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Review paper

Effects of family-centred care interventions on preterm infants and parents in neonatal intensive care units: A systematic review and meta-analysis of randomised controlled trials

Xiang Ding, RN [a]
Lihui Zhu, RN, MSc [a, *]
Rong Zhang, MD, MSc [b]
Li Wang, RN, MSc [a]
Ting-Ting Wang, MSc [c]
Jos M. Latour, RN, PhD [a, d]

[a] Department of Nursing, Hunan Children's Hospital, Changsha, Hunan Province, People's Republic of China
[b] Neonatal Intensive Care Unit, Division of Neonatal Medicine, Hunan Children's Hospital, Changsha, Hunan Province, People's Republic of China
[c] Department of Epidemiology and Health Statistics, Xiangya School of Public Health, Central South University, Changsha, Hunan Province, People's Republic of China
[d] School of Nursing and Midwifery, Faculty of Health and Human Sciences, University of Plymouth, Plymouth, UK

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ABSTRACT

Objective: The objective of this study was to review English and Chinese randomised controlled trials (RCTs) to determine the effects of family-centred care (FCC) interventions on preterm infants' and parental outcomes in the neonatal intensive care units and to conduct a meta-analysis.
Review method used: Systematic review and meta-analysis.
Data sources: Medline, CINAHL, Embase, PsycINFO, BNI, and AMED and the Chinese databases CNKI and Wanfang Data were searched in April 2017 and updated in August 2018.
Review methods: Only RCTs were included. Participants were preterm infants ≤37 weeks gestational age and parents. Interventions were related to FCC, and outcome measures were infant and parent clinical outcomes. Included studies were assessed for risk of bias using Cochrane Manual 5.1.0. Meta-analyses used mean differences (MDs), standardised mean differences (SMDs), or odds ratio (OR), followed by 95% confidence interval (CI). Heterogeneity was tested with Cochran's Q chi-squared test, tau-squared test, and inconsistency index (I^2).
Results: Nineteen studies (10 from English and 9 from Chinese databases) were included; meta-analysis included 15 studies (7 English and 8 Chinese RCTs). Meta-analysis showed significant improvements in weight gain (7 studies: MD, 4.57; 95% CI, 2.80–6.34; P < 0.001; I^2 94%); readmission (3 studies: OR, 0.23; 95% CI, 0.10–0.52; P < 0.001; I^2 = 0%); parent satisfaction (5 studies: OR, 11.20; 95% CI, 4.76–26.34; p < 0.001; I^2 = 0%); skills of parents (4 studies: SMD, 2.57; 95% CI, 2.19–2.96; P < 0.001; I^2 = 53%); knowledge of parents (4 studies: SMD, 2.74; 95% CI, 2.47–3.00; P < 0.001; I^2 = 0%); parental anxiety at follow-up (3 studies: SMD, −0.19; 95% CI, −0.28 to −0.09; P < 0.001; I^2 = 0%); parent depression at follow-up (2 studies: SMD, 0.37; 95% CI, −0.63 to −0.12; P = 0.004; I^2 = 44%); and parental stress (3 studies: MD, −0.20; 95% CI, −0.26 to −0.13; P < 0.001; I^2 = 0%). No statistical differences were observed in neurobehavioural development (3 studies) and hospital length of stay (7 studies).
Conclusions: FCC interventions can improve weight gain and readmission in preterm infants as well as parent satisfaction, knowledge, and skills, and possibly long-term anxiety, depression, and stress. Developing standardised outcome sets for testing family-centred care interventions is recommended.
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* Corresponding author at: Nursing Department, Hunan Children's Hospital, Ziyuan Road, Changsha, 41007, Hunan Province. People's Republic of China.
E-mail addresses: 28866222@qq.com (X. Ding), 877845375@qq.com (L. Zhu), zhangrong8426@163.com (R. Zhang), 465279395@qq.com (L. Wang), 404140498@qq.com (T.-T. Wang), jos.latour@plymouth.ac.uk (J.M. Latour).

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1. Introduction

The concept of family-centred care (FCC) has been implemented over the last 60 years in various healthcare settings.[1,2] FCC has not been described clearly as a care model but rather an approach and has been defined as the involvement of family members in patient care and emphasises the patient's emotional, social, and developmental needs.[3] It is an innovative approach to develop a trustworthy, respectful partnership between healthcare professionals and family members. The overall principals of FCC have been described as dignity and respect, sharing of information, participation in care, and decision-making.[4,5] Although FCC has been widely accepted in paediatric settings, the reality remains that in many countries, parents have limited access to neonatal intensive care units (NICUs) and limited involvement in the care of their infant.[6–8] Therefore, it can be assumed that FCC practices are still developing.

With the continuous improvements in medical technology, birth and survival rates of preterm infants have been greatly improved. The World Health Organization statistics in 2012 showed that 15 million preterm infants are born each year globally, accounting for up to 11.1% of all newborns, and China ranks second for the number of preterm infants, with more than 250,000 preterm births in 2010.[9] A survey in 2005 among 80 Chinese hospitals recorded 43,289 neonates in 80 hospitals, and among them, 26.2% were preterm infants.[10] Compared to their previous survey in 2002, the number of premature infants increased by 6.5% and is expected to rise every year. A more recent survey in 2011 from mainland China described a retrospective analysis of 101,163 newborns from 39 hospitals.[11] The low-birth-weight infants (<2500 g) were recorded at an incidence rate of 6.1%.

The birth and hospitalisation of a preterm infant may impose pressure on parents and other family members and could potentially lead to a family crisis. Research shows that FCC can decrease anxiety and support them to adapt into their new roles.[12] In addition, FCC practices also support parents to understand the importance of interaction with their infant which can improve infants' growth and development.[13] The FCC model has already drawn attention from international institutions and medical communities. While the developed countries have studied the impact of FCC on preterm infants and parents, China is still in the beginning of implementing and testing this innovative practice. The outcome of infants and parents in the NICU with FCC practices remains unclear, and robust evidence supporting FCC compared to standard care (SC) is sparse. SC varies but usually includes limitations on parents visiting the NICU or providing basic care to their baby. Therefore, it is timely to conduct a systematic review and meta-analysis to support the body of knowledge and clinical practice. The aims of our study are to 1) systematically review English and Chinese randomised controlled trials (RCTs) related to the effects of FCC interventions on preterm infants' and parental outcomes in NICUs and 2) conduct a meta-analysis of the identified RCTs.

2. Methods

2.1. Design

This systematic review and meta-analysis is structured and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[14]

2.2. Eligibility criteria

Only RCTs were eligible if the study aim was related to test an FCC intervention. We defined that an FCC intervention should be related to one or more components of FCC including educational support (skills and knowledge of care), partnership in care (empowerment and involvement in care), personalised care (needs and wishes), parent support (psychological and visiting access), information and communication, and NICU environment (noise and light levels and design/layout of the NICU).[3,5,12] SC in this review was defined as care with no or limited support to parents, i.e., limitations in visiting or involvement of care. The study population included preterm infants with a gestational age of ≤37 weeks and their parents.

The Population, Intervention, Comparison and Outcome (PICO) question was defined as follows: Does family-centred care (I) compared to SC (C) improve clinical outcomes (O) in preterm infants and parents in the NICU (P)?

2.3. Information sources

The following international databases were used: Medline, Cummulative Index of Nursing and Allied Health Literature (CINAHL), Excerpta Medica dataBASE (Embase), PsycINFO, British Nursing Index (BNI), and Allied and Complementary Medicine Database (AMED). The Cochrane Database of Systematic Reviews was used to identify RCTs in previously published reviews. The Chinese databases China National Knowledge Infrastructure (CNKI) and Wanfang Data were used to identify Chinese articles. In addition, reference mapping was performed manually by searching the reference lists of identified articles. The searches in both English and Chinese databases were performed in April 2017. An update search in August 2018 resulted in three additional English articles.

2.4. Search strategy

The search strategy used both English and Chinese Medical Subject Headings (MeSH) terms and keywords. The English articles were searched using the keywords parent(s), preterm infant(s), family centred care, family nursing, and randomized controlled trial. A full search strategy is available online (Electronic Supplement Material 1). The Chinese articles were searched using the Chinese characters: 家庭式护理 (family-centred care), 家庭护理干预 (family nursing), 家庭式参与护理 (family involvement), 家长参与式护理 (family-integrated care), 新生儿 (neonate), 早产儿 (preterm infant), 随机对照实验 (randomised controlled trial), and 随机对照临床实验 (randomised controlled clinical trial). The search terms in Chinese are slightly different from the English search terms because the meaning of Chinese characters cannot always directly be translated into English. For Chinese readers, the full Chinese search strategy is available online (Electronic Supplement Material 1).

Studies reported in English and Chinese were considered, and no date limit was set because FCC has been described in the literature since the 1960s. The searches of the English databases were conducted by J.M.L and X.D, and the searches of Chinese databases were conducted by R.Z and X.D.

2.5. Study selection

Only articles with an RCT design testing an FCC intervention were included. The intervention should have been defined as an FCC intervention by the authors and related to the main principles of FCC. Articles published in English and Chinese from the time of the establishment of the database to April 2017 were included. Three researchers (X.D, J.M.L and R.Z) screened all titles and abstracts that were identified in the search strategy based on the FCC definition, eligibility criteria, and the PICO question. Discrepancies

were discussed until consensus was reached. All discussions throughout the full review process were in English as all authors had overseas training background with an experience in NICUs with FCC practices and proficient level of English.

2.6. Data collection process

The data were extracted from each article by three researchers (X.D, J.M.L and R.Z) in a data extraction form including authors, year of publication, country, study design, setting, participants, FCC intervention, outcome measures, and main outcomes.

2.7. Risk of bias in individual studies

The Cochrane Handbook for Systematic Reviews or Interventions (version 5.1.0) was used to assess the risk of bias and quality of the included RCTs.[15] Although the Cochrane handbook explicitly discourages the assessment of quality or risk of bias, we have evaluated the studies by two researchers (X.D and J.M.L) using a score of low, unclear, or high risk for seven bias categories: selection bias (random sequence), selection bias (allocation concealment), performance bias, detection bias, attrition bias, reporting bias, and other bias. A quality score was given based on the total score of the seven categories: score 1 (low risk) and score 0 (unclear or high risk).

2.8. Synthesis of results

All analyses were performed using R, version 3.4.1, (R Foundation for Statistical Computing) and the meta package (version 4.8–4). Mean differences (MDs) or standardised mean difference (SMD) and the corresponding 95% confidence interval (CI) were calculated using fixed-effects model (FEM) or using random-effects model (REM) if there is any heterogeneity. In the same way, the pooled odds ratio (OR) and its 95% CI were calculated. Cochran's Q chi-square (χ^2) was used to assess heterogeneity, with a P-value >0.1 interpreted as the effect size being homogeneous across studies and thus allowing an FEM to be used. The inconsistency index (I^2), the proportion of heterogeneity not due to chance, and tau-squared (τ^2), the estimate of the variance in effect size when an REM is used, were also calculated. If studies were heterogeneous, an REM was applied to calculate the consolidated effect value. I^2 value of ≤25% represents a low heterogeneity; 26–50%, a moderate heterogeneity; 51–75%, a high heterogeneity; and 76–100%, a very high heterogeneity. Meta-analysis was performed with the outcome measures if two or more studies presented the data that could be pooled. The meta-analysis of the outcome measures including only two or three studies are presented in detail in Electronic Supplement Material 5 of this article.

3. Results

3.1. Study selection

In the identification phase, the searches in English and Chinese databases revealed 121 articles (Fig. 1). After removing duplicates (n = 49), 72 titles and abstracts were reviewed in the screening phase, and 38 articles were removed, leaving 34 articles for full-text assessment in the eligibility phase. We excluded 18 articles based

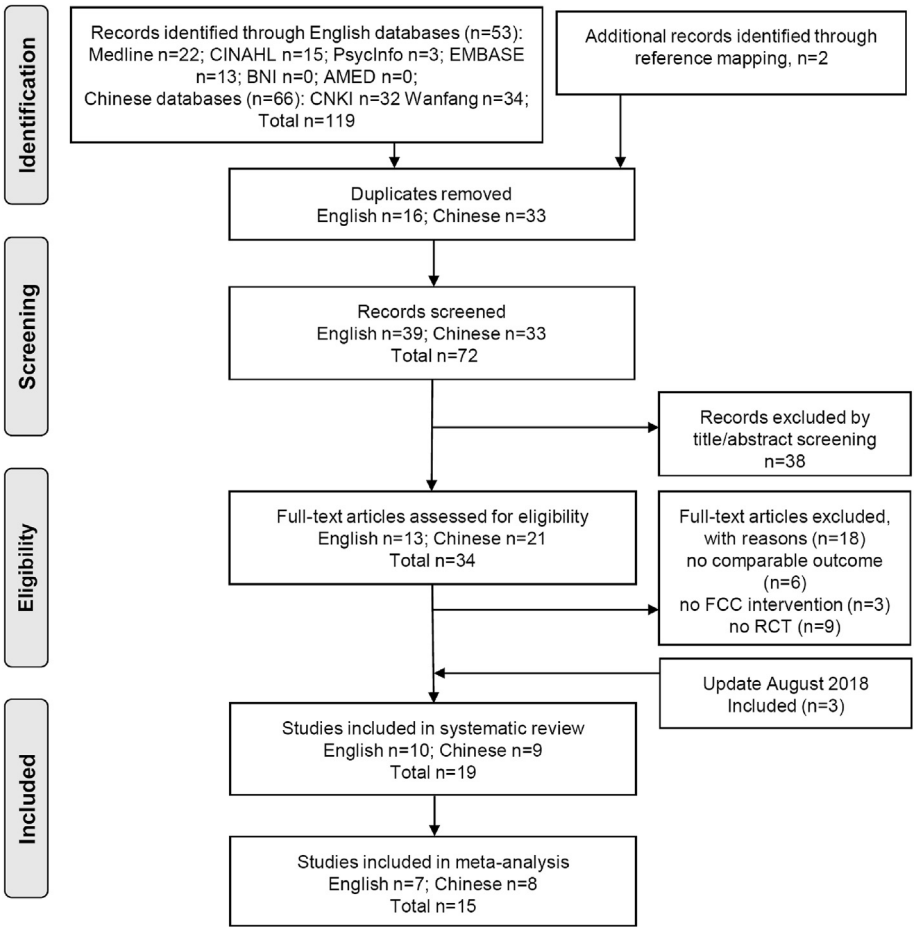

Fig. 1. Flow diagram of study selection in April 2017 and updated in August 2018.

on the study design; no FCC intervention was defined such as a pain intervention or endotracheal suctioning and no comparable outcomes such as salivary cortisol (Fig. 1). In the inclusion phase, we included seven English articles[16–22] and nine Chinese articles.[23–31] Because the full search strategy was conducted in April 2017, an update search was performed in August 2018, and three additional articles were included.[32–34] The systematic review eventually included 19 articles. Of these, 15 articles were included in the meta-analysis. Four RCTs were excluded from the meta-analysis because of limited requisite information. One study provided only mean values of the parent anxiety scores, and these data could not be pooled with data from other studies.[22] Similarly, two studies provided only the interquartile range of the outcome measures.[17,32] One Chinese study used a neurodevelopment tool which was not comparable with other studies.[24]

3.2. Study characteristics

All included studies used an RCT design.[16–34] Most studies (n = 13) were conducted at a single-centre NICU (Table 1). The total numbers of study participants were 4478 preterm infants and 3158 parents in studies using parental outcome measures. One study included infants with a gestational age up to 39 weeks rather than 37 weeks.[22] It was decided to include this study in the systematic review but not in the meta-analysis.

Most studies were unclear in defining parents, mothers and/or fathers. In particular, studies reporting parent outcome measures (n = 13) were often unclear if the surveys were completed by both the mother and father individually or together (Table 1). Only Weis et al. (2013)[20] reported the completion of a parent stress scale by mothers and fathers individually and documented that mothers had higher stress levels than fathers (2.91 vs 2.58; $p < 0.001$). Two studies provided outcome measures of mothers only,[17,21] and in four studies, mothers and fathers were included, but the data were not reported separately.[16,19,23,27,31] The remaining six studies did not specify the parent's role of study participant.[22,28–30,33,34]

Studies differed in the components of FCC interventions (Electronic Supplement Material 2). Most FCC interventions were related to the component *Educational* support (n = 16) with seven studies from the English literature and all Chinese studies.[14,15,17,19,21–32] Most of the studies including an educational program in their FCC intervention also included the component of *Partnership in care*.[15,17,19,20,22,27–29,31,32] The next most common component of FCC described in the studies was *Information and communication*.[14,18–20,32] The other FCC components described in the FCC interventions were *Personalised care*,[18] *Parent* support,[32] and *NICU environment*.[16]

The studies included various outcome measures (Table 1). Six studies used only infants' clinical outcome measures,[18,19,24–26,32] four studies used only parent-reported outcome measures,[20–22,27] and nine studies used both infants and parent outcome measures.[16,17,23,28–31,33,34] Five Chinese RCTs used parent satisfaction as an outcome measure.[27–31] Of these, three self-designed parent satisfaction questionnaires were identified. We were able to obtain two questionnaires (Electronic Supplement Material 4). Four Chinese RCTs measured parental knowledge and skills.[27,28,30,31] An example of the self-reported knowledge questionnaire used by two RCTs is presented in the Electronic Supplement Material 4. Two Chinese RCTs specifically described the assessment of parental skills[27,31] which were assessed by a research nurse using a care checklist.

3.3. Risk of bias within studies

The risk of bias and methodological quality was low in five of the nine Chinese articles.[23,24,26,28,29] and two of the English articles[21,22] (Table 1 and Electronic Supplement Material 3). The most common reasons for a low score among Chinese articles were the poor reporting of selection, performance, and detection bias. The two English articles reported incomplete data.

3.4. Meta-analysis infant outcomes

Seven studies (four Chinese and three English) reported the infants' daily weight gain (grams per day) as an outcome measure between the FCC group and the SC group.[19,23,25,26,28,33,34] According to the heterogeneity test, high heterogeneity existed (I^2 = 94%, τ^2 = 4.63, χ^2 = 93.27, $P < 0.001$). Therefore, REM was applied to consolidate the effect value. Fig. 2.A shows that the weight gain in the FCC group was significantly higher than that in the SC group (MD, 4.57; 95% CI, 2.80–6.34; $P < 0.001$).

The hospital length of stay was reported in seven studies, five English and two Chinese.[16,18,19,25,31,33,34] The studies were heterogeneous, confirmed by the heterogeneity test (I^2 = 100%, τ^2 = 49.38, χ^2 = 2002.91, P = 0.0). The REM was used to consolidate effect value. The pooled MD = −3.73 (95% CI, −9.25 to 1.79) (Fig. 2.B), showing that the hospital length of stay in the FCC group was shorter than that in the SC group, but not significant (P = 0.185).

There were four studies reporting readmission rates and the heterogeneity test resulted in homogeneity (I^2 = 0%, τ^2 = 0, χ^2 = 0.10, P = 0.992), and FEM was used.[21,29–31] The pooled OR = 0.23 (95% CI, 0.10–0.52) (Fig. 2.C). The readmission rate in the FCC group was significantly lower than that in the SC group ($P < 0.001$).

There are three Chinese studies (total n = 213) measuring behavioural outcomes using the same instrument, the neonatal behavioural neurological assessment. In brief, the neonatal behavioural neurological assessment scores in the FCC group were higher than those in the SC group, but not statistically significant (Data presented in detail in the Electronic Supplement Material 5).

3.5. Meta-analysis parent outcomes

Parent satisfaction was used as an outcome measure in only Chinese RCTs (n = 5).[27–31] The studies were homogeneous (I^2 = 0%, τ^2 = 0, χ^2 = 3.39, P = 0.494). Thus, FEM was applied to combine with the effect values. The pooled OR = 11.20 (95% CI, 4.76–26.34) represents that the odds of parent satisfaction (number satisfied/number not satisfied) in the FCC group was 11.2 times higher than that in the SC group (Fig. 3.A). The difference was statistically significant ($P < 0.001$).

Four Chinese studies with an educational FCC intervention measured the nursing skills of parents.[27,28,30,31] The skills were observed by a researcher, and it was unclear if they used the same instrument. Therefore, the SMD was used. These studies were not homogeneous (I^2 = 53%, τ^2 = 0.08, χ^2 = 6.36, P = 0.095). The REM and effect value were used. Fig. 3.B shows the pooled SMD = 2.57 (95% CI, 2.19–2.96), representing that the nursing skills of parents in the FCC group was higher than those of parents in the SC group ($P < 0.001$). The same studies also measured the knowledge of parents. Two of these studies used a similar survey to test the parental knowledge.[27,31] We were unable to obtain the questionnaires of the other two studies.[28,30] Therefore, SMD was applied in the meta-analysis. Heterogeneity test resulted that there was no heterogeneity between the studies (I^2 = 0%, τ^2 = 0, χ^2 = 0.36, P = 0.947); thus, we used FEM. Fig. 3.C shows the pooled SMD = 2.74 (95% CI: 2.47–3.00). The FCC group had more parental knowledge than the SC group ($P < 0.001$).

The meta-analyses of parental anxiety, depression, and stress are presented in detail in the Electronic Supplement Material 5. Parental anxiety was measured in three studies (two English and

Table 1
Characteristics of studies included in the systematic review.

Source and country	Design	Settings	Study participants	FCC intervention[1]	Outcome measures	Main outcomes	Quality
Melnyk et al. (2006) [16] USA	RCT	2 NICUs: A 52-bed NICU and a 60-bed NICU	138 intervention 109 control Infants with GA 26–34 weeks Parents: mothers and fathers. If fathers not involved in care, mothers could select a significant other to participate	COPE	Parents: - Trait Anxiety Inventory (A-Trait) - State Anxiety Inventory (A-State) - Beck Depression Inventory (BDI-II) - Parental Stressor Scale (PSS-NICU) - Index of Parent Behaviour-NICU (IPB) - Interaction with Infant-NICU (VAS-I) - Involvement in Infant Care-NICU (VAS-C) - Sensitivity to Needs of Infant-NICU (VAS-S) - Parental Beliefs Scale (PBS) Infants: - LOS NICU - LOS Hospital	Parents: - A-Trait at T1: NSD - A-State at T2: NSD - BDI at T2: NSD - PSS-NICU at T2: 1.78 vs 1.98 ($p = 0.03$) - IPB at T3: NSD - VAS-I at T3: NSD - VAS-C at T3: NSD - VAS-S at T3: NSD - PBS at T2: 66.57 vs 61.48 ($p < 0.001$) Infants: - LOS NICU: All infants: 31.86 vs 35.63 ($p \leq 0.05$) VLBW infants: 51.81 vs 60.12 ($p \leq 0.05$) - LOS Hospital: All infants: 35.29 vs 39.19 ($p \leq 0.05$) VLBW infants: 57.16 vs 65.03 ($p \leq 0.05$)	7/7
Glazebrook et al. (2007) [17] UK	Cluster RCT	6 NICUs	112 intervention 121 control Infants: GA <32 weeks Parents: mothers only	PBIP	Mothers: - Parenting Stress Index-Short Form (PSI-SF) - Nursing Child Assessment Teaching Scale (NCATS) Infants: - Neurobehavioural Assessment of the Preterm Infant (NAPI) - Home Observation for Measurement of the Environment (HOME) (subscale responsiveness only)	Parents: - PSI-SF: NSD - NCATS: NSD Infants: - NAPI z scores: NSD - HOME (responsiveness): NSD	6/7
Ortenstrand et al. (2010) [18] Sweden	RCT	2 NICUs	177 intervention 168 control Infants: GA <37 weeks Parents: at least 1 parent stay 24 h a day during entire hospital stay	FC ward	Infants: - LOS NICU - LOS Hospital - Morbidity: Sepsis, NEC, PDA, IVH, ROP, BPD, and severe morbidity	Infants: - LOS NICU: 13.3 vs 18.0 ($p = 0.02$) - LOS Hospital: 27.4 vs 32.8 ($p = 0.25$); but subgroup GA < 30 weeks 56.6 vs 66.7 ($p = 0.02$) - Moderate-to-severe BPD: 3% vs 11% (adjusted OR 0.18; 95% CI 0.04–0.8) - Other morbidities NSD	5/7
Chen et al. (2013) [19] Taiwan	RCT	3 NICUs	120 intervention CBIP group n = 57 HBIP group n = 63 58 control 62 term group Infants: GA <37 weeks Birth weight <1500 g Parents: mothers and fathers	CBIP HBIP	Infants: - Morbidity: LOS hospital, ventilation days, CPAP days, duration of oxygen use, PDA, Grade II IVH, mild-to-severe BPD, stage II -III ROP, and sepsis. - Growth: Enteral feeding, feeding desaturation, and weight gain. - Neurodevelopment: Neonatal Neurobehavioral Examination—Chinese version (NNE-C)	Infants: - Stage II–III ROP: 12% vs 15% ($p \leq 0.05$) - Other morbidities: NSD - Feeding desaturation: 3% vs 7% ($p \leq 0.05$) - Weight gain (g/d): 25.6 vs 23.7 ($p \leq 0.05$) - Enteral feeding: NSD - NNE-C: NSD	5/7
Weis et al. (2013) [20] Denmark	RCT	1 NICU: 38-bed NICU	74 intervention 60 control Infants: GA ≤34 weeks Parents: mothers and fathers	GFCC	Parents: - Parental Stressor Scale (PSS-NICU) - Nurse Parent Support Tool (NPST)	Parents: - PSS-NICU overall: NSD - PSS-NICU mothers vs fathers: 2.91 vs 2.58 ($p < 0.001$) - NPST: NSD	7/7
	RCT	1 NICU		FCC	Parents:	Parents:	0/7

(*continued on next page*)

Table 1 (*continued*)

Source and country	Design	Settings	Study participants	FCC intervention[1]	Outcome measures	Main outcomes	Quality
Bastani et al. (2015) [21] Iran			47 intervention 44 control Infants: GA 30–36 weeks Parents: mothers only		- Maternal satisfaction (self-designed) Infants: - Hospital readmission rate	- Satisfaction: 22.36 vs 59.28 ($p < 0.001$) Infants: - Readmission (1x): 2 vs 6 ($p = 0.04$)	
Clarke - Pounder et al. (2015) [22] USA	RCT	1 NICU	9 intervention 10 control Infants: GA 23–39 weeks Parents: not specified	N-DMT	Parents: - State-Trait Anxiety Inventory (STAI) - Family Inventory of Needs—Pediatrics (FIN-PED) - Decision-making tool for the neonatal intensive care unit (N-DMT)	Parents: All outcome measure: NSD	0/7
Verma et al. (2017) [32] India	RCT	1 NICU	148 intervention 147 control Infants: GA not specified (<42 weeks)	FCC	Infants: - Nosocomial infection rate (culture positive and negative) - LOS hospital - Mortality - Breastfeeding at discharge	Infants: - Nosocomial infection rate: NSD - LOS hospital: NSD - Mortality: NSD - Breastfeeding rate: 98% vs 119% ($p = 0.007$)	4/7
Yu et al. (2017) [33] Taiwan	RCT	3 NICUs	122 intervention 129 control Infants: GA <37 weeks and birth weight <1500 g Parents: not specified	FCIP	Infants: - Neonatal Neurobehavioral Examination–Chinese version (NNE-C) - Morbidity: duration oxygen use, sepsis, BPD, ROP, LOS hospital, and postmenstrual age (PA) at discharge - Feeding: time to full enteral feeding, feeding desaturation - Growth: daily weight gain from 36 to 40 weeks GA and weight/normalized weight (z) at term Parents: - Parental adherence to Intervention related to NNE-C and weight gain	Infants: - NNN-C total score: 71.5 vs 70.2 ($p < 0.05$) - Morbidity: NSD; PA at discharge (wks), 37.7 vs 38.3 ($p < 0.05$) - Feeding: PA to full enteral feeding (wks), 35.5 vs 36.6 ($p < 0.05$); feeding desaturation NSD - Growth: Weight gain (g/d), 40.0 vs 36.7 ($p < 0.05$); (z) NSD Parents: - Parental motivation in hospital positively associated with NNE-C (tone and motor) $r = 0.21$, $p = 0.02$; total scores at term age $r = 0.28$, $p = 0.002$ - Full FCIP goal achievement correlated with greater weight gain $r_{pb} = 0.31$, $p = 0.001$	5/7
O'Brien et al. (2018) [34] Canada, Australia, and New Zealand	Cluster RCT	26 NICUs	895 intervention 891 control Infants: GA ≤33 weeks Parents: not specified	FICare	Infants: - Weight gain, high-frequency breast-feeding at hospital discharge, NICU mortality, neonatal morbidities, and LOS hospital Parents: - Parental Stress Scale (PSS:NICU) - State-Trait Anxiety Index (STAI).	Infants: - Weight gain Z score at 21 days: 1.58 vs 1.45 (<0·0001) - Weight gain (g/d): 26.7 vs 24.8 (<0·0001) - High-frequency breastfeeding (>6 times/d) at discharge home: 70% vs 63% ($p = 0·016$) - LOS hospital: NSD - Mortality: NSD - Morbidities: NSD Parents: PSS:NICU day 21: 2.3 vs 2.5 ($p < 0·001$) STAI day 21: 70.8 vs 74.2 ($p = 0·0045$)	7/7
Zhao et al. (2008) [23] China	RCT	1 NICU	13 intervention 10 control Infants: GA 28–36 weeks Parents: mothers or fathers	FCC	Parents: - Self-Rating Depression Scale (SDS) - Self-Rating Anxiety Scale (SAS) Infants: - Weight gain, length, head circumference	Parents: - SDS significant at 40 weeks corrected age: 36.62 vs 43.10 ($p < 0.05$) - SAS is NSD Infants:	1/7

					- Neonatal Behavioural Neurological Assessment (NBNA)	- Weight gain (g/d): 23.45 vs 17.83 ($p < 0.05$) - Length and head circumference NSD - NBNA domain behaviour: 10.46 vs 9.30 ($p < 0.05$) other NBNA domains NSD	
Hou et al. (2012) [24] China	RCT	1 NICU	30 intervention 30 control 30 term group Infants: not specified Parents: not specified	FIC	Infants: - Neurodevelopment by Gesell Developmental Scale with domains gross motor, fine motor, language, social behaviour, and adaptation	Infants: - Gross motor: 91.97 vs 86.04 vs 93.85 ($p < 0.001$) - Fine motor: 88.97 vs 84.36 vs 93.48 ($p < 0.001$) - Language: 89.53 vs 82.30 vs 89.89 ($p < 0.001$) - Social behaviour: 92.81 vs 88.17 vs 95.50 ($p < 0.001$) - Adaptation: 95.47 vs 89.35 vs 95.89 ($p < 0.001$)	1/7
Ying et al. (2012) [25] China	RCT	1 NICU	50 intervention 50 control Infants: GA 27–35 weeks Parents: not specified	Developmental caring model	Infants: - LOS hospital - Weight gain - Sleep duration - Intake of milk	Infants: - Weight gain (g/d):18.5 vs 12.8 ($p < 0.01$) - Sleep duration (t/d):19.82 vs 16.71 ($p < 0.01$) - Intake of milk (ml): 50.2 vs 36.8 ($p < 0.01$) - LOS hospital: 18.50 vs 26.57 ($p < 0.01$)	5/7
Chang et al. (2013) [26] China	RCT	1 NICU	45 intervention 45 control Infants: GA 28–36 weeks Parents: not specified	FCC	Infants: - Weight gain, length, head circumference - Neonatal Behavioural Neurological Assessment (NBNA)	Infants: - Weight gain (g/d): 23.65 vs 17.86 ($p < 0.05$) - Length, head circumference: NSD - NBNA domain behaviour: 10.47 vs 9.32 ($p < 0.05$); other NBNA domains: NSD	1/7
Wang et al. (2013) [27] China	RCT	1 NICU	82 intervention 80 control Infants: GA 27–35 weeks Parents: mothers or fathers	PPN	Parents: - Parent knowledge and skills questionnaire - Parent satisfaction questionnaire - Attending follow-up clinics	Parents: - Knowledge: 82.5 vs 73.3 ($p < 0.05$) - Skills: 86.3 vs 72.5 ($p < 0.05$) - Satisfaction: 98.78% vs 72.50% ($p < 0.05$) - Number of follow-up visits: 84.14 vs 43.75 ($p < 0.05$)	3/7
Wang et al. (2015) [28] China	RCT	1 NICU	50 intervention 50 control Infants: GA 28–36 weeks Parents: not specified	FCC	Parents: - Parent knowledge and skills questionnaire - Parent satisfaction questionnaire Infant: - Weight gains, length, and head circumference - Neonatal Behavioural Neurological Assessment (NBNA)	Parents: - Knowledge: 91.61 vs 68.78 ($p < 0.05$) - Skills: 92.37 vs 66.45 ($p < 0.01$) - Satisfaction: 98.12% vs 76.37% ($p < 0.05$) Infants: - Weight gain (g/d): 26.34 vs 18.73 ($p < 0.05$) - Length and head circumference: NSD - NBNA domain behaviour: 12.38 vs 9.69 ($p < 0.01$) other domains NSD	1/7
Kang et al. (2016) [29] China	RCT	1 NICU	48 intervention 48 control Infants: GA 28–32 weeks Parents: not specified	FIC	Parents: - Parent satisfaction questionnaire Infants: - Sleep quality - Weight gain - Visiting follow-up clinics - Rate of pure breastfeeding - Readmission	Parents: - Satisfaction: 95.83% vs 79.17% ($p < 0.05$) Infants: - Sleep quality (h/d): 19 vs 15 ($p < 0.05$) - Weight gain (g/w): 138.1 vs 96 ($p < 0.05$)	1/7

(*continued on next page*)

Table 1 (*continued*)

Source and country	Design	Settings	Study participants	FCC intervention[1]	Outcome measures	Main outcomes	Quality
						- Visiting follow-up clinics: 95.83% vs 68.75% ($p < 0.05$) - Rate of pure breastfeeding: 72.92 vs 52.08 ($p < 0.05$) - Readmission rates: 4.17 vs 16.67 ($p < 0.05$)	
Li et al. (2016) [30] China	RCT	1 NICU	23 intervention 23 control Infants: GA 28–34 weeks Parents: not specified	FIC	Parents: - Parent knowledge and skills questionnaire - Parent satisfaction questionnaire Infants: - Readmission	Parents: - Knowledge: 89.72 vs 76.63 ($p < 0.05$) - Skill: 85.54 vs 73.52 ($p < 0.05$) - Satisfaction: 98.83% vs 93.67% ($p < 0.05$) Infants: - Readmission: 0 vs 8.7 ($p < 0.05$)	4/7
Xiao et al. (2016) [31] China	RCT	1 NICU	65 intervention 65 control Infants: not specified Parents: mothers or fathers	FIC	Parents: - Parent knowledge and skills questionnaire - Parent satisfaction questionnaire Infants: - Weight gains, length, and head circumference - LOS hospital - Readmission	Parents: - Knowledge: 83.32 vs 74.03 ($p < 0.05$) - Skill: 87.16 vs 73.23 ($p < 0.05$) - Satisfaction: 98.46% vs 86.15% ($p < 0.05$) Infants: - Weight gain (g/day): 26.34 vs 18.73 ($p < 0.05$) - Length (cm): 54.76 vs 53.45 ($p < 0.05$) - Head circumference (cm): 37.16 vs 35.96 ($p < 0.05$) - LOS hospital: 24.78 vs 25.46 ($p = 0.742$) Readmission: 3 vs 10 ($p < 0.05$)	4/7

[1] For intervention details, see Electronic Supplement Material 3: Characteristics of family-centred care interventions; BPD = broncopulmonary dysplasia; CBIP = clinic-based intervention program; CI = confidence interval; COPE = Creating Opportunities for Parent Empowerment; CPAP = Continuous Positive Airway Pressure; FC = family care; FCC = family-centred care; FCIP = Family-Centered Intervention Program; FIC = family-integrated care; GA = gestational age; GFCC = guided family-centred care; HBIP = Home-Based Intervention Program; IVH = intraventricular haemorrhage; LOS = length of stay; NBNA = neonatal behavioural neurological assessment; N-DMT = decision-making tool for the neonatal intensive care unit; NEC = necrotising enterocolitis; NICU = neonatal intensive care unit; NSD = no significant difference; OR = odds ratio; PBIP = Parent Baby Interaction Programme; PDA = patent ductus arteriosus; PPN = parent participation in nursing; RCT = randomised controlled trial; ROP = retinopathy of prematurity; VLBW = very low birth weight.

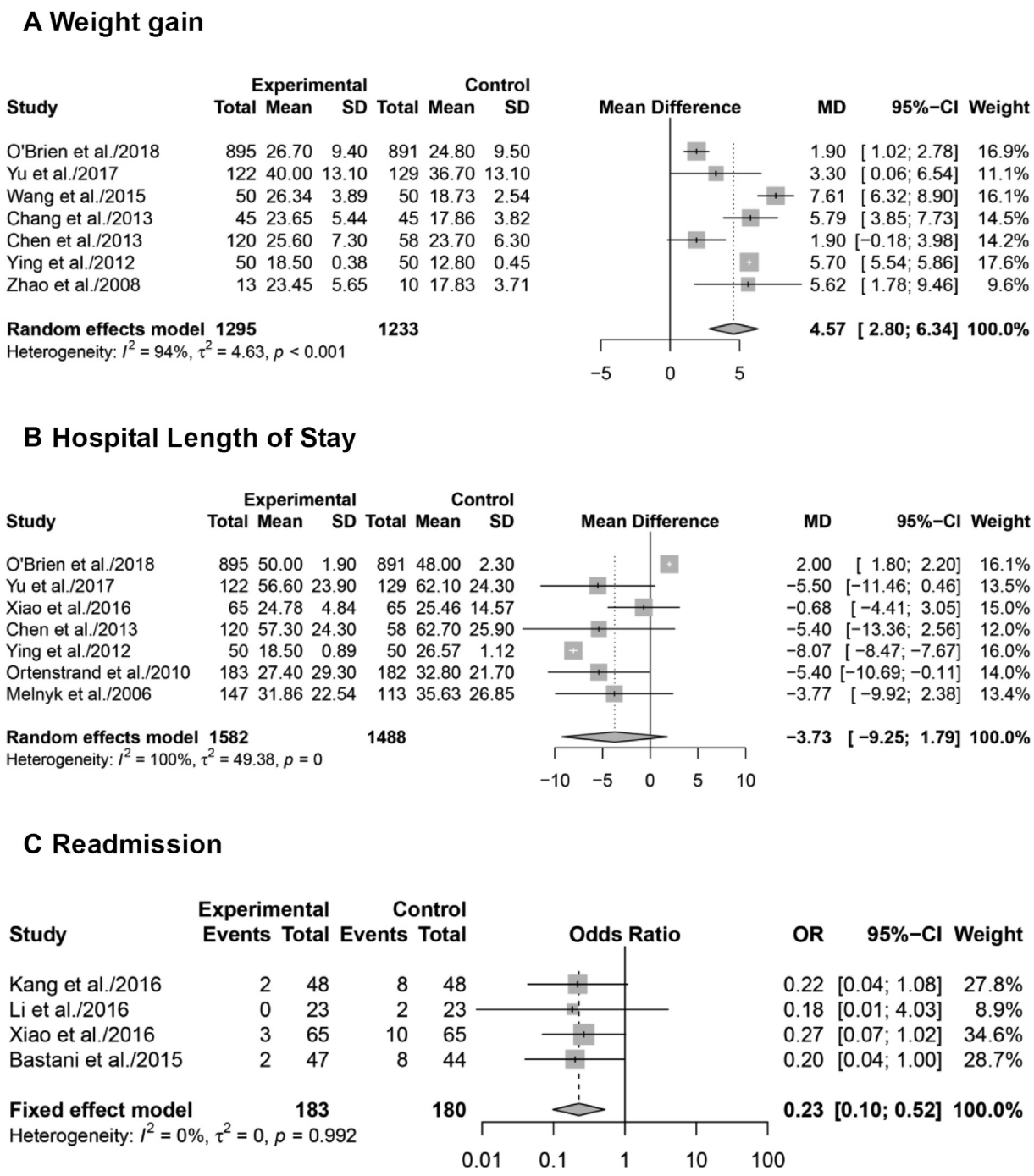

Fig. 2. Forest plots of infant clinical outcomes; (A) weight gain; (B) hospital length of stay; (C) readmission.

one Chinese).[16,23,34] Two studies used the State Trait Anxiety Inventory index,[16,34] and one study, the Self-Rating Anxiety Scale.[23] In brief, at follow-up (time point 3), the parents in the FCC group showed significantly less anxiety than those in the SC group (Electronic Supplement Material 5). Parental depression was measured by two studies using the Self-Rating Depression Scale and the Beck Depression Inventory.[16,23] In brief, at follow-up (time point 3), the FCC group had significantly less depression than those in the SC group (Electronic Supplement Material 5). Parental stress was measured in three studies using the Parental Stressor Scale:-neonatal intensive care unit.[16,20,34] Stress in the FCC group was significantly lower than that in the SC group (Electronic Supplement Material 5).

4. Discussion

This systematic review and meta-analysis identified 19 RCTs testing FCC interventions. Various FCC interventions were described, mostly related to education and training of parents followed by active involvement and participation in care. Surprisingly, the studies did not clearly define SC received by the control group. All studies provided data that support a positive association between the intervention and at least one outcome measure. Our meta-analysis confirmed that FCC interventions are associated with improved clinical outcomes of infants and parent-reported outcomes. In terms of publication date, eight out of nine Chinese RCTs were from the past six years, possibly indicating that there is an

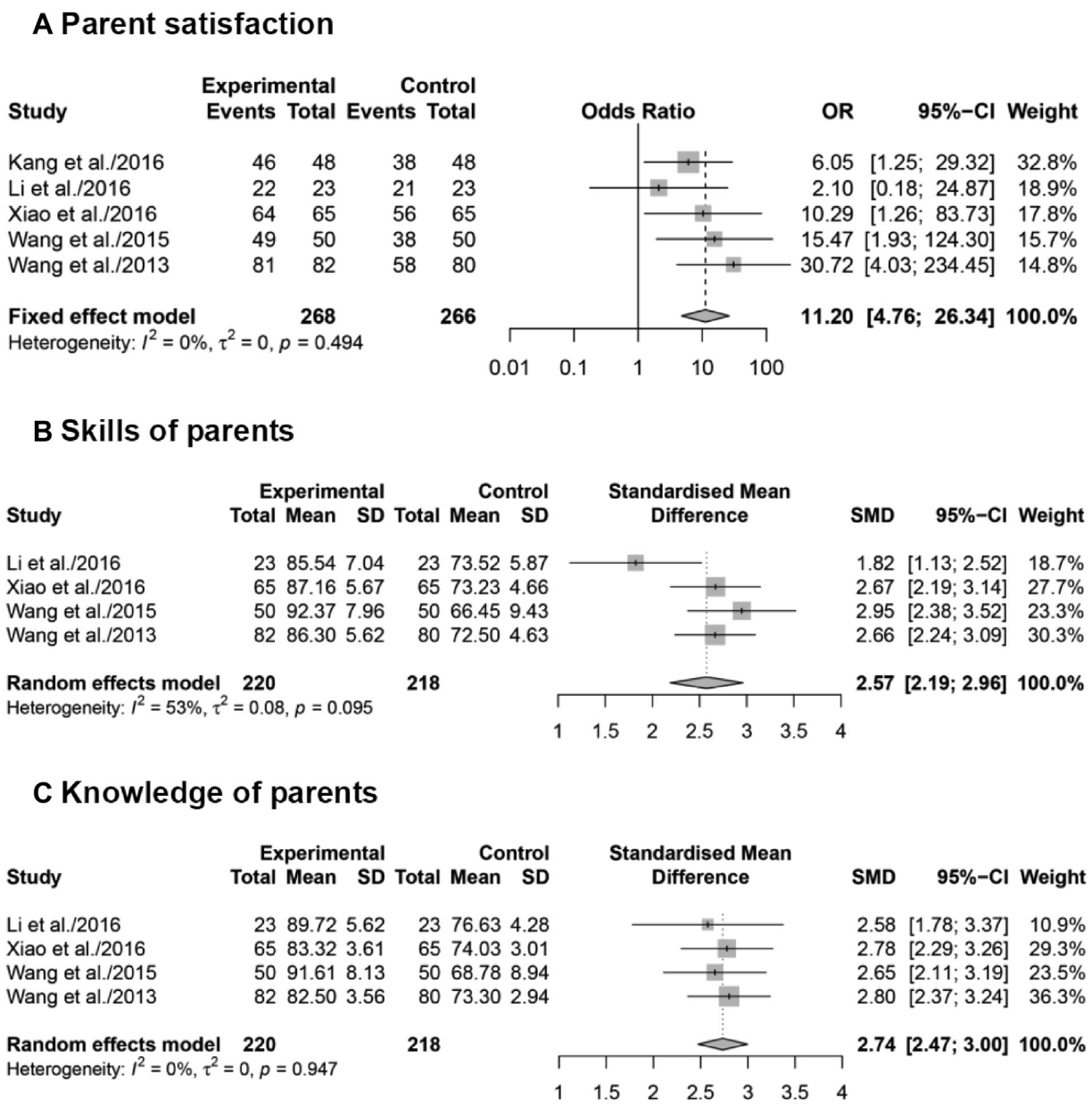

Fig. 3. Forest plots of parent-reported outcomes; (A) parent satisfaction; (B) skills of parents; (C) knowledge of parents.

increased interest in implementing FCC practices in Chinese NICUs. However, the publication date of the English RCTs (seven out of 10 published in the last six years) did not differ much from that of the Chinese RCTs, considering that FCC has been a model of care in NICUs for some decades in many parts of the developed world. Overall, in the past six years, there seems to be an increased interest to implement and test the effect of FCC interventions in Chinese and non-Chinese NICUs.

Although FCC is an accepted care model in many NICUs, our systematic review revealed that there is no uniform approach with FCC interventions. Recently, an international group of experts tried to define eight principles for patient-centred and FCC in NICUs.[12] The principles, such as 24-h access, psychological support, supportive environment, and other basic caring procedures, provide NICU clinicians guidance to deliver care according to the infants and family needs. In our review, most RCTs have designed and tested an FCC intervention related to education/information for parents and their active involvement in care and decision-making. The heterogeneity of the interventions might implicate the difficulty in confirming that FCC as a practice model in NICUs is beneficial to preterm infants and their parents. FCC as a concept is responsible for the improvements seen, or given the heterogeneity observed, some aspects of FCC are efficacious, and others are not. The fact that some outcomes displayed heterogeneity and other not may suggest both possibilities are correct depending on the outcome. In addition, the reality remains that FCC is not yet fully accepted in many NICUs across the world. For example, many NICUs in China do not welcome parents to visit their infant. However, in the past five years, several Chinese NICUs are becoming more flexible in visiting hours and allowing parents to become involved in the care.[35] Evidence suggests that European NICUs also have limited visiting hours such as in Spain, Italy, and France, and most NICUs have restrictions to parental presence during rounds or procedures.[36] Implementing FCC can be challenging for clinicians. A study in 11 NICUs in Europe identified that the lowest rated principles of FCC were emotional support, parental involvement in

decision-making, and fathers' involvement in care.[37] Guidelines are available and might help NICU clinicians in further developing and implementing FCC practices.[38]

Only one RCT performed subgroup analysis according to gestational age.[18] In this study, hospital length of stay was not significantly different between FCC and SC groups for the total study population. However, within infants with gestational age <30 weeks (n = 20; total n = 183), the FCC group appeared to have a significantly shorter length of stay than the SC group using the mean (95% CI) and median (25^{th}–75th) in their parametric and nonparametric analysis. This study suggests that FCC interventions may result in a shorter length of stay for premature infants with a gestational age <30 weeks. Future studies may benefit from considering subgroup analysis based on gestational age.

The results of our meta-analysis provide evidence that FCC interventions might improve infants' clinical outcomes. The analysis included only RCTs, but other studies with other study designs have reported similar clinical outcomes.[39–41] A currently ongoing large international trial is the family-integrated care study initiated by colleagues in Canada.[42] Part of this trial is recently published and included in this review,[34] and the trial is currently expanding in China.[43] In their pilot cohort study, the authors reported a significant increase in weight gain in the intervention group (n = 31) compared with the matched control group (n = 62).[44] Other significantly improved clinical outcomes were retinopathy of prematurity stage 3 and breastfeeding.

A few limitations need to be addressed. Although articles are available using other study methods, we only included RCT studies. This might have limited the results of the meta-analysis. However, 15 of the 19 included articles were used in the meta-analysis. The total number of studies included in the meta-analysis of the individual outcome measures was limited between two and seven studies. Furthermore, several articles were limited by the reporting quality, failing to describe several bias effects. We did not exclude poor-quality RCTs from the meta-analysis. This might influence the overall outcomes presented in this review. Finally, the meta-analysis of the hospital length of stay must be interpreted with caution. The data of the included RCTs were likely to be skewed, which can question the validity of the presented statistical tests. Ideally, this meta-analysis should be performed with the geometric mean.[15] However, we did not obtain the raw data from the authors of the articles but instead used the reported mean and standard deviation of the hospital length of stay.

The implication for clinical practice of our results can be translated to some recommendations. NICUs with limited FCC practices should start implementing FCC with interventions related to education of parents and encourage them to become actively involved in the care of their infant. NICUs with advanced FCC practices should consider using standardised parent-reported outcome measures such as a validated parent satisfaction questionnaire.[45] Studies evaluating FCC interventions in NICUs reported many different outcomes measures. Our review demonstrated the variation and possible limitations of studies when comparing or combining the findings. Using a core outcome set for FCC intervention studies is recommended, and it is hoped that such outcome sets become available in the near future.[46] Our review strengthens the evidence of the principles of patient- and family-centred care in the NICU.[12] Five of the described principles are related to patient-centred care, namely, pain management, postural support, skin-to-skin care, breastfeeding, and sleep protection.[12] The other three principles are related to FCC, namely, 24-h unlimited access, psychological support, and NICU environment. In 16 identified FCC interventions, the patient-centred care principles were included in the parent education programs. This strengthens the recommendation that NICU clinicians should consider to include issues of pain management, positioning, skin-to-skin care, breastfeeding, promotion of sleep, and supportive environment in their parent education programs. The FCC principle of 24-h access[12] is essential to all FCC interventions and should be promoted by all NICUs. Psychological support[12] should be provided to parents throughout the NICU admission. However, it is recommended to identify standardised outcome measures to assess stress, anxiety, and depression, including a general agreement about uniform time points of the measurements, because our review identified a variety of measurement instruments and time points.

To our knowledge, this is the first systematic review and meta-analysis of FCC interventions in NICU settings. The novelty of our review is based on the inclusion of RCTs published in Chinese journals, representing a large part of the world. However, we acknowledge that we have not included RCTs published in Spanish or Portuguese journals, which represents another large part of the world. Only one meta-analysis of FCC interventions in adult intensive care settings has been identified in a recent review.[49] Their review used the FCC definition of the Institute of Medicine including respect of patients, information, education, access to care, emotional support, family involvement, continuity of care, physical support, and coordination of care. The authors of this adult intensive care article identified 32 different FCC interventions in the 46 included studies.[47] Similar to our review, their review also reported heterogeneous outcome measures.

In conclusion, several FCC interventions have been identified and tested by a variety of outcome measures. The FCC interventions of RCTs performed in China were mostly related to parental education followed by their involvement and participation in the basic care. The RCTs published in the English literature tested FCC interventions related to education, information, and communication tools or a new NICU environment with separate family rooms in the NICU. The outcome measures in the RCTs were heterogeneous using a wide variety of preterm infants' clinical outcomes and parent-reported outcomes. This meta-analysis revealed that the tested FCC interventions improved the infant's weight gain and readmission rates. The FCC interventions also improved the parent-reported outcomes, parent satisfaction, skills, and knowledge. Follow-up data revealed that anxiety, depression, and stress of parents can be improved after an FCC intervention. The meta-analysis of the neurobehavioural development tested with three studies indicated no statistically significant differences. No benefits for infants were observed in the meta-analysis regarding hospital length of stay; however, as stated in the limitations, this needs to be concluded with caution. Nearly half of the included RCTs were of low quality, leading to some caution of interpreting the meta-analysis results. More high-quality studies are needed to further evaluate the impact of FCC practices in NICUs. Developing standardised FCC interventions and core outcome measures will benefit studies and enable future comparison of the clinical effectiveness of FCC interventions. This will enhance the evidence base for FCC practices in preterm infants and their parents.

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Authors' contributions

Xiang Ding contributed to the development of the review proposal, searches of databases, data collection, data analysis, and

interpretation; wrote the first draft of the manuscript and the revised version; approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Li-hui Zhu** contributed to the development of the review proposal; ensures funding support for the project; reviewed and approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Rong Zhang** contributed to the development of the review proposal, searches of databases, data collection, data analysis, and interpretation; reviewed and approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Wang Li** contributed to the development of the review proposal; reviewed and approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Ting-Ting Wan** contributed to the development of the review proposal, data collection, and data analysis; contributed in writing the first draft of the manuscript and reviewed and approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. **Jos M. Latour** contributed to the development of the review proposal, searches of databases, data collection, data analysis, and interpretation; contributed in writing the first draft of the manuscript and the revised version; reviewed and approved the final and revised version for submission; and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2018.10.007.

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