Supplementary files for:

Characteristics of intervention studies on family-centred care in neonatal intensive care units: a scoping review of randomised controlled trials

Supplemental File 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist*

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	6
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	6
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	7
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7-9
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Supplemental file 2
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8-9
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	9-10
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	9-10
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	-
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	Figure 1

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Supplemental file 4
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	-
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	Supplemental file 4
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	10-16
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	17-19
Limitations	20	Discuss the limitations of the scoping review process.	19
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	17-18
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	20

Notes: * Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

Reference: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Abbreviations: JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

Supplemental File 2. Search strategy

1. PUBMED

((((((((((((((((((((((((((("Family"[Mesh]) OR (famil*)) OR ("Nuclear Family"[Mesh])) OR ("Fathers"[Mesh])) OR (father*)) OR (paternal)) OR ("Mothers"[Mesh])) OR (mother*)) OR (maternal)) OR ("Parents"[Mesh])) OR (parent*)) OR ("Siblings"[Mesh])) OR (sibling*)) OR (sister*)) OR (brother*)) OR ("Caregivers"[Mesh])) OR (caretaker*)) OR (caregiver*)) OR ("Legal Guardians"[Mesh])) OR ("legal custodian*")) OR ("legal tutor*")) OR ("legal guardian*")) OR (guardian*)) OR ("spouses"[MeSH Terms])) OR (spouses)) OR (couple*)) OR (marital)) OR (partner)) OR (partners)) OR (kins)) OR (relatives))
AND ((((((((((("Infant, Newborn"[Mesh]) OR ("Infant, Newborn, Diseases"[Mesh])) OR (newborn*)) OR (new-born*)) OR (neonat*)) OR (infant*)) OR (baby)) OR (babies)) OR (prematur*)) OR (preterm*))
AND ((((((((((((("Intensive Care Units"[Mesh]) OR ("Intensive Care Units, Neonatal"[Mesh])) OR ("intensive care")) OR (ICU)) OR (ICUs)) OR (NICU)) OR ("special care")) OR (SCBU)) OR ("neonatal unit*")) OR ("neonatal unit*")) OR ("Critical Care"[Mesh])) OR ("critical care")) OR ("kangaroo unit*")) OR ("semi-intensive")))
AND ((((((((((((((((((((((((((((((((((((intervention*) OR (environment*)) OR ("Health Facility Environment"[Mesh])) OR (Health Facility Environment)) OR (Health Care Environment)) OR (reorganis*)) OR (reorganiz*)) OR ("Parent-Child Relations"[Mesh])) OR (interact*)) OR ("Policy"[Mesh])) OR (policy)) OR (policies)) OR ("Family Nursing"[Mesh])) OR (family nursing)) OR (integrat*)) OR (centred)) OR (centered)) OR (participat*)) OR (involv*)) OR (engage*)) OR (decision making)) OR (care decision)) OR ("partnership")) OR ("care delivery")) OR ("Patient Participation"[Mesh])) OR (collaborat*)) OR ("Communication"[Mesh])) OR (communicat*)) OR ("Education"[Mesh])) OR (educat*)) OR (lesson*)) OR ("Social Support"[Mesh])) OR (support*)) OR ("parent-to-parent")) OR ("Peer to peer") OR (empower*)) OR ("Personal Satisfaction"[Mesh])) OR ("Patient Satisfaction"[Mesh])) OR (satisf*)) OR (bond*)) OR ("Stress Disorders, Traumatic"[Mesh])) OR (Stress*))
AND ((((((((((((("Randomized Controlled Trial" [Publication Type]) OR ("Randomized Controlled Trial*")) OR ("Randomised Controlled Trial*")) OR (RCT)) OR (RCTs)) OR (randomized)) OR (randomised)) OR (randomly)) OR ("Controlled Clinical Trial*")) OR ("Controlled Clinical Trial" [Publication Type])) OR ("randomized Trial*")) OR ("randomised Trial*")) OR ("randomised clinical trial*") OR ("randomized clinical trial*"))

Filter: humans

2. EMBASE

("Family"/exp OR famil* OR "Father"/exp OR father* OR paternal OR "Mother"/exp OR mother* OR maternal OR parent* OR sibling* OR sister* OR brother* OR "Caregiver"/exp OR caretaker* OR caregiver* OR "Legal Guardian"/exp OR "legal custodian*" OR "legal tutor*" OR "legal guardian*" OR guardian* OR spouses OR couple* OR marital OR partner OR partners OR kins OR relatives)
AND (("Infant"/exp OR newborn* OR new-born* OR neonat* OR infant* OR baby OR babies OR prematur* OR preterm*)
AND ("Intensive Care"/exp OR "intensive care" OR ICU OR ICUs OR NICU OR "special care" OR SCBU OR "neonatal unit*" OR "neonatal unit*" OR "critical care" OR "kangaroo unit*" OR "semi-intensive"))
AND (intervention* OR environment* OR Health Facility Environment OR Health Care Environment OR reorganis* OR reorganiz* OR "child parent relation"/exp OR interact* OR "Policy"/exp OR policy OR policies OR "Family Nursing"/exp OR family nursing OR integrat* OR centred OR centered OR participat* OR involv* OR engage* OR decision making OR care decision OR "partnership" OR "care delivery" OR "Patient Participation"/exp OR collaborat* OR " interpersonal communication"/exp OR communicat* OR "Education"/exp OR educat* OR lesson* OR "Social Support"/exp OR support* OR "parent-to-parent" OR "Peer to peer" OR empower* OR "Satisfaction"/exp OR satisf* OR bond* OR "physiological Stress"/exp OR Stress*)
AND ("Randomized Controlled Trial"/exp OR "Randomized Controlled Trial*" OR "Randomised Controlled Trial*" OR RCT OR RCTs OR randomized OR randomised OR randomly OR "Controlled Clinical Trial*" OR "Controlled Clinical Trial"/exp OR "randomized Trial*" OR "randomised Trial*" OR "randomised clinical trial*" OR "randomized clinical trial*")

3. COCHRANE LIBRARY
(famil* OR father* OR paternal OR mother* OR maternal OR parent* OR sibling* OR sister* OR brother* OR caretaker* OR caregiver* OR "legal custodian*" OR "legal tutor*" OR "legal guardian*" OR guardian* OR spouses OR couple* OR marital OR partner OR partners OR kins OR relatives) AND ((newborn* OR new-born* OR neonat* OR infant* OR baby OR babies OR prematur* OR preterm*) AND ("intensive care" OR ICU OR ICUs OR NICU OR "special care" OR SCBU OR "neonatal unit*" OR "neonatal unit*" OR "critical care" OR "kangaroo unit*" OR "semi-intensive")) AND (intervention* OR environment* OR “Health Facility Environment” OR “Health Care Environment” OR reorganis* OR reorganiz* OR "child parent relation" OR interact* OR policy OR policies OR “family nursing” OR integrat* OR centred OR centered OR participat* OR involv* OR engage* OR “decision making” OR “care decision” OR "partnership" OR "care delivery" OR collaborat* OR communicat* OR educat* OR lesson* OR support* OR "parent-to-parent" OR "Peer to peer" OR empower* OR satisf* OR bond* OR Stress*) AND ("Randomized Controlled Trial*" OR "Randomised Controlled Trial*" OR “RCT” OR “RCTs” OR randomized OR randomised OR randomly OR “Controlled Clinical Trial*” OR "randomized Trial*" OR "randomised Trial*" OR "randomised clinical trial*" OR "randomized clinical trial*")
4. WEB OF SCIENCE
famil* OR father* OR paternal OR mother* OR maternal OR parent* OR sibling* OR sister* OR brother* OR caretaker* OR caregiver* OR "legal custodian*" OR "legal tutor*" OR "legal guardian*" OR guardian* OR spouses OR couple* OR marital OR partner OR partners OR king OR relatives (All Fields) and ((newborn* OR new-born* OR neonat* OR infant* OR baby OR babies OR prematur* OR preterm*) AND ("intensive care" OR ICU OR ICUs OR NICU OR "special care" OR scab OR "neonatal unit*" OR "neonatal unit*" OR "critical care" OR "kangaroo unit*" OR "semi-intensive")) (All Fields) and intervention* OR environment* OR “Health Facility Environment” OR “Health Care Environment” OR reorganis* OR reorganiz* OR "child parent relation" OR interact* OR policy OR policies OR “family nursing” OR integrat* OR centred OR centered OR participat* OR involv* OR engage* OR “decision making” OR “care decision” OR "partnership" OR "care delivery" OR collaborat* OR communicat* OR educat* OR lesson* OR support* OR "parent-to-parent" OR "Peer to peer" OR empower* OR satisf* OR bond* OR Stress* (All Fields) and "Randomized Controlled Trial*" OR "Randomised Controlled Trial*" OR “RCT” OR “RCTs” OR randomized OR randomised OR randomly OR “Controlled Clinical Trial*” OR "randomized Trial*" OR "randomised Trial*" OR "randomised clinical trial*" OR "randomized clinical trial*" (All Fields)

Supplemental File 3. List of included studies	
Abdel Latif 2015	Abdel Latif 2015: Abdel-Latif ME, Boswell D, Broom M, et al Parental presence on neonatal intensive care unit clinical bedside rounds: randomised trial and focus group discussion Archives of Disease in Childhood - Fetal and Neonatal Edition 2015;100:F203-F209.
Affleck 1989	Affleck G, Tennen H, Rowe J, Roscher B, Walker L. Effects of formal support on mothers' adaptation to the hospital-to-home transition of high-risk infants: the benefits and costs of helping. Child Dev. 1989 Apr;60(2):488-501. doi: 10.1111/j.1467-8624.1989.tb02730.x. PMID: 2494024.
Al-Maghaireh 2020	Al-Maghaireh, D.F., Khalaf, I.A., Abdullah, K.L., Chan, C.M., Basyoun, N.R., & Kawafha, M.M. (2020). The effect of an emotional support training program on acute stress disorder among mothers of preterm infants hospitalized in neonatal intensive care units. Journal of Neonatal Nursing, 26, 273-277. https://doi.org/10.1016/j.jnn.2020.06.003.
Alijanzadeh Zaferani 2021	Alijanzadeh Zaferani, S. F., Zabihi, A., Jafarian-Amiri, S. R., Akbarian-Rad, Z., & Hajian, K. A. (2021). Evaluating the Effect of Positive Touch on Moods of Mothers of Premature Infants Hospitalized in NICU: A Randomized Clinical Trial. Iranian Journal of Psychiatry and Behavioral Sciences, 15(3). doi:10.5812/ijpbs.109251
Als 1994	Als H, Lawhon G, Duffy FH, McAnulty GB, Gibes-Grossman R, Blickman JG. Individualized developmental care for the very low-birth-weight preterm infant. Medical and neurofunctional effects. JAMA. 1994 Sep 21;272(11):853-8. PMID: 8078162.
Als 2003	Als H, Gilkerson L, Duffy FH, McAnulty GB, Buehler DM, Vandenberg K, Jones KJ. A three-center, randomized, controlled trial of individualized developmental care for very low birth weight preterm infants: Medical, neurodevelopmental, parenting, and caregiving effects. Journal of Developmental & Behavioral Pediatrics. 2003; 24(6):399–408.
Als 2004	Als H, Duffy FH, McAnulty GB, Rivkin MJ, Vajapeyam S, Mulkern RV, Warfield SK, Huppi PS, Butler SC, Conneman N, Fischer C, Eichenwald EC. Early experience alters brain function and structure. Pediatrics. 2004 Apr;113(4):846-57. doi: 10.1542/peds.113.4.846. PMID: 15060237.
Als 2011	Als H, Duffy FH, McAnulty GB, et al. (2011) Is the newborn individualized developmental care and assessment program (NIDCAP) effective for preterm infants with intrauterine growth restriction? Journal of Perinatology 31: 130–136. (NIDCAP)
Als 2012	Als 2012: Als H, Duffy FH, McAnulty G, Butler SC, Lightbody L, Kosta S, Weisenfeld NI, Robertson R, Parad RB, Ringer SA, Blickman JG, Zurakowski D, Warfield SK. NIDCAP improves brain function and structure in preterm infants with severe intrauterine growth restriction. J Perinatol. 2012 Oct;32(10):797-803. doi: 10.1038/jp.2011.201. Epub 2012 Feb 2. PMID: 22301525; PMCID: PMC3461405.
Andrews 2020	Andrews KG, Martin MW, Shenberger E, Pereira S, Fink G, McConnell M. Financial Support to Medicaid-Eligible Mothers Increases Caregiving for Preterm Infants. Matern Child Health J. 2020 May;24(5):587-600. doi: 10.1007/s10995-020-02905-7. PMID: 32277384.
Ariagno 1997	Ariagno RL, Thoman EB, Boeddiker MA, Kugener B, Constantinou JC, Mirmiran M, Baldwin RB. Developmental care does not alter sleep and development of premature infants. Pediatrics. 1997 Dec;100(6):E9. doi: 10.1542/peds.100.6.e9. PMID: 9382910.

Bastani 2015	Bastani F, Abadi TA, Haghani H. Effect of family-centered care on improving parental satisfaction and reducing readmission among premature infants: a randomized controlled trial. J Clin Diagn Res 2015;9(1):SC04e8.
Beebe 2018	Beebe B, Myers MM, Lee SH, Lange A, Ewing J, Rubinchik N, Andrews H, Austin J, Hane A, Margolis AE, Hofer M, Ludwig RJ, Welch MG. Family nurture intervention for preterm infants facilitates positive mother-infant face-to-face engagement at 4 months. Dev Psychol. 2018 Nov;54(11):2016-2031. doi: 10.1037/dev0000557.
Beheshtipour 2014	Beheshtipour N, Baharlu SM, Montaseri S, RazavinezhadArdakani SM. The effect of the educational program on Iranian premature infants' parental stress in a neonatal intensive care unit: a double-blind randomized controlled trial. Int J Community Based Nurs Midwifery 2014, 2(4): 240-250
Benzies 2020	Benzies KM, Aziz K, Shah V, Faris P, Isaranuwatchai W, Scotland J, Larocque J, Mrklas KJ, Naugler C, Stelfox HT, Chari R, Soraisham AS, Akierman AR, Phillipos E, Amin H, Hoch JS, Zanoni P, Kurilova J, Lodha A; Alberta FICare Level II NICU Study Team. Effectiveness of Alberta Family Integrated Care on infant length of stay in level II neonatal intensive care units: a cluster randomized controlled trial. BMC Pediatr. 2020 Nov 28;20(1):535. doi: 10.1186/s12887-020-02438-6. PMID: 33246430; PMCID: PMC7697372.
Bernard 2011	Bernard RS, Williams SE, Storfer-Isser A, Rhine W, Horwitz SM, Koopman C, Shaw RJ. Brief cognitive-behavioral intervention for maternal depression and trauma in the neonatal intensive care unit: A pilot study. Journal of Traumatic Stress. 2011; 24(2):230–234.
Borghini 2014	Borghini A, Habersaat S, Forcada-Guex M, Nessi J, Pierrehumbert B, Ansermet F, et al. Effects of an early intervention on maternal post-traumatic stress symptoms and the quality of mother–infant interaction: The case of preterm birth. Infant Behavior & Development 2014, 37(4): 624-631.
Brisch 2003	Brisch KH, Bechinger D, Betzler S, Heinemann H. Early preventive attachment-oriented psychotherapeutic intervention program with parents of a very low birthweight premature infant: results of attachment and neurological development. Attachment & Human Development. 2003; 5(2):120–135.
Browne 2005	Browne JV, Talmi A (2005) Family-based intervention to enhance infant parent relationships in the neonatal intensive care unit. J Pediatr Psychol 30:667–677.
Campbell-Yeo 2021	Campbell-Yeo M, Kim T, Disher T, Richardson B, Dol J, Bishop T, Delahunty-Pike A, Dorling J, Glover M, Inglis D, Johnson T, Macmillan D, Mcgrath P, Monaghan J, Orovec A, Simpson DC, Skinner N, Whitehead L, Wozney L; Chez NICU Home team in alphabetical order. Do Single-Family Rooms Increase Parental Presence, Involvement, and Maternal Well-Being in Neonatal Intensive Care? J Perinat Neonatal Nurs. 2021 Oct-Dec 01;35(4):350-361. doi: 10.1097/JPN.0000000000000600. PMID: 34726653.
Chen 2013	Chen LC, Wu YC, Hsieh WS, Hsu CH, Leng CH, Chen WJ, et al. The effect of inhospital developmental care on neonatal morbidity, growth and development of preterm Taiwanese infants: a randomized controlled trial. Early Hum Dev 2013;89(5):301e6.
Cheng 2019	Cheng C., Linda S. Franck, Xiang Y. Ye, Sarah A. Hutchinson, Shoo K. Lee & Karel O'Brienon behalf of the FICare Study Group and FICare Parent Advisory Board (2019): Evaluating the effect of Family Integrated Care on maternal stress and anxiety in neonatal intensive care units, Journal of Reproductive and Infant Psychology, DOI: 10.1080/02646838.2019.1659940

Church 2020	Church PT, Grunau RE, Mirea L, Petrie J, Soraisham AS, Synnes A, Ye XY, O'Brien K. Family Integrated Care (FICare): Positive impact on behavioural outcomes at 18 months. Early Hum Dev. 2020 Dec;151:105196. doi: 10.1016/j.earlhumdev.2020.105196.
Clarke-pounder 2014	Clarke-pounder JP, Boss RD, Roter DL, Hutton N, Larson S, Donohue PK. Communication intervention in the neonatal intensive care unit: can it backfire? J Palliat Med 2014;18(2):157e61.
Cobiella 1990	Cobiella CW, Mabe PA, Forehand RL. A comparison of two stress-reduction treatments for mothers of neonates hospitalized in a neonatal intensive care unit. Children's Health Care. 1990;19:93–100.
Colditz 2019	Colditz PB, Boyd RN, Winter L, Pritchard M, Gray PH, Whittingham K, O'Callaghan M, Jardine L, O'Rourke P, Marquart L, Forrest K, Spry C, Sanders MR. A Randomized Trial of Baby Triple P for Preterm Infants: Child Outcomes at 2 Years of Corrected Age. J Pediatr. 2019 Jul;210:48-54.e2. doi: 10.1016/j.jpeds.2019.01.024. Epub 2019 Mar 8. PMID: 30857773.
Dusing 2015	Dusing SC, Brown SE, Van Drew CM, Thacker LR, Hendricks-Muñoz KD. Supporting Play Exploration and Early Development Intervention From NICU to Home: A Feasibility Study. Pediatr Phys Ther. 2015 Fall;27(3):267-74. doi: 10.1097/PEP.0000000000000161. PMID: 26102168.
Dusing 2018	Dusing SC, Tripathi T, Marcinowski EC, Thacker LR, Brown LF, Hendricks-Muñoz KD. Supporting play exploration and early developmental intervention versus usual care to enhance development outcomes during the transition from the neonatal intensive care unit to home: a pilot randomized controlled trial. BMC Pediatr. 2018 Feb 9;18(1):46. doi: 10.1186/s12887-018-1011-4. PMID: 29426320; PMCID: PMC5809115.
Feeley 2012	Feeley N, Zelkowitz P, Shrier I, Stremler R, Westreich R, Dunkley D, et al. Follow-up of the Cues and Care Trial: mother and infant outcomes at 6 months. Journal of Early Intervention 2012, 34(2): 65-81.
Finlayson 2020	Finlayson F, Olsen J, Dusing SC, Guzzetta A, Eeles A, Spittle A. Supporting Play, Exploration, and Early Development Intervention (SPEEDI) for preterm infants: A feasibility randomised controlled trial in an Australian context. Early Hum Dev. 2020 Dec;151:105172. doi: 10.1016/j.earlhumdev.2020.105172. Epub 2020 Sep 1. PMID: 33137579
Fontana 2018	Fontana C, Menis C, Pesenti N, Passera S, Liotto N, Mosca F, Roggero P, Fumagalli M. Effects of early intervention on feeding behavior in preterm infants: A randomized controlled trial. Early Hum Dev. 2018 Jun;121:15-20. doi: 10.1016/j.earlhumdev.2018.04.016. Epub 2018 May 3. PMID: 29730130.
Fontana 2020	Fontana C, De Carli A, Ricci D, Dessimone F, Passera S, Pesenti N, Bonzini M, Bassi L, Squarcina L, Cinnante C, Mosca F, Fumagalli M. Effects of Early Intervention on Visual Function in Preterm Infants: A Randomized Controlled Trial. Front Pediatr. 2020 Jun 4;8:291. doi: 10.3389/fped.2020.00291. PMID: 32582595; PMCID: PMC7287146.
Fontana 2021	Fontana C, Marasca F, Provitera L, Mancinelli S, Pesenti N, Sinha S, Passera S, Abrignani S, Mosca F, Lodato S, Bodega B, Fumagalli M. Early maternal care restores LINE-1 methylation and enhances neurodevelopment in preterm infants. BMC Med. 2021 Feb 5;19(1):42. doi: 10.1186/s12916-020-01896-0. PMID: 33541338; PMCID: PMC7863536.

Fotiou 2016	Fotiou 2016: Fotiou C, Vlastarakos PV, Bakoula C, Papagaroufalis K, Bakoyannis G, Darviri C, Chrousos G. Parental stress management using relaxation techniques in a neonatal intensive care unit: A randomised controlled trial. Intensive Crit Care Nurs. 2016 Feb;32:20-8. doi: 10.1016/j.iccn.2015.08.006. PMID: 26520208.
Garfield 2016	Garfield CF, Lee YS, Kim HN, Rutsohn J, Kahn JY, Mustanski B, Mohr DC. Supporting Parents of Premature Infants Transitioning from the NICU to Home: A Pilot Randomized Control Trial of a Smartphone Application. Internet Interv. 2016 May;4(Pt 2):131-137. doi: 10.1016/j.invent.2016.05.004. Epub 2016 Jun 4.
Glazebrook 2007	Glazebrook C, Marlow N, Israel C, Croudace T, Johnson S, White IR, et al. Randomized trial of a parenting intervention during neonatal intensive care. Arch Dis Child Fetal Neonatal Ed 2007;92(6):438e43.
Gray 2000	Gray JE, Safran C, Davis RB, Pompilio-Weitzner G, Stewart JE, Zaccagnini L, Pursley D. Baby CareLink: using the internet and telemedicine to improve care for high-risk infants. Pediatrics. 2000 Dec;106(6):1318-24. doi: 10.1542/peds.106.6.1318. PMID: 11099583.
Hane 2015	Hane AA, Myers MM, Hofer MA, Ludwig RJ, Halperin MS, Austin J, Glickstein SB, Welch MG. Family nurture intervention improves the quality of maternal caregiving in the neonatal intensive care unit: evidence from a randomized controlled trial. J Dev Behav Pediatr. 2015 Apr;36(3):188-96. doi: 10.1097/DBP.0000000000000148. PMID: 25757070.
Harrison 1986	Harrison LL, Twardosz S. Teaching mothers about their preterm infants. J Obstet Gynecol Neonatal Nurs. 1986 Mar-Apr;15(2):165-72. doi: 10.1111/j.1552-6909.1986.tb01384.x.
Hauglann 2015	Hauglann L, Handegaard BH, Ulvund SE, Nordhov M, Rønning JA, Kaaresen PI. Cognitive outcome of early intervention in preterms at 7 and 9 years of age: a randomised controlled trial. Arch Dis Child Fetal Neonatal Ed. 2015 Jan;100(1):F11-6. doi: 10.1136/archdischild-2014-306496. Epub 2014 Sep 23. PMID: 25249191.
Hei 2021	Hei M, Gao X, Li Y, Gao X, Li Z, Xia S, Zhang Q, Han S, Gao H, Nong S, Zhang A, Li J, Wang Y, Ye XY, Lee SK. Family Integrated Care for Preterm Infants in China: A Cluster Randomized Controlled Trial. J Pediatr. 2021 Jan;228:36-43.e2. doi: 10.1016/j.jpeds.2020.09.006.
Heo 2019	Yoo Jin Heo, Won-Oak Oh, The effectiveness of a parent participation improvement program for parents on partnership, attachment infant growth in a neonatal intensive care unit: A randomized controlled trial, International Journal of Nursing Studies, Volume 95,2019, Pages 19-27, ISSN 0020-7489, https://doi.org/10.1016/j.ijnurstu.2019.03.018
Hoffenkamp 2015	Hoffenkamp HN, Tooten A, Hall RA, Braeken J, Eliëns MP, Vingerhoets AJ, van Bakel HJ. Effectiveness of hospital-based video interaction guidance on parental interactive behavior, bonding, and stress after preterm birth: A randomized controlled trial. J Consult Clin Psychol. 2015 Apr;83(2):416-29.
Holditch-Davis 2013	Holditch-Davis D, White-Traut R, Levy J, Williams KL, Ryan D, Vonderheid S. Maternal satisfaction with administering infant interventions in the neonatal intensive care unit. J Obstet Gynecol Neonatal Nurs. 2013 Nov-Dec;42(6):641-54. doi: 10.1111/1552-6909.12255. PMID: 25803213; PMCID: PMC4531372.

Holditch-Davis 2014	Holditch-Davis D, White-Traut RC, Levy JA, O'Shea TM, Geraldo V, David RJ. Maternally administered interventions for preterm infants in the NICU: effects on maternal psychological distress and mother–infant relationship. Infant Behav Dev. 2014;37:695-710.
Horwitz 2015	Horwitz SM, Leibovitz A, Lilo E, Jo B, Debattista A, St John N, Shaw RJ. Does an intervention to reduce maternal anxiety, depression and trauma also improve mothers' perceptions of their preterm infants' vulnerability? Infant Ment Health J. 2015 Jan-Feb;36(1):42-52. doi: 10.1002/imhj.21484. Epub 2014 Dec 1. Erratum in: Infant Ment Health J. 2015 May-Jun;36(3):352. PMID: 25452159; PMCID: PMC4413008.
Jafarzadeh 2019	Jafarzadeh Z, Maghsoudi, J., Barekatain, B., Marofi, M. Effect of Telenursing on Attachment and Stress in Mothers of Preterm Infants. Iranian Journal of Neonatology IJN, 2019; 10(1): 65-71. doi: 10.22038/ijn.2018.29890.1406
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Yilmaz 2021	Yilmaz 2021: Yilmaz G, Küçük Alemdar D. The Effect of Supportive Nursing Interventions on Reducing Stress Levels of Mothers of Infants in the Neonatal Intensive Care Unit: A Randomized Controlled Trial. Clin Nurs Res. 2021 Sep 24:10547738211047359. doi: 10.1177/10547738211047359.
Yu 2017	Yu, Y. T., Hsieh, W. S., Hsu, C. H., Lin, Y. J., Lin, C. H., Hsieh, S., … Yao, N. J. (2017). Family-centered care improved neonatal medical and neurobehavioral outcomes in preterm infants: Randomized controlled trial. Physical Therapy, 97(12), 1158–1168
Zelkovitz 2011	Zelkowitz P, Feeley N, Shrier I, Stremler R, Westreich R, Dunkley D, Steele R, Rosberger Z, Lefebvre F, Papageorgiou A. The cues and care randomized controlled trial of a neonatal intensive care unit intervention: effects on maternal psychological distress and mother-infant interaction. J Dev BehavPediatr. 2011 Oct;32(8):591-9.
Zeraati 2017	H. Zeraati, F. Nasimi,M. Milan Dalei, J. Shahinfar, A. Momenizade, A. Barfidokht. The Effect of Family-centered Care Program on Maternal Attachment in Mothers of Premature Infants. J Babol Univ Med Sci; 19(6); Jun 2017; PP: 22-7

Zhang 2018	Zhang 2018: Zhang R, Huang RW, Gao XR, Peng XM, Zhu LH, Rangasamy R, Latour JM. Involvement of Parents in the Care of Preterm Infants: A Pilot Study Evaluating a Family-Centered Care Intervention in a Chinese Neonatal ICU. Pediatr Crit Care Med. 2018 Aug;19(8):741-747. doi: 10.1097/PCC.0000000000001586. PMID: 29781955.

Supplemental File 4. Characteristics of included RCTs

Author and year of publication	Study design (pilot, long term extension)	Country	WB Level	Setting (n° of facilities involved)	Receivers of the intervention[1]		Health professionals		FCC components of the intervention	Interventions both in hospital and after discharge
					Parents (mothers [M], fathers [F])	Newborns (birth weight, gestational age)	Involved in the intervention delivery[2]	Involved as receiver of an educational intervention		
Abdel Latif 2015	Cross-over RCT	Australia	HIC	NICU (1)	72 parents (M, F)	NS	Yes	No	CI	No
Affleck 1989	RCT	USA	HIC	NICU (1)	94 parents (M, F)	NS (all infants admitted in NICU)	Yes	No	EDI	Yes
Alijanzadeh Zaferani 2021	RCT	Iran	L-MIC	NICU (2)	80 M	80 (all newborns admitted in NICU)	Yes	No	EDI	No
Al-Maghaireh 2020	RCT	Jordan	U-MIC	NICU (1)	50 M	50 (30-35 wks, NS)	Yes	No	EDI	No
Als 1994	RCT	USA	HIC	NICU (1)	NS	38 (<30 wks, <1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Als 2003	RCT	USA	HIC	NICU (3)	92 M	92 (< 28 wks, <1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Als 2004	RCT	USA	HIC	NICU (2)	NS	30 (28-33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Als 2011	RCT	USA	HIC	NICU (1)	30 parents (M, F)	30 (28-33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Als 2012	RCT	USA	HIC	NICU (1)	NS	30 (27-33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Andrews 2020	RCT	USA	HIC	NICU (2)	46 M	46 (30-36 wks, NS)	No	No	FSI	No
Ariagno 1997	RCT	USA	HIC	NICU (1)	NS	35 (<30 wks, <1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Bastani 2015	RCT	Iran	L-MIC	NICU (1)	110 M	110 (30-34 wks, NS)	Yes	No	EDI	No
Beebe 2018	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	71 M	71 (26–34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Beheshtipour 2014	RCT	Iran	L-MIC	NICU (1)	120 parents (60 M, 60 F)	60 (28-37 wks, NS)	Yes	No	EDI	No
Benzies 2020	RCT	Canada	HIC	NICU (10)	654 M	765 (32-34 wks, NS)	Yes	Yes	CI,EDI,FSI	No
Bernard 2011	RCT (pilot)	USA	HIC	NICU (1)	56 M	NS (<37wks, >1000g)	Yes	Yes	CI, EDI	No
Borghini 2014	RCT	Switzerland	HIC	NICU (1)	60 M	N 60 (<33 wks, NS)	Yes	Yes	EDI	Yes
Brisch 2003	RCT	Germany	HIC	NICU (1)	87 M	87 (24-35 wks, ≤1500g)	Yes	No	EDI, FSI	Yes
Browne 2005	RCT	USA	HIC	NICU (1)	84 M	84 (<36 wks, NS)	Yes	No	EDI	No
Campbell-Yeo 2021	RCT (single-centered)	Canada	HIC	NICU (1)	71 M	71 (<34 wks; NS)	No	No	ENI	No
Chen 2013	RCT	Taiwan	HIC	NICU (3)	NS	178 (NS, <1500gr) + 62 term control newborns	Yes	No	EDI	Yes
Cheng 2019	RCT (cluster, secondary publication of O'Brien 2018)	Canada, Australia, New Zealand	HIC	NICU (26)	1383 M	NS (≤33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Church 2020	RCT	Canada	HIC	NICU (14)	185 M	185 (≤33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Clarke-pounder 2014	RCT	USA	HIC	NICU (1)	19 parents (M, F)	19 (NO wks or weight restrictions)	Yes	No	CI	No
Cobiella 1990	RCT	USA	HIC	NICU (1)	30 M	30 (<36 wks, <2500g)	Yes	No	EDI	No

Colditz 2019	RCT	Australia	HIC	NICU (1)	323 parents (M, F)	384 (<32 wks, NS)	Yes	Yes	EDI	Yes
Dusing 2015	RCT (pilot)	USA	HIC	NICU (1)	NS	10 (≤34 wks, NS)	Yes	Yes	EDI	Yes
Dusing 2018	RCT (pilot)	USA	HIC	NICU (1)	NS	14 (<29 wks, NS)	Yes	Yes	EDI	Yes
Feeley 2012	RCT (long term extension of Zelkovitz 2011)	Canada	HIC	NICU (2)	121 M	121 (NS, <1500g)	Yes	Yes	EDI	Yes
Finlayson 2020	RCT (pilot)	Australia	HIC	NICU (1)	NS	17 (≤30 wks, NS)	Yes	Yes	EDI	Yes
Fontana 2018	RCT	Italy	HIC	NICU (1)	NS	70 (25-29+6 wks, NS)	Yes	No	EDI	Yes
Fontana 2020	RCT	Italy	HIC	NICU (1)	NS	57 (25+0 - 29+6 wks, NS)	Yes	No	EDI	Yes
Fontana 2021	RCT	Italy	HIC	NICU (1)	NS	34 (25-29+6 wks, NS)	Yes	No	EDI	Yes
Fotiou 2016	RCT	Greece	HIC	NICU (1)	84 parents (M, F)	NS (<37 wks, NS)	Yes	No	EDI	Yes
Garfield 2016	RCT (pilot)	USA	HIC	NICU (1)	82 parents (41 M, 41 F)	54 (NS, <1500 g)	No	No	EDI	Yes
Glazebrook 2007	RCT (crossover)	UK	HIC	NICU (6)	210 M	233 (<32 wks, NS)	Yes	Yes	EDI	Yes
Gray 2000	RCT	USA	HIC	NICU (1)	75 parents (M, F)	75 (NS, <1500g)	Yes	No	EDI	Yes
Hane 2015	RCT	USA	HIC	NICU (1)	65 M	65 (26-34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Harrison 1986	RCT	USA	HIC	NICU (2)	30 M	30 (28-35 wks, NS)	Yes	No	EDI	No
Hauglann 2015	RCT (long term extension of Kaaresen 2006)	Norway	HIC	NICU (1)	NS	146 (NS, <2000g)	Yes	Yes	EDI	Yes
Hei 2021	RCT (cluster)	China	U-MIC	NICU (11)	601 M	601 (28-35 wks, >400g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Heo 2019	RCT	South Korea	HIC	NICU (1)	132 parents (66 M, 66 F)	66 (<37 wks, NS)	Yes	No	CI, EDI	No
Hoffenkamp 2015	RCT	Netherlands	HIC	NICU (9)	294 parents (150 M,144 F)	150 (<37 wks, NS)	Yes	Yes	EDI	No
Holditch-Davis 2013	RCT	USA	HIC	NICU (4)	240 M	240 (NS, <1750g)	Yes	No	EDI	Yes
Holditch-Davis 2014	RCT (secondary publication of Holditch-Davis 2013)	USA	HIC	NICU (4)	240 M	240 (NS, < 1750g)	Yes	No	EDI	Yes
Horwitz 2015	RCT (secondary publication of Shaw 2013)	USA	HIC	NICU (4)	105 M	NS (25-34 wks, >600g)	Yes	Yes	EDI	No
Jafarzadeh 2019	RCT	Iran	L-MIC	NICU (1)	50 M	NS (33-37 wks, NS)	Yes	No	EDI, FSI	Yes
Johnson 2009	RCT (cluster, long term extension of Glazebrook 2007)	UK	HIC	NICU (7)	210 M	233 (<32 wks, NS)	Yes	Yes	EDI	Yes
Kaaresen 2006	RCT	Norway	HIC	NICU (1)	NS	146 (<37 wks, <2000g) +75 term control newborns	Yes	Yes	EDI	Yes
Kaaresen 2008	RCT (long term extension of Kaaresen 2006)	Norway	HIC	NICU (1)	225 parents (122 M, 103 F)	146 (<37 wks, <2000g)	Yes	Yes	EDI	Yes
Kachoosangy 2020	RCT	Iran	L-MIC	NICU (2)	45 M	45 (<37 wks, 1000-2500g)	Yes	No	EDI	Yes

Kang 1995	RCT	USA	HIC	NICU (3)	245 M	327 (<36 wks, NS)	Yes	Yes	EDI	Yes
Karbandi 2015	RCT	Iran	L-MIC	NICU (1)	70 M	70 (<37 wks, NS)	No	No	EDI	Yes
Kleberg 2002	RCT (long term extension of Westrup 2000)	Sweden	HIC	NICU (1)	NS	20 (<32 wks, NA)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Koldewijn 2009	RCT	Netherlands	HIC	NICU (7)	NS	176 (<32 wks, <500g)	Yes	Yes	EDI	Yes
Koldewijn 2010	RCT (long term extension of Koldewijn 2009)	Netherlands	HIC	NICU (7)	NS	176 (<32 wks, <1500g)	Yes	Yes	EDI	Yes
Kynø 2012	RCT (long term extension of Ravn 2011)	Norway	HIC	NICU (1)	NS	82 (30-36 wks, NS)	Yes	Yes	EDI	Yes
Landsem 2014	RCT (long term extension of Kaaresen 2006)	Norway	HIC	NICU (1)	262 parents (131 M, 131 F)	146 (<37 wks, <2000 g) +75 term control newborns	Yes	Yes	EDI	Yes
Lee 2019	RCT	China	U-MIC	NICU (1)	30 M	30 (<32 wks, NS)	Yes	No	EDI	Yes
Maguire 2009	RCT	Netherlands	HIC	NICU (2)	NS	164 (<32 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Matricardi 2013	RCT	Italy	HIC	NICU (1)	84 parents (42 M, 42 F)	42 (<32 wks, NS)	Yes	Yes	EDI	No
McAnulty 2009	RCT	USA	HIC	NICU (1)	NS	107 (<29 wks,<1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
McAnulty 2010	RCT (long term extension of Als 1994)	USA	HIC	NICU (1)	38 parents (M, F)	38 (≤29 wks, ≤1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
McAnulty 2013	RCT (long term extension of Als 2011)	USA	HIC	NICU (1)	23 parents (M, F)	23 (29-33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
McLean 2022	RCT (cluster)	Canada	HIC	NICU (12)	126 M	126 (<33 wks; NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Melnyk 2001	RCT (pilot)	USA	HIC	NICU (1)	42 M	42 (<37 wks, NS)	Yes	No	EDI	Yes
Melnyk 2006	RCT	USA	HIC	NICU (2)	414 caregivers: 260 M + 154 F/other significant caregiver	260 (26-34+6 wks, NS)	Yes	No	EDI	Yes
Meyer 1994	RCT	USA	HIC	NICU (1)	34 parents (M, F)	34 (NS, ≤1500g)	Yes	No	EDI, FSI	No
Mianaei 2014	RCT	Iran	L-MIC	NICU (2)	90 M	90 (<34 wks, NS)	Yes	No	EDI	Yes
Milgrom 2010	RCT	Australia	HIC	NICU (2)	45 M	52 (<30 wks, NS)	Yes	No	EDI	Yes
Milgrom 2013	RCT	Australia	HIC	NICU (2)	109 M	123 (<30 wks, NS)	Yes	No	EDI	Yes
Milgrom 2019	RCT (long term extension of Milgrom 2013)	Australia	HIC	NICU (2)	109 M	123 (<30 wks, NS)	Yes	No	EDI	Yes
Mousavi 2021	RCT	Iran	L-MIC	NICU (2)	143 M	143 (<37 wks, <2500g)	Yes	No	EDI	No
Murphy 2021	RCT (cluster)	Canada	HIC	NICU (10)	654 M	765 (32-34+6wks; NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Myers 2015	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	150 M	150 (26-34+6 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Namprom 2018	RCT	Thailand	U-MIC	NICU (2)	50 M	50 (28-32 wks; <2500g)	Yes	No	EDI	No
Newnham 2009	RCT	Australia	HIC	NICU (1)	68 M	68 (<37 wks, NS)	Yes	No	EDI	Yes
Nordhov 2010 (a)	RCT	Norway	HIC	NICU (1)	NS	146 (NS, <2000g)	Yes	Yes	EDI	Yes
Nordhov 2010 (b)	RCT	Norway	HIC	NICU (1)	131 parents (M, F)	146 (NS, <2000g)	Yes	Yes	EDI	Yes

Nordhov 2012	RCT(long term extension of Kaaresen 2006)	Norway	HIC	NICU (1)	131 parents (M, F)	146 (<37 wks, <2000g) +75 term control newborns	Yes	Yes	EDI	Yes
Northrup 2016	RCT	USA	HIC	NICU (1)	138 parents (M, F)	NS (NS, ≤1000 g)	No	No	FSI	No
Nurcombe 1984	RCT	USA	HIC	NICU (1)	NS	74 (<37 wks, <2200g)	Yes	Yes	EDI	Yes
Oberg 2020	RCT (secondary publication of Ustad 2016)	Norway	HIC	NICU (3)	NS	153 (< 32 wks, NS)	Yes	No	EDI	No
O'Brien 2018	RCT (cluster, multinational)	Canada, Australia, New Zealand	HIC	NICU (25: Canada 18, Australia 6, NZ 1)	1443 M	1786 (≤33 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Oehler 1990	RCT	USA	HIC	NICU (1)	31 siblings	NS	No	No	FCP	No
Ohgi 2004	RCT	Japan	HIC	NICU (1)	NS (M)	24 (NS, <2500g)	No	Yes	EDI	Yes
Olafsen 2008	RCT (long term extension of Kaaresen 2006)	Norway	HIC	NICU (1)	146 parents (M, F)	146 (<37 wks, <2000 g) +75 term control newborns	Yes	Yes	EDI	Yes
Örtenstrand 2010	RCT	Sweden	HIC	NICU (2)	NS	366 (<37 wks; NS)	Yes	No	ENI	No
Oyekunle 2021	RCT (cluster)	Nigeria	L-MIC	NCU (2)	41 M	41 (NS, NS)	Yes	No	EDI, FSI	No
Peters 2009	RCT	Canada	HIC	NICU (1)	NS	111 (<32 wks, 500-1250g)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Petteys 2018	RCT (pilot)	USA	HIC	NICU (1)	55 parents (M, F)	55 (<35 wks, NS)	Yes	Yes	EDI	No
Pillai 2021	RCT	India	L-MIC	NICU (1)	116 parents (M, F)	147 (28-33 wks, >750g)	Yes	Yes	EDI	No
Pineda 2021	RCT	USA	HIC	NICU (1)	70 parents (M, F)	70 (≤32 wks, NS)	Yes	Yes	EDI	No
Pisoni 2021	RCT	Italy	HIC	NICU (1)	42 families	42 (≤32 wks, ≤1500g)	Yes	Yes	EDI	No
Porges 2019	RCT	USA	HIC	NICU (1)	115 M	150 (26-34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Rajabi 2021	RCT	Iran	L-MIC	NICU (1)	80 M	NS (34-36 wks, NS)	Yes	Yes	EDI	No
Ravn 2011	RCT	Norway	HIC	NICU (1)	236 parents (118 M, 118 F)	118 (30-36 wks, NS)	Yes	Yes	EDI	Yes
Ravn 2012 (a)	RCT	Norway	HIC	NICU (1)	106 M	118 (30-36wks, NS)	Yes	Yes	EDI	Yes
Ravn 2012 (b)	RCT	Norway	HIC	NICU (1)	82 F	118 (30-36 wks, NS)	Yes	Yes	EDI	Yes
Rostami 2020	RCT (cluster)	Iran	L-MIC	NICU (4)	72 parents (M, F)	72 (28-34 wks, <2500g)	No	No	EDI	No
Russel 2021	RCT	USA	HIC	NICU (1)	97 parents (67 M, 30 F)	100 (≥28 wks, NS)	Yes	No	EDI, FSI	No
Sajadi 2020	RCT	Iran	L-MIC	NICU (1)	40 M	NS (26-37 wks, < 2500 g)	Yes	No	EDI	No
Schroeder 2006	RCT (mulicenter)	USA	HIC	NICU (2)	16 M	16 (<28 wks, <1500g)	Yes	No	EDI	No
Schwab 1983	RCT	USA	HIC	NICU (1)	16 siblings	13	Yes	No	FCP	No
Seiiedi-Biarag 2021	RCT	Iran	L-MIC	NICU (1)	66 M	NS (28-33 wks, NS)	Yes	Yes	EDI, FSI	No
Seyedrasooli 2020	RCT	Iran	L-MIC	NICU (1)	50 M	50 (NS, NS)	Yes	No	EDI	No
Shaw 2013	RCT	USA	HIC	NICU (4)	105 M	NS (25-34 wks, >600g)	Yes	Yes	EDI	No
Shaw 2014	RCT (long term extension of Shaw 2013)	USA	HIC	NICU (4)	105 M	NS (25-34 wks, > 600g)	Yes	Yes	EDI	No

Silverstein 2011	RCT (pilot)	USA	HIC	NICU (2)	50 M	NS (≤33 wks, NS)	Yes	Yes	EDI	Yes
Synnes 2022	RCT (cluster, long term extension of O'Brien 2018)	Canada	HIC	NICU (10)	NS	445 (<29 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Tavasolnia 2017	RCT	Iran	L-MIC	NICU (1) + maternity ward (1)	84 M	NS	Yes	No	EDI	No
Teti 2009	RCT	USA	HIC	NICU (2)	138 M	138 (<37 wks, NS)	No	No	EDI	Yes
Turan 2008	RCT	Turkey	U-MIC	NICU (1)	40 M	40 (24-37 wks, NS)	Yes	No	CI, EDI	No
Twohig 2021	RCT	Ireland	HIC	NICU (1)	80 M	98 (≤32 wks, NS)	Yes	Yes	EDI	No
Ustad 2016	RCT	Norway	HIC	NICU (3)	153 parents (M, F)	153 (<32 wks, NA)	Yes	No	EDI	No
Van der Pal 2007	2 consecutive RCT	Netherlands	HIC	NICU (2)	168 parents (M, F)	168 (< 32 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Van der Pal 2008 (a)	RCT (long term extension of Van der Pal 2007)	Netherlands	HIC	NICU (2)	144 parents (M, F)	168 (< 32 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Van der Pal 2008 (b)	RCT (long term extension of Van der Pal 2007)	Netherlands	HIC	NICU (2)	144 parents (M, F)	168 (<32 wks; NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Verkerk 2012	RCT (long term extension of Koldewijn 2009)	Netherlands	HIC	NICU (7)	NS	176 (<32 wks, <1500g)	Yes	Yes	EDI	Yes
Verma 2017	RCT	India	L-MIC	NICU (1)	NS (2-3 caregivers per newborn including mothers/fathers/grandparents/relatives)	295 (preterm and term, NS)	Yes	Yes	EDI	No
Viera 2010	RCT	Chile	L-MIC	NICU (1)	58 M	59 (<37 wks, NS)	Yes	Yes	EDI	No
Villamizar-Carvajal 2018	RCT	Colombia	U-MIC	NICU (3)	66 M	NS (< 34wks, NS)	Yes	No	EDI	Yes
Vonderheid 2016	RCT (secondary publication of White-Traut 2014)	USA	HIC	NICU (2)	147 M	147 (29-34 wks, NS)	Yes	No	EDI, FSI	Yes
Vonderheid 2020	RCT (secondary publication of White-Traut 2015)	USA	HIC	NICU (1) + maternity ward (2)	121 M	121 (29-34 wks, NS)	Yes	No	EDI, FSI	Yes
Weis 2013	RCT	Denmark	HIC	NICU (1)	134 parents (75 M, 59 F)	104 (≤34 wks, NS)	Yes	Yes	CI, EDI	No
Welch 2013	RCT	USA	HIC	NICU (1)	230 parents (115 M, 115 F)	150 (26-35 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Welch 2014	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	115 M	150 (26-34+6 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Welch 2015	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	150 M	150 (26-34+6 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Welch 2016	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	115 M	150 (26-34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Welch 2017	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	NS	150 (26-34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No

Welch 2020 (a)	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	115 M	150 (26- 34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Welch 2020 (b)	RCT (long term extension of Welch 2013)	USA	HIC	NICU (1)	150 M	150 (26-34 wks, NS)	Yes	Yes	ENI, EDI, FSI	No
Westrup 2000	RCT	Sweden	HIC	NICU (1)	25 parents (M, F)	25 (<32 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Westrup 2004	RCT (long term extension of Westrup 2000)	Sweden	HIC	NICU (1)	NS	41(<32 wks, NS)	Yes	Yes	ENI, FCP, CI, EDI, FSI	No
Whitehill 2021	RCT	USA	HIC	NICU (1)	70 parents (M, F)	70 (≤ 32 wks, NS)	Yes	Yes	EDI	No
White-Traut 1988	RCT (multi-centered)	USA	HIC	NICU (4)	26 M	26 (21-32 wks, NA)	Yes	No	EDI	Yes
White-Traut 2012	RCT (single-centered)	USA	HIC	NICU (1)	33 M	33 (28-35 wks, NA)	Yes	No	EDI	Yes
White-Traut 2013	RCT	USA	HIC	NICU (2)	142 M	142 (29-34 wks, NS)	Yes	No	EDI, FSI	Yes
White-Traut 2015	RCT (secondary publication of White-Traut 2013)	USA	HIC	NICU (2)	182 M	182 (29-34 wks, NS)	Yes	No	EDI, FSI	Yes
Wu 2014	RCT	Taiwan	HIC	NICU (3)	NS	178 (<37 wks; <1800g)	Yes	No	EDI	Yes
Xie 2019	RCT	China	U-MIC	NICU (1)	162 M	162 (28-34 wks, NS)	Yes	No	EDI	Yes
Yilmaz 2021	RCT	Turkey	U-MIC	NICU (1)	100 M	NS (28-38 wks, >1500g)	Yes	No	EDI	No
Yu 2017	RCT	Taiwan	HIC	NICU (3)	NS	251 (<37 wks, <1500g)	Yes	No	ENI, EDI	Yes
Zelkovitz 2011	RCT	Canada	HIC	NICU (2)	121 M	121 (NS, <1500g)	Yes	Yes	EDI	Yes
Zeraati 2017	RCT	Iran	L-MIC	NICU (1)	60 M	NS (30-36 wks, NS)	Yes	No	EDI	No
Zhang 2018	RCT (pilot)	China	U-MIC	NICU (1)	120 parents (M, F)	66 (< 37 wks, NS)	Yes	No	ENI, CI, EDI	No

Notes: [1] Actors involved in the study and in the sample receiving and delivering the intervention; [2] RCTs do not difference between delivering and receiving an educational intervention, health professionals were involved only in educational intervention.

Abbreviations: CI=communication interventions; EDI=educational interventions; ENI=environmental interventions; F=fathers; HIC=high income country; L-MIC=lower-middle income country; FCC= family-centred care; FCP=family-centred policies; FSI=family support interventions; M=mothers; NS=not specified; NICU=neonatal intensive care unit; RCT=randomized controlled trial; U-MIC=upper-middle income country; UK=United Kingdom; USA=United States of America; WB=world bank; wks=weeks.

Supplemental File 5. Classification of the identified FCC interventions

	Overall N=146 n (%)	MIC N=28 n (%)	HIC N=118 n (%)	p-value	RCTs published up to 2016 N=93 n (%)	RCTs published after 2016 N=53 n (%)	p-value
Single FCC intervention							
Educational interventions	86 (58.9)	22 (78.6)	64 (54.2)	0.019	56 (60.2)	30 (56.6)	0.670
Family support interventions	2 (1.4)	0 (0)	2 (1.7)	>0.999	1 (1.1)	1 (1.9)	>0.999
Environmental interventions	2 (1.4)	0 (0)	2 (1.7)	>0.999	1 (1.1)	1 (1.9)	>0.999
Communication interventions	2 (1.4)	0 (0)	2 (1.7)	>0.999	2 (2.2)	0 (0)	0.534
Family-centred policies	2 (1.4)	0 (0)	2 (1.7)	>0.999	2 (2.2)	0 (0)	0.534
Multiple FCC interventions							
Family support interventions & Educational interventions & Communication interventions & Family-centred policies & Environmental interventions	24 (16.4)	1 (3.6)	23 (19.5)	0.047	17 (18.3)	7 (13.2)	0.427
Family support interventions & Educational interventions	10 (6.8)	3 (10.7)	7 (5.9)	0.448	5 (5.4)	5 (9.4)	0.351
Educational interventions & Communication interventions	4 (2.7)	1 (3.6)	3 (2.5)	0.578	3 (3.2)	1 (1.9)	>0.999
Educational interventions & Environmental interventions	1 (0.7)	0 (0)	1 (0.8)	>0.999	0 (0)	1 (1.9)	0.363
Family support interventions & Educational interventions & Communication interventions	1 (0.7)	0 (0)	1 (0.8)	>0.999	0 (0)	1 (1.9)	0.363
Educational interventions & Communication interventions & Environmental interventions	1 (0.7)	1 (3.6)	0 (0)	0.192	0 (0)	1 (1.9)	0.363
Family support interventions & Educational interventions & Environmental interventions	11 (7.5)	0 (0)	11 (9.3)	0.124	6 (6.5)	5 (9.4)	0.511
ANY Categories (single+multiple FCC intervention)*							
Educational interventions	138 (94.5)	28 (100.0)	110 (93.2)	0.335	87 (93.5)	51 (96.2)	0.737
Family support interventions	48 (32.9)	4 (14.3)	44 (37.3)	0.035	29 (31.2)	19 (35.8)	0.760
Environmental interventions	39 (26.7)	2 (7.1)	37 (31.4)	0.018	24 (25.8)	15 (28.3)	0.955
Communication interventions	32 (21.9)	3 (10.7)	29 (24.6)	0.180	22 (23.7)	10 (18.9)	0.595
Family-centred policies	26 (17.8)	1 (3.6)	25 (21.2)	0.055	19 (20.4)	7 (13.2)	0.353

Notes: * This section of the table shows the frequency of RCTs reporting each intervention category, one RCT can report more than one category. Abbreviations: FCC=family-centred care.