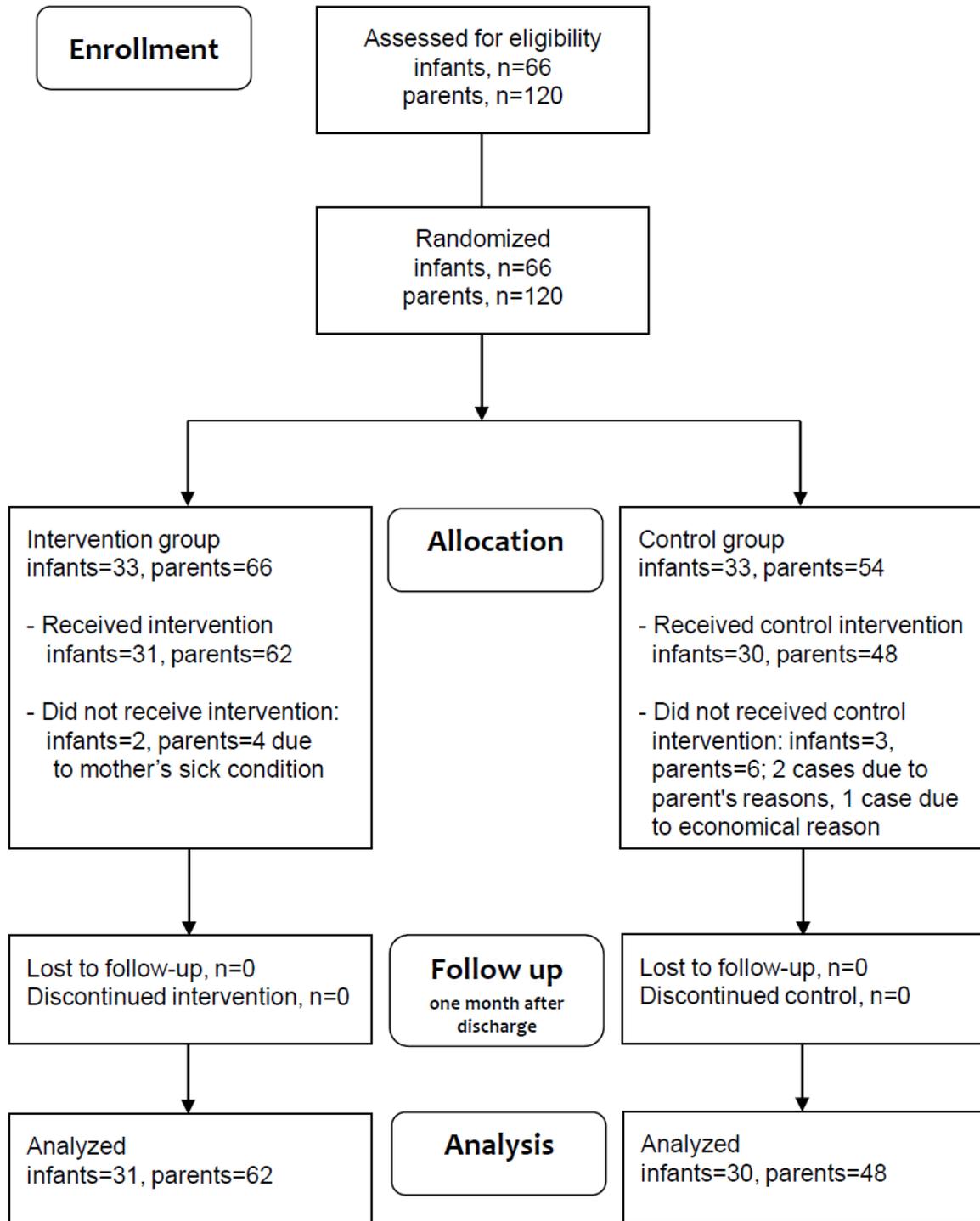
Student t-test for continuous variables and the Chi-square test for categorical variables were used to analyze the primary and secondary outcomes. We also used hierarchical linear or logistic regression models to analysis the relevance between the risk factors and education outcomes among parents. Data are presented as FCC group versus control group. Statistical significance was defined as  $p \leq 0.05$

## **Ethics**

Ethical approval was granted by the Ethics Committee of Hunan Children's Hospital (HCHLL-2014-015). Parents were informed about the study objectives, written informed consent was obtained, and parents were able to withdraw from participation at any time.

## **RESULTS**

A total of 120 parents of 66 premature infants consented to participate. Of these, parents of five infants were excluded due to reasons shown in Figure 1. We included six twins in our study of which six infants were assigned in the control group while the other six infants and the parents were assigned in the FCC group. Included in the final analysis were 61 infants and 110 parents (**Fig. 1**).



**Fig 1.** Study participants flow diagram

All included preterm infants weighted >1000g with gestational age between 28-36<sup>+6</sup> weeks. No differences were observed between the FCC and control group (**Table 1**).

The demographic characteristics of parents between both groups did not reveal differences (**Table 1**).

**Table 1. Infants' and parents' characteristics**

<b>Infants</b>	<b>FCC (n=31)</b>	<b>Control group (n=30)</b>	<b>P value</b>
GA on admission in weeks; mean, (SD)	31.79 (2.31)	31.78 (2.29)	0.916
Birth weight (g); mean, (SD)	1663 (449)	1632 (434)	0.896
Admission weight (g); mean, (SD)	1737 (436)	1730 (409)	0.878
Study enrollment weight (g); mean, (SD)	1958 (446)	1967 (434)	0.918
Gender, Male (n; %)	17 (54.84)	20 (66.67)	0.353
Vaginal delivery (n; %)	20 (64.52)	16 (53.33)	0.383
Asphyxia (n; %)	16 (52.63)	18 (60.00)	0.698
<b>Parents</b>	<b>FCC (n=62)</b>	<b>Control group (n=48)</b>	<b>P value</b>
Father's age in years; mean, (SD)	31.81 (4.79)	32.60 (5.38)	0.283
Mother's age in years; mean, (SD)	27.61 (4.71)	28.13 (5.03)	0.709
Education level fathers (n; %)			
Low level educated	2 (6.45)	2 (6.67)	0.607
Middle level educated	21 (67.74)	19 (63.33)	0.608
High level educated	8 (25.81)	9 (30.00)	0.621
Education level mothers (n; %)			
Low level educated	3 (9.68)	1 (3.33)	0.575
Middle level educated	15 (48.39)	16 (53.33)	0.568
High level educated	13 (41.94)	13 (43.33)	0.547
Family incomes in ¥; mean, (SD)	2.52 (0.72)	2.60 (0.77)	0.690

GA=Gestational Age; g=grams; SD=Standard Deviation; FCC=Family-Centered Care; ¥: 1) 1000-3000; 2) 3001-6000; 3) 6001-9000; 4) >9000; Low level educated is below middle school; Middle level educated is between middle and high school; High level educated is equal or above bachelor degree.

The primary outcome of weight gain was higher in the FCC group (886g vs. 542g; p=0.013) and no difference was observed in length-of-stay (43 vs. 46 days; p=0.937).

Both readmission rates at one week (41.9 vs. 70.0;  $p=0.045$ ) and at one month (6.5% vs. 50%;  $p<0.001$ ) were lower in the FCC group (**Table 2**).

**Table 2. Infants' primary outcomes**

Outcomes infants	FCC (n=31)	Control (n=30)	Mean difference; (95% CI)	P value
Discharge weight (g); mean, (SD)	2871 (398)	2474 (376)	935; (545; 1259)	0.023
Weight gain (g)	886 (274)	542 (206)	453; (163; 743)	0.013
Weight gain (%)	32.62	20.91	14.32; (7.04; 25.67)	0.021
NICU LOS in days; mean, (SD)	43 (11)	46 (12)	3.3; (-2.8; 9.4)	0.937
<30 <sup>0</sup> / <sub>7</sub> wk; mean, (SD)	n=7 47(13)	n=6 50(11)	-3.4; (-18.3; 11.5)	0.625
30 <sup>0</sup> / <sub>7</sub> - 34 <sup>6</sup> / <sub>7</sub> wk; mean, (SD)	n=20 41(11)	n=20 45(13)	-4.2; (-10.4; 3.3)	0.305
35 <sup>0</sup> / <sub>7</sub> - 36 <sup>6</sup> / <sub>7</sub> wk ; mean, (SD)	n=4 40(14)	n=4 40(16)	-0.3; (-26.8; 26.3)	0.982
Readmission rate after 1 week (%)	41.9	70.0	-0.3; (-0.5; -0.1)	0.045
Readmission rate after 1 month (%)	6.5	50.0	-0.4; (-0.6; -0.2)	<0.001

G=grams; SD=Standard Deviation; NICU=Neonatal Intensive Care Unit; LOS=Length-Of-Stay; FCC=Family-Centered Care; Weight gain (g) = Discharge weight-study enrollment weight; Weight gain (%) = (discharge weight-study enrollment weight)/discharge weight; wk=weeks

The neurological outcomes as measured with NBNA scores were higher in the FCC group (33.71 vs. 30.8;  $p<0.001$ ), and breastfeeding rate was also higher (29% vs. 8%;  $p<0.001$ ). The incidence of ROP (3 % vs. 10%;  $p=0.04$ ), nosocomial infection rates (3% vs. 10%;  $p=<0.001$ ), and code blue incident rates (1% vs. 10%;  $p=0.032$ ) were lower in the FCC group. No differences in NEC or BPD were observed between the groups (**Table 3**).

**Table 3. Infants' secondary outcomes**

Outcomes infants	FCC (n=31)	Control (n=30)	Mean difference; (95% CI)	P value
NBNA scores; mean, (SD)	33.71 (1.7)	30.80 (2.06)	-2.9; (-3.9; -1.9)	<0.001
Breastfeeding rate, (n; %)	29 (93.55)	8 (26.67)	0.7; (0.5; 0.9)	<0.001
NEC rate, (n; %)	4 (12.90)	6 (20.00)	-0.7; (-0.3; 0.1)	0.140
ROP rate, (n; %)	3 (9.68)	10 (33.33)	-0.1; (-0.3; -0.1)	0.040
BPD rate, (n; %)	6 (19.35)	8 (26.67)	-0.1; (-0.4; 0.1)	0.160
Hospital infection rate, (n; %)	3 (9.68)	10 (33.33)	-0.2; (-0.4; -0.03)	<0.001
Code blue rate, (n; %)	1 (3.23)	3 (10.00)	-0.1; (-0.2 -0.1)	0.032

FCC=Family-Centered Care; NBNA= Neonatal Behavior Neurological Assessment; NEC= Necrotizing Enterocolitis; ROP= Retinopathy of Prematurity; BPD= Bronchopulmonary Dysplasia; SD=Standard Deviation

All parents stayed on average one month with their infants. The parents' reported less anxiety and depression, showed higher satisfaction rates, and the educational knowledge and skills of resuscitation, hand hygiene, basic neonatal care and respiratory care were higher in the FCC group (**Table 4**).

**Table 4. Parents' outcome measures**

Outcomes parents	FCC (n=62) mean (SD)	Control (n=48) mean (SD)	Mean difference; (95% CI)	P value
Parent's stress <sup>1</sup>	42.06 (3.77)	59.40 (9.14)	16.9; (13.3; 20.6)	<0.001
Parent's anxiety <sup>1</sup>	41.61 (4.83)	59.40 (9.48)	17.79; (13.9; 21.7)	0.007
Parent's satisfaction <sup>1</sup>	96.39 (2.55)	90.30 (4.23)	-6.1; (-7.9; -4.3)	<0.001
Resuscitation training <sup>2</sup>	95.68 (2.44)	80.43 (0.60)	-15.2; (-19.3; -11.2)	<0.001
Neonatal care <sup>2</sup>	95.19 (1.82)	82.87 (9.62)	-12.32; (-16.0; -8.7)	<0.001
Hand hygiene <sup>2</sup>	96.19 (2.41)	83.00 (9.97)	-13.2; (-17.0; -9.4)	<0.001
Respiratory skills <sup>2</sup>	18.10 (0.65)	13.40 (2.89)	-4.70; (-5.8; -3.6)	<0.001

FCC=Family-Centered Care; SD=Standard Deviation; <sup>1</sup>questionnaire completed per couple parents; <sup>2</sup>questionnaires completed separate by mother and father.

## DISCUSSION

Our pilot study aimed to assess a Family-Centered Care intervention to support parents of infants in a NICU. The rationale of our study was to support FCC practices in Chinese NICUs. Although this was a small pilot study, the results showed that FCC may provide beneficial effects on infants' clinical outcomes and parent reported outcomes and skills without additional harm. The FCC intervention was associated with greater weight gain at discharge, breastfeeding rates, and favorable neurological outcomes. Parents in the FCC group experienced less anxiety and depression while satisfaction scores increased. The results are promising to promote FCC practice in Chinese NICUs, which have been mainly closed units for parents for many decades.

Our study showed that infants in the FCC group had higher weight gain at discharge and lower readmission rates. Regarding weight gain, a pilot study testing the family-integrated care model also observed an increase in weight gain at 21 days after enrolment (19). However, it was noted that the rate of change in weight gain was only significant after adjusting for other risk factors (19, 20). In our study we observed that infants in the FCC group had higher weight at discharge compared to the control group. This is consistent with other studies from China (14, 21).

The length-of-stay in our study did not differ between both groups. This is in contrast with other studies (15, 22). The Stockholm neonatal family-centered care study used two NICU wards and implemented on one NICU ward the FCC model, where parents could stay 24 hours. The hospital length-of-stay decreased by 5.3 days in the FCC group to a mean of 27.4 days (15). Based on the Creating Opportunities for Parent Empowerment (COPE) educational intervention, Melnyk et al. (22) demonstrated that the intervention group had a mean NICU length-of-stay of 31.86 days versus 35.63 days in the control group. The length-of-stay in our study did not improve. Perhaps this could be due to organizational and culturally related factors. Our NICU does not have a designated step-down unit and infants are discharged directly from the NICU. Also, parents are deciding to take their infant home after the NICU physicians have agreed that the infant is medically fit for discharge. Therefore, length-of-stay remains a difficult metric to interpret and compare with other studies (5, 15, 22).

The readmission rates one week and one month after discharge were lower in the FCC group. Parents in the FCC group with a readmission could stay again with their infant and parental education was repeated. This might explain the very low readmission rate one month after discharge. Readmission rates have been used as

an outcome measure in studies. Farideh et al. (9) stated that the number and duration of readmissions decreased in the FCC intervention group. Erdve et al. (23) reported that the number of readmissions and referrals to physicians decreased in their FCC intervention group. In this study from Thailand, the infants and mothers stayed in a private room in the hospital instead of the NICU while the control infants stayed in a closed NICU without mother's participating in the care. Overall, decreasing readmission might benefit the hospital expenditures. However, studies are needed to assess the effect of FCC and its cost-effectiveness for hospitals.

Family-centered care program can increase parent satisfaction with care as demonstrated by an integrative review (24). After synthesizing twelve studies, including nine quantitative, two qualitative, and one mixed method study, the findings showed that the majority of parents were highly satisfied with the care in the NICU. These findings provide directions to the importance of satisfying parents whose infants are admitted to a NICU (25). Parents of premature infants experience multiple stressors related to preterm birth, such as postpartum medical condition of the mother and/or infant, admission of their infant to the NICU, and the transition process to parenthood (13, 26). Our research showed a significant reduction of stress among parents in the FCC group. Additionally, clinical education decreased the perception of parental stress. However, the quality of family-centered care, such as parental role alteration to more involvement in care and education programs can still be improved and should be based on the individual needs and wishes of parents.

Many studies emphasized that parental education by NICU staff might improve health related quality of life (27, 28). Our FCC intervention included a series of classes including hand hygiene, neonatal resuscitation, daily nursing care and respiratory support. The training course scores were higher in the FCC group.

However, we acknowledge that parents' educational support is an ongoing exercise throughout the NICU admission including follow-up clinics at one month after discharge.

Studies reporting FCC interventions have used various outcome measures. Some studies have used infant clinical outcome measures such as length-of-stay in the NICU or hospital (14, 15, 22, 29) or infant's weight gain (14, 19). It is also noted that several RCTs measure the incidence of NEC, BPD, ROP and neurological outcomes (14, 15, 30). Studies testing an FCC intervention related to communication and information have used mainly parental reported outcome measures such as stress, anxiety or satisfaction (9, 22, 30-32). Unfortunately, to date, there is no core set of outcome measures in NICU (33). For studies testing FCC interventions, this could be important to compare study results to strengthen the benefits of FCC in NICUs across the world.

This study has several limitations. Firstly, our study was conducted in a single-center NICU. The findings may not be applicable to other (Chinese) NICUs. However, we aimed to pilot a FCC intervention which will lead to planning of a main multi-center RCT study in China. A second limitation is that we did not investigate the involvement and attitude of NICU staff in delivering the FCC intervention. It might be possible that medical staff could have different attitudes towards implementing FCC. This human factor might have influenced the delivery of the FCC education program and guidance of parents and thus impacting the study results such as the differences in breastfeeding rates. Although NICU staff encourage breastfeeding to all parents, the parents in the control group might have difficulties in pumping the breastmilk at home and transporting the milk to the hospital. This could influence their motivation to provide breastmilk and we did not record the parental attitudes of breastfeeding

among this group. Also, the Chinese culture “zuo yuezi” where mothers are expected to rest indoors and avoid physical activity for one month might be a factor influencing the breastfeeding rates in the control group. The mothers in the FCC group might have stepped away from this tradition. Therefore, we need to be cautious in stating that the FCC intervention influence directly breastfeeding rates and could be a confounding – or a cultural – factor. The third limitation is that the self-assessment questionnaires measuring stress, anxiety, and satisfaction were not delivered to fathers and mothers separately. Instead, these were completed by both parents together. Evidence exists that fathers might have different perceptions as mothers. Therefore, we are unable to present the results separately which could have been an important indicator to improve FCC practice.

## **CONCLUSION**

Involving parents in the care of their infant might improve clinical outcomes of infants such as weight gain, breastfeeding, and infection rates. Involving parents in the care of their infant in a NICU contributes to a better understanding of parent’s clinical knowledge, decrease stress levels and increases satisfaction. For decades, parents were not allowed to visit the NICUs in China without medical staff’s permission. However, a paradigm shift is observed towards a more liberal approach to invite parents in Chinese NICUs. Our study suggests that collaboratively working with parents in feasible and contributes to the quality and safety of NICU services.

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